

Cohere Medical Policy – Radiology Medicare Advantage

Clinical Guidelines for Medical Necessity Review

Consolidated Reference • 108 Policies

Updated on 05/26/2026

Important Notices

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Cohere Medicare Advantage Policy – Computed Tomography Angiography (CTA), Head and Neck

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medicare Advantage Policy - Computed Tomography Angiography (CTA), Head and Neck

Policy Number: CHP-188-3

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Computed Tomography Angiography (CTA), Head and Neck

Related Centers for Medicare & Medicaid Services (CMS) Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Cohere defines CMS coverage criteria as follows¹:

- Fully established: Applicable LCD or NCD is comprehensive and does not require additional criteria to determine medical necessity consistently.
- Not fully established: Additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently. The additional Cohere criteria will provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

For each jurisdiction, Cohere's internal coverage criteria will only be applied when CMS guidance is not fully established and additional guidelines are needed to support consistent and appropriate decision-making.

Cohere Health's position on NCDs or LCDs related to *Cohere Medicare Advantage Policy - Computed Tomography Angiography (CTA), Head and Neck* is reflected in Table 1 below. For the LCDs that are not fully established, please refer to the far right column as a guide for the application of Cohere Medicare Advantage criteria.

Table 1 – Related CMS Policies (NCDs or LCDs)

Type	Title	Number	Cohere Definition of CMS Policy Establishment	Indications not fully established by CMS policy (refer to Cohere Health MA medical necessity criteria for these topics):
NCD	No NCD available	N/A	N/A	• Not applicable
LCD	Not Applicable – No LCD Available for Jurisdiction	N/A	N/A	• Use Cohere Medicare Advantage internal coverage criteria

Description

Computed tomography angiography (CTA) is a noninvasive imaging technique that rapidly evaluates head and neck vasculature. Radiographic technology, combined with an iodinated contrast dye injected into a vein, is used to reconstruct detailed images of blood vessels. A scanner takes radiographic images of the patient and captures the contrast as it travels through the arteries of the head and neck. CTA can identify and characterize vascular diseases and evaluate vascular anatomy for the management of extravascular disorders.¹

Medical Necessity Criteria

Indications

Computed tomography angiography (CTA), head is indicated if **ANY** of the following is **TRUE**:

- Known or suspected recent stroke or transient ischemic attack (TIA)²; **OR**
- Neoplastic conditions, including surgical and radiation therapy localization, planning, and neuronavigation to delineate the vascular anatomy¹; **OR**
- Trauma-related conditions, including **ANY** of the following:
 - Blunt cerebrovascular injury (BCVI) is suspected based on the mechanism and location of trauma^{3,4}; **OR**
 - Head trauma with suspected intracranial arterial injury based on clinical risk factors or positive findings on initial imaging⁵; **OR**
 - Traumatic and nontraumatic orbital pathology with clinical or imaging findings that indicate vascular involvement⁶; **OR**
 - Traumatic vascular injuries¹; **OR**
 - Suspected carotid or vertebral artery dissection secondary to trauma⁵; **OR**
- Vascular conditions, known or suspected, including **ANY** of the following:
 - Aneurysm, known or suspected, with **ANY** of the following^{2,7-9}:
 - Screening for cerebral artery aneurysm with **ALL** of the following:
 - Screening is no more than every 5 years⁶; **AND**
 - **ANY** of the following:
 - Aortic aneurysm^{9,10}; **OR**
 - Aortic dissection^{9,11}; **OR**
 - Autosomal dominant polycystic kidney disease¹²; **OR**
 - Bicuspid aortic valve¹³; **OR**
 - Coarctation of the aorta⁹; **OR**
 - Fibromuscular dysplasia¹⁴; **OR**
 - Known aortic coarctation (after age 16)¹⁵; **OR**
 - Loeys-Dietz syndrome¹⁶; **OR**
 - Marfan syndrome¹⁶; **OR**
 - Microcephalic osteoblastic primordial dwarfism¹⁷; **OR**
 - Moyamoya disease⁹; **OR**

- Two or more first-degree relatives (parent, brother, sister, or child) with a history of intracranial aneurysm or subarachnoid hemorrhage^{18,19}; **OR**
 - Type 4 Ehlers-Danlos syndrome¹⁶; **OR**
- **ANY** of the following:
 - Intracerebral hemorrhage⁹; **OR**
 - Subarachnoid hemorrhage⁹; **OR**
- Surveillance of known intracerebral aneurysm; **OR**
- Intracranial arterial dissection, suspected; **OR**
- Intracranial occlusive disease, suspected; **OR**
- Pseudoaneurysm¹; **OR**
- Cranial neuropathy, with initial imaging suspicious for a vascular pathology²⁰; **OR**
- Acute unexplained intracranial hemorrhage¹; **OR**
- Known or suspected atherosclerotic stenosis or occlusive disease based on initial imaging¹; **OR**
- Intracranial vasculopathy when MRI is contraindicated or cannot be performed, and **ANY** of the following²:
 - Noninflammatory (e.g., radiation vasculopathy), **OR**
 - Inflammatory (e.g., vasculitis, infection)²¹; **OR**
- Vascular malformation and fistula based on initial imaging¹; **OR**
- Cerebrovascular disease, known or suspected, including **ANY** of the following⁹:
 - Central nervous system (CNS) vasculitis, if MRI is contraindicated; **OR**
 - Cerebral aneurysm, treated or untreated; **OR**
 - Cerebral vasospasm; **OR**
 - Moyamoya disease or suspected arteriopathy; **OR**
 - Vascular malformation; **OR**
- Headache with **ANY** of the following²²:
 - Acute onset worst headache of life/thunderclap headache; **OR**
 - New onset or pattern during pregnancy or peripartum period; **OR**
 - Associated with exercise, exertion, Valsalva, or sexual activity; **OR**
- Vertigo, known or suspected, as indicated by **ANY** of the following^{23,24}:
 - Acute persistent vertigo, when abnormal neurologic examination or Head Impulse-Nystagmus-Test of Skew (HINTS)^A is consistent with central vertigo; **OR**
 - Chronic recurrent vertigo associated with other brainstem neurologic deficits; **OR**

- Persistent vertigo with or without neurological symptoms (central vertigo); **OR**
- Pulsatile tinnitus, unilateral or bilateral²⁵; **OR**
- Hearing impairment, including **ANY** of the following²⁴:
 - Asymmetric hearing loss; **OR**
 - Surgical planning for acquired conductive hearing loss secondary to cholesteatoma or neoplasm with suspected intracranial or inner ear extension; **OR**
- Preoperative assessment of vascular anatomy or pathology, with **ANY** of the following:
 - Open vascular or endovascular procedure; **OR**
 - Procedure with a high risk for vascular injury (including radiation treatment); **OR**
- Post-treatment follow-up to monitor treatment results and surveillance of vascular condition; **OR**
- Congenital conditions associated with cerebrovascular abnormalities (e.g., chronic anemic conditions) when MRI (and MRA) is contraindicated.⁷

Computed tomography venography (CTV), head is indicated if **ANY** of the following is **TRUE**:

- Vascular conditions, known or suspected, including **ANY** of the following^{2,9}:
 - Venous/dural sinus abnormalities such as **ANY** of the following:
 - Acquired thrombosis/occlusion; **OR**
 - Venous sinus stenosis; **OR**
 - Large vein injury secondary to trauma; **OR**
 - Vascular invasion or displacement by tumor; **OR**
- Headache with **ANY** of the following²²:
 - New onset or pattern during pregnancy or peripartum period; **OR**
 - Headache with features of intracranial hypertension (e.g., papilledema, pulsatile tinnitus, visual symptoms worse on Valsalva); **OR**
- Initial diagnostic, one-time pre- or post-treatment evaluation for treatment planning or evidence of clinical concern for vascular malformation.

Computed tomography angiography (CTA), neck is considered appropriate for **ANY** of the following:

- Evaluation of a pulsatile neck mass²⁶; **OR**
- Trauma-related conditions as indicated by **ANY** of the following:

- Trauma-related spine injuries (cervical and upper thoracic)⁴; **OR**
- Blunt cerebrovascular injury (BCVI) is suspected based on the mechanism and location of trauma⁴; **OR**
- Suspected carotid or vertebral artery dissection secondary to trauma or spontaneous due to weakness of the vessel wall; **OR**
- Traumatic vascular injury¹; **OR**
- Acute hemorrhage²; **OR**
- Vascular conditions, known or suspected, including **ANY** of the following:
 - Screening for cerebral artery aneurysm with **ANY** of the following^{1,2}:
 - Fibromuscular dysplasia¹⁴; **OR**
 - Loeys-Dietz syndrome¹⁶; **OR**
 - Spontaneous coronary artery dissection (SCAD)¹⁴; **OR**
 - Type 4 Ehlers-Danlos syndrome¹⁶; **OR**
 - Arterial aneurysm; **OR**
 - Pseudoaneurysm¹; **OR**
 - Known or suspected atherosclerotic stenosis or occlusive disease based on initial imaging¹; **OR**
 - Cerebrovascular disease, known or suspected, including **ANY** of the following⁹:
 - Asymptomatic carotid stenosis, when ultrasound is nondiagnostic; **OR**
 - Asymptomatic cervical bruit, when ultrasound is nondiagnostic; **OR**
 - Cervical vascular dissection or injury, known or suspected; **OR**
 - Noninflammatory vasculopathy; **OR**
 - Giant cell and Takayasu arteritis⁹; **OR**
 - Subclavian steal syndrome for treatment planning⁹; **OR**
 - Vascular malformation or fistula based on initial imaging; **OR**
 - Horner syndrome without localizing neurological abnormalities²⁷; **OR**
- Cranial neuropathy, with initial imaging suspicious for a vascular pathology²⁰; **OR**
- Preoperative assessment of vascular anatomy or pathology, with **ANY** of the following:
 - Open vascular or endovascular procedure; **OR**
 - Procedure with a high risk for vascular injury (including radiation treatment); **OR**
- Post-treatment follow-up to monitor treatment results and surveillance of vascular condition.

Computed tomography angiography (CTA), head and neck is considered appropriate for **ANY** of the following:

- Known or suspected recent stroke or transient ischemic attack (TIA)²; **OR**
- Trauma-related conditions as indicated by **ANY** of the following:
 - Blunt cerebrovascular injury (BCVI) is suspected based on the mechanism and location of trauma^{3,4}; **OR**
 - Head trauma with suspected intracranial arterial injury based on clinical risk factors or positive findings on initial imaging⁵; **OR**
 - Trauma of the head with a suspected intracranial arterial injury based on clinical findings or initial imaging⁵; **OR**
 - Traumatic and nontraumatic orbital pathology with clinical or imaging findings that indicate vascular involvement⁶; **OR**
 - Traumatic vascular injuries¹; **OR**
 - Suspected carotid or vertebral artery dissection secondary to trauma or spontaneous due to weakness of the vessel wall⁹; **OR**
- Vascular conditions, known or suspected, including **ANY** of the following:
 - Screening for cerebral artery aneurysm with **ANY** of the following:
 - Fibromuscular dysplasia¹⁴; **OR**
 - Loeys-Dietz syndrome¹⁶; **OR**
 - Spontaneous coronary artery dissection (SCAD)¹⁴; **OR**
 - Type 4 Ehlers-Danlos syndrome¹⁶; **OR**
- Cervical bruit or thrill with suspicion of carotid stenosis²; **OR**
- Horner syndrome without localizing neurological abnormalities²⁶; **OR**
- Vertigo, known or suspected, as indicated by **ANY** of the following^{23,24}:
 - Acute persistent vertigo, when abnormal neurologic examination or Head Impulse-Nystagmus-Test of Skew (HINTS)^A is consistent with central vertigo; **OR**
 - Chronic recurrent vertigo associated with other brainstem neurologic deficits; **OR**
 - Persistent vertigo with or without neurological symptoms (central vertigo); **OR**
- Pulsatile tinnitus, unilateral or bilateral²⁵; **OR**
- Preoperative assessment of vascular anatomy or pathology, with **ANY** of the following:
 - Open vascular or endovascular procedure; **OR**
 - Procedure with a high risk for vascular injury (including radiation treatment); **OR**

- Post-treatment follow-up to monitor treatment results and surveillance of vascular condition; **OR**
- Congenital conditions associated with cerebrovascular abnormalities (e.g., chronic anemic conditions) when MRI (and MRA) is contraindicated.⁶

Repeat imaging is considered appropriate when **ALL** of the following are **TRUE**:

- Repeat request following recent imaging within the past 3 months of the same anatomic region with the same or similar modality; **AND**
- No established guidelines for repeat imaging; **AND**
- **ANY** of the following:
 - Need for a one-time clarifying follow-up of a prior indeterminate finding; **OR**
 - New or worsening symptoms not addressed in the guidelines, such that repeat imaging would influence treatment; **OR**
 - No change in symptoms and a well-established clinical need for ongoing monitoring that will influence management.

Non-Indications

Computed tomography angiography (CTA), head and neck, or computed tomography venography (CTV), head are not considered appropriate if **ANY** of the following is **TRUE**:

- The request is for CPT 70496 and 70498 when CTA head and neck are being performed together.

Definitions and Notes

^AHINTS: Three bedside tests (Head Impulse, Nystagmus, Test of Skew) to assess whether acute vestibular symptoms (AVS, e.g., vertigo, nausea) are due to a central cause.

-The head impulse test measures the vestibulo-ocular reflex (VOR) by having the patient focus on a central target during rapid side-to-side head rotation. Inability to maintain fixation in one direction is considered abnormal.

-Nystagmus (i.e., rapid, involuntary eye movements). Nystagmus suggestive of a central cause of AVS includes vertical nystagmus, torsional nystagmus, or nystagmus that changes direction.

-Skew deviation (vertical misalignment of the eyes due to an imbalance of vestibular tone in the oculomotor system) is typically assessed by covering each eye in isolation, assessing for vertical correction of the eye position.

Disclaimer on Radiation Exposure in Pediatric Populations

Cohere Health is committed to ensuring that every patient has access to appropriate and safe imaging studies in accordance with established guidelines. While radiographic studies, such as computed tomography (CT), can provide critical clinical information, exposure to ionizing radiation has the potential to increase lifetime cancer risk. Risk is higher in pediatric patients due to their greater radiosensitivity and longer expected lifespan.

Radiation-induced risks can be reduced by ensuring that imaging is medically necessary and by optimizing procedures to use the lowest dose necessary to achieve diagnostic quality images, consistent with ALARA (As Low As Reasonably Achievable) principles. Alternative modalities that do not involve ionizing radiation should be considered when clinically feasible, such as ultrasound or magnetic resonance imaging (MRI). Providers should adjust equipment and dose to pediatric body sizes and track cumulative radiation exposure for patients requiring multiple imaging studies.

These measures align with guidance from the US Food and Drug Administration (FDA) initiative to reduce unnecessary radiation exposure, the National Cancer Institute pediatric CT risk guidelines, and the Image Gently Alliance and Image Wisely Alliance recommendations for pediatric radiation safety.^{29–33}

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70471	Computed tomographic angiography (CTA), head and neck, with contrast material(s), including noncontrast images, when performed, and image postprocessing
70496	Computed tomographic angiography (CTA), head; with contrast material(s), including non-contrast images, if performed, and image postprocessing
70498	Computed tomographic angiography (CTA), of neck; with contrast material(s), including non-contrast images, if performed, and image post-processing

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.¹

The potential clinical harms of using these criteria for computed tomography angiography (CTA), head and neck, may include^{2,3,8,10}:

- Adverse effects from delayed or denied treatment of cerebrovascular diseases or stroke-related conditions.
- Increased healthcare costs and complications from the inappropriate use of additional interventions.

The clinical benefits of using these criteria for CTA, head and neck, may include^{2,3,8,10}:

- Improved patient selection for the treatment of cerebrovascular diseases or stroke-related conditions.
- Maintenance of rigorous patient safety standards aligned to best available evidence.
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.
- Enhanced overall patient satisfaction and healthcare experience.

Medical Evidence

Tu et al. (2022) conducted a retrospective review on the utilization of head and neck computed tomography angiography (CTA) in the emergency department (ED). Head and neck CTA in the ED has shown a disproportionate increase compared to other neuroimaging examinations. The study contrasted utilization and the frequency of communicating non-routine results across the top 50 patient chief concerns. A total of 17,903 CTAs for 833 distinct chief concerns were included, which accounts for 2.5% of 708,145 ED visits. The rates of ordering and communication of non-standard results exhibit significant variability across different chief concerns. Approximately half of the non-standard communications made by radiologists pertain to acute indications. Understanding the trends in ordering head and neck CTA and communicating non-standard results can aid in refining patient selection and enhancing radiologist interactions in the ED.³⁴

Schenk et al. (2021) report on a retrospective review of stroke in young adults. The use of CTA head and neck diagnostic yield for anterior circulation ischemic stroke evaluation is discussed. The review included adults aged 18–50 who presented to the Mayo Clinic Rochester ED. Carotid dissection is a predominant cause of anterior circulation ischemic stroke, as evidenced by findings on CTA. Carotid webs were rare findings in the patients studied, and the authors emphasized the importance of distinguishing them from intimal flaps, as carotid webs are associated with recurrent stroke. The authors did not cite a significant disparity in the prevalence of carotid atherosclerosis between the symptomatic and asymptomatic sides. Clinicians can recognize high-risk morphological attributes of carotid plaque observed on CT angiography, even in cases with no discernible stenosis.³⁵

Paladino et al. (2021) performed a systematic review to determine the efficacy of CTA neck in determining vascular or aerodigestive injuries (ADI). CTA covering the entire neck region is now an integral component of the standard diagnostic approach for patients with penetrating neck trauma (PNT) who do not necessitate immediate surgical intervention for ADI. While many studies have highlighted the usefulness of CTA to rule out arterial injuries, consensus is lacking regarding the capability of CTA neck to detect ADI.³⁶

Heit et al. (2016) conducted an 11-year single-center retrospective review to analyze the yield of digital subtraction angiography (DSA) in patients with subarachnoid hemorrhage. DSA reveals vascular abnormalities in 13% of patients who initially test negative for subarachnoid hemorrhage (SAH) on CTA. Upon subsequent DSA, aneurysms or pseudoaneurysms are found in 4% of cases. Utilization of DSA may be appropriate for all patients with SAH-negative CT scans. To aid the clinician, the type of SAH pattern observed with DSA may offer clues to the underlying cause of the hemorrhage.³⁷

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Policy Revision History/Information

Original Date: September 19, 2024		
Review History		
Version 1	09/19/2024	New policy.
Version 2	09/11/2025	Annual review. No changes to medical necessity criteria or procedure codes. Indications linked to references. Rearranged bullets for improved usability and organization. Updated standard DI non-indication language. Expanded the Medical Evidence section to include a new technology; added the corresponding reference.
Version 3	02/26/2026	Revision. Added CPT 70471 and 70498. Policy title changed (formerly "Cohere Medical Policy - Computed Tomography Angiography (CTA), Head"). Incorporated indications for CTA Neck from the retired Cohere policy "Cohere Medical Policy - Computed Tomography Angiography (CTA), Neck."

		Created new “CTA, head and neck” section. Aligned criteria across sections where appropriate. Updated template, including addition of “Table 1 – Related CMS Policies” that describes Cohere definition of which LCDs/NCDs are not fully established. Added requirement that screening for cerebral artery aneurysm in patients with vascular conditions should be performed no more than every 5 years. Added specific genetic disorders to the vascular conditions section. Combined pediatric and adult indications and consolidated criteria for both populations. Broadened cranial neuropathy indication and removed specifics for cranial nerve symptoms. Added MRI prerequisite for intracranial vasculopathy. Added non-indication for when the request is for CPT 70496 and 70498 when CTA head and neck are being performed together, as CPT 70471 should be used for the combined service. Updated references for ACR appropriateness criteria and NCCN clinical practice guidelines.



Cohere Medicare Advantage Policy – Computed Tomography Angiography (CTA), Head

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 19, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography Angiography (CTA), Head

Date of last literature review: 9/16/2024

Document last updated: 9/18/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Computed Tomography Angiography (CTA), Head

Benefit Category

Not applicable.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for CTA Head.

Recommended Clinical Approach

Computed tomography angiography (CTA) and CT venography (CTV) of the head help detect and characterize vascular disease and anatomy relevant to treating extravascular disorders. CTA may be used as the primary modality for detecting disease, as an adjunctive tool for characterizing a known disease, or to assess changes over time.¹ Magnetic resonance angiography (MRA) or magnetic resonance venography (MRV) is the preferred imaging study due to the lack of ionizing radiation.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of CTA of the head. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.²⁻⁵
- Potential danger to pregnancy: CT imaging completed during

pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.⁶ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁶

- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁷

The clinical benefits of using these criteria include:

- Accuracy: CTA of the head is effective in diagnosing acute ischemic stroke. A study assessing acute stroke imaging found that CTA compared to non-contrast CT, increased the diagnosis of acute ischemic stroke.⁸
- Patient outcomes: CTA has a low risk of allergic reaction and contrast-induced neuropathy; adverse patient outcomes are minor.⁹
- Early diagnosis: Improved resolution of CTA may lead to early diagnosis of vascular abnormalities.¹⁰
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography angiography (CTA), head** is indicated if **ANY** of the following is **TRUE**:

- ◆ Neoplastic conditions including surgical and radiation therapy localization, planning, and neuronavigation to delineate the

vascular anatomy (e.g., tumor is in the vicinity or encases a major artery or occludes major vein)¹; **OR**

- ◆ Trauma-related conditions as indicated by **ANY** of the following:
 - Head trauma with suspected intracranial arterial injury due to clinical risk factors or positive findings on prior imaging¹¹; **OR**
 - Blunt cerebrovascular injury (BCVI) is suspected based on the mechanism and location of trauma (CT neck is also indicated with CT head)¹²; **OR**
 - Traumatic vascular injuries¹; **OR**
 - Suspected carotid or vertebral artery dissection secondary to trauma; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Aneurysm with **ANY** of the following¹³⁻¹⁸:
 - Screening for cerebral artery aneurysm when **ANY** of the following is **TRUE**¹⁹⁻²⁷:
 - ◆ Autosomal dominant polycystic kidney disease (adults); **OR**
 - ◆ The patient has two or more first-degree relatives (parent, brother, sister, or child) with a history of intracranial aneurysm; **OR**
 - ◆ The patient is symptomatic with one first-degree relative who has a history of intracranial aneurysm^{13-15,28}; **OR**
 - ◆ Fibromuscular dysplasia; **OR**
 - ◆ Loeys-Dietz syndrome; **OR**
 - ◆ Spontaneous coronary arteries dissection (SCAD); **OR**
 - ◆ Known aortic coarctation (after age 10); **OR**
 - **ANY** of the following:
 - ◆ Diagnosis of intracranial hemorrhage; **OR**
 - ◆ Diagnosis of subarachnoid hemorrhage; **OR**
 - ◆ Intracerebral hemorrhage, known or suspected²⁹; **OR**
 - ◆ The patient has a history of subarachnoid hemorrhages¹⁴; **OR**
 - Cervical bruit or thrill with suspicion of neck carotid stenosis; **OR**

- Headache with **ANY** of the following:
 - Acute onset worst/thunderclap headache³⁰; **OR**
 - New onset or pattern during pregnancy or peripartum period; **OR**
 - Associated with exercise, exertion, Valsalva, or sexual activity; **OR**
- Intracranial arterial dissection, suspected; **OR**
- Intracranial occlusive disease (arterial or venous), suspected³¹; **OR**
- Intracranial hypertension (idiopathic), suspected; **OR**
- Pseudoaneurysm¹; **OR**
- Recent stroke, up to 6 months (remote history is not an indication unless recent TIA episodes)¹; **OR**
- Cranial neuropathy as indicated by **ANY** of the following and prior imaging is suspicious for a vascular pathology (e.g., aneurysm, arteriovenous fistulas [AVF])^{1,16-17}:
 - Lower cranial nerve palsies, weakness or paralysis (CN IX-XII) (i.e., glossopharyngeal neuralgia); **OR**
 - Unilateral isolated weakness or paralysis of the tongue (hypoglossal nerve, CN XII); **OR**
 - Refractory trigeminal neuralgia when done for surgical planning; **OR**
 - Isolated third nerve palsy (oculomotor) with pupil involvement to evaluate for aneurysm; **OR**
 - Any combination or isolated involvement of cranial nerves where prior imaging is suspicious for vascular pathology; **OR**
- Acute or recent unexplained intracranial hemorrhage¹; **OR**
- Atherosclerotic stenosis or occlusive disease, including suspected vasospasm or thromboembolism with **ANY** of the following¹:
 - Patient has documented symptoms suggestive of stroke or TIA; **OR**
 - Based on prior imaging; **OR**
- Vasculopathy that is non-atherosclerotic, non-inflammatory (e.g., radiation vasculopathy) and suspected on prior imaging (e.g., CT, MRI)¹; **OR**
- The patient has **ANY** of the following:
 - Abnormal neurologic signs; **OR**

- Fever; **OR**
 - Visual disturbance; **OR**
 - Vertigo; **OR**
 - Weight loss; **OR**
- Vascular malformation and fistula based on prior imaging¹; **OR**
- Cerebrovascular disease in a patient age 18 or older including **ANY** of the following¹⁸:
 - Acute subarachnoid hemorrhage (SAH), suspected or known on CT; **OR**
 - Central nervous system (CNS) vasculitis, suspected; **OR**
 - Cerebral aneurysm (treated or untreated), known; **OR**
 - Cerebral vasospasm, suspected; **OR**
 - High-flow vascular malformation (AVM/AVF), known; **OR**
 - Aneurysmal SAH in a younger patient who is at-risk of de novo aneurysm formation; **OR**
 - The patient has **ANY** of the following:
 - ◆ Moyamoya disease; **OR**
 - ◆ Bicuspid aortic valve; **OR**
 - ◆ Aortic aneurysm; **OR**
 - ◆ Coarctation of the aorta; **OR**
- Cerebrovascular disease in a patient age 17 or younger and **ANY** of the following is **TRUE**³⁰:
 - Acute stroke is suspected with **ANY** of the following:
 - ◆ Non-sickle-cell related with new focal fixed or worsening neurologic deficit lasting less than 24 hours from last seen normal state and there are no contraindications to emergent intervention; **OR**
 - ◆ Known or suspected arteriopathy or moyamoya¹⁷⁻¹⁸; **OR**
 - ◆ Known or suspected central nervous system vasculitis; **OR**
 - ◆ Known or suspected low- or high-flow vascular anomaly; **OR**
 - ◆ The patient is not a candidate for emergent intervention; **OR**

- Acute subarachnoid hemorrhage (SAH), suspected or known on CT; **OR**
- Spontaneous cervicocranial arterial dissection based on clinical or imaging findings. (CTA head and neck ordered together); **OR**
- Nontraumatic intracranial hemorrhage (hematoma) of unknown etiology found on CT or MRI and additional imaging study is needed; **OR**
- Nontraumatic SAH detected by non-contrast CT; **OR**
- Vertebrobasilar insufficiency (VBI) as indicated by **ANY** of the following^{29,31}:
 - Abnormal neurologic examination is consistent with central vertigo; **OR**
 - Associated with other brainstem neurologic deficits; **OR**
 - HINTS (Head Impulse–Nystagmus–Test of Skew) examination is consistent with central vertigo; **OR**
 - Neurological symptoms (central vertigo); **OR**
- ◆ For evaluation of **ANY** of the following miscellaneous pathologies when prior testing has failed:
 - Headache with an unrevealing MRI and **ANY** of the following is **TRUE**:
 - Persistent in nature; **OR**
 - Undifferentiated; **OR**
 - Unexplained; **OR**
 - Pulsatile tinnitus (unilateral or bilateral) as evidenced by **ANY** of the following^{1,32–33}:
 - Localized to one ear (prior testing not required); **OR**
 - Focal neurological abnormalities (consider MRI brain internal auditory canal [IAC] protocol first); **OR**
 - Asymmetric hearing loss (consider MRI brain internal auditory canal [IAC] protocol first); **OR**
 - Visual impairment including **ANY** of the following³²:
 - Isolated third nerve palsy (oculomotor) with pupil involvement to evaluate for aneurysm; **OR**
 - Suspected venous thrombosis (e.g., dural sinus thrombosis) when MRV is contraindicated or cannot be performed; **OR**
- ◆ Preoperative assessment of vascular anatomy or pathology; **OR**

- ◆ Post-treatment follow-up to monitor treatment result and surveillance of vascular condition; **OR**
- ◆ Congenital conditions or anomalies including vascular abnormality associated with chronic anemic conditions (e.g., sickle cell disease) (MRA head is preferred in pediatric patients)³⁵⁻³⁶; **OR**

→ **Computed tomography venography (CTV), head** is indicated if **ANY** of the following is **TRUE**:

- ◆ Ultrasound and CT venography (CTV) are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to IV contrast reaction, pregnancy, pediatric); **OR**
- ◆ **ANY** of the following is **TRUE**:
 - Vascular conditions, known or suspected, including **ANY** of the following:
 - Venous/dural sinus abnormalities such as **ANY** of the following:
 - ◆ Acquired thrombosis/occlusion; **OR**
 - ◆ Venous sinus stenosis; **OR**
 - Large vein injury secondary to trauma; **OR**
 - Vascular invasion or displacement by tumor; **OR**
 - Headache with **ANY** of the following:
 - New onset or pattern during pregnancy or peripartum period; **OR**
 - Headache with features of intracranial hypertension (e.g., papilledema, pulsatile tinnitus, visual symptoms worse on Valsalva)³⁰; **OR**
 - Initial diagnostic, one-time pre or one-time post-treatment evaluation for treatment planning or evidence of clinical concern for vascular malformation.

→ **Repeat imaging** (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- ◆ New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- ◆ One-time clarifying follow-up of a prior indeterminate finding; **OR**

- ◆ In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography angiography (CTA) or computed tomography venography (CTV), head**, is not considered appropriate if **ANY** of the following is **TRUE**³⁷:

- ◆ If contrast is used, history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{4,38}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{4,38}

Cumulative Dose Monitoring: Implement systems to track cumulative

radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{4,38}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{4,38}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70496	Computed tomographic angiography (CTA), head; with contrast material(s), including non-contrast images, if performed, and image postprocessing

Medical Evidence

Tu et al. (2022) conducted a retrospective review on the utilization of head and neck computed tomography angiography (CTA) in the emergency department (ED). Head and neck CTA in the ED has shown a disproportionate increase compared to other neuroimaging examinations. The study contrasted utilization and the frequency of communicating non-routine results across different patient chief concerns. The study identified the top 50 primary concerns leading to the most CTA examinations. A total of 17903 CTAs for 833 distinct chief concerns were included, which accounts for 2.5% of 708,145 ED visits. The rates of ordering and communication of non-standard results exhibit significant variability across different chief concerns. Approximately half of the non-standard communications made by radiologists pertain to acute indications. Understanding the trends in ordering head and neck CTA and communicating non-standard results can aid in refining patient selection and enhancing radiologist interactions in the ED.³⁹

Schenk et al. (2021) report on a retrospective review of stroke in young adults. The use of CTA head and neck diagnostic yield for anterior circulation ischemic stroke evaluation is discussed. The review included adults aged 18–50 who presented to the Mayo Clinic Rochester ED. Carotid dissection is a predominant cause of anterior circulation ischemic stroke, as evidenced by findings on CTA. Studies found that carotid webs were infrequent in the patients studied, while carotid atherosclerosis was relatively rare – the presence of carotid webs, understanding their potential to trigger recurrent strokes. The authors did not cite a significant disparity in the prevalence of carotid atherosclerosis between the symptomatic and asymptomatic sides. Clinicians can recognize high-risk morphological attributes of carotid plaque observed on CT angiography, even in cases with no discernible stenosis.⁴⁰

Heit et al. (2016) conducted an 11-year single-center retrospective review to analyze the yield of digital subtraction angiography (DSA) in patients with subarachnoid hemorrhage. DSA reveals vascular abnormalities in 13% of patients who initially test negative for subarachnoid hemorrhage (SAH) on CTA. Upon subsequent DSA, aneurysms or pseudoaneurysms are found in 4% of cases. Utilization of DSA may be appropriate for all patients with SAH-negative CT scans. To aid the clinician, the type of SAH pattern observed with DSA may offer clues to the underlying cause of the hemorrhage.⁴¹

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Clinical Guideline Revision History/Information

Original Date: September 19, 2024		
Review History		



Cohere Medicare Advantage Policy – Positron Emission Tomography (PET), Brain

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 26, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Positron Emission Tomography (PET), Brain

Date of last literature review: 9/25/2024

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: PET Brain

Benefit Category

Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹⁸⁻²¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- [National Coverage Determination \(NCD\) FDG PET for Refractory Seizures 220.6.9.](#)
- [National Coverage Determination \(NCD\) Positron Emission Tomography \(FDG\) for Oncologic Conditions 220.6.17](#)
- [National Coverage Determination \(NCD\) FDG PET for Dementia and Neurodegenerative Diseases 220.6.13](#)
- [Billing and Coding: NCD Coding Article for Positron Emission Tomography \(PET\) Scans Used for Non-Oncologic Conditions \(A53134\)](#)
- [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Recommended Clinical Approach

Two distinct types of positron emission tomography (PET) of the brain are considered for different indications. Utilizing ¹⁸F-FDG (fluorodeoxyglucose) PET/CT imaging enables the assessment of metabolic activity and cerebral function. Specifically, ¹⁸F-FDG brain imaging proves valuable across a spectrum of clinical scenarios, such as dementia, seizure disorders, and the detection of new or recurring brain tumors.¹ FDG-PET imaging reveals regional variations in glucose metabolism, serving as a marker for neurodegeneration. These patterns not only signify the existence of neurological decline but also offer insight into the specific cerebral regions and pathways affected by the condition.² Amyloid imaging is advised for identifying the presence or absence of abnormal Aβ amyloid deposits in individuals experiencing progressive cognitive decline or dementia of unknown cause, where Alzheimer's disease is considered a potential diagnosis.²

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Positron Emission Tomography (PET) of the brain. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of PET imaging, including cumulative radiation exposure, allergy, and harm to breast milk.^{1,17}
- Potential danger to pregnancy: PET imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹⁶ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹⁶
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹⁵

The clinical benefits of using these criteria include:

- Improved diagnostic accuracy: PET imaging, and in particular, FDG PET, can visualize certain pathologies before those conditions are visible on other imaging modalities, such as CT and MRI.¹ PET has also been shown to significantly impact clinical management and decision-making, even among patients with mild symptomatology, which is of particular importance in the context of neurodegenerative conditions.¹⁴
- Noninvasive: As an imaging modality, PET of the brain is noninvasive; it is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers. It also utilizes no injected contrast agent, conferring an inherent safety benefit.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Positron emission tomography (PET), brain** is considered appropriate if **ANY** of the following is **TRUE**:

◆ **Fluorodeoxyglucose (FDG) PET brain** and the patient has **ANY** of the following exam findings³:

- Seizure disorder (epilepsy) refractory to medical therapy for which invasive treatment is considered ^{1,6,19}; **OR**
- Tumor, strongly suspected or known, for initial or subsequent treatment strategy^{7-8,20}; **OR**
- Cognitive decline or suspected diagnosis of dementia for differentiation of Alzheimer's dementia and frontotemporal dementia, and the patient has had **ALL** of the following^{1-2,4,18}:
 - Evaluation by a physician experienced in the diagnosis and assessment of dementia; **AND**
 - Abnormal cognitive testing (MMSE, MoCA, SLUMS or similar); **AND**
 - Relevant lab values are available (B12, TSH); **AND**
 - Prior MRI or CT imaging of the brain; **OR**

◆ **Single Amyloid PET** is considered appropriate if **ALL** of the following are **TRUE**⁹:

- Alzheimer's disease following an interdisciplinary evaluation with **ALL** of the following:
 - General medical and neurological examination; **AND**
 - Laboratory testing; **AND**

- Mental status testing; **AND**
 - Structural neuroimaging; **AND**
 - Imaging is needed to determine the extent of the amyloid build-up prior to treatment with amyloid beta-directed antibodies (e.g., Lecanemab).
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

* NOTE: MRI is the preferred imaging modality for follow-up imaging following an initial amyloid PET scan.

Non-Indications

→ **Positron emission tomography (PET), brain** is not considered appropriate for **ANY** of the following:

- ◆ PET evaluation of perfusion of the brain.^{[21](#)}

*NOTE: PET in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

**NOTE: PET scans should be scheduled at least 4–6 weeks after radiation therapy or surgery to avoid false positives due to inflammation from recent treatments.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and

the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.¹⁰⁻¹¹

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.¹⁰⁻¹¹

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.¹⁰⁻¹¹

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.¹⁰⁻¹¹

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
78609	Brain imaging, positron emission tomography (PET); perfusion evaluation (this code is non-covered by CMS)

78811	Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)

Medical Evidence

Spano et al. (2023) analyzed the efficacy of PET imaging in cases of cognitive decline, specifically its significance in diagnosing Alzheimer's disease (AD). While FDG PET remains the predominant PET tracer in clinical use, several PET radiotracers enable the observation of underlying pathophysiological processes in AD, including A β deposition, tau deposition, synaptic density loss, neuroinflammation, cholinergic cell death, and reduced monoamine neurotransmission. Three FDA-approved 18F-labeled radiopharmaceuticals exist, including florbetaben (NeuraCeq), florbetapir (Amyvid), and flutemetamol (Vizamyl). These assess A β deposition, predominantly utilized in clinical trials with limited reimbursement for diagnostic purposes. The advancement of PET radiotracers in routine practice allows clinicians to diagnose and intervene in neurodegenerative diseases effectively.¹²

Quigg et al. (2022) report on using positron emission tomography with fluorine-18 fluorodeoxyglucose (¹⁸F-FDG-PET) to map brain glucose metabolism patterns. This imaging modality aids in assessing normal brain function and identifying metabolic abnormalities in various brain disorders. Traditional PET methods cannot distinguish normal from pathological tissue, particularly in conditions such as brain neoplasms or focal epilepsy. The aim is to enhance the functional mapping of metabolic activity within the target organ. Recent technological advancements may broaden dynamic PET across various clinical settings.¹³

Rabinovici et al. (2019) conducted a single-group, multi-center longitudinal study called Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) (ClinicalTrials.gov Identifier: NCT02420756). The study assessed whether amyloid PET scans influence the subsequent management decisions for patients diagnosed with mild cognitive impairment (MCI) or dementia of uncertain origin. Participants (n=11409) at 343 imaging centers underwent amyloid PET. Within 90 days of evaluation, participants diagnosed with MCI or dementia of uncertain origin who underwent amyloid PET scans exhibited alterations in clinical management. Further research is needed to ascertain whether amyloid PET correlates with enhanced clinical outcomes.¹⁴

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Cohere Medicare Advantage Policy – Positron Emission Tomography (PET), Brain

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 26, 2024

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Guideline Information:

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Guideline Name: Positron Emission Tomography (PET), Brain

Date of last literature review: 9/25/2024

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Medical Necessity Criteria

Service: PET Brain

Benefit Category

Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹⁸⁻²¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- [National Coverage Determination \(NCD\) FDG PET for Refractory Seizures 220.6.9.](#)
- [National Coverage Determination \(NCD\) Positron Emission Tomography \(FDG\) for Oncologic Conditions 220.6.17](#)
- [National Coverage Determination \(NCD\) FDG PET for Dementia and Neurodegenerative Diseases 220.6.13](#)
- [Billing and Coding: NCD Coding Article for Positron Emission Tomography \(PET\) Scans Used for Non-Oncologic Conditions \(A53134\)](#)
- [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Recommended Clinical Approach

Two distinct types of positron emission tomography (PET) of the brain are considered for different indications. Utilizing ¹⁸F-FDG (fluorodeoxyglucose) PET/CT imaging enables the assessment of metabolic activity and cerebral function. Specifically, ¹⁸F-FDG brain imaging proves valuable across a spectrum of clinical scenarios, such as dementia, seizure disorders, and the detection of new or recurring brain tumors.¹ FDG-PET imaging reveals regional variations in glucose metabolism, serving as a marker for neurodegeneration. These patterns not only signify the existence of neurological decline but also offer insight into the specific cerebral regions and pathways affected by the condition.² Amyloid imaging is advised for identifying the presence or absence of abnormal Aβ amyloid deposits in individuals experiencing progressive cognitive decline or dementia of unknown cause, where Alzheimer's disease is considered a potential diagnosis.²

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Positron Emission Tomography (PET) of the brain. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of PET imaging, including cumulative radiation exposure, allergy, and harm to breast milk.¹⁷
- Potential danger to pregnancy: PET imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹⁶ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹⁶
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹⁵

The clinical benefits of using these criteria include:

- Improved diagnostic accuracy: PET imaging, and in particular, FDG PET, can visualize certain pathologies before those conditions are visible on other imaging modalities, such as CT and MRI.¹ PET has also been shown to significantly impact clinical management and decision-making, even among patients with mild symptomatology, which is of particular importance in the context of neurodegenerative conditions.¹⁴
- Noninvasive: As an imaging modality, PET of the brain is noninvasive; it is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers. It also utilizes no injected contrast agent, conferring an inherent safety benefit.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Positron emission tomography (PET), brain** is considered appropriate if **ANY** of the following is **TRUE**:

◆ **Fluorodeoxyglucose (FDG) PET brain** and the patient has **ANY** of the following exam findings³:

- Seizure disorder (epilepsy) refractory to medical therapy for which invasive treatment is considered ^{1,6,19}; **OR**
- Tumor, strongly suspected or known, for initial or subsequent treatment strategy^{7-8,20}; **OR**
- Cognitive decline or suspected diagnosis of dementia for differentiation of Alzheimer's dementia and frontotemporal dementia, and the patient has had **ALL** of the following^{1-2,4,18}:
 - Evaluation by a physician experienced in the diagnosis and assessment of dementia; **AND**
 - Abnormal cognitive testing (MMSE, MoCA, SLUMS or similar); **AND**
 - Relevant lab values are available (B12, TSH); **AND**
 - Prior MRI or CT imaging of the brain; **OR**

◆ **Single Amyloid PET** is considered appropriate if **ALL** of the following are **TRUE**⁹:

- Alzheimer's disease following an interdisciplinary evaluation with **ALL** of the following:
 - General medical and neurological examination; **AND**
 - Laboratory testing; **AND**

- Mental status testing; **AND**
 - Structural neuroimaging; **AND**
 - Imaging is needed to determine the extent of the amyloid build-up prior to treatment with amyloid beta-directed antibodies (e.g., Lecanemab).
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

* NOTE: MRI is the preferred imaging modality for follow-up imaging following an initial amyloid PET scan.

Non-Indications

→ **Positron emission tomography (PET), brain** is not considered appropriate for **ANY** of the following:

- ◆ PET evaluation of perfusion of the brain.^{[21](#)}

*NOTE: PET in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

**NOTE: PET scans should be scheduled at least 4–6 weeks after radiation therapy or surgery to avoid false positives due to inflammation from recent treatments.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and

the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.¹⁰⁻¹¹

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.¹⁰⁻¹¹

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.¹⁰⁻¹¹

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.¹⁰⁻¹¹

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
78609	Brain imaging, positron emission tomography (PET); perfusion evaluation (this code is non-covered by CMS)

78811	Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)

Medical Evidence

Spano et al. (2023) analyzed the efficacy of PET imaging in cases of cognitive decline, specifically its significance in diagnosing Alzheimer's disease (AD). While FDG PET remains the predominant PET tracer in clinical use, several PET radiotracers enable the observation of underlying pathophysiological processes in AD, including A β deposition, tau deposition, synaptic density loss, neuroinflammation, cholinergic cell death, and reduced monoamine neurotransmission. Three FDA-approved 18F-labeled radiopharmaceuticals exist, including florbetaben (NeuraCeq), florbetapir (Amyvid), and flutemetamol (Vizamyl). These assess A β deposition, predominantly utilized in clinical trials with limited reimbursement for diagnostic purposes. The advancement of PET radiotracers in routine practice allows clinicians to diagnose and intervene in neurodegenerative diseases effectively.¹²

Quigg et al. (2022) report on using positron emission tomography with fluorine-18 fluorodeoxyglucose (¹⁸F-FDG-PET) to map brain glucose metabolism patterns. This imaging modality aids in assessing normal brain function and identifying metabolic abnormalities in various brain disorders. Traditional PET methods cannot distinguish normal from pathological tissue, particularly in conditions such as brain neoplasms or focal epilepsy. The aim is to enhance the functional mapping of metabolic activity within the target organ. Recent technological advancements may broaden dynamic PET across various clinical settings.¹³

Rabinovici et al. (2019) conducted a single-group, multi-center longitudinal study called Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) (ClinicalTrials.gov Identifier: NCT02420756). The study assessed whether amyloid PET scans influence the subsequent management decisions for patients diagnosed with mild cognitive impairment (MCI) or dementia of uncertain origin. Participants (n=11409) at 343 imaging centers underwent amyloid PET. Within 90 days of evaluation, participants diagnosed with MCI or dementia of uncertain origin who underwent amyloid PET scans exhibited alterations in clinical management. Further research is needed to ascertain whether amyloid PET correlates with enhanced clinical outcomes.¹⁴

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Cohere Medicare Advantage Policy – 3D Rendering of Imaging Studies

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Medical Necessity Criteria

Service: 3D Rendering of Imaging Studies

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no applicable NCDs or LCDs for 3D rendering of imaging studies.

Recommended Clinical Approach

Three-dimensional (3D) rendering of imaging studies is a technique that is performed by organizing thin sections of 2D images to reconstruct a 3D image. The resulting 3D image can enhance hard-to-visualize structures and therefore help to better visualize a pathology and guide clinical management. This technique is also known as 3D reconstruction or 3D reformation. 3D rendering can be performed for ultrasound (US), echocardiography, CT, MRI, MRA, CTA, DSA, and other tomographic imaging modalities. 3D reconstruction is not to be utilized to report coronal, sagittal, multiplanar, or oblique reformats constructed from axial imaging. 3D reformatting should not be standard protocol for US, MRI, and CT scanning.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of 3D rendering of imaging studies. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a possibility of inadequate visualization of pathologies that are denied 3D rendering using these criteria; however, the policy was written based on the current clinical knowledge base and best radiological practices.
- There is no direct risk to the patient, as 3D rendering is performed after the initial imaging.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The potential clinical benefits of using these criteria include:

- Reduced spending due to the complete visualization of pathology without the need for advanced, resource-intensive imaging.
- Appropriate, advanced visualization of certain conditions, particularly in the preoperative setting, necessitating complete characterization prior to other invasive interventions. Adequate visualization may confer a reduced operative time, shorter duration under anesthesia, complete repair or excision of an anomaly, and therefore improved patient outcomes.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **3D Imaging** is considered medically necessary if **ALL** of the following are **TRUE**²:

- ◆ When 3D imaging is required in order to obtain complete diagnostic information that would be critical to clinical management and cannot be ascertained through traditional (2D or multiplanar reformatted) imaging²; **AND**
- ◆ **ANY** of the following is true:
 - The patient requires preoperative planning for a complex surgical case²; **OR**
 - The patient has a known or suspected tumor with invasion of adjacent structure, such that 3D imaging may impact treatment¹⁻⁵; **OR**
 - The patient has vascular system pathology with planned procedural intervention, including **ANY** of the following⁶⁻¹⁵:
 - Aneurysms⁶⁻¹⁵; **OR**
 - Vascular abnormalities or malformations⁶⁻¹⁵; **OR**
 - Preprocedural and postprocedural evaluation of organ transplantation²⁹⁻³²; **OR**
 - Orthopedic imaging for **ANY** of the following¹⁶⁻²¹:
 - Spine surgery; **OR**
 - Acetabular osteotomy; **OR**
 - Wrist fracture; **OR**
 - Facial trauma; **OR**
 - Intra-articular fracture; **OR**
 - Other complex fractures with or without dislocation of any joint; **OR**
 - Evaluation of congenital craniofacial abnormalities^{27,28}; **OR**
 - Other not previously specified conditions wherein 3D image rendering would provide information that cannot otherwise be obtained by traditional 2D imaging or multiplanar reformatted images, and such information is critical to clinical management²²⁻²⁴; **OR**
 - Repeat 3D imaging (defined as repeat request following recent 3D imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**²:
 - New or worsening symptoms, such that repeat imaging would influence treatment²; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding²; **OR**

- In the absence of change in symptoms, there is an established need for monitoring which would influence management².

Non-Indications

→ **3D Imaging** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The patient has undergone 3D imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms; **OR**
- ◆ When used with an imaging study that is considered not medically necessary; **OR**
- ◆ For routine use by the imaging facility without specifically being ordered by the requesting physician.²

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation
76377	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Three-dimensional (3D) rendering of imaging studies is an enhanced visualization technique that generates a reconstructed 3D image. This is utilized to provide a better view of specific structures and guide clinical management in certain clinical scenarios. 3D imaging is most commonly used in the preoperative setting to aid in surgical or procedural planning. It is also beneficial when visualizing congenital anomalies, including vascular malformations. Importantly, 3D reconstruction is distinct from coronal, sagittal, multiplanar, or oblique reformatting constructed from axial imaging. It is a highly specialized adjunct to traditional imaging that is limited in use due to the excellent diagnostic accuracy of 2D imaging.

3D imaging is of particular use with musculoskeletal pathologies, such as a patient with traumatic fractures. The principal intent of 3D imaging in this setting is to improve patient outcomes by limiting the need for post-operative revision. Certain fracture locations – including orbital fractures – are unable to be visualized directly and therefore benefit from 3D reconstruction. 3D imaging of eligible pathologies allows orthopedic surgeons to optimize their surgical approach, reduce operative time, and improve precision.^{[16-21](#)}

A 2020 study in the *Journal of Vascular Surgery* provided clinical validation of 3D reconstruction of abdominal aortic aneurysms (AAAs), demonstrating a significantly improved reproducibility as compared to 2D imaging and mitigating the known challenges associated with 2D imaging, including operator-dependent variability which impacts accurate visualization and diagnosis of potentially unstable aneurysms.^{[12](#)}

When reserved for clinical scenarios that benefit most from complete, three-dimensional visualization, 3D rendering of imaging studies can be a valuable adjunct for diagnosing and treating specific pathologies.

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Original Date: February 6, 2025		
Review History		



Cohere Medicare Advantage Policy – 3D Rendering of Imaging Studies

Clinical Policy for Medical Necessity Review

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Policy Number: CHP-014-2

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Important Notices

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medicare Advantage Policy - 3D Rendering of Imaging Studies

Policy Number: CHP-014-2

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: 3D Rendering of Imaging Studies

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁸

- [Local Coverage Determination \(LCD\). Transesophageal Echocardiography \(TEE\) \(L34337\)](#)
 - [Billing and Coding: Transesophageal Echocardiography \(TEE\) \(A56809\)](#)
- [Local Coverage Determination \(LCD\). Transesophageal Echocardiography \(TEE\) \(L33579\)](#)
 - [Billing and Coding: Transesophageal Echocardiography \(TEE\) \(A52868\)](#)
- [Local Coverage Determination \(LCD\). Transthoracic echocardiography \(TTE\) \(L34338\)](#)
 - [Billing and Coding: Transthoracic echocardiography \(TTE\) \(A57306\)](#)
- [Local Coverage Determination \(LCD\). Transthoracic echocardiography \(TTE\) \(L33577\)](#)
 - [Billing and Coding: Transthoracic echocardiography \(TTE\) \(A56781\)](#)

Description

Three-dimensional (3D) rendering of imaging studies is a technique that is performed by organizing thin sections of 2D images to reconstruct a 3D image. The resulting 3D image can enhance hard-to-visualize structures, thereby helping to better understand a pathology and guide clinical management. This technique is also known as 3D reconstruction or 3D reformation. 3D rendering can be performed for ultrasound (US), echocardiography, computed tomography (CT), magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), computed tomography angiography (CTA), digital subtraction angiography (DSA), and other tomographic imaging modalities.

Medical Necessity Criteria

Indications

3D rendering of imaging studies is considered medically necessary when **ANY** of the following are **TRUE**:

- Performed for transesophageal echocardiography (TEE) or transthoracic echocardiography (TTE), and **ANY** of the following:
 - 3D echocardiography with TEE for **ANY** of the following^{1,3}:
 - Preoperative planning of valve repair for multiple etiologies of mitral regurgitation⁹; **OR**
 - Assessment of mitral stenosis and the accurate calculation of mitral valve area¹⁰; **OR**
 - Preoperative planning for diagnosis and treatment of atrial septal defects¹¹; **OR**
 - Preoperative and intraoperative planning for interventional cardiac procedures (e.g., transcatheter placement of occluders for atrial septal defect or patent foramen ovale, or paravalvular dehiscence or leak)^{12,13}; **OR**
 - Intraoperative mapping for atrial ablation procedures^{12,14}; **OR**
 - Evaluation of tricuspid valve disease¹⁵; **OR**
 - 3D echocardiography with TTE for **ANY** of the following^{5,7}:
 - Preoperative planning in patients who will be having surgery to repair mitral valve prolapse¹⁶; **OR**
 - Monitoring the mitral valve area in patients with moderate to severe mitral stenosis¹⁷; **OR**
- Performed for other imaging studies with **ALL** of the following:
 - Complete diagnostic information that would be critical to clinical management cannot be ascertained through traditional (2D or multiplanar reformatted) imaging¹⁸; **AND**
 - An associated imaging study is clearly identified (e.g., ultrasound, computed tomography [CT], magnetic resonance imaging [MRI], angiography, etc.)¹⁸; **AND**
 - **ANY** of the following:
 - Preoperative planning is required for a complex surgical case¹; **OR**
 - Known or suspected tumor with invasion of adjacent structures, such that 3D imaging may impact treatment¹⁹⁻²³; **OR**

- Vascular system pathology with planned procedural intervention, including **ANY** of the following²⁴⁻³³:
 - Aneurysms; **OR**
 - Vascular abnormalities or malformations; **OR**
- Congenital heart disease, requiring **ANY** of the following³⁴:
 - Initial diagnosis; **OR**
 - Presurgical planning; **OR**
 - Volumetric or anatomical assessment is required for surveillance or postoperative evaluation; **OR**
- Preprocedural and postprocedural evaluation of organ transplantation; **OR**
- Orthopedic imaging for preoperative planning of **ANY** of the following procedures³⁵⁻⁴⁰:
 - Acetabular osteotomy; **OR**
 - Facial trauma; **OR**
 - Intra-articular fracture; **OR**
 - Other complex fractures with or without dislocation of any joint; **OR**
 - Spine surgery; **OR**
- Evaluation of congenital craniofacial abnormalities; **OR**
- Other not previously specified conditions where 3D image rendering would provide information that cannot otherwise be obtained by traditional 2D imaging or multiplanar reformatted images, and such information is critical to clinical management.⁴¹⁻⁴³

Repeat imaging is considered appropriate when **ALL** of the following are **TRUE**:

- Repeat request following recent imaging within the past 3 months of the same anatomic region with the same or similar modality; **AND**
- No established guidelines for repeat imaging; **AND**
- **ANY** of the following:
 - Need for a one-time clarifying follow-up of a prior indeterminate finding; **OR**
 - New or worsening symptoms not addressed in the guidelines, such that repeat imaging would influence treatment; **OR**
 - No change in symptoms and a well-established clinical need for ongoing monitoring that will influence management.

Non-Indications

3D rendering of imaging studies is not considered appropriate if **ANY** of the following is **TRUE**:

- The request is in conjunction with an imaging study that is considered not medically necessary (e.g., for the calculation of volumetric studies in TEE or TTE)^{1,3,5,7}; **OR**
- The request is for 3D rendering alone without documentation of an associated imaging study and the reasons for the study⁴⁴; **OR**
- The request is for magnetic resonance angiography (MRA), computed tomography angiography (CTA), or coronary computed tomography angiography (CCTA), as 3D rendering is considered inclusive in such imaging (e.g., CPT 75572, 75573, 75574)⁴⁵⁻⁴⁷; **OR**
- The request is for 3D echocardiographic imaging and postprocessing for TEE or TTE exams, as 3D rendering is considered inclusive in such requests (e.g., 93319, 93355).⁷

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation
76377	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established." When clinical coverage criteria are "not fully established," Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for 3D rendering of imaging studies may include:

- No direct risk to the patient, as 3D rendering is performed after the initial imaging study has been completed; however, the utilization of medical necessity criteria for 3D imaging may increase time to care for cases in which 2D or other advanced imaging techniques suffice.^{[48](#)}
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The potential clinical benefits of using these criteria for 3D rendering of imaging studies may include:

- Appropriate, advanced visualization of certain conditions, particularly in the preoperative setting, which necessitates complete characterization prior to other invasive interventions. Adequate visualization may confer a reduced operative time, shorter duration under anesthesia, complete repair or excision of an anomaly, and therefore improved patient outcomes.^{[49](#)}
- Enhanced overall patient satisfaction and healthcare experience.

Medical Evidence

Timmins et al. (2022) conducted three-dimensional (3D) morphology measurements of 127 unruptured intracranial aneurysms in 112 patients to investigate the relationship between change in aneurysm size and 3D morphologic changes. The types of 3D measurements assessed included surface area, compactness, elongation, flatness, sphericity, shape index, and curvedness, with categoric growth defined as an increase of at least 1 mm in 2D length or width. The authors found that the continuous growth of an unruptured intracranial aneurysm was associated with an increase in surface area and flatness. They also found an inverse association between growth and shape index and curvedness. The authors concluded that further studies are needed to determine whether morphologic changes and/or size can predict aneurysm rupture.¹⁷

Ghulam et al. (2020) compared interoperator reproducibility among non-physician ultrasound technicians when performing both 2D and 3D ultrasound for the surveillance of abdominal aortic aneurysms. 90 patients with asymptomatic infrarenal abdominal aortic aneurysm underwent ultrasound imaging to measure the maximum diameter of the aneurysm. Interoperator reproducibility was found to be superior for 3D ultrasound compared to 2D ultrasound (intraclass correlation 0.97 vs 0.93, respectively).²¹

Thong et al. (2016) analyzed 3D reconstructions of 915 spinal radiographs from 663 adolescent patients with scoliosis, using a machine learning algorithm to identify potential subgroupings within this population. Overall, the machine learning algorithm identified 11 unique subgroups. The main discriminating factors were the location of the main curve, kyphosis, and lordosis. This algorithm could help simplify 3D spine models without compromising the complexity of the measured parameters.²⁸

3D medical imaging and 3D printing tools have rapidly expanded clinical care. A recent review (Christensen and Rybicki, 2017) emphasized that 3D printing relies entirely on the accuracy of the originating imaging study, because the volumetric dataset determines the anatomical models used for surgical planning, education, or template creation.³⁵ The authors emphasized that 3D printing does not replace imaging, but rather extends visualization.³⁵

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Policy Revision History/Information

Original Date: February 6, 2025		
Review History		
Version 2	01/29/2026	Annual review. Added indications for TEE (L34337, L33579) and TTE (L34338, L33577). Added indications to require that the associated imaging study be clearly identified. Added indications for congenital heart disease. Added non-indications for 3D rendering alone without documentation of an associated imaging study and the reasons for the study; for CTA, CCTA, or MRA; and for 3D echocardiographic imaging and postprocessing for TEE or TTE exams. Expanded the Medical Evidence section.



Cohere Medicare Advantage Policy – Cardiac Contractility Modulation (CCM)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 24, 2024

Important Notices

Notices & Disclaimers:

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medicare Advantage Policy - Cardiac Contractility Modulation (CCM)

Date of last literature review: 10/22/2024

Document last updated: 10/23/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Cardiac Contractility Modulation (CCM)

Benefit Category

Not Applicable

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for cardiac contractility modulation (CCM)

Recommended Clinical Approach

This service is clinically unproven and not medically necessary. Cardiac contractility modulation (CCM) is a device-based therapy proposed for heart failure (HF) patients with decreased left ventricular ejection fraction (LVEF) who are not candidates for other treatments such as cardiac resynchronization therapy.¹ Electrical impulses delivered to the heart muscle are purported to assist the heart in pumping blood more effectively and potentially reduce symptoms such as breathlessness, fatigue, and lower extremity edema.²⁻⁵

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of cardiac contractility modulation (CCM). This process helps prevent incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Meta-analysis of randomized controlled trials (RCTs) of all-cause mortality outcomes of usage of cardiac contractility monitoring (CCM)

in patients with dilated cardiomyopathy and ineligible for cardiac resynchronization therapy (CRT) revealed no significant reduction in all-cause mortality compared to standard therapy.²

- CCM has not shown any impact on hospitalization or death in patients with cardiomyopathy in randomized controlled trials (RCTs).⁶⁻⁹
- Hospitalizations have occurred more frequently for patients with CCM than those with cardiac resynchronization therapy and defibrillator (CRT-D).¹⁰
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- A retrospective study comparing patients with cardiac contractility modulation (CCM) versus those with cardiac resynchronization therapy with defibrillator (CRT-D) showed that intrinsic QRS width was stable with CCM.¹⁰
- A study comparing the Optimizer Smart and the Optimizer Smart Mini CCM devices concluded that in both randomized and nonrandomized clinical trials, New York Heart Association (NYHA) Class II-III patients with left ventricular ejection fraction (LVEF) between 25% and 45% most often benefited from CCM therapy.⁵
- Four randomized controlled trials (RCTs) have shown benefits in exercise capacity and quality of life (QOL) with CCM therapy.⁶⁻⁹
- A 2-year multi-site evaluation of CCM in patients with heart failure concluded that CCM provides a safe and effective long-term symptomatic and functional improvement in heart failure independent of baseline LVEF and was associated with a safety profile similar to published device trials.¹¹
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, using these criteria will likely decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **Cardiac contractility monitoring (CCM)** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

- **Cardiac contractility monitoring (CCM)** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ This is not applicable, as there are no indications.

Level of Care Criteria

None

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0408T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes
0409T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator only
0410T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic

	parameters; atrial electrode only
0411T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; ventricular electrode only
0412T	Removal of permanent cardiac contractility modulation system; pulse generator only
0413T	Removal of permanent cardiac contractility modulation system; transvenous electrode (atrial or ventricular
0414T	Removal and replacement of permanent cardiac contractility modulation system pulse generator only
0415T	Repositioning of previously implanted cardiac contractility modulation transvenous electrode, (atrial or ventricular lead)
0416T	Relocation of skin pocket for implanted cardiac contractility modulation pulse generator
0417T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable cardiac contractility modulation system
0418T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Nadeem and colleagues (2020) conducted a systematic review and updated meta-analysis of randomized controlled trials regarding all-cause mortality outcomes of usage of cardiac contractility monitoring (CCM) in patients with dilated cardiomyopathy who were ineligible for cardiac resynchronization therapy (CRT). Patients in this group had dilated cardiomyopathy and were divided into a CCM group and a standard therapy group and were followed for 12 weeks or longer. In their analysis of 930 patients, the CCM therapy group showed no significant reduction in all-cause mortality compared to the standard therapy group. The researchers concluded that there was a need for a large, randomized, controlled trial to determine CCM efficacy.²

Pipilas et al. (2023) published a systematic literature review regarding the current and future directions of CCM for heart failure. At the time of their review, only two devices, the Optimizer Smart and the Optimizer Smart Mini had received FDA approval. Their review concluded that in both randomized and nonrandomized clinical trials, New York Heart Association (NYHA) Class II-III patients with left ventricular ejection fraction between 25% and 45% most often benefited from CCM therapy. They stated that a positive effect exists with CCM; however, verification and further study in prospective, randomized controlled trials is necessary.⁵

In a 2016 systematic review, Abi-Samra and Gutterman discussed the clinical results of the current literature at that time. FDA-approved pharmacological and device-based treatments for heart failure with reduced ejection fraction (HFrEF) were stated to be limited, and CCM could fill the gap in current treatment for selected patients. Regarding long-term outcomes, the writers discuss retrospective trial outcomes and acknowledge that at that time, there had been no prospective CCM trials with mortality as a primary outcome. The need for such a prospective randomized trial is emphasized. Special applications and evaluations in CCM use include expansion of duration of daily CCM stimulus, use in cardiac resynchronization therapy (CRT) failures, heart failure with preserved ejection fraction, and atrial fibrillation.⁴

According to the 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure, four randomized controlled trials (RCTs) have shown benefits in

exercise capacity and quality of life (QOL); however, as of yet, no benefits in reducing death or hospitalizations have been shown.¹²

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Clinical Guideline Revision History/Information

Original Date: October 24, 2024		
Review History		



Cohere Medicare Advantage Policy – Cardiac Contractility Modulation (CCM)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 24, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medicare Advantage Policy - Cardiac Contractility Modulation (CCM)

Date of last literature review: 10/22/2024

Document last updated: 10/23/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Cardiac Contractility Modulation (CCM)

Benefit Category

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Medical Necessity Criteria

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Non-Indications

→ **Cardiac contractility monitoring (CCM)** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ This is not applicable, as there are no indications.

Level of Care Criteria

None

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0408T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes
0409T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator only
0410T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic

	parameters; atrial electrode only
0411T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; ventricular electrode only
0412T	Removal of permanent cardiac contractility modulation system; pulse generator only
0413T	Removal of permanent cardiac contractility modulation system; transvenous electrode (atrial or ventricular
0414T	Removal and replacement of permanent cardiac contractility modulation system pulse generator only
0415T	Repositioning of previously implanted cardiac contractility modulation transvenous electrode, (atrial or ventricular lead)
0416T	Relocation of skin pocket for implanted cardiac contractility modulation pulse generator
0417T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable cardiac contractility modulation system
0418T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Nadeem and colleagues (2020) conducted a systematic review and updated meta-analysis of randomized controlled trials regarding all-cause mortality outcomes of usage of cardiac contractility monitoring (CCM) in patients with dilated cardiomyopathy who were ineligible for cardiac resynchronization therapy (CRT). Patients in this group had dilated cardiomyopathy and were divided into a CCM group and a standard therapy group and were followed for 12 weeks or longer. In their analysis of 930 patients, the CCM therapy group showed no significant reduction in all-cause mortality compared to the standard therapy group. The researchers concluded that there was a need for a large, randomized, controlled trial to determine CCM efficacy.²

Pipilas et al. (2023) published a systematic literature review regarding the current and future directions of CCM for heart failure. At the time of their review, only two devices, the Optimizer Smart and the Optimizer Smart Mini had received FDA approval. Their review concluded that in both randomized and nonrandomized clinical trials, New York Heart Association (NYHA) Class II-III patients with left ventricular ejection fraction between 25% and 45% most often benefited from CCM therapy. They stated that a positive effect exists with CCM; however, verification and further study in prospective, randomized controlled trials is necessary.⁵

In a 2016 systematic review, Abi-Samra and Gutterman discussed the clinical results of the current literature at that time. FDA-approved pharmacological and device-based treatments for heart failure with reduced ejection fraction (HFrEF) were stated to be limited, and CCM could fill the gap in current treatment for selected patients. Regarding long-term outcomes, the writers discuss retrospective trial outcomes and acknowledge that at that time, there had been no prospective CCM trials with mortality as a primary outcome. The need for such a prospective randomized trial is emphasized. Special applications and evaluations in CCM use include expansion of duration of daily CCM stimulus, use in cardiac resynchronization therapy (CRT) failures, heart failure with preserved ejection fraction, and atrial fibrillation.⁴

According to the 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure, four randomized controlled trials (RCTs) have shown benefits in

exercise capacity and quality of life (QOL); however, as of yet, no benefits in reducing death or hospitalizations have been shown.¹²

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Clinical Guideline Revision History/Information

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Cohere Medicare Advantage Policy – Computed Tomography (CT), Abdomen/Pelvis

Clinical Guidelines for Medical Necessity Review

Version: 1
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Important Notices

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Medical Necessity Criteria

Service: Computed Tomography (CT), Abdomen/Pelvis

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁵

- [National Coverage Determination \(NCD\). Computed tomography \(CT\) \(220.1\)](#)
- [Local Coverage Determination \(LCD\). CT of the Abdomen and Pelvis \(L34415\)](#)
- [Billing and Coding: CT of the Abdomen and Pelvis \(A56421\)](#)
- [Local Coverage Determination \(LCD\). Multiple Imaging in Oncology \(L35391\)](#)
- [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Recommended Clinical Approach

Computed tomography (CT) of the abdomen/pelvis should be initiated by the referring physician or an appropriate allied healthcare professional involved in the patient's care. The request should contain all the necessary information regarding the patient's signs and symptoms, history, and known and suspected diagnoses to determine the appropriate imaging modalities.⁶

Bosniak Classification ¹⁻³		
Stage	Malignancy Risk (%)	Features
I	0	Hairline-thin wall; water attenuation; no septa, calcifications, or solid components; non-enhancing.
II	0	1. Few thin septa with or without perceived (not measurable) enhancement; fine calcification or a short segment of slightly thickened calcification in the wall or septa. 2. Homogeneously high-attenuating masses less than or equal to 3 cm that are sharply margined and do not enhance.
IIF	5	1. Minimally thickened or more than a few thin septa with or without perceived (not measurable) enhancement that may have thick or nodular calcification. 2. Intrarenal non-enhancing hyperattenuating renal masses greater than 3 cm.
III	50	Thickened (less than 3 mm) wall or septa with enhancement.
IV	90	Soft tissue components (e.g., nodules) with measurable enhancement.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of computed tomography (CT), abdomen/pelvis. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

A computed tomographic (CT) image is a display of the anatomy of a cross section of the body developed from multiple x-ray absorption measurements made around the periphery of the body. The CT image is constructed mathematically using data arising from the section of interest that are oriented essentially perpendicular to the axial dimensions of the body. The final CT image can be accomplished in any plane.²

The potential clinical harms of using these criteria may include:

- An inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁹⁻¹²
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹³ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹³
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹⁴

The clinical benefits of using these criteria include²⁰:

- Detailed images of bone, soft tissue, and blood vessels allow for diagnosing conditions as well as for treatment planning and evaluation. Exploratory surgery and biopsy may be unnecessary in some scenarios due to the detail that CT provides.^{15,31}
- Appendicitis is the most common reason for emergency abdominal surgery and is difficult to diagnose clinically. Diagnostic accuracy of acute appendicitis is 93 to 98% with CT.¹⁶ When compared to ultrasound, CT has a higher sensitivity and positive predictive value.^{17, 29}
- CT scans of thorax, abdomen, or pelvic organs have been shown to be most effective in diagnosing cancers. Due to widespread availability and relatively low cost, CT is a valuable approach for cancer screening.¹⁸
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous

clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), abdomen or abdomen/pelvis** is considered appropriate if **ANY** of the following is **TRUE**⁶:

◆ **ANY** of the following indications:

- Abdominal, including pain in the general abdomen, lower abdomen, or pelvic area^{2,19-21}; **OR**
- Abnormality in the hepatobiliary system (e.g., liver, bile ducts, gallbladder, and associated structures); **OR**
- Diffuse liver disease (e.g., cirrhosis, steatosis, iron deposition disease); **OR**
- Autoimmune or inflammatory processes (e.g., pancreatitis³⁰ autoimmune hepatitis, primary biliary cirrhosis); **OR**
- Preoperative or postoperative evaluation; **OR**
- Splenic or perisplenic abnormalities; **OR**
- Abnormalities of the kidneys and adrenal gland when **ANY** of the following is **TRUE**^{7-10,36-37}:
 - Characterization of renal cysts that do not appear to be simple on ultrasound⁷⁻⁸; **OR**
 - Indeterminate renal and adrenal masses; **OR**
- Abdominal masses or fluid collections, known or suspected²; **OR**
- Abnormalities in abdominal or pelvic vascular structures (e.g., aortic aneurysm, pulsatile abdominal mass, retroperitoneal bleed³⁸, etc.)²; **OR**
- Trauma²; **OR**
- Clarification of findings from other imaging studies of the abdomen²; **OR**
- Confirmation of abdominal pathology suggested by laboratory abnormalities²; **OR**
- Guidance for interventional diagnostic or therapeutic procedures²; **OR**
- Planning for radiation therapy²; **OR**

- Evaluation for transcatheter aortic valve implantation/replacement (TAVI/TAVR) if patient has not undergone a CT of the abdomen within the preceding 60 days^{2,22-24}; **OR**
- Neoplastic conditions for **ANY** of the following⁴:
 - Initial staging; **OR**
 - Treatment planning; **OR**
 - Response assessment; **OR**
 - Surveillance, and **ANY** of the following is **TRUE**^{4-5,26-28}:
 - ◆ The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - ◆ Suspected recurrence/progression; **OR**
 - ◆ Evaluation of response to treatment when a change in therapy is contemplated; **OR**
- Conditions related to the prostate, including **ANY** of the following²:
 - Prostatitis when symptoms are worsening despite treatment; **OR**
 - Prostate cancer for **ANY** of the following indications:
 - ◆ Initial staging
 - ◆ Assessment of treatment response when carcinoma is poorly differentiated; **OR**
 - ◆ Restaging, when metastases are suspected; **OR**
- Unexplained lymphadenopathy²; **OR**
- Genitourinary (GU) disorders including **ALL** of the following:
 - when the physician cannot make a diagnosis based on physical exam and/or ultrasound²; **AND**
 - **ANY** of the following:
 - ◆ Further evaluation of known bladder pathology seen on cystoscopy or ultrasound²; **OR**
 - ◆ Other reproductive organs, including the uterus/ovaries/testicle/fallopian tube/cervix when ultrasound is indeterminate (MRI is preferred)²; **OR**
 - ◆ An undescended testicle (MRI is preferred); **OR**
 - ◆ Postpartum hemorrhage³²; **OR**
 - ◆ Ovarian cysts or indeterminate masses; **OR**

- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography (CT), abdomen/pelvis with contrast** is **NOT** considered appropriate if **ANY** of the following is **TRUE**²⁵:

- ◆ History of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for

pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{11,33}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{11,33}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{11,33}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{11,33}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72192	Computed tomography (CT), pelvis; without contrast material
72193	Computed tomography (CT), pelvis; with contrast material

72194	Computed tomography (CT), pelvis; without contrast material, followed by contrast material(s) and further sections
74150	Computed tomography (CT), abdomen; without contrast material
74160	Computed tomography (CT), abdomen; with contrast material
74170	Computed tomography (CT), abdomen; without contrast material, followed by contrast material(s) and further sections
74176	Computed tomography (CT), abdomen and pelvis; without contrast material
74177	Computed tomography (CT), abdomen and pelvis; with contrast material
74178	Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions
76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Shah et al. (2022) performed a retrospective review of patients who had at least one CT scan of the abdomen ($\pm$ pelvis) or MRI of the abdomen ($\pm$ pelvis) at least 30 days post-diagnosis of Crohn's disease (CD) or ulcerative colitis (UC). The review identified factors associated with patients undergoing more than 5 CT scans of the abdomen between 2010 and 2019 and included 176,110 patients with CD and 143,460 patients with UC. From 2010 to 2019, the prevalence of individuals undergoing at least one annual CT scan of the abdomen increased with a mean annual percentage change of +3.6% for CD and +4.9% for UC. A 3.8% increase was found in the proportion of CD patients receiving greater than or equal to 5 CT scans of the abdomen annually compared to a 2.4% increase among UC patients over the ten years. The authors conclude that the prevalence of CT scans in IBD patients has escalated. Future research is needed regarding the determinants influencing the utilization of CT and MRI scans.³⁴

Oldroyd et al. (2021) conducted a meta-analysis that focused on using CT to identify underlying asymptomatic cancers. CT scans of thorax, abdomen, or pelvic organs proved to be the most effective in diagnosing cancer cases, accounting for most detections (5 out of 18, 28%). Due to widespread availability and relatively low cost, CT scanning is a potentially valuable approach for cancer screening.¹⁸

Baron et al. (2018) performed a systematic review and meta-analysis on the accuracy of CT in the diagnosis of intra-abdominal injuries in patients presenting to the emergency department (ED) with anterior abdominal stab wounds. The study aimed to assess the precision of abdominal and pelvic computed tomography (CTAP) in diagnosing intra-abdominal injuries that necessitate therapeutic laparotomy (THER-LAP) in ED patients with acute abdominal or abdominal and pelvic blunt trauma. A total of 575 patients were included. For stable patients with suspected abdominal aortic syndromes, relying solely on a negative CT scan without a period of observation is insufficient to rule out significant intra-abdominal injuries.³⁵

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Clinical Guideline Revision History/Information

Original Date: October 29, 2024		
Review History		



Cohere Medicare Advantage Policy – Computed Tomography (CT), Abdomen/Pelvis

Clinical Policy for Medical Necessity Review

Version: 2

Cohere Health UMC Approval Date: October 16, 2025

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Next Annual Review: October 16, 2026

Important Notices

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Abdomen/Pelvis

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Abdomen/Pelvis

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁵

- [National Coverage Determination \(NCD\). Computed tomography \(CT\) \(220.1\)](#)
- [Local Coverage Determination \(LCD\). CT of the abdomen and pelvis \(L34415\)](#)
 - [Billing and Coding: CT of the abdomen and pelvis \(A56421\)](#)
- [Local Coverage Determination \(LCD\). Multiple imaging in oncology \(L35391\)](#)
 - [Billing and Coding: Multiple imaging in oncology \(A56848\)](#)

Description

Computed tomography (CT) of the abdomen/pelvis is a cross-sectional imaging modality that visualizes the abdomen and pelvis. CT generates detailed images, especially of the soft tissue, bones, and blood vessels. Intravenous and oral contrast can be used to better characterize certain pathologies in greater detail.⁶⁻⁹

Medical Necessity Criteria

Indications

Computed tomography (CT), abdomen is considered appropriate if **ANY** of the following is **TRUE²**:

- Evaluation of **ANY** of the following:
 - Abdominal pain; **OR**
 - Abdominal masses (known or suspected); **OR**
 - Fluid collections (known or suspected); **OR**
 - Malignancies (primary or metastatic); **OR**
 - Abdominal inflammatory processes; **OR**
 - Abnormalities of abdominal vascular structures; **OR**
 - Abdominal trauma; **OR**
- Clarification of findings from other imaging studies of the abdomen; **OR**
- Laboratory abnormalities suggesting abdominal pathology; **OR**
- Guidance for interventional diagnostic or therapeutic procedures within the abdomen; **OR**
- Treatment planning for radiation therapy; **OR**
- Patient is being evaluated for potential transcatheter aortic valve implantation/replacement (TAVI or TAVR) and has not undergone a CT of the abdomen within the preceding 60 days.

Computed tomography (CT), pelvis is considered appropriate if **ANY** of the following is **TRUE²**:

- Evaluation of **ANY** of the following:
 - Cysts, tumors, or masses of the pelvic structure; **OR**
 - Metastases or primary cancers to the pelvic region; **OR**
 - Inflammatory processes in the pelvis; **OR**
 - Abnormalities of pelvic vascular structures; **OR**
 - Lymphadenopathy in this region; **OR**
 - Pain of **ANY** of the following;
 - Lower abdomen; **OR**
 - Generalized abdomen; **OR**
 - Pelvis; **OR**
 - Genitourinary (GU) disorders in which the physician cannot make a diagnosis on physical examination or by ultrasound; **OR**
 - Trauma to the pelvic structure/organs; **OR**

- Effectiveness of a radiation treatment plan; **OR**
- Patient is being evaluated for potential transcatheter aortic valve implantation/replacement (TAVI or TAVR) and has not undergone a CT of the abdomen within the preceding 60 days.

Non-Indications

Computed tomography (CT), abdomen/pelvis with contrast is not considered appropriate if **ANY** of the following is **TRUE**¹⁰:

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Definitions

Bosniak Classification ⁹⁻¹⁰		
Stage	Malignancy Risk (%)	Features
I	0	Hairline-thin wall; water attenuation; no septa, calcifications, or solid components; non-enhancing.
II	0	1. Few thin septa with or without perceived (not measurable) enhancement; fine calcification or a short segment of slightly thickened calcification in the wall or septa. 2. Homogeneously high-attenuating masses less than or equal to 3 cm that are sharply margined and do not enhance.
IIF	5	1. Minimally thickened or more than a few thin septa with or without perceived (not measurable) enhancement that may have thick or nodular calcification. 2. Intrarenal non-enhancing hyperattenuating renal masses greater than 3 cm.
III	50	Thickened (less than 3 mm) wall or septa with enhancement.
IV	90	Soft tissue components (e.g., nodules) with measurable enhancement.

Disclaimer on Radiation Exposure in Pediatric Populations

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{[11,12](#)}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{[11,12](#)}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{[11,12](#)}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{[11,12](#)}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72192	Computed tomography (CT), pelvis; without contrast material
72193	Computed tomography (CT), pelvis; with contrast material
72194	Computed tomography (CT), pelvis; without contrast material, followed by contrast material(s) and further sections
74150	Computed tomography (CT), abdomen; without contrast material
74160	Computed tomography (CT), abdomen; with contrast material
74170	Computed tomography (CT), abdomen; without contrast material, followed by contrast material(s) and further sections
74176	Computed tomography (CT), abdomen and pelvis; without contrast material
74177	Computed tomography (CT), abdomen and pelvis; with contrast material
74178	Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions
76380	Computed tomography, limited or localized follow-up study

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for computed tomography of the abdomen/pelvis may include:

- An inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁹⁻¹²
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹³ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹³
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹⁴

The clinical benefits of using these criteria computed tomography of the abdomen/pelvis include¹⁵:

- Detailed images of bone, soft tissue, and blood vessels allow for diagnosing conditions as well as for treatment planning and evaluation. Exploratory surgery and biopsy may be unnecessary in some scenarios due to the detail that CT provides.^{16,17}
- Appendicitis is the most common reason for emergency abdominal surgery and is difficult to diagnose clinically. Diagnostic accuracy of acute appendicitis is 93 to 98% with CT.¹⁸ When compared to ultrasound, CT has a higher sensitivity and positive predictive value.^{19,20}

- CT scans of thorax, abdomen, or pelvic organs have been shown to be most effective in diagnosing cancers. Due to widespread availability and relatively low cost, CT is a valuable approach for cancer screening.²¹
- Enhanced overall patient satisfaction and healthcare experience.

Medical Evidence

Shah et al. (2022) performed a retrospective review of patients who had at least one CT scan of the abdomen (with or without pelvis) or MRI of the abdomen (with or without pelvis) at least 30 days post-diagnosis of Crohn's disease (CD) or ulcerative colitis (UC). The review identified factors associated with patients undergoing more than 5 CT scans of the abdomen between 2010 and 2019 and included 176,110 patients with CD and 143,460 patients with UC. From 2010 to 2019, the prevalence of individuals undergoing at least one annual CT scan of the abdomen increased with a mean annual percentage change of +3.6% for CD and +4.9% for UC. A 3.8% increase was found in the proportion of CD patients receiving greater than or equal to 5 CT scans of the abdomen annually compared to a 2.4% increase among UC patients over the ten years. The authors concluded that the prevalence of CT scans in inflammatory bowel disease patients has escalated. Future research is needed regarding the determinants influencing the utilization of CT and MRI scans.¹³

Oldroyd et al. (2021) conducted a meta-analysis that focused on using CT to identify underlying asymptomatic cancers. CT scans of the thorax, abdomen, or pelvic organs proved to be most effective in diagnosing cancer cases, accounting for most detections (5 out of 18, 28%). Due to widespread availability and relatively low cost, CT scanning is a potentially valuable approach for cancer screening.¹⁴

Baron et al. (2018) performed a systematic review and meta-analysis on the accuracy of CT in the diagnosis of intra-abdominal injuries in patients presenting to the emergency department (ED) with anterior abdominal stab wounds. The study aimed to assess the precision of abdominal and pelvic computed tomography (CTAP) in diagnosing intra-abdominal injuries that necessitate therapeutic laparotomy (THER-LAP) in ED patients with acute abdominal or abdominal and pelvic blunt trauma. A total of 575 patients were included. For stable patients with suspected abdominal aortic syndromes, relying solely on a negative CT scan without a period of observation is insufficient to rule out significant intra-abdominal injuries.²²

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Policy Revision History/Information

Original Date: October 29, 2024		
Review History		
Version 2	10/16/2025	Annual review Rewrote indications to conform to L34415. Reframed indications for concision and clarity. Updated conservative care language. Updated DI non-indication language (e.g. removed contrast allergy bullet). Updated references.



Cohere Medicare Advantage Policy – Computed Tomography (CT), Brain

Clinical Policy for Medical Necessity Review

Version: 2

Cohere Health UMC Approval Date: October 23, 2025

Last Annual Review: October 23, 2025

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Next Annual Review: October 23, 2026

Important Notices

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Brain

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Brain

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁹

- [National Coverage Determination \(NCD\). Computed Tomography \(220.1\)](#)
- [Local Coverage Determination \(LCD\). CT of the Head \(L34417\)](#)
 - [Billing and Coding: CT of the Head \(A56612\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L37373\)](#)
 - [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57204\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L35175\)](#)
 - [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\)](#)
- [Local Coverage Determination \(LCD\). Multiple Imaging in Oncology \(L35391\)](#)
 - [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Description

Computed tomography (CT) of the brain is often used when magnetic resonance imaging (MRI) is unavailable or contraindicated. CT of the brain will often be the initial screening examination to evaluate for acute, life-threatening conditions, but it will commonly be supplemented by MRI evaluation.¹⁰

Medical Necessity Criteria

Indications

Computed tomography (CT), brain is considered appropriate if **ANY** of the following is **TRUE**:

- Neoplastic conditions for **ANY** of the following⁸:
 - Initial staging; **OR**
 - For staging of known lung cancer, breast cancer, and lymphomas which are likely to metastasize early to the brain²; **OR**
 - Response assessment; **OR**
 - Treatment planning; **OR**
 - Surveillance, and **ANY** of the following¹¹⁻¹³:
 - The patient is assumed to have either no known disease or a disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - Suspected recurrence/progression; **OR**
 - Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6-8 weeks since the prior imaging evaluation); **OR**
- Characterization of a specific lesion² with atypical features on prior imaging for further evaluation or follow-up; **OR**
- Bone tumor or abnormality of the skull; **OR**
- Known or suspected pituitary tumors or sella turcica tumor (MRI is contraindicated or cannot be performed); **OR**
- Skull lesion (e.g., fibrous dysplasia, Paget disease, histiocytosis, osteolytic lesion, skeletal tumors)¹⁰; **OR**
- Intracranial lesions large enough to cause increased intracranial pressure^{4,6}; **OR**
- New onset seizures, particularly if a focal component is present^{4,6}; **OR**
- Detection of defects in blood/brain barrier (e.g., infarcts, tumors, infection, vasculitis)^{2,4,6}; **OR**
- Suspected recurrence with prior history of central nervous system [CNS] cancer (either primary or secondary) based on neurological symptoms or examination findings (MRI is contraindicated or cannot be performed); **OR**
- Suspected elevated intracranial pressure¹⁰; **OR**
- Histiocytic neoplasms (e.g., Langerhans cell histiocytosis, Erdheim-Chester disease, Rosai-Dorfman disease) to assess treatment

response and surveillance of known brain/skull lesions when MRI is contraindicated or cannot be performed; **OR**

- Infection or an infectious disorder, known or suspected, with **ALL** of the following¹⁰:
 - MRI is contraindicated or cannot be performed; **AND**
 - **ANY** of the following:
 - Suspected intracranial abscess or brain infection with altered mental status or abnormal lab findings; **OR**
 - Follow-up assessment during or after treatment completed; **OR**
 - Endocarditis with suspected septic emboli; **OR**
 - Suspected primary CNS vasculitis based on neurological signs and symptoms with completed infectious or inflammatory lab work-up; **OR**
- Trauma-related conditions as indicated by **ANY** of the following^{10,14,15}:
 - Head trauma, acute; **OR**
 - Nonaccidental trauma (e.g., abuse); **OR**
 - Known coagulopathy or on anticoagulation; **OR**
 - Repeat scan 24-hour post head trauma for anticoagulated or coagulopathic patients with a suspected diagnosis of delayed subdural hematoma; **OR**
 - Postconcussive syndrome with **ALL** of the following¹⁶:
 - MRI is contraindicated or cannot be performed; **AND**
 - Symptoms are worsening or not improving; **AND**
 - Previous imaging has not been performed; **OR**
 - Subacute or chronic traumatic brain injury with **ALL** of the following:
 - MRI is contraindicated or cannot be performed; **AND**
 - Unexplained cognitive and/or neurologic deficit; **OR**
 - Known or suspected skull fracture by physical exam and/or prior imaging; **OR**
- Vascular conditions, known or suspected, including **ANY** of the following:
 - Intraparenchymal hemorrhage, known or suspected¹⁷; **OR**
 - Intracranial hemorrhage, known or suspected, including follow-up¹⁰; **OR**
 - Ischemic infarct, known or suspected¹⁷; **OR**
 - Other acute CNS hemorrhage^{4,6}; **OR**
 - Encephalomalacia^{4,6}; **OR**
 - Cerebrovascular accident (i.e., stroke or transient ischemic attack [TIA]), suspected^{2,17}; **OR**
 - Venous sinus thrombosis, known or suspected¹⁷; **OR**

- For evaluation of **ANY** of the following miscellaneous pathologies when prior testing has failed:
 - Syncope with clinical concern for seizure or associated neurological signs and symptoms when MRI is contraindicated or cannot be performed; **OR**
 - For evaluation of cranial nerve and visual abnormalities when MRI is contraindicated or cannot be performed; **OR**
 - Congenital skull and brain lesions (e.g., craniosynostosis, macrocephaly, and microcephaly)¹⁰; **OR**
 - Established initial clinical diagnosis of dementia, including **ALL** of the following:
 - MRI is contraindicated or cannot be performed; **AND**
 - **ANY** of the following:
 - Abnormal cognitive status testing according to objective screening tool including **ANY** of the following¹⁸⁻²⁰:
 - Montreal cognitive assessment (MoCA) less than 26; **OR**
 - Mini-mental state examination (MMSE) score less than 23²⁰; **OR**
 - Saint Louis University mental status (SLUMS) score less than 19²¹; **OR**,
 - Informant questionnaire on cognitive decline in the elderly (IQCODE) score greater than or equal to 3.4²²; **OR**
 - Mini-cog score less than 3; **OR**
 - Formal neuropsychological testing; **OR**
 - Detailed history showing 6 months longer of cognitive decline, memory loss, or impairment of daily activities; **AND**
 - Completed screen for depression; **AND**
 - Completed metabolic workup (e.g., testing for anemia, thyroid function testing, liver and kidney function testing, complete blood count, electrolytes, diabetes mellitus, and B12 deficiency); **OR**
 - The patient has, or is suspected to have, a seizure disorder and **ALL** of the following:
 - MRI is contraindicated or cannot be performed; **AND**
 - **ANY** of the following:
 - New onset of seizures or newly identified change in seizure activity/pattern; **OR**
 - Known seizure disorder without prior imaging; **OR**
 - Medically refractory epilepsy; **OR**

- New neurologic deficit or no return to previous neurologic baseline; **OR**
- Repeat testing for “Epilepsy Protocol” or preoperative or treatment planning; **OR**
- For the evaluation of a headache, with **ANY** of the following conditions⁴⁶:
 - Vision problems; **OR**
 - After a head injury to rule out intracranial bleeding; **OR**
 - Unusual duration (greater than two weeks) not responding to medical therapy to rule out the possibility of a tumor; **OR**
 - Sudden and severe onset to rule out the possibility of an aneurysm, bleeding, and/or arteriovenous malformation; **OR**
- New onset headache in an adult patient (18 years of age or older) with **ALL** of the following⁴⁷:
 - MRI is contraindicated or cannot be performed; **AND**
 - **ANY** of the following:
 - Patient is aged 50 years or older; **OR**
 - History of head trauma; **OR**
 - Headache preceded by cough, sneeze, valsalva, physical exertion, or sexual activity; **OR**
 - Pregnant or less than 3 months postpartum; **OR**
 - Cancer history or immunosuppression; **OR**
 - Headache that wakes the patient from sleep; **OR**
 - Chronic headache with significant change in character, severity, or frequency of headache; **OR**
 - Primary trigeminal autonomic cephalalgias (e.g., cluster headache); **OR**
 - Headache accompanied by seizures, vomiting, focal neurological symptoms, vision changes, altered mental status, or acute hypertension; **OR**
- For the evaluation of headaches in a pediatric patient with **ALL** of the following⁴⁸:
 - MRI is contraindicated or cannot be performed; **AND**
 - **ANY** of the following:
 - 5 years of age or younger; **OR**
 - Headaches awaken the patient from sleep or are always present upon waking; **OR**
 - Focal findings or symptoms on neurologic examination, including diplopia; **OR**

- Clumsiness (common description of gait or coordination problems in young children); **OR**
- Headaches associated with morning nausea/vomiting; **OR**
- Seizures; **OR**
- Papilledema on physical exam; **OR**
- Headache precipitated by coughing, sneezing, physical exertion, or Valsalva; **OR**
- Progressive worsening in headache frequency and severity without a period of temporary improvement; **OR**
- Systemic symptoms (e.g., persistent fever, weight loss, rash, or joint pain); **OR**
- The patient is immunocompromised; **OR**
- Known history of cancer of any type; **OR**
- Known autoimmune or rheumatologic disease; **OR**
- Known genetic disorder with predisposition to intracranial mass lesions; **OR**
- History of stable chronic headaches with recent significant change in frequency or severity; **OR**
- Focal neurological complaints, including dizziness, visual change, acute hypertension or altered mental status; **OR**
- Movement disorders with **ALL** of the following¹⁹:
 - MRI is contraindicated or cannot be performed; **AND**
 - **ANY** of the following neurodegenerative diseases:
 - Acute onset of a movement disorder with concern for stroke or hemorrhage; **OR**
 - For evaluation of Parkinson's disease with atypical features or other movement disorders (e.g., suspected Huntington's disease, chorea, hemiballismus, atypical dystonia) to exclude an underlying structural lesion; **OR**
- The patient has ataxia or other signs of focal neurological disease with **ALL** of the following^{10,17}:
 - MRI is contraindicated or cannot be performed; **AND**
 - **ANY** of the following:
 - Brain structural abnormality identified or suspected on prior imaging; **OR**
 - Acute, new, or fluctuating neurologic symptoms or deficits that suggest a localizing neurologic process, including **ANY** of the following:

- Sensory deficits, including **ANY** of the following:
 - Involvement of two limbs on the same side of the body; **OR**
 - Face and limb involvement; **OR**
- Limb weakness, including **ANY** of the following:
 - Involvement of two limbs on the same side of the body; **OR**
 - Face and limb involvement; **OR**
- Abnormal reflexes (pathological, asymmetric, hyperreflexia); **OR**
- Speech difficulties; **OR**
- Lack of coordination or gait disturbance; **OR**
- Mental status changes; **OR**
- Babinski/Hoffman sign; **OR**
- Increased tone in affected limb; **OR**
- Bladder or bowel dysfunction; **OR**
- Cranial nerve palsy, not otherwise explained (e.g., Bell's palsy or diabetic CN III palsy); **OR**
- Horner syndrome (unilateral miosis, ptosis, facial anhidrosis); **OR**
- Papilledema; **OR**
- New visual disturbance (e.g., diplopia, visual field defect, nystagmus, visual loss); **OR**
- Chronic disequilibrium with signs of cerebellar ataxia²³; **OR**
- Pathology involving the cranial nerve²⁴; **OR**
- Vertigo, unexplained by history or physical examination, with **ANY** of the following²⁵:
 - Worsening; **OR**
 - Affected daily function; **OR**
 - Associated hearing loss or other neurological deficits; **OR**
 - History of prior infection (e.g., otitis or meningitis); **OR**
 - History of prior trauma; **OR**
- With developmental delay in a child less than 18 years of age when MRI is contraindicated or cannot be performed¹; **OR**
- Preoperative, postoperative, or pretreatment evaluation for **ANY** of the following¹⁰:
 - CT guidance and image integration for procedure or surgery; **OR**
 - Postoperative evaluation following intracranial surgery; **OR**
- Congenital conditions (e.g., hydrocephalus, including shunt malfunctions or shunt revision), and **ANY** of the following is **TRUE**^{10,26,27}:

- Perioperatively, if indicated based on the underlying disease and preoperative radiographic findings; **OR**
- 6–12 months after placement; **OR**
- With neurologic symptoms that suggest shunt malfunction; **OR**
- Annual follow-up if the patient continues to exhibit symptoms (more frequent follow-up may be necessary if symptoms persist); **OR**
- Repeat imaging (defined as a repeat request following recent imaging of the same anatomic region with the same or similar modality) will be considered reasonable and necessary if **ALL** of the following are **TRUE**:
 - There are no established guidelines; **AND**
 - **ANY** of the following:
 - There are new or worsening symptoms not addressed in the guidelines, such that repeat imaging would influence treatment; **OR**
 - There is need for a one-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

Computed tomography (CT), brain is not considered appropriate if **ANY** of the following is **TRUE**:

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms²⁸; **OR**
- The imaging is for cancer staging in the absence of signs or symptoms suggesting brain involvement, with **ANY** of the following cancer types ^{4,6}:
 - Esophageal cancer; **OR**
 - Oropharynx cancer; **OR**
 - Prostate cancer; **OR**
 - Non-melanoma skin cancer.

*For malignancies that commonly metastasize to the brain, staging in the absence of neurological findings may be appropriate.

**NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

***NOTE: CT in pregnant patients should be requested at the discretion of the

ordering provider and obstetric care provider.

****NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Populations

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure. [29,30](#)

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography. [29,30](#)

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation. [29,30](#)

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images. [29,30](#)

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70450	Computed tomography (CT), head or brain; without contrast material
70460	Computed tomography (CT), head or brain; with contrast material(s)
70470	Computed tomography (CT), head or brain; without contrast material, followed by contrast material(s) and further sections
76380	Computed tomography, limited or localized follow-up study

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for CT, brain may include:

- The inherent risk of the procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.^{[31-34](#)}
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.^{[33](#)} Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.^{[34](#)}
- Compared to adults, children are more sensitive to radiation. CT exposure among children may increase their risk of leukemia and brain cancer.^{[35](#)}
- Adverse effects from delayed or denied treatment, such as subarachnoid hemorrhage, intracranial aneurysm, stroke, and other major health concerns.^{[36-38](#)}
- Increased healthcare costs and complications from the inappropriate use of additional interventions.^{[39](#)}

The clinical benefits of using these criteria for CT, brain include:

- Compared to other neuroimaging modalities, CT is widely available and can be performed quickly and at relatively low cost.^{[40](#)}
- Computed tomography can be particularly useful in the evaluation of patients unable to tolerate magnetic resonance imaging (MRI).^{[41](#)}

- Compared to MRI, CT can provide clearer depictions of calcification, a particularly salient advantage in evaluations of populations at risk for calcified lesions or vascular or cavernous malfunctions.⁴¹
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Bedernik et al. (2022) conducted a randomized controlled trial (RCT) to assess image quality by comparing single-energy computed tomography (SECT) with automated tube voltage adaptation (TVA) to dual-energy CT (DECT) weighted average images. A total of 80 patients underwent SECT or radiation dose-matched DECT. The effective radiation dose (ED) showed no significant difference between the SECT and DECT study groups. Compared to the SECT group, the DECT group exhibited significantly higher contrast-to-noise ratio differences (CNRD) for jugular veins relative to fatty tissue and muscle tissue relative to fatty tissue. However, the CNRD for jugular veins relative to muscle tissue was comparable between groups. Image artifacts were also less pronounced, and overall diagnostic acceptability was higher in the DECT group. Overall, DECT-weighted average images demonstrate superior objective and subjective image quality compared to SECT performed with TVA in head and neck imaging.⁴⁰

Smith-Bindman et al. (2020) performed an RCT to study the efficacy of interventions to lower the amount of radiation patients are exposed to. The RCT included 864,080 adults at 100 facilities who underwent a CT scan, including CT Head (1,156,657 total scans). The study included two primary measures: the percentage of high-dose CT scans and the average effective dose administered at the facility level. The study's secondary measure included the doses received by specific organs. Outcomes were assessed concerning the impact of the interventions and outcomes post-intervention. Data were contrasted with pre-intervention data, utilizing hierarchical generalized linear models that accounted for temporal patterns and patient attributes. In conclusion, data regarding CT radiation dosage and practical recommendations may improve quality, including significant dose reductions, especially for organ-specific doses.³⁵

Tranvinh et al. (2019) examined the evidence backing the utilization of neuroimaging in adult patients experiencing a new-onset seizure. In the acute setting, unenhanced CT serves as the primary imaging modality for adults encountering their first unprovoked seizure, prioritizing the exclusion of urgent or emergent conditions. An initial unenhanced head CT scan may rule

out treatable intracranial abnormalities promptly. If the CT findings are negative but clinical suspicion persists for a structural cause of the seizure, MRI should be considered, particularly in acute cases. MRI offers supplementary advantages and is helpful for patients with negative initial CT findings in acute scenarios and those experiencing new-onset seizures in non-acute circumstances.⁴¹

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Policy Revision History/Information

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Review History		
Version 2	10/23/2025	Annual review. Added indications for neoplastic conditions in alignment with L35391. Added indications for intracranial lesions, new onset seizures, blood/brain barrier defects, other acute CNS hemorrhage, encephalomalacia, and cerebrovascular accident in alignment with L37373 and L35175. Edited indications for headache evaluation in alignment with L37373 and L35175. Added non-indication for imaging of the same body part within 3 months without treatment or new/worsening symptoms. Updated Harms & Benefits section.



Cohere Medicare Advantage Policy – Computed Tomography, Cardiac

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

Important Notices

Notices & Disclaimers:

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Cardiac

Date of last literature review: 10/2/2024

Document last updated: 10/3/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Cardiac

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁵

- [National Coverage Determination \(NCD\). Computed tomography \(CT\) \(220.1\)](#)
- [Local Coverage Determination \(LCD\). Cardiac computed tomography \(CCT\) and coronary computed tomography angiography \(CCTA\) \(L33559\)](#)
- [Local Coverage Determination \(LCD\). Cardiac computed tomography \(CCT\) and coronary computed tomography angiography \(CCTA\) \(L33947\)](#)
- [Local Coverage Determination \(LCD\). Coronary computed tomography angiography \(CCTA\) \(L35121\)](#)
- [Local Coverage Determination \(LCD\). Cardiac computed tomography and angiography \(CCTA\) \(L33423\)](#)

Recommended Clinical Approach

The referring clinician determines the appropriate clinical indication in consultation with a cardiac imaging expert. The patient's pertinent medical history should justify the exam. The examination is primarily performed with IV contrast; however, non-contrast examinations are typically used for calcium scoring and in other limited clinical scenarios. The techniques used to detect

and quantify coronary artery calcification (CAC) have evolved. Newer generations of CT scanners have widely replaced electron-beam CT (EBCT).

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Cardiac CT. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁶⁻⁹
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹⁰ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹⁰
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹¹

The clinical benefits of using these criteria include:

- Planning of transcatheter aortic valve replacement (TAVR): Cardiac CT is established for TAVR to assess potential complications and to provide procedural guidance. Cardiac CT is also used for annular assessment.¹²
- Detect subclinical disease.¹³
- Monitor disease progression.¹³
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are

employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), cardiac with contrast** is considered appropriate if **ANY** of the following is **TRUE**¹⁴:

- ◆ Documented or suspected neoplastic conditions of the heart (including cardiac masses or mass-like conditions); **OR**
- ◆ Infection or an infectious disorder, including infective endocarditis; **OR**
- ◆ Cardiac trauma-related conditions, including iatrogenic injury¹⁵; **OR**
- ◆ Cardiovascular conditions, known or suspected, including **ANY** of the following:
 - Suspected intracardiac thrombus, mass, aneurysm, or pseudoaneurysm when ECHO is indeterminate¹⁶; **OR**
 - Cardiomyopathies including **ANY** of the following:
 - Hypertrophic cardiomyopathy¹⁷; **OR**
 - Suspected arrhythmogenic cardiomyopathy of ventricular origin; **OR**
- ◆ Preoperative or pre-treatment evaluation including **ANY** of the following:
 - Atrial septal defect/patent foramen ovale (ASD/PFO) closure if TEE is indeterminate; **OR**
 - Aortic root replacement; **OR**
 - Pacemaker placement planning, including the evaluation of coronary vein before biventricular pacing; **OR**
 - Pulmonary vein ablation therapy for cardiac dysrhythmia; **OR**
 - Surgical valve replacement; **OR**

- Surgical myectomy or septal ablation hypertrophic cardiomyopathy; **OR**
- Transcatheter left atrial appendage occlusion; **OR**
- Planning for aortic endovascular valve replacement; **OR**
- Post-procedure follow-up or complication to evaluate complications of valve repair or replacement (open or endovascular), including **ANY** of the following:
 - Leaflet thrombosis; **OR**
 - Pannus formation; **OR**
 - Paravalvular leak; **OR**
 - Pseudoaneurysms; **OR**
 - Root abscess; **OR**
- Ventricular assist devices; **OR**
- Pre-procedural planning for atrial fibrillation-related procedures¹⁸; **OR**
 - Left atrial ablation (pulmonary vein isolation); **OR**
 - Left atrial appendage endovascular occlusion; **OR**
 - Electrical cardioversion or Pharmacologic cardioversion when an indicated TEE has a contraindication or is unable to be completed; **OR**
- Planned transcatheter treatment and the patient has valvular heart disease with **ANY** of the following:
 - Mitral replacement or repair; **OR**
 - Pulmonary replacement or repair; **OR**
 - Transcatheter aortic; **OR**
 - Tricuspid replacement or repair; **OR**
- ◆ Congenital anomalies and variants (e.g., cardiac, vascular) including **ANY** of the following as indicated in cited references^{14, 19-20}:
 - **ANY** of the following:
 - Aortic and pulmonary anomalies; **OR**
 - Atrial and ventricular septal defects; **OR**
 - Coronary artery anomalies; **OR**
 - Left-sided cardiac obstructive disorders; **OR**
 - Right-sided cardiac obstructive disorders; **OR**
 - Systemic and pulmonary venous anomalies; **OR**

- Other complex structural disorders of the cardiac chambers, morphology, and valves (e.g., heterotaxy); **OR**
- Follow-up of corrected or palliated congenital heart disease and assessment of postoperative complications (e.g., shunt or conduit stenosis, thrombosis, pseudoaneurysms) in children and adults; **OR**
- Postoperative evaluation of corrected or palliated congenital heart disease, including **ANY** of the following:
 - Pseudoaneurysms; **OR**
 - Stenosis (shunt/conduit); **OR**
 - Thrombosis; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Computed tomography (CT), cardiac without contrast** is considered appropriate if **ANY** of the following is **TRUE**¹⁴:

- ◆ Cardiac surgical preoperative planning; **OR**
- ◆ Detection or evaluation of **ANY** of the following:
 - Ascending aorta; **OR**
 - Calcification of coronary arteries when there is no pre-test knowledge of sufficiently extensive calcification of the suspect coronary segment that would diminish the interpretive value²; **OR**
 - Cardiac masses; **OR**
 - Cardiac valves; **OR**
 - Pericardium; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in

the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography (CT), cardiac** is not considered appropriate if **ANY** of the following is **TRUE** if contrast is used:

- ◆ If contrast is used, history of anaphylactic allergic reaction to iodinated contrast media; **OR**
- ◆ The request is for a calcium scoring scan or electron beam CT (EBCT); **OR**
- ◆ Imaging is being performed for screening purposes in the absence of signs, symptoms or disease²⁻³; **OR**
- ◆ The anticipated results are not expected to provide new, additional information to that already previously obtained from other tests (e.g., stress myocardial perfusion images or cardiac ultrasound)²⁻³; **OR**
- ◆ It is anticipated that the patient may require invasive cardiac angiography for further diagnosis or for therapeutic intervention (e.g., angina decubitus, unstable angina, Prinzmetal angina, etc.)²⁻³; **OR**
- ◆ When imaging is used for cardiac evaluation if there is pre-test knowledge of sufficiently extensive calcification of the suspect coronary segment that would diminish the interpretive value.²⁻³

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.²¹

**NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

***NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{8,22}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{8,22}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{8,22}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{8,22}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
75571	Computed tomography (CT) of heart; without contrast material, with quantitative evaluation of coronary calcium
75572	Computed tomography (CT), heart; with contrast material, for evaluation of cardiac structure and morphology (including 3-dimensional [3D] image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)
75573	Computed tomography (CT), heart; with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation)
76380	Computed tomography, limited or localized follow-up study
S8092	Electron beam computed tomography (also known as EBCT or Ultrafast CT)

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Baldassarre et al. (2022) conducted a state-of-the-art review on the advances in multimodality imaging in cardio-oncology. Cardiac computed tomography (CT) is used to evaluate cardiac tumors, pericardial conditions, valve functionality/disorders, and preplanning for transcatheter valve interventions. The modality can produce imaging quickly and is widely available. In addition, cardiac CT can be assessed for non-cardiovascular consequences of radiation exposure. These include the identification of a porcelain aorta, detection of carotid artery disease, and evaluation for radiation-induced pulmonary fibrosis, all of which can elevate the risks associated with surgical interventions. Complementary imaging modalities such as contrast-enhanced cardiac CT and positron emission tomography (PET) with 18F-fluorodeoxyglucose (FDG) can aid in distinguishing between benign lesions and malignant cardiac tumors, mainly when cardiac magnetic resonance (CMR) evaluation is not feasible.²³

Grandhi et al. (2022) performed a study that sought to assess the efficacy of coronary artery calcium (CAC) as an initial diagnostic modality for excluding obstructive coronary artery disease (CAD). The study specifically examined the utilization of CAC to rule out obstructive CAD in the emergency department (ED). A total of 2902 participants were identified from an extensive registry of patients admitted to the ED due to acute chest pain and deemed at low to intermediate risk for acute coronary syndrome. Fifty-six percent had a CAC score of 0. The diagnosis among participants included CAD (4.6%), non-obstructive CAD (3.9%), and obstructive CAD (0.7%). Among participants with a CAC score greater than 0, obstructive CAD was reported in 23%. The authors conclude that implementing CAC testing at the outset of CP evaluation may enhance patient triage by determining who can safely delay further testing and invasive procedures.²⁴

Korsholm et al. (2020) published a review of expert recommendations on cardiac CT for planning transcatheter left atrial appendage occlusion. Guidance is provided on preparing for, conducting, reconstructing, and interpreting cardiac CT scans before left atrial appendage occlusion (LAAO) procedures. This presents a consistent protocol for physicians seeking to

integrate 3D cardiac CT seamlessly into their workflow for LAAO. Despite the benefits associated with cardiac CT, widespread implementation before procedures has been difficult. Challenges include the absence of a standardized imaging protocol, limited familiarity with image and software adjustments, and apprehensions regarding radiation exposure, contrast utilization, and financial considerations. Before the LAAO procedure, cardiac CT should be conducted to assess the anatomical suitability, accurately measuring LAA dimensions to aid in device selection and procedural planning, and confirm the absence of LAA thrombus. Cardiac CT holds promise as a potential replacement for the current gold standard in preprocedural planning for LAAO.²⁵

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Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		



Cohere Medicare Advantage Policy – Computed Tomography, Cardiac

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

Important Notices

Notices & Disclaimers:

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Cardiac

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Cardiac

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁵

- [National Coverage Determination \(NCD\). Computed tomography \(CT\) \(220.1\)](#)
- [Local Coverage Determination \(LCD\). Cardiac computed tomography \(CCT\) and coronary computed tomography angiography \(CCTA\) \(L33559\)](#)
- [Local Coverage Determination \(LCD\). Cardiac computed tomography \(CCT\) and coronary computed tomography angiography \(CCTA\) \(L33947\)](#)
- [Local Coverage Determination \(LCD\). Coronary computed tomography angiography \(CCTA\) \(L35121\)](#)
- [Local Coverage Determination \(LCD\). Cardiac computed tomography and angiography \(CCTA\) \(L33423\)](#)

Recommended Clinical Approach

The referring clinician determines the appropriate clinical indication in consultation with a cardiac imaging expert. The patient's pertinent medical history should justify the exam. The examination is primarily performed with IV contrast; however, non-contrast examinations are typically used for calcium scoring and in other limited clinical scenarios. The techniques used to detect

and quantify coronary artery calcification (CAC) have evolved. Newer generations of CT scanners have widely replaced electron-beam CT (EBCT).

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Cardiac CT. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁶⁻⁹
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹⁰ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹⁰
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹¹

The clinical benefits of using these criteria include:

- Planning of transcatheter aortic valve replacement (TAVR): Cardiac CT is established for TAVR to assess potential complications and to provide procedural guidance. Cardiac CT is also used for annular assessment.¹²
- Detect subclinical disease.¹³
- Monitor disease progression.¹³
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are

employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), cardiac with contrast** is considered appropriate if **ANY** of the following is **TRUE**¹⁴:

- ◆ Documented or suspected neoplastic conditions of the heart (including cardiac masses or mass-like conditions); **OR**
- ◆ Infection or an infectious disorder, including infective endocarditis; **OR**
- ◆ Cardiac trauma-related conditions, including iatrogenic injury¹⁵; **OR**
- ◆ Cardiovascular conditions, known or suspected, including **ANY** of the following:
 - Suspected intracardiac thrombus, mass, aneurysm, or pseudoaneurysm when ECHO is indeterminate¹⁶; **OR**
 - Cardiomyopathies including **ANY** of the following:
 - Hypertrophic cardiomyopathy¹⁷; **OR**
 - Suspected arrhythmogenic cardiomyopathy of ventricular origin; **OR**
- ◆ Preoperative or pre-treatment evaluation including **ANY** of the following:
 - Atrial septal defect/patent foramen ovale (ASD/PFO) closure if TEE is indeterminate; **OR**
 - Aortic root replacement; **OR**
 - Pacemaker placement planning, including the evaluation of coronary vein before biventricular pacing; **OR**
 - Pulmonary vein ablation therapy for cardiac dysrhythmia; **OR**
 - Surgical valve replacement; **OR**

- Surgical myectomy or septal ablation hypertrophic cardiomyopathy; **OR**
- Transcatheter left atrial appendage occlusion; **OR**
- Planning for aortic endovascular valve replacement; **OR**
- Post-procedure follow-up or complication to evaluate complications of valve repair or replacement (open or endovascular), including **ANY** of the following:
 - Leaflet thrombosis; **OR**
 - Pannus formation; **OR**
 - Paravalvular leak; **OR**
 - Pseudoaneurysms; **OR**
 - Root abscess; **OR**
- Ventricular assist devices; **OR**
- Pre-procedural planning for atrial fibrillation-related procedures¹⁸; **OR**
 - Left atrial ablation (pulmonary vein isolation); **OR**
 - Left atrial appendage endovascular occlusion; **OR**
 - Electrical cardioversion or Pharmacologic cardioversion when an indicated TEE has a contraindication or is unable to be completed; **OR**
- Planned transcatheter treatment and the patient has valvular heart disease with **ANY** of the following:
 - Mitral replacement or repair; **OR**
 - Pulmonary replacement or repair; **OR**
 - Transcatheter aortic; **OR**
 - Tricuspid replacement or repair; **OR**
- ◆ Congenital anomalies and variants (e.g., cardiac, vascular) including **ANY** of the following as indicated in cited references^{14, 19-20}:
 - **ANY** of the following:
 - Aortic and pulmonary anomalies; **OR**
 - Atrial and ventricular septal defects; **OR**
 - Coronary artery anomalies; **OR**
 - Left-sided cardiac obstructive disorders; **OR**
 - Right-sided cardiac obstructive disorders; **OR**
 - Systemic and pulmonary venous anomalies; **OR**

- Other complex structural disorders of the cardiac chambers, morphology, and valves (e.g., heterotaxy); **OR**
- Follow-up of corrected or palliated congenital heart disease and assessment of postoperative complications (e.g., shunt or conduit stenosis, thrombosis, pseudoaneurysms) in children and adults; **OR**
- Postoperative evaluation of corrected or palliated congenital heart disease, including **ANY** of the following:
 - Pseudoaneurysms; **OR**
 - Stenosis (shunt/conduit); **OR**
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- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Computed tomography (CT), cardiac without contrast** is considered appropriate if **ANY** of the following is **TRUE**¹⁴:

- ◆ Cardiac surgical preoperative planning; **OR**
- ◆ Detection or evaluation of **ANY** of the following:
 - Ascending aorta; **OR**
 - Calcification of coronary arteries when there is no pre-test knowledge of sufficiently extensive calcification of the suspect coronary segment that would diminish the interpretive value²; **OR**
 - Cardiac masses; **OR**
 - Cardiac valves; **OR**
 - Pericardium; **OR**
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the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

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- ◆ If contrast is used, history of anaphylactic allergic reaction to iodinated contrast media; **OR**
- ◆ The request is for a calcium scoring scan or electron beam CT (EBCT); **OR**
- ◆ Imaging is being performed for screening purposes in the absence of signs, symptoms or disease²⁻³; **OR**
- ◆ The anticipated results are not expected to provide new, additional information to that already previously obtained from other tests (e.g., stress myocardial perfusion images or cardiac ultrasound)²⁻³; **OR**
- ◆ It is anticipated that the patient may require invasive cardiac angiography for further diagnosis or for therapeutic intervention (e.g., angina decubitus, unstable angina, Prinzmetal angina, etc.)²⁻³; **OR**
- ◆ When imaging is used for cardiac evaluation if there is pre-test knowledge of sufficiently extensive calcification of the suspect coronary segment that would diminish the interpretive value.²⁻³

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.²¹

**NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

***NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{8,22}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{8,22}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{8,22}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{8,22}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
75571	Computed tomography (CT) of heart; without contrast material, with quantitative evaluation of coronary calcium
75572	Computed tomography (CT), heart; with contrast material, for evaluation of cardiac structure and morphology (including 3-dimensional [3D] image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)
75573	Computed tomography (CT), heart; with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation)
76380	Computed tomography, limited or localized follow-up study
S8092	Electron beam computed tomography (also known as EBCT or Ultrafast CT)

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Baldassarre et al. (2022) conducted a state-of-the-art review on the advances in multimodality imaging in cardio-oncology. Cardiac computed tomography (CT) is used to evaluate cardiac tumors, pericardial conditions, valve functionality/disorders, and preplanning for transcatheter valve interventions. The modality can produce imaging quickly and is widely available. In addition, cardiac CT can be assessed for non-cardiovascular consequences of radiation exposure. These include the identification of a porcelain aorta, detection of carotid artery disease, and evaluation for radiation-induced pulmonary fibrosis, all of which can elevate the risks associated with surgical interventions. Complementary imaging modalities such as contrast-enhanced cardiac CT and positron emission tomography (PET) with 18F-fluorodeoxyglucose (FDG) can aid in distinguishing between benign lesions and malignant cardiac tumors, mainly when cardiac magnetic resonance (CMR) evaluation is not feasible.²³

Grandhi et al. (2022) performed a study that sought to assess the efficacy of coronary artery calcium (CAC) as an initial diagnostic modality for excluding obstructive coronary artery disease (CAD). The study specifically examined the utilization of CAC to rule out obstructive CAD in the emergency department (ED). A total of 2902 participants were identified from an extensive registry of patients admitted to the ED due to acute chest pain and deemed at low to intermediate risk for acute coronary syndrome. Fifty-six percent had a CAC score of 0. The diagnosis among participants included CAD (4.6%), non-obstructive CAD (3.9%), and obstructive CAD (0.7%). Among participants with a CAC score greater than 0, obstructive CAD was reported in 23%. The authors conclude that implementing CAC testing at the outset of CP evaluation may enhance patient triage by determining who can safely delay further testing and invasive procedures.²⁴

Korsholm et al. (2020) published a review of expert recommendations on cardiac CT for planning transcatheter left atrial appendage occlusion. Guidance is provided on preparing for, conducting, reconstructing, and interpreting cardiac CT scans before left atrial appendage occlusion (LAAO) procedures. This presents a consistent protocol for physicians seeking to

integrate 3D cardiac CT seamlessly into their workflow for LAAO. Despite the benefits associated with cardiac CT, widespread implementation before procedures has been difficult. Challenges include the absence of a standardized imaging protocol, limited familiarity with image and software adjustments, and apprehensions regarding radiation exposure, contrast utilization, and financial considerations. Before the LAAO procedure, cardiac CT should be conducted to assess the anatomical suitability, accurately measuring LAA dimensions to aid in device selection and procedural planning, and confirm the absence of LAA thrombus. Cardiac CT holds promise as a potential replacement for the current gold standard in preprocedural planning for LAAO.²⁵

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Original Date: October 3, 2024		
Review History		



Cohere Medicare Advantage Policy – Computed Tomography (CT), Cerebral Perfusion Analysis

Clinical Policy for Medical Necessity Review

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Policy Number: CHP-317-1

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Next Annual Review: February 26, 2027

Important Notices

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Cerebral Perfusion Analysis

Policy Number: CHP-317-1

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Cerebral Perfusion Analysis

Related Centers for Medicare & Medicaid Services (CMS) Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Cohere defines CMS coverage criteria as follows¹:

- Fully established: Applicable LCD or NCD is comprehensive and does not require additional criteria to determine medical necessity consistently.
- Not fully established: Additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently. The additional Cohere criteria will provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

For each jurisdiction, Cohere's internal coverage criteria will only be applied when CMS guidance is not fully established and additional guidelines are needed to support consistent and appropriate decision-making.

Cohere Health's position on NCDs or LCDs related to *Cohere Medicare Advantage Policy - Computed Tomography (CT), Cerebral Perfusion Analysis* is reflected in Table 1 below. For the LCDs that are not fully established, please refer to the far right column as a guide for the application of Cohere Medicare Advantage criteria.

Table 1 – Related CMS Policies (NCDs or LCDs)²⁻⁵

Type	Title	Number	Cohere Definition of CMS Policy Establishment	Indications not fully established by CMS policy (refer to Cohere Health MA medical necessity criteria for these topics):
NCD	No NCD available	N/A	N/A	Not applicable
LCD	Computed Tomography Cerebral Perfusion Analysis (CTP)	L38667	Fully established	Not applicable
LCD	Computed Tomography Cerebral Perfusion Analysis (CTP)	L38694	Fully established	Not applicable
LCD	Computed Tomography Cerebral Perfusion Analysis (CTP)	L38769	Fully established	Not applicable
LCD	Computed Tomography Cerebral Perfusion Analysis (CTP)	L38709	Fully established	Not applicable
LCD	No LCD Available for Jurisdiction	N/A	N/A	Use Cohere Medicare Advantage internal coverage criteria

Description

Computed tomography (CT), cerebral perfusion analysis is an advanced imaging technique that rapidly evaluates blood flow in the brain. Cerebral perfusion is measured during a CT scan by injecting iodinated contrast to detect changes in blood flow. These measurements are used to generate perfusion maps that show cerebral blood flow, cerebral blood volume, and mean transit time. From there, clinicians can characterize perfusion health and tissue viability.^{6–8}

Medical Necessity Criteria

Indications

Computed tomography (CT), cerebral perfusion analysis is considered appropriate if **ANY** of the following is **TRUE**:

- Acute ischemic stroke, known or suspected, within the first 6–24 hours of symptom onset^{9–12}; **OR**
- Cerebral vasospasm, suspected, following recent subarachnoid hemorrhage^{13,14}; **OR**
- Evaluation of intra-axial brain tumors and **ALL** of the following:
 - Magnetic resonance imaging (MRI), including MR perfusion, is contraindicated or cannot be performed^{15,16}; **AND**
 - **ANY** of the following:
 - Differentiation between brain metastasis and radiation necrosis¹⁷; **OR**
 - Follow-up when there is a new or enlarging lesion on post-treatment surveillance imaging^{15,16,18}; **OR**
 - Pre-treatment evaluation after initial imaging^{15,16,18}; **OR**
 - Post-treatment surveillance for known history of brain tumor.^{15,16,18}

Repeat imaging is considered appropriate when **ALL** of the following are **TRUE**:

- Repeat request following recent imaging within the past 3 months of the same anatomic region with the same or similar modality; **AND**
- No established guidelines for repeat imaging; **AND**
- **ANY** of the following:
 - Need for a one-time clarifying follow-up of a prior indeterminate finding; **OR**

- New or worsening symptoms not addressed in the guidelines, such that repeat imaging would influence treatment; **OR**
- No change in symptoms and a well-established clinical need for ongoing monitoring that will influence management.

Non-Indications

Computed tomography (CT), cerebral perfusion analysis is not considered appropriate if **ANY** of the following is **TRUE**:

- Confirmation of brain death¹⁹; **OR**
- If cerebral perfusion is being performed in conjunction with CT or CTA, CPT 70473 cannot be used; **OR**
- Known or suspected ischemic stroke, less than 6 hours after symptom onset¹⁰; **OR**
- MRI cerebral perfusion analysis has already been performed¹⁰; **OR**
- Recent ischemic infarct, greater than 24 hours after symptom onset¹⁰; **OR**
- Routine post-procedure surveillance following carotid artery revascularization procedures²⁰; **OR**
- Surveillance imaging for prior ischemic infarct.¹⁰

Disclaimer on Radiation Exposure in Pediatric Populations

Cohere Health is committed to ensuring that every patient has access to appropriate and safe imaging studies in accordance with established guidelines. While radiographic studies, such as computed tomography (CT), can provide critical clinical information, exposure to ionizing radiation has the potential to increase lifetime cancer risk. Risk is higher in pediatric patients due to their greater radiosensitivity and longer expected lifespan.

Radiation-induced risks can be reduced by ensuring that imaging is medically necessary and by optimizing procedures to use the lowest dose necessary to achieve diagnostic quality images, consistent with ALARA (As Low As Reasonably Achievable) principles. Alternative modalities that do not involve ionizing radiation should be considered when clinically feasible, such as ultrasound or magnetic resonance imaging (MRI). Providers should adjust equipment and dose to pediatric body sizes and track cumulative radiation exposure for patients requiring multiple imaging studies.

These measures align with guidance from the US Food and Drug Administration (FDA) initiative to reduce unnecessary radiation exposure,^{21,22} the National Cancer Institute pediatric CT risk guidelines,²³ and the Image Gently Alliance and Image Wisely Alliance recommendations for pediatric radiation safety.^{24,25}

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70472	Computed tomographic (CT) cerebral perfusion analysis with contrast material(s), including image postprocessing performed with concurrent CT or CT angiography of the same anatomy (List separately in addition to code for primary procedure)
70473	Computed tomographic (CT) cerebral perfusion analysis with contrast material(s), including image postprocessing performed without concurrent CT or CT angiography of the same anatomy

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.¹

The potential clinical harms of using these criteria for computed tomography (CT), cerebral perfusion analysis may include:

- Adverse effects from delayed or denied treatment, such as surveillance of patients with extracranial carotid and vertebral artery disease following carotid artery revascularization procedures.²⁰
- Failure to identify salvageable brain tissue when patients are outside of the recommended treatment window (6–24 hours).^{9,11,12}

The clinical benefits of using these criteria for CT, cerebral perfusion analysis may include:

- Improved patient selection for endovascular therapy, resulting in better long-term outcomes. The American Heart Association/American Stroke Association (AHA/ASA) supports CT cerebral perfusion for selected patients 6–24 hours after the onset of acute stroke with large vessel occlusion (LVO) to identify salvageable brain tissue and to guide patient selection for mechanical thrombectomy.⁹
- Appropriate and timely evaluation of intra-axial brain tumors when magnetic resonance imaging (MRI) or MR perfusion is contraindicated or cannot be performed.^{15,16}
- Maintenance of rigorous patient safety standards aligned to best available evidence.^{9,10}
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.¹⁰

Medical Evidence

Bobbe et al. (2025) performed a systematic literature review to assess the effectiveness of computed tomography perfusion (CTP) for the evaluation and management of acute ischemic stroke. A total of 39 articles were included for analysis, and most studies involved CTP in combination with CT, CT angiography (CTA), or magnetic resonance imaging (MRI). CTP showed promising results for estimating infarct core and penumbra volumes, particularly within 6 hours of the stroke. CTP-derived parameters, such as cerebral blood volume (CBV), cerebral blood flow (CBF), and mean transit time (MTT), showed positive correlations with clinical outcome and hemorrhagic transformation risk. CTP was limited in its precision for core estimation, and the authors noted that multimodal imaging (e.g., diffusion-weight imaging [DWI] or standard MRI) provides optimal results. This review, comprising mostly retrospective studies and post hoc analyses, showed that CTP is an effective but still evolving tool for the comprehensive evaluation of stroke and stroke-related outcomes.²⁶

Bergin et al. (2023) conducted a systematic literature review and meta-analysis comparing CTA and CTP for the diagnosis of cerebral vasospasm, a common complication following aneurysmal subarachnoid hemorrhage. A total of 22 studies were included in the systematic review, most of which compared CTA or CT perfusion with digital subtraction angiography (DSA), the gold standard for diagnosing cerebral vasospasms. Only 7 CTA studies and 6 CTP studies were included in the meta-analysis due to differences in reporting outcomes and heterogeneity across diagnostic thresholds (e.g., stenosis percentages used to define vasospasm). This analysis found that CTP had superior sensitivity (0.81–0.92) and specificity (0.72–0.80) compared with CTA (0.95–0.98 and 0.92–0.95, respectively). The authors demonstrated that CTP may be superior to CTA for diagnosing cerebral vasospasm after aneurysmal subarachnoid hemorrhage.⁸

Nogueira et al. (2018) conducted the DAWN randomized controlled trial evaluating endovascular thrombectomy (EVT) in acute ischemic stroke patients presenting 6–24 hours after onset. Patients with a clinical mismatch between the severity of the clinical deficit and infarct volume were

randomized to thrombectomy plus standard care or standard care alone. The trial was stopped early for efficacy because interim results showed overwhelming benefit: 49% of EVT patients achieved functional independence (i.e., global disability on a modified Rankin Scale score of 0–2 at 90 days) versus 13% of controls, without increased symptomatic intracranial hemorrhage.¹¹

Albers et al. (2017) conducted the DEFUSE 3 randomized controlled trial to evaluate patients with internal carotid artery (ICA) or middle cerebral artery (MCA) occlusion 6–16 hours after symptom onset. Patients were randomized to endovascular therapy plus medical management or medical management alone. Significant improvements in functional outcomes were observed at 90 days among the endovascular therapy plus medical management group compared with the control group (45% versus 17% functional independence). The trial was stopped early for efficacy, with no significant increase in mortality or symptomatic intracranial hemorrhage. Like the DAWN trial, this study confirmed CTP as the dominant tool for triaging late-window EVT candidates.¹²

The 2024 ACR Appropriateness Criteria rated CTP as “may be appropriate” for evaluating suspected ischemia in stroke, especially beyond early windows or when advanced imaging alters management.¹⁰ The 2023 AHA/ASA aneurysmal subarachnoid hemorrhage guideline acknowledged advanced imaging, including CTP, as a reasonable option for detecting cerebral vasospasm or delayed cerebral ischemia in the neurocritical care phase.¹³ The 2018 American Heart Association/American Stroke Association (AHA/ASA) acute ischemic stroke guideline recommended against routine perfusion imaging in the first 6 hours but supports CTP (or MR perfusion) for selected patients 6–24 hours after onset with large vessel occlusion (LVO) to identify salvageable brain tissue and to guide patient selection for mechanical thrombectomy.⁹

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Cohere Medicare Advantage Policy – Computed Tomography (CT), Chest

Clinical Policy for Medical Necessity Review

CHP-249-3 Version 3

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Procedure Codes (CPT/HCPCS)

Service: Computed Tomography (CT), Chest

Code	Description
71250	Computed tomography, thorax, diagnostic; without contrast material
71260	Computed tomography, thorax, diagnostic; with contrast material(s)
71270	Computed tomography, thorax, diagnostic; without contrast material, followed by contrast material(s) and further sections
76380	Computed tomography, limited or localized follow-up study
G0680	Detection and quantification of coronary artery calcium and/or aortic valve calcification from algorithmic analysis of computed tomography of the chest with report

Service: Repeat Imaging

Code	Description
71250	Computed tomography, thorax, diagnostic; without contrast material
71260	Computed tomography, thorax, diagnostic; with contrast material(s)
71270	Computed tomography, thorax, diagnostic; without contrast material, followed by contrast material(s) and further sections
76380	Computed tomography, limited or localized follow-up study
G0680	Detection and quantification of coronary artery calcium and/or aortic valve calcification from algorithmic analysis of computed tomography of the chest with report

Service: Artificial Intelligence (AI)-Enabled, FDA-Cleared, Computed Tomography (CT)-Based Quantitative Coronary Artery Calcium or Aortic Valve Calcification Analysis (AI-CAC)

Code	Description
G0680	Detection and quantification of coronary artery calcium and/or aortic valve calcification from algorithmic analysis of computed tomography of the chest with report

Important Notices

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Service: Computed Tomography (CT), Chest - Description

Computed tomography (CT) of the chest is a common, noninvasive imaging modality that uses rotating radiograph technology to create detailed cross-sectional images of the body. The CT scanner consists of an X-ray tube and a detector array. As the tube rotates around the patient, it measures how different tissues absorb X-rays, which are transformed into cross-sectional images. CT can be used to visualize various parts of the body for detecting disease pathologies.⁶

Service: Computed Tomography (CT), Chest - Medical Necessity Criteria

Related Centers for Medicare & Medicaid Services (CMS) Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Cohere defines CMS coverage criteria as follows¹:

- Fully established: Applicable LCD or NCD is comprehensive and does not require additional criteria to determine medical necessity consistently.
- Not fully established: Additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently. The additional Cohere criteria will provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

For each jurisdiction, Cohere's internal coverage criteria will only be applied when CMS guidance is not fully established and additional guidelines are needed to support consistent and appropriate decision-making.

Cohere Health's position on NCDs or LCDs related to Cohere Medicare Advantage Policy - Computed Tomography (CT), Chest is reflected in Table 1 below. For the LCDs that are not fully established, please refer to the far right column as a guide for the application of Cohere Medicare Advantage criteria.

Table 1 - Related CMS Policies (NCDs or LCDs)²⁻⁴

Type	Title	Number	Cohere Definition of CMS Policy Establishment	Indications not fully established by CMS policy (refer to Cohere Health MA medical necessity criteria for these topics):
NCD	Computed tomography	220.1	Not fully established	● All specific indications for CT, chest ● Artificial intelligence (AI)-enabled, FDA-cleared, computed tomography (CT)-based quantitative coronary artery calcium or aortic valve calcification analysis (AI-CAC)
LCD	Computerized axial tomography (CT), thorax	L33459	Not fully established	● Artificial intelligence (AI)-enabled, FDA-cleared, computed tomography (CT)-based quantitative coronary artery calcium or aortic valve calcification analysis (AI-CAC)
LCD	Multiple imaging in oncology	L35391	Not fully established	● All specific indications for follow-up CT, chest ● Artificial intelligence (AI)-enabled, FDA-cleared, computed tomography (CT)-based quantitative coronary artery calcium or aortic valve calcification analysis (AI-CAC)
LCD	No LCD Available for Jurisdiction	N/A	N/A	Use NCD 220.1 and Cohere Medicare Advantage internal coverage criteria

Indications

- **Computed tomography (CT), chest** is considered appropriate when **ANY** of the following is **TRUE**:
 - Abnormality discovered or partially imaged on other imaging modalities (excluding pulmonary nodules and masses, see below)^{6,7}; **OR**
 - Neoplastic conditions (including masses or mass-like conditions), including **ANY** of the following⁸:
 - Chest wall mass with **ANY** of the following⁷:
 - Palpable chest wall mass with non-diagnostic chest radiograph or ultrasound; **OR**
 - Chest wall mass identified on prior imaging when further information is needed to determine the need for biopsy or surgery; **OR**
 - Preoperative planning following biopsy; **OR**
 - Pulmonary nodule or mass and **ANY** of the following is **TRUE**^{5,9}:
 - Incidentally detected pulmonary nodule on prior CT chest, and the patient meets criteria specified in Fleischner Society Guidelines⁵ (see Table 2); **OR**
 - Pulmonary nodules detected on lung cancer screening CT, and the patient meets Lung-RADS® (2022) criteria⁹ (see Table 3); **OR**
 - Incidentally detected pulmonary nodule or mass seen on imaging other than dedicated chest CT (e.g., CT abdomen/pelvis, CT neck, MRI, etc.) and lesion measures greater than 8 mm¹⁰; **OR**
 - Incidentally detected pulmonary nodule seen on imaging other than dedicated chest CT and measures less than or equal to 8 mm on non-CT chest imaging, and the patient meets criteria specified in Fleischner Society Guidelines¹⁰; **OR**
 - Other thoracic mass lesions when detected on prior imaging, including **ANY** of the following⁵:
 - Mediastinal mass; **OR**
 - Pancoast tumor; **OR**
 - Pleural mass; **OR**
 - Thymoma; **OR**
 - Tracheal or endobronchial lesion; **OR**
 - Concern for thymoma in a patient with myasthenia gravis¹¹; **OR**
 - Staging, management, or surveillance of known primary malignancy (except for invasive breast cancer without pulmonary symptoms; or for asymptomatic very-low-, low-, and intermediate-risk prostate cancer with a life expectancy of 5 years or less)^{8,9}; **OR**
 - Staging, management, or surveillance of lung cancer or other primary thoracic malignancy¹⁴⁻¹⁷; **OR**
 - Cardiothoracic manifestation of known extrathoracic diseases with **ALL** of the following^{5,18-20}:
 - Chest radiograph has been performed and is **ANY** of the following:
 - Nondiagnostic; **OR**

- ☐ Further evaluation is indicated; **AND**
- **ANY** of the following¹⁸:
 - ☐ Anti-glomerular basement membrane antibody disease; **OR**
 - ☐ Ankylosing spondylitis (AS); **OR**
 - ☐ Eosinophilic Granulomatosis with Polyangiitis (EGPA); **OR**
 - ☐ Granulomatosis with polyangiitis; **OR**
 - ☐ Polymyositis and dermatomyositis; **OR**
 - ☐ Progressive systemic sclerosis; **OR**
 - ☐ Rheumatoid arthritis (RA); **OR**
 - ☐ Sjögren's syndrome; **OR**
 - ☐ Systemic lupus erythematosus (SLE); **OR**
- Infection or an infectious disorder for **ANY** of the following:
 - Pneumonia when **ANY** of the following is **TRUE**:
 - ☐ Repeat chest radiograph shows no improvement following at least 4-6 weeks of medical treatment⁹; **OR**
 - ☐ Recurrence of pneumonia on chest radiograph in the same location within 6 months²¹; **OR**
 - ☐ Evaluation of known or suspected complications of pneumonia following nondiagnostic chest radiograph; **OR**
 - ☐ Immunosuppressed patients with signs or symptoms of pneumonia following chest radiograph^{22,23}; **OR**
 - For the diagnosis and management of miscellaneous infectious or inflammatory conditions, including **ANY** of the following⁷:
 - ☐ Lung abscess; **OR**
 - ☐ Mediastinitis; **OR**
 - ☐ Other infectious or inflammatory condition that is symptomatic; **OR**
 - ☐ Sternal wound infection/dehiscence; **OR**
- For the diagnosis and management of blunt or penetrating trauma to the thorax and further evaluation is needed following chest radiograph; **OR**
- For the management (including treatment response), suspected or known, of a parenchymal lung disease, including **ALL** of the following²⁴⁻²⁶:
 - Chest radiograph is non-diagnostic; **AND**
 - **ANY** of the following are suspected:
 - ☐ Bronchiectasis; **OR**
 - ☐ Bronchiolitis obliterans; **OR**
 - ☐ Interstitial lung disease (including idiopathic pulmonary fibrosis [IPF]); **OR**
 - ☐ Occupational lung disease (e.g., silicosis, asbestosis, coal workers' pneumoconiosis); **OR**
 - ☐ Sarcoidosis; **OR**
- Vascular conditions, known or suspected, including **ANY** of the following (CTA preferred)^{6-7,11}:
 - Pulmonary hypertension; **OR**
 - Pulmonary vascular malformations; **OR**
 - Pulmonary venous abnormalities; **OR**
- For evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when applicable:
 - The patient has **ALL** of the following:
 - ☐ Non-diagnostic chest radiograph; **AND**
 - ☐ **ANY** of the following:
 - ▲ Chest pain that persists despite treatment; **OR**
 - ▲ Hemoptysis (CTA preferred)²⁷; **OR**
 - ▲ Other symptoms that are unlikely to be cardiac in origin; **OR**
 - ▲ Shortness of breath; **OR**
 - Cough (chronic or persistent lasting more than 8 weeks) and **ALL** of the following:
 - ☐ Cough does not respond to appropriate treatment; **AND**
 - ☐ Cough is unexplained by clinical evaluation (including, but not limited to, reflux disease, post-nasal drip, medications causing cough); **AND**
 - ☐ Chest radiograph, and/or pulmonary function testing or spirometry does not explain symptoms^{28,29}; **OR**
 - Cough (chronic or persistent) in immunosuppressed individuals unexplained by chest radiograph^{23,30}; **OR**
 - Fever of unknown origin with **ANY** of the following:
 - ☐ Unexplained fever in an immunocompromised patient; **OR**
 - ☐ **ALL** of the following:
 - ▲ Duration greater than 3 weeks; **AND**
 - ▲ Fever remains unexplained following a standard diagnostic evaluation (including chest radiograph) to identify the source; **OR**
 - Vocal cord paralysis with **ALL** of the following:
 - ☐ Confirmed on direct laryngoscopy by otolaryngologist (ear, nose, and throat [ENT] specialist); **AND**
 - ☐ CT neck is also being ordered or has been performed³¹; **OR**
 - Pleural disease including **ANY** of the following^{7,32}:
 - ☐ Bronchopulmonary fistula suspected based on radiographs and clinical parameters; **OR**
 - ☐ Chylothorax; **OR**
 - ☐ Empyema; **OR**
 - ☐ Hemothorax; **OR**

- ☐ Pleural effusion when further evaluation is required for etiology and/or is not resolving on chest radiograph; **OR**
- ☐ Recurrent or unexplained pneumothorax; **OR**
- Unintentional weight loss exceeding 5% of the patient's body weight within a 12-month interval and **ANY** of the following is **TRUE**^{33,34}:
 - ☐ Persistent weight loss after a period of observation with a negative comprehensive clinical evaluation and **ALL** of the following:
 - ▲ Documentation of complete history and physical examination; **AND**
 - ▲ Patient is up-to-date on age-appropriate cancer screening^{A,35-37}; **AND**
 - ▲ Chest radiograph has been performed; **AND**
 - ▲ Initial laboratory evaluation has been performed; **OR**
 - ☐ Positive findings of malignancy on history, physical exam, imaging, or laboratory evaluation; **OR**
- Preoperative imaging for surgical (interventional or bronchoscopic included) planning when surgery is already planned or a bronchoscopy procedure is already approved^{32,38}; **OR**
- Postoperative evaluation for **ANY** of the following⁷:
 - Postoperative complications; **OR**
 - Post-transplant if complications or infection are suspected and chest radiograph is non-diagnostic; **OR**
 - Response to therapies including chemotherapy, immunotherapy, and lung-directed ablative therapies⁷; **OR**
- Evaluation of thoracic aortic disease with **ALL** of the following (CTA preferred)³⁹:
 - **ANY** of the following:
 - ☐ The patient has renal insufficiency; **OR**
 - ☐ The request explicitly states that dye is not wanted; **OR**
 - ☐ Cardiothoracic surgeon preference; **AND**
 - **ANY** of the following:
 - ☐ Initial diagnosis of a suspected thoracic aortic aneurysm based on an abnormality on **ANY** of the following:
 - ▲ Chest radiograph; **OR**
 - ▲ Echocardiogram; **OR**
 - ☐ Evaluation of known or suspected thoracic aortic disease progression/complication based on signs, symptoms, or other imaging studies (e.g., chest pain, suspicion for rupture)⁷; **OR**
 - ☐ Surveillance of known thoracic aortic aneurysm in a patient with non-syndromic/non-hereditary cause for **ANY** of the following:
 - ▲ At baseline if the ascending aorta is not adequately imaged on transthoracic echocardiogram (TTE); **OR**
 - ▲ 6 months after the initial diagnosis; **OR**
 - ▲ Annual surveillance for thoracic aortic aneurysms less than 5 cm; **OR**
 - ▲ Surveillance every 6 months for thoracic aortic aneurysm greater than or equal to 5 cm; **OR**
 - ▲ Surveillance every 6 months for aneurysms that are growing by more than 0.5 cm/year; **OR**
 - ☐ Surveillance of known syndromic/hereditary/genetic aortic disease for **ANY** of the following³⁹:
 - ▲ Marfan syndrome with **ANY** of the following³⁹:
 - △ At baseline if the ascending aorta is not adequately imaged on TTE; **OR**
 - △ 6 months after baseline imaging; **OR**
 - △ Surveillance every 2 years if the patient does not have a thoracic aortic aneurysm; **OR**
 - △ Annual surveillance if aneurysm is growing by less than 0.3 cm/year; **OR**
 - △ Annual surveillance if aneurysm is less than 4.5 cm in size; **OR**
 - △ Surveillance every 6 months if aneurysm is growing by more than 0.3 cm/year; **OR**
 - △ Surveillance every 6 months if aneurysm is greater than 4.5 cm; **OR**
 - ▲ Bicuspid aortic valve (BAV) with **ANY** of the following³⁹:
 - △ At baseline if the ascending aorta is not adequately imaged on TTE; **OR**
 - △ 6 months after baseline imaging; **OR**
 - △ Surveillance every 2 years if the patient does not have a thoracic aortic aneurysm; **OR**
 - △ Annual surveillance if the aneurysm is growing by less than 0.3 cm/year; **OR**
 - △ Annual surveillance if the aneurysm is less than 4.5 cm in size; **OR**
 - △ Surveillance every 6 months if the aneurysm is growing by more than 0.3 cm/year; **OR**
 - △ Surveillance every 6 months if the aneurysm is greater than 4.5 cm; **OR**
 - ▲ Turner Syndrome with **ANY** of the following³⁹:
 - △ At baseline if the ascending aorta is not adequately imaged on TTE; **OR**
 - △ 6 months after baseline imaging; **OR**
 - △ Surveillance every 2 years if the patient does not have a thoracic aortic aneurysm; **OR**
 - △ Annual surveillance if the thoracic aortic aneurysm has an indexed diameter (aortic size index - ASI) greater than 2 cm/m²; **OR**
 - ▲ Loeys-Dietz syndrome with **ANY** of the following³⁹:
 - △ At baseline if the ascending aorta is not adequately imaged on TTE; **OR**
 - △ 6 months after baseline imaging; **OR**
 - △ Annual surveillance if the aneurysm is less than 4.0 cm; **OR**
 - △ Annual surveillance if the aneurysm is growing less than 0.3 cm growth/year; **OR**
 - △ Surveillance every 6 months if the aneurysm is greater than 4 cm; **OR**
 - △ Surveillance every 6 months if the aneurysm is growing by more than 0.3 cm/year; **OR**

- ▲ Vascular Ehlers-Danlos syndrome (VEDS) with **ANY** of the following³⁹:
 - △ At baseline if the ascending aorta is not adequately imaged on TTE; **OR**
 - △ At 6 months after baseline imaging; **OR**
 - △ Annual surveillance if the aneurysm is less than 5.0 cm; **OR**
 - △ Annual surveillance if the aneurysm is growing less than 0.5 cm growth/year; **OR**
 - △ Surveillance every 6 months if the aneurysm is greater than 5 cm; **OR**
 - △ Surveillance every 6 months if the aneurysm is growing by more than 0.5 cm/year; **OR**
- Initial screening CT for a first-degree relative (parent, sibling, or child) of a patient with confirmed aortic disease attributable to a heritable or genetic cause; **OR**
- Surveillance of known thoracic aortic dissection; **OR**
- Congenital thoracic anomalies, including **ANY** of the following:
 - Congenital pulmonary airway malformation (pediatric); **OR**
 - Chest wall deformities including but not limited to pectus excavatum (pediatric only); **OR**
 - Evaluation and management of diaphragmatic hernia; **OR**
 - Pulmonary sequestration.

Non-Indications

- **Computed tomography (CT), chest with contrast** is not considered appropriate if **ANY** of the following is **TRUE**:
 - The patient has undergone advanced imaging of the same body part and for the same indication within 3 months without undergoing treatment or developing new or worsening symptoms.⁴⁶

Definitions and Notes

^A**Age-appropriate cancer screening** includes the below imaging. If the screenings are completed and there are concerning findings, a CT chest would be appropriate to order^{34–37}:

- Breast Cancer: Ages 40–74, a screening mammography is performed biennially
- Colorectal Cancer: Ages 50–75, a screening colonoscopy is performed every 10 years
- Cervical Cancer: Ages 21–29: screening with cervical cytology every 3 years; Ages 30–65: screening with cervical cytology every 3 years, screening with high-risk papillomavirus (hrHPV) testing alone every 5 years, or screening every 5 years with hrHPV testing in combination with cytology (cotesting).

Tables

Table 2.

Fleischner Society 2017 Guidelines for Management of Incidentally Detected Pulmonary Nodules in Adults ⁶				
Solid Nodules*				
	Size			
Nodule Type	<6mm (<100 mm ³)	6–8 mm (100–250 mm ³)	>8 mm (>250 mm ³)	Comments
<i>Single</i>				
Low Risk**	No routine follow-up	CT at 6–12 months, then consider CT at 18–24 months	Consider CT at 3 months, PET/CT, or tissue sampling	Nodules <6 mm do not require routine follow-up in low-risk patients (recommendation 1A).
High Risk**	Optional CT at 12 months	CT at 6–12 months, then CT at 18–24 months	Consider CT at 3 months, PET/CT, or tissue sampling	Certain patients at high-risk with suspicious nodule morphology, upper lobe location, or both may warrant a 12-month follow-up (recommendation 1A).
<i>Multiple</i>				
Low Risk**	No routine follow-up	CT at 3–6 months, then consider CT at 18–24 months	CT at 3–6 months, then consider CT at 18–24 months	Use most suspicious nodule as guide to management. Follow-up intervals may vary according to size and risk (recommendation 2A).

High Risk**	Optional CT at 12 months	CT at 3–6 months, then at 18–24 months	CT at 3–6 months, then at 18–24 months	Use most suspicious nodule as guide to management. Follow-up intervals may vary according to size and risk (recommendation 2A).
Subsolid Nodules*				
	Size			
Nodule Type	<6mm (<100 mm ³)	> 6 mm (>100 mm ³)	Comments	
Single				
Ground Glass	No routine follow-up	CT at 6–12 months to confirm persistence, then CT every 2 years until 5 years	In certain suspicious nodules <6 mm, consider follow-up at 2 and 4 years. If solid component(s) or growth develops, consider resection. (Recommendations 3A and 4A).	
Part Solid	No routine follow-up	CT at 3–6 months to confirm persistence. If unchanged and solid component remain <6 mm, annual CT should be performed for 5 years.	In practice, part-solid nodules cannot be defined as such until >6 mm, and nodules <6 mm do not usually require follow-up. Persistent part-solid nodules with solid components 6mm should be considered highly suspicious (recommendations 4A–4C).	
Multiple	CT at 3–6 months. If stable, consider CT at 2 and 4 years	CT at 3–6 months. Subsequent management based on the most suspicious nodule(s)	Multiple <6 mm pure ground-glass nodules are usually benign, but consider follow-up in selected patients at high risk at 2 and 4 years(recommendation 5A).	

Table 3.

Lung-RADS® (2022) ⁷			
Lung-RADS	Category Descriptor	Findings	Management
0	Incomplete Estimated Population Prevalence: ~1%	Prior chest CT examination being located for comparison (see note 9)	Comparison to prior chest CT
		Part of all of the lungs cannot be evaluated	Additional lung cancer screening CT imaging needed
		Findings suggestive of an inflammatory or infectious process (see note 10)	1-3 month LDCT
1	Negative Estimated Population Prevalence: 39%	No lung nodules; OR	12-month screening LDCT
		Nodule with benign features: ● Complete, central, popcorn, or concentric ring calcifications; OR ● Fat-containing	
2	Benign Based on imaging features or indolent behavior Estimated Population Prevalence: 45%	Juxtapleural Nodule ● < 10 mm (524 mm³) mean diameter at baseline or new; AND ● Solid; smooth margins; and oval, lentiform, or triangular shape Solid Nodule ● < 6 mm (< 113 mm³) at baseline; OR	

		● New <4 mm (< 34 mm³)	
		Part Solid Nodule ● < 6 mm (< 113 mm³) total mean diameter at baseline	
		Non-Solid Nodule (GGN) ● <30 mm (< 14,137 mm³) at baseline, new or growing; OR ● >30 mm (> 14,137 mm³) stable or slowly growing (see note 7)	
		Airway nodule , subsegmental - at baseline, new, or stable (see note 11)	
		● Category 3 lesion that is stable or decreased in size at 6-month follow-up CT; OR ● Category 4B lesion proven to be benign in etiology following appropriate diagnostic workup	
3	Probably Benign Based on imaging features or behavior Estimated Population Prevalence: 9%	Solid Nodule ● > 6 mm to < 8 mm (> 113 to < 268 mm³) at baseline; OR ● New 4 mm to <6 mm (34 to < 113 mm³) Part Solid Nodule ● > 6 mm (> 113 mm ³) total mean diameter with solid component < 6 mm (< 113 mm ³) at baseline ● New < 6 mm (< 113 mm ³) total mean diameter Non-Solid Nodule (GGN) ● > 30 mm (> 14,137 mm ³) at baseline or new Atypical Pulmonary Cyst (see note 12) ● Growing cystic component (mean diameter) of a thick-walled cyst Category 4A lesion that is stable or decreased in size at 3-month follow-up CT (excluding airway nodules)	6-month LDCT
4A	Suspicious Estimated Population Prevalence: 4%	Solid Nodule ● > 8 mm to < 15 mm (> 268 to < 1767 mm³) at baseline; OR ● Growing < 8 mm (< 268 mm³) ● New 6 to < 8 mm (113 to < 268 mm³) Part Solid Nodule ● > 6 mm (> 113 mm³) total mean diameter with solid component > 6 mm to < 8 mm (> 113 to < 268 mm³) at baseline; OR ● New or growing <4 mm (< 34 mm³) solid component Airway Nodule , segmental or more proximal - at baseline (see note 11) Atypical Pulmonary Cyst (see note 12) ● Thick-walled cyst; OR ● Multilocular cyst at baseline; OR ● Thin- or thick-walled cyst that becomes multilocular	3-month LDCT; PET/CT may be considered if there is a > 8 mm (> 268 mm ³) solid nodule or solid component
4B	Very Suspicious Estimated Population Prevalence: 2%	Airway Nodule , segmental or more proximal - stable or growing (see note 11) Solid Nodule ● > 15 mm (> 1767 mm³) at baseline; OR ● New or growing > 8 mm (> 268 mm³) Part Solid Nodule ● Solid component > 8 mm (> 268 mm³) at baseline; OR	Referral for further clinical evaluation Diagnostic chest CT with or without contrast; PET/CT may be considered if there is a > 8 mm (> 268 mm ³) solid nodules or solid component; Tissue sampling; and/or referral for further clinical evaluation; Management depends on clinical evaluation, patient preference, and the probability of malignancy (see note 13)

		● New or growing > 4 mm (> 34 mm³) solid component	
		Atypical Pulmonary Cyst (see note 12) ● Thick-walled cyst with growing wall thickness/nodularity; OR ● Growing multilocular cyst (mean diameter); OR ● Multilocular cyst with increased loculation or new/increased opacity (nodular, ground glass, or consolidation)	
		Slow-growing solid or part-solid nodule that demonstrates growth over multiple screening exams (see note 8)	
4X	Estimated Population Prevalence: <1%	Category 3 or 4 nodules with additional features or imaging findings that increase suspicion for lung cancer (see note 14)	
S	Significant or Potentially Significant Estimated Population Prevalence: 10%	Modifier: May add to category 0-4 for clinically significant or potentially clinically significant findings unrelated to lung cancer (see note 15)	As appropriate to the specific finding

Service: Repeat Imaging - Medical Necessity Criteria

Related Centers for Medicare & Medicaid Services (CMS) Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Cohere defines CMS coverage criteria as follows¹:

- Fully established: Applicable LCD or NCD is comprehensive and does not require additional criteria to determine medical necessity consistently.
- Not fully established: Additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently. The additional Cohere criteria will provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

For each jurisdiction, Cohere's internal coverage criteria will only be applied when CMS guidance is not fully established and additional guidelines are needed to support consistent and appropriate decision-making.

Cohere Health's position on NCDs or LCDs related to Cohere Medicare Advantage Policy - Computed Tomography (CT), Chest is reflected in Table 1 below. For the LCDs that are not fully established, please refer to the far right column as a guide for the application of Cohere Medicare Advantage criteria.

Table 1 - Related CMS Policies (NCDs or LCDs)²⁻⁴

Type	Title	Number	Cohere Definition of CMS Policy Establishment	Indications not fully established by CMS policy (refer to Cohere Health MA medical necessity criteria for these topics):
NCD	Computed tomography	220.1	Not fully established	● All specific indications for CT, chest ● Artificial intelligence (AI)-enabled, FDA-cleared, computed tomography (CT)-based quantitative coronary artery calcium or aortic valve calcification analysis (AI-CAC)
LCD	Computerized axial tomography (CT), thorax	L33459	Not fully established	● Artificial intelligence (AI)-enabled, FDA-cleared, computed tomography (CT)-based quantitative coronary artery calcium or aortic valve calcification analysis (AI-CAC)
LCD	Multiple imaging in oncology	L35391	Not fully established	● All specific indications for follow-up CT, chest ● Artificial intelligence (AI)-enabled, FDA-cleared, computed tomography (CT)-based quantitative coronary artery calcium or aortic valve calcification analysis (AI-CAC)
LCD	No LCD Available for Jurisdiction	N/A	N/A	Use NCD 220.1 and Cohere Medicare Advantage internal coverage criteria

Indications

- Repeat imaging is considered appropriate when **ALL** of the following are **TRUE** ^{40,41}:
 - Repeat request following recent imaging within the past 3 months of the same anatomic region with the same or similar modality; **AND**
 - No established guidelines for repeat imaging; **AND**
 - **ANY** of the following:
 - Need for a one-time clarifying follow-up of a prior indeterminate finding; **OR**
 - New or worsening symptoms not addressed in the guidelines, such that repeat imaging would influence treatment; **OR**
 - No change in symptoms and a well-established clinical need for ongoing monitoring that will influence management.

Non-Indications

- **Computed tomography (CT), chest with contrast** is not considered appropriate if **ANY** of the following is **TRUE**:
 - The patient has undergone advanced imaging of the same body part and for the same indication within 3 months without undergoing treatment or developing new or worsening symptoms.⁴⁶

Service: Artificial Intelligence (AI)-Enabled, FDA-Cleared, Computed Tomography (CT)-Based Quantitative Coronary Artery Calcium or Aortic Valve Calcification Analysis (AI-CAC) - Medical Necessity Criteria

Related Centers for Medicare & Medicaid Services (CMS) Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Cohere defines CMS coverage criteria as follows¹:

- Fully established: Applicable LCD or NCD is comprehensive and does not require additional criteria to determine medical necessity consistently.
- Not fully established: Additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently. The additional Cohere criteria will provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

For each jurisdiction, Cohere's internal coverage criteria will only be applied when CMS guidance is not fully established and additional guidelines are needed to support consistent and appropriate decision-making.

Cohere Health's position on NCDs or LCDs related to Cohere Medicare Advantage Policy - Computed Tomography (CT), Chest is reflected in Table 1 below. For the LCDs that are not fully established, please refer to the far right column as a guide for the application of Cohere Medicare Advantage criteria.

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LCD	Multiple imaging in oncology	L35391	Not fully established	● All specific indications for follow-up CT, chest ● Artificial intelligence (AI)-enabled, FDA-cleared, computed tomography (CT)-based quantitative coronary artery calcium or aortic valve calcification analysis (AI-CAC)
LCD	No LCD Available for Jurisdiction	N/A	N/A	Use NCD 220.1 and Cohere Medicare Advantage internal coverage criteria

Indications

- **Artificial intelligence (AI)-enabled, FDA-cleared, computed tomography (CT)-based quantitative coronary artery calcium or aortic valve calcification analysis (AI-CAC)** is considered appropriate if **ALL** of the following are **TRUE**:
 - Chest CT must be for a medically necessary indication Chest CT must be for a medically necessary indication^{42,43}; **AND**
 - Analysis must be performed in a hospital outpatient department (HOPD)⁴⁴; **AND**
 - Associated imaging study must be a non-gated non-contrast chest CT acquired on a General Electric (GE) scanner⁴²; **AND**
 - Adult greater than or equal to 40 years of age^{42,43}; **AND**
 - Results are expected to impact clinical management.⁴⁵

Non-Indications

- **Artificial intelligence (AI)-enabled, FDA-cleared, computed tomography (CT)-based quantitative coronary artery calcium or aortic valve calcification analysis (AI-CAC)** is not considered appropriate if **ANY** of the following is **TRUE**⁴⁵:
 - Analysis would duplicate findings quantitatively assessed by a dedicated cardiac CT calcium scoring study (e.g., computed tomography coronary angiography [CCTA]); **OR**
 - Associated CT chest imaging is inadequate for CAC assessment; **OR**
 - Known coronary artery disease (CAD) of high risk on therapy; **OR**
 - Previous AI-CAC has been performed and shows abnormal calcium.

Disclaimer on Radiation Exposure in Pediatric Populations

Cohere Health is committed to ensuring that every patient has access to appropriate and safe imaging studies in accordance with established guidelines. While radiographic studies, such as computed tomography (CT), can provide critical clinical information, exposure to ionizing radiation has the potential to increase lifetime cancer risk. Risk is higher in pediatric patients due to their greater radiosensitivity and longer expected lifespan.

Radiation-induced risks can be reduced by ensuring that imaging is medically necessary and by optimizing procedures to use the lowest dose necessary to achieve diagnostic quality images, consistent with ALARA (As Low As Reasonably Achievable) principles. Alternative modalities that do not involve ionizing radiation should be considered when clinically feasible, such as ultrasound or magnetic resonance imaging (MRI). Providers should adjust equipment and dose to pediatric body sizes and track cumulative radiation exposure for patients requiring multiple imaging studies.

These measures align with guidance from the US Food and Drug Administration (FDA) initiative to reduce unnecessary radiation exposure,^{47,48} the National Cancer Institute pediatric CT risk guidelines,⁴⁹ and the Image Gently Alliance and Image Wisely Alliance recommendations for pediatric radiation safety.^{50,51}

Clinical Harms and Benefits

Cohere Health Medicare Advantage determinations are made in accordance with CMS's decisioning requirements outlined in 42 CFR 422.101. When CMS guidelines are not fully established, Cohere Health develops publicly accessible medical necessity criteria based on widely accepted medical society guidelines and/or robust clinical literature. The additional Cohere criteria will provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.¹

Internal coverage criteria in *Cohere Medicare Advantage Policy - Computed Tomography (CT), Chest* are developed to provide the following:

- Improved patient selection for chest CT, supporting better health outcomes.⁶
- Emphasis on patient safety and standard of care aligned with the best available evidence.^{6,8}
- Care aligned to recommendations of American College of Radiology (ACR) and the American Heart Association (AHA).^{6,8,45}
- Appropriate allocation of healthcare resources, such as mitigating avoidable use of emergency services and additional treatments.

The American Heart Association (AHA) emphasizes that artificial intelligence (AI)-enabled coronary artery calcium analysis (AI-CAC) requires additional research and validation to support appropriate integration into clinical practice. While current literature describes algorithm feasibility and potential clinical utility, it does not provide evidence of improved patient outcomes.

Formal recommendations have not yet been established, and the evidence is still evolving to support clinical reliability and best practices.⁴⁵ Two AI-CAC software devices have received premarket notifications for FDA clearance, AVIEW CAC and Bunkerhill AVC.^{42,43}

Hassankhani et al. (2023) conducted a systematic review and meta-analysis of the diagnostic utility of multidetector computed tomography (MDCT) scans in penetrating diaphragmatic injuries. The study investigates the diagnostic efficacy of MDCT in detecting diaphragmatic injuries caused by penetrating trauma, with a focus on the potential risks of missed injuries and complications in cases managed nonoperatively despite the recognized value of CT scans for stable patients. The progression of CT technology, notably with the emergence of MDCT, has significantly improved the capacity to identify and assess diaphragmatic injuries caused by penetrating trauma. Although CT has solidified its role in evaluating blunt abdominal trauma patients who are hemodynamically stable, becoming the preferred imaging method in this regard, utilization in cases of penetrating thoracoabdominal trauma remains an ongoing subject of investigation. The study underscores the efficacy of MDCT in identifying diaphragmatic injury resulting from penetrating trauma with moderate to high diagnostic accuracy.⁵²

Cramer et al. (2021) provide a secondary analysis of a randomized control trial (RCT) on the incidence of second primary lung cancer after low-dose CT versus chest X-ray screening in head and neck cancer survivors. A total of 53,452 participants were enrolled in the study; 171 survivors of head and neck cancer were identified (82 had screening via low-dose CT of the chest and 89 via chest X-ray). The average age of participants was 61 years, with 132 being male (77%). The incidence of lung cancer was notably higher among head and neck cancer survivors compared to those without. In head and neck cancer survivors, the incidence of second primary lung cancer was 2610

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Policy Revision History/Information

Clinical Policy Version	Date	Review History
Version 1	10/29/2024	Original Date.
Version 2	10/16/2025	Annual review. Rearranged bullets for improved usability and organization. Added sub-indication for neoplastic conditions for evaluating response to treatment/change in therapy. Updated the indication for assessment of injury or complications to include "invasive procedure such as pacemaker placement, chest tube placement, or mechanical ventilation." Added indication for "CT-guided biopsies and drainage procedures when fluoroscopy is inadequate." Clarified indications for repeat imaging to improve usability and organization. Removed duplicative language for aortic dissection. Added non-indication for "advanced imaging of the same body part and for the same indication within 3 months without undergoing treatment or developing new or worsening symptoms." Removed note for contrast anaphylaxis allergy.
Version 3	05/21/2026	Revision. Added HCPCS code G0680. Updated template, including addition of "Table 1 - Related CMS Policies" that describes Cohere definition of which LCDs/NCDs are not fully established. Cohere MA criteria updated for internal alignment across policies. Added indications and non-indications for "Artificial intelligence (AI)-enabled, FDA-cleared, computed tomography (CT)-based quantitative coronary artery calcium or aortic valve calcification analysis (AI-CAC)." Added references 42–45.



Cohere Medicare Advantage Policy – Computed Tomography (CT), Chest

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 29, 2024

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Chest (Version 1)

Date of last literature review: 10/28/2024

Document last updated: 10/28/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Cohere Medicare Advantage Policy - Computed Tomography (CT), Chest

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹⁻³

- [National Coverage Determination \(NCD\). Computed tomography \(220.1\)](#)
- [Local Coverage Determination \(LCD\). Computerized Axial Tomography \(CT\), Thorax \(L33459\)](#)
- [Local Coverage Determination \(LCD\). Multiple Imaging in Oncology L35391](#)
- [Billing and Coding: Computerized Axial Tomography \(CT\), Thorax \(A56580\)](#)
- [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Recommended Clinical Approach

Computed tomography (CT) of the chest can be performed as a screening examination in high-risk patients and to diagnose and evaluate a myriad of thoracic processes involving the lungs, mediastinum/hilum, pleura, and chest wall. Contrast usage is guided by the clinical scenario being investigated.⁴

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Computed Tomography (CT), Chest. This process helps to prevent both incorrect denials and inappropriate approvals

of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.¹⁻⁴
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy. Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁵
- Compared to adults, children are more sensitive to radiation. CT exposure among children may increase their risk of leukemia and brain cancer.⁶
- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁷

The clinical benefits of using these criteria include:

- Low-dose CT scans are essential for screening survivors of head and neck cancer, a population at high risk for secondary cancers, including lung cancer.⁸
- CT can provide timely diagnosis of early-stage lung cancer and reduce lung cancer-related mortality among high-risk individuals.⁸
- When examining for penetrating injuries in the thoraco-abdominal region, multidetector computed tomography (MDCT) is a less invasive alternative to procedures such as diagnostic laparoscopy.⁹
- MCDT can provide scans of the chest within an interval of breath, thereby reducing imaging time and keeping the artifacts of respiratory movement to a minimum.¹⁰
- Computed tomography is effective in diagnosing diaphragmatic injuries caused by penetrating trauma, particularly in patients with good blood circulation and stable heart rates.¹⁰

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Fleischner Society 2017 Guidelines for Management of Incidentally Detected Pulmonary Nodules in Adults ¹				
Solid Nodules*				
	Size			
Nodule Type	<6mm (<100 mm ³)	6–8 mm (100–250 mm ³)	>8 mm (>250 mm ³)	Comments
<i>Single</i>				
Low Risk**	No routine follow-up	CT at 6–12 months, then consider CT at 18–24 months	Consider CT at 3 months, PET/CT, or tissue sampling	Nodules <6 mm do not require routine follow-up in low-risk patients (recommendation 1A).
High Risk**	Optional CT at 12 months	CT at 6–12 months, then CT at 18–24 months	Consider CT at 3 months, PET/CT, or tissue sampling	Certain patients at high-risk with suspicious nodule morphology, upper lobe location, or both may warrant a 12-month follow-up (recommendation 1A).
<i>Multiple</i>				
Low Risk**	No routine follow-up	CT at 3–6 months, then	CT at 3–6 months, then	Use most suspicious nodule as guide to

		consider CT at 18–24 months	consider CT at 18–24 months	management. Follow-up intervals may vary according to size and risk (recommendation 2A).
High Risk**	Optional CT at 12 months	CT at 3–6 months, then at 18–24 months	CT at 3–6 months, then at 18–24 months	Use most suspicious nodule as guide to management. Follow-up intervals may vary according to size and risk (recommendation 2A).
Subsolid Nodules*				
	Size			
Nodule Type	<6mm (<100 mm³)	≥ 6 mm (≥100 mm³)	Comments	
<i>Single</i>				
Ground Glass	No routine follow-up	CT at 6–12 months to confirm persistence, then CT every 2 years until 5 years	In certain suspicious nodules <6 mm, consider follow-up at 2 and 4 years. If solid component(s) or growth develops, consider resection. (Recommendations 3A and 4A).	
Part Solid	No routine follow-up	CT at 3–6 months to confirm persistence. If unchanged and solid component remain <6 mm, annual CT should be performed for 5 years.	In practice, part-solid nodules cannot be defined as such until ≥6 mm, and nodules <6 mm do not usually require follow-up. Persistent part-solid nodules with solid components 6mm should be considered highly suspicious (recommendations 4A–4C).	
<i>Multiple</i>	CT at 3–6 months. If stable, consider CT at 2 and 4 years	CT at 3–6 months. Subsequent management based on the most suspicious	Multiple <6 mm pure ground-glass nodules are usually benign, but consider follow-up in selected patients at high risk at 2 and 4 years (recommendation 5A).	

		nodule(s)	

Lung-RADS® (2022) ²			
Lung-RADS	Category Descriptor	Findings	Management
0	Incomplete Estimated Population Prevalence: ~1%	Prior chest CT examination being located for comparison (see note 9)	Comparison to prior chest CT
		Part of all of the lungs cannot be evaluated	Additional lung cancer screening CT imaging needed
		Findings suggestive of an inflammatory or infectious process (see note 10)	1-3 month LDCT
1	Negative Estimated Population Prevalence: 39%	No lung nodules; OR	12-month screening LDCT
		Nodule with benign features: - Complete, central, popcorn, or concentric ring calcifications; OR - Fat-containing	
2	Benign Based on imaging features or indolent behavior Estimated Population Prevalence: 45%	Juxtapleural Nodule < 10 mm (524 mm^3) mean diameter at baseline or new; AND - Solid; smooth margins; and oval, lentiform, or triangular shape	
		Solid Nodule < 6 mm ($< 113 \text{ mm}^3$) at baseline; OR - New < 4 mm ($< 34 \text{ mm}^3$)	
		Part Solid Nodule < 6 mm ($< 113 \text{ mm}^3$) total mean diameter at baseline	
		Non-Solid Nodule (GGN) < 30 mm ($< 14,137 \text{ mm}^3$) at baseline, new or growing; OR $\geq 30 \text{ mm}$ ($\geq 14,137 \text{ mm}^3$) stable or slowly growing (see note 7)	
		Airway nodule , subsegmental - at baseline, new, or stable (see note 11)	
		Category 3 lesion that is stable or decreased in size at 6-month follow-up	

		CT; OR • Category 4B lesion proven to be benign in etiology following appropriate diagnostic workup	
3	Probably Benign Based on imaging features or behavior Estimated Population Prevalence: 9%	Solid Nodule ≥ 6 mm to < 8 mm (≥ 113 to < 268 mm³) at baseline; OR - New 4 mm to < 6 mm (34 to < 113 mm³) Part Solid Nodule ≥ 6 mm (≥ 113 mm³) total mean diameter with solid component < 6 mm (< 113 mm³) at baseline - New < 6 mm (< 113 mm³) total mean diameter Non-Solid Nodule (GGN) ≥ 30 mm (≥ 14,137 mm³) at baseline or new Atypical Pulmonary Cyst (see note 12) - Growing cystic component (mean diameter) of a thick-walled cyst Category 4A lesion that is stable or decreased in size at 3-month follow-up CT (excluding airway nodules)	6-month LDCT
4A	Suspicious Estimated Population Prevalence: 4%	Solid Nodule ≥ 8 mm to < 15 mm (≥ 268 to < 1767 mm³) at baseline; OR - Growing < 8 mm (< 268 mm³) - New 6 to < 8 mm (113 to < 268 mm³) Part Solid Nodule ≥ 6 mm (≥ 113 mm³) total mean diameter with solid component ≥ 6 mm to < 8 mm (≥ 113 to < 268 mm³) at baseline; OR - New or growing < 4 mm (< 34 mm³) solid component Airway Nodule, segmental or more proximal – at baseline (see note 11) Atypical Pulmonary Cyst (see note 12) - Thick-walled cyst; OR - Multilocular cyst at baseline; OR - Thin- or thick-walled cyst that becomes multilocular	3-month LDCT; PET/CT may be considered if there is a ≥ 8 mm (≥ 268 mm ³) solid nodule or solid component
		Airway Nodule , segmental or more proximal – stable or growing (see note 11)	Referral for further clinical evaluation

4B	Very Suspicious Estimated Population Prevalence: 2%	Solid Nodule • ≥ 15 mm (≥ 1767 mm³) at baseline; OR • New or growing ≥ 8 mm (≥ 268 mm³)	Diagnostic chest CT with or without contrast; PET/CT may be considered if there is a ≥ 8 mm (≥ 268 mm ³) solid nodules or solid component; Tissue sampling; and/or referral for further clinical evaluation; Management depends on clinical evaluation, patient preference, and the probability of malignancy (see note 13)
		Part Solid Nodule • Solid component ≥ 8 mm (≥ 268 mm³) at baseline; OR • New or growing ≥ 4 mm (≥ 34 mm³) solid component	
		Atypical Pulmonary Cyst (see note 12) • Thick-walled cyst with growing wall thickness/nodularity; OR • Growing multilocular cyst (mean diameter); OR • Multilocular cyst with increased loculation or new/increased opacity (nodular, ground glass, or consolidation)	
		Slow-growing solid or part-solid nodule that demonstrates growth over multiple screening exams (see note 8)	
4X	Estimated Population Prevalence: <1%	Category 3 or 4 nodules with additional features or imaging findings that increase suspicion for lung cancer (see note 14)	
S	Significant or Potentially Significant Estimated Population Prevalence: 10%	Modifier: May add to category 0–4 for clinically significant or potentially clinically significant findings unrelated to lung cancer (see note 15)	As appropriate to the specific finding

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), chest** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Chest radiograph and physical examination have been performed and are indeterminate, or findings require further evaluation **AND** any of the following:

- Evaluation of pulmonary, mediastinal, pleural or chest wall infections and their complications; **OR**
- Neoplastic or hematologic conditions with involvement or potential involvement of the thorax¹¹ for **ANY** of the following:
 - Diagnosis and management of mediastinal neoplasms and other processes, including but not limited to thymoma mediastinal adenopathy.
 - Initial staging; **OR**
 - Treatment planning; **OR**
 - Response assessment; **OR**
 - Surveillance, and **ANY** of the following is **TRUE**¹²⁻¹⁶:
 - ◆ The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6–12 months for an overall duration [e.g., 5 years]); **OR**
 - ◆ Suspected recurrence/progression; **OR**
- ◆ For the evaluation of cardiopulmonary failure or insufficiency (e.g. unexplained shortness of breath, heart failure); **OR**
- ◆ Cardiovascular abnormalities, known or suspected, including **ANY** of the following⁴:
 - Aneurysm; **OR**
 - Embolism; **OR**
 - Thrombosis; **OR**
 - Congenital anomalies; **OR**
 - Postoperative complications; **OR**
 - Sequelae of atherosclerotic disease; **OR**
- ◆ For diagnosis and management of pulmonary or pleural fluid collections, including but not limited to **ANY** of the following:
 - Abscess; **OR**
 - Empyema; **OR**
 - Effusion; **OR**
 - Pneumothorax; **OR**
- ◆ For diagnosis and management of interstitial and alveolar lung disease, including but not limited to idiopathic, allergic, collagen-vascular, environmental or other causes⁴; **OR**
- ◆ For the evaluation of thoracic sequelae of remote processes, including but not limited to **ANY** of the following:

- Pancreatitis; **OR**
- Gastrointestinal perforation; **OR**
- ◆ For the assessment of injury or complications due to **ANY** of the following:
 - Trauma; **OR**
 - Burns; **OR**
 - Surgery; **OR**
 - Organ Transplantation; **OR**
 - Radiation therapy; **OR**
 - Chemotherapy⁴; **OR**
 - Invasive procedure, including but not limited to **ANY** of the following:
 - Pacemaker placement; **OR**
 - Chest tube placement; **OR**
 - Mechanical ventilation; **OR**
- ◆ For the evaluation of symptoms that may be arising from the chest or be referred to the chest, including but not limited to **ANY** of the following:
 - Cough; **OR**
 - Hemoptysis; **OR**
 - Chest pain; **OR**
 - Abdominal pain; **OR**
- ◆ For the evaluation of a patient with myasthenia gravis to rule out thymic tumors; **OR**
- ◆ For guidance for interventional procedures¹¹; **OR**
- ◆ Concern for aortic dissection due to symptoms or imaging including but not limited to **ANY** of the following:
 - Sudden excruciating back or chest pain; **OR**
 - Sudden neurologic episode; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**

- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography (CT), chest with contrast** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ History of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{[17-18](#)}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{[17-18](#)}

Cumulative Dose Monitoring: Implement systems to track cumulative

radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.¹⁷⁻¹⁸

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.¹⁷⁻¹⁸

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
71250	Computed tomography (CT), thorax; without contrast material
71260	Computed tomography (CT), thorax; with contrast material(s)
71270	Computed tomography (CT), thorax; without contrast material, followed by contrast material(s) and further sections
76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Hassankhani et al. (2023) conducted a systematic review and meta-analysis of the diagnostic utility of multidetector computed tomography (MDCT) scans in penetrating diaphragmatic injuries. The study investigates the diagnostic efficacy of MDCT in detecting diaphragmatic injuries caused by penetrating trauma, with a focus on the potential risks of missed injuries and complications in cases managed nonoperatively despite the recognized value of CT scans for stable patients. The progression of CT technology, notably with the emergence of MDCT, has significantly improved the capacity to identify and assess diaphragmatic injuries caused by penetrating trauma. Although CT has solidified its role in evaluating blunt abdominal trauma patients who are hemodynamically stable, becoming the preferred imaging method in this regard, utilization in cases of penetrating thoracoabdominal trauma remains an ongoing subject of investigation. The study underscores the efficacy of MDCT in identifying diaphragmatic injury resulting from penetrating trauma with moderate to high diagnostic accuracy.¹⁰

Cramer et al. (2021) provide a secondary analysis of a randomized control trial (RCT) on the incidence of second primary lung cancer after low-dose CT versus chest X-ray screening in head and neck cancer survivors. A total of 53,452 participants were enrolled in the study; 171 survivors of head and neck cancer were identified (82 had screening via low-dose CT of the chest and 89 via chest X-ray). The average age of participants was 61 years, with 132 being male (77%). The incidence of lung cancer was notably higher among head and neck cancer survivors compared to those without. In head and neck cancer survivors, the incidence of second primary lung cancer was 2610 cases per 100,000 person-years in the low-dose CT group versus 1594 cases per 100,000 person-years in the chest X-ray group. Overall survival in head and neck cancer survivors was 7.07 years with low-dose CT compared to 6.66 years with chest X-ray. The secondary analysis of the RCT indicates that head and neck cancer survivors face a heightened risk of developing second primary lung cancer. Low-dose CT screening is essential for such survivors, particularly individuals with a significant history of cigarette smoking who are deemed suitable for curative treatment.⁸

Oldroyd et al. (2021) performed a systematic review and meta-analysis to determine the clinical factors linked with cancer susceptibility in idiopathic inflammatory myopathies (IIMs) and conduct a comprehensive review of the available evidence concerning cancer screening within this context. The meta-analysis assessed the cancer risk linked with numerous clinical risk factors and myositis-specific autoantibodies (MSAs), providing insights for cancer screening strategies among IIM patients. The authors note that

findings can collectively contribute to refining cancer screening guidelines, potentially facilitating earlier cancer detection and enhancing patient outcomes.¹⁹

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Clinical Guideline Revision History/Information

Original Date: October 29, 2024		
Review History		



Cohere Medicare Advantage Policy – Computed Tomography (CT), Colonography

Clinical Guidelines for Medical Necessity Review

Version: 1
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Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Colonography

Date of last literature review: 10/21/2024

Document last updated: 10/23/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Colonography

Benefit Category

Colorectal Cancer Screening Tests
Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹⁻⁵

[National Coverage Determination \(NCD\). Colorectal Cancer Screening Tests \(210.3\)](#)

[National Coverage Determination \(NCD\). Computed Tomography \(220.1\)](#)

[Local Coverage Determination \(LCD\). Virtual Colonoscopy \(CT Colonoscopy\) \(L33452\)](#)

[Local Coverage Determination \(LCD\). Computed Tomographic \(CT\) Colonography for Diagnostic Uses \(L33562\)](#)

[Local Coverage Determination \(LCD\). Virtual Colonoscopy \(CT Colonoscopy\) \(L34055\)](#)

[Billing and Coding: Virtual Colonoscopy \(CT Colonoscopy\) \(A56772\)](#)

[Billing and Coding: Virtual Colonoscopy \(CT Colonoscopy\) \(A56800\)](#)

[Billing and Coding: Computed \(CT\) Colonography for Diagnostic Uses \(A57026\)](#)

Recommended Clinical Approach

The decision to utilize computed tomography (CT) colonography is determined by stratifying individuals into average, moderate, and high-risk categories. High-risk individuals are advised to undergo an optical

colonoscopy without delay. The procedure should be conducted in a facility compliant with the standards of the American College of Radiology (ACR), and performed by a physician trained in CT colonography. Bowel preparation for CT colonography is akin to an optical colonoscopy.⁶

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Computed Tomography, Colonography. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁷⁻¹⁰
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹¹ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹¹
- CT Colonography is contraindicated for patients with active colonic inflammation, due to a high risk of bowel perforation.¹²
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹³

The clinical benefits of using these criteria include:

- CT Colonography is an effective and minimally invasive imaging scan employed to detect colorectal cancer.⁶
- CT Colonoscopy, unlike stool-based cancer screening tests, can detect precancerous polyps before they become cancerous, and may allow

endoscopic evaluations to be conducted on the same day, if necessary.^{6,14}

- Compared to instrument colonoscopy, CT colonography has a lower risk of complications. Furthermore, CT colonography does not require sedation and is relatively safe for individuals with medical comorbidities that preclude colonoscopy.¹⁴
- CT colonography requires a less frequent testing interval than stool-based screening test.¹⁴
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT) colonography** is considered appropriate if **ALL** of the following are **TRUE**:

- ◆ Colonoscopy is contraindicated or incomplete for **ANY** of the following reasons:
 - Prior optical colonoscopy was incomplete due to secondary conditions such as, but not limited to, **ANY** of the following^{6,15-18}:
 - An obstructing neoplasm; **OR**
 - Intrinsic scarring; **OR**
 - Stricture; **OR**
 - Redundant or tortuous colon; **OR**
 - Spasm; **OR**
 - Obstruction from prior surgery, radiation, or diverticular disease; **OR**

- Extrinsic compression; **OR**
- The patient is at increased risk for complications during an optical colonoscopy when **ANY** of the following is **TRUE**⁶:
 - Anticoagulant use that cannot be safely reversed before the procedure; **OR**
 - Coagulopathy; **OR**
 - Complications from prior optical colonoscopy; **OR**
 - Increased risk of bowel perforation; **OR**
 - Sedation risk as indicated by an American Association of Anesthesiologists (ASA) Physical Status classification of IV or above¹⁹; **OR**
- The patient is 76 to 85 years of age, and medical necessity is determined based on symptoms or risk factors²⁰; **AND**
- ◆ **ANY** of the following is **TRUE**:
 - Evaluation of a submucosal abnormality detected on colonoscopy or another imaging study¹⁵; **OR**
 - Screening for colorectal cancer if **ANY** of the following is **TRUE**:
 - Routine screening for an average-risk individual greater than or equal to 45 years old²⁰⁻²⁴; **OR**
 - Prior CT colonography at least 5 years ago¹⁸⁻²⁴; **OR**
 - An incomplete optical colonoscopy has been attempted⁶; **OR**
 - Optical colonoscopy cannot be performed¹⁹; **OR**
 - Surveillance in moderate and high-risk individuals as defined by **ALL** of the following:
 - Documented discussion with the patient on the inferiority of CT colonography in this setting; **AND**
 - **ANY** of the following is **TRUE**:
 - ◆ Biopsy-proven precancerous polyps on prior colonoscopy and **ANY** of the following is **TRUE**:
 - Evaluation 3 years after resection of newly diagnosed small (less than 5mm diameter) adenomatous polyps when only a single polyp was detected (after 1 negative 3-year follow-up examination, subsequent surveillance intervals may be increased to 5 years^{25,26}; **OR**

- Evaluation at 1 and 4-year intervals after resection of multiple or large (greater than 10mm) adenomatous polyps (subsequent surveillance intervals may then be increased to every 5 years)^{25,26}; **OR**
- Evaluation in 1 year after the removal of multiple adenomas if **ANY** of the following is **TRUE**^{25,26}:
 - If examination proves to be negative, then repeat in 3 years; **OR**
 - After 1 negative 3-year follow-up examination, repeat exam every 5 years; **OR**
- ◆ A first-degree relative before age 60 or two first-degree relatives at any age with CRC or an advanced adenoma every 5 to 10 years starting at age 40 to 50 years of age or 10 years younger than the affected relative's age²⁷; **OR**
- ◆ Prior therapeutic abdominal or pelvic radiation – every 5 years beginning at age 35 for at-risk survivors or 10 years after the completion of radiotherapy (whichever occurs last)²⁸; **OR**
- ◆ Personal or family history (first or second-degree relative) of hereditary syndromes that do NOT cause polyposis, virtual colonography starting as early as age 10 and up to annually depending on clinical indication, including **ANY** of the following:
 - Hereditary nonpolyposis colorectal cancer (HNPCC)²⁹⁻³⁰; **OR**
 - Bloom syndrome; **OR**
 - PTEN hamartoma tumor syndrome (PHTS) when colonoscopy is contraindicated; **OR**
- Diagnostic examination in symptomatic patients with **ALL** of the following⁶:

- Documented discussion with the patient that optical colonoscopy is considered the gold standard in this setting; **AND**
- The patient has signs or symptoms suggesting colorectal cancer, including **ANY** of the following:
 - ◆ The positive test result indicates a relative elevation in risk (e.g., positive fecal immunochemical test, positive fecal occult blood test [FOBT]); **OR**
 - ◆ Iron-deficiency anemia; **OR**
 - ◆ Weight loss; **OR**
- Post-surgical follow-up of a patient for a colonic stoma or after a colectomy⁶; **OR**
- Before colorectal cancer surgery for the identification of synchronous lesions⁶; **OR**
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography (CT) colonography** is **NOT** considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The patient has undergone advanced imaging of the same body part and for the same indication within 3 months, without being on treatment; **OR**
- ◆ If intravenous contrast is used, history of anaphylactic allergic reaction to iodinated contrast media; **OR**
- ◆ When used for first-time screening in the absence of contraindications to colonoscopy, regardless of family history or

- other risk factors for the development of colonic disease³¹⁻³³; **OR**
- ◆ History of colorectal surgery within 1 month; **OR**
- ◆ History of polypectomy or mucosectomy within 1 week; **OR**
- ◆ Attempted colonoscopy within 48 hours; **OR**
- ◆ Symptomatic colon-containing hernia^{6,34}; **OR**
- ◆ Known or suspected current colon perforation^{6,34}; **OR**
- ◆ High-grade or symptomatic small bowel obstruction^{6,34}; **OR**
- ◆ Routine follow-up of inflammatory bowel disease^{6,34}; **OR**
- ◆ Hereditary polyposis syndromes such as familial adenomatous polyposis (FAP) (applies to virtual colonoscopy as it is unlikely to provide clinical benefit)^{6,34}; **OR**
- ◆ Evaluation of anal canal disease such as peri-anal fissure.^{6,34}

*NOTE: CT Colonography should not be performed if the patient has symptomatic acute conditions such as colitis, diarrhea, or recent acute diverticulitis.^{6,34}

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{35,36}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{35,36}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging

based on clinical evaluation.^{35,36}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{35,36}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
74261	Computed tomography (CT) colonography, diagnostic; without contrast material, with image post-processing
74262	Computed tomography (CT) colonography, diagnostic; with contrast material and non-contrast images, with image post-processing
74263	Computed tomographic (CT) colonography, screening, including image postprocessing
76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Jain et al. (2022) outline the updated colorectal cancer (CRC) screening strategies recommended by the United States Preventive Services Task Force (USPSTF) in 2021. Average-risk individuals should start screening at age 45. The Task Force suggests several screening methods: high-sensitivity guaiac fecal occult blood test (HSgFOBT), fecal immunochemical test (FIT), multi-target stool DNA (mt-sDNA) test, computed tomographic (CT) colonography (virtual colonoscopy), flexible sigmoidoscopy, flexible sigmoidoscopy with FIT, or traditional colonoscopy. Numerous emerging and innovative screening approaches are being researched and are on the horizon for primary screening in average-risk individuals. These include blood-based screening or "liquid biopsy," colon capsule endoscopy, urinary metabolomics, and stool-based microbiome testing to detect colorectal polyps or CRC. Compared to traditional colonoscopy, the advantages of CT colonography include a lower risk of complications, less invasive, sedation not required, and the clinician being able to visualize the entire colon. In addition, CT colonography requires a less frequent testing interval than stool-based modalities and is relatively safe for individuals with medical comorbidities that preclude colonoscopy. Same-day endoscopic evaluation may also be performed if indicated.¹⁴

Gupta et al. (2022) review CRC screening for identifying polyps and cancer within the colon. The sensitivity for detecting lesions greater than or equal to 1 cm varies between 67 and 94%, while specificity ranges from 86 to 98%. Notably, an estimated incidence of potentially significant extracolonic findings necessitating further investigation, ranging from 3.4–26.9%, with 1.3–11.4% possibly requiring follow-up due to incomplete characterization. Several studies have shown superior sensitivity in detecting colorectal cancer compared to colonoscopy, mainly when the endoscopist is unaware of CT colonography results. Repeat screening every 5 years is recommended by the USPSTF.³⁷

Shaukat et al. (2022) discuss CT colonography to facilitate the identification and pinpointing of polyps and cancers within the colon through a reconstructed 3D or 4D visualization. Two extensive trials have evaluated the

diagnostic efficacy of CT colonography against optical colonoscopy conducted on the same day. One study involving 1233 individuals at average risk showcased CT colonography's test characteristics, revealing 92% sensitivity and 96% specificity for adenomas measuring 10mm or larger as detected by optical colonoscopy. Additionally, it demonstrated 86% sensitivity and 80% specificity for adenomas measuring 6mm or larger. The National CT Colonography Trial (NCTC), sponsored by the American College of Radiology Imaging Network (ACRIN), comprised 2600 asymptomatic participants undergoing same-day CT colonography and optical colonoscopy. Results revealed a sensitivity of 84% for adenomas or colorectal cancer (CRC) measuring 10mm or larger, with a specificity of 85%. Furthermore, a sensitivity of 70% was observed for adenomas measuring 6mm or larger, with a specificity of 86%. A notable critique of CT colonography is the failure to report lesions smaller than 6mm, the clinical significance of which remains uncertain.³⁸

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Review History		



Cohere Medicare Advantage Policy – Computed Tomography (CT), Colonography

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 24, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Colonography

Date of last literature review: 10/21/2024

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Colonography

Benefit Category

Colorectal Cancer Screening Tests
Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹⁻⁵

[National Coverage Determination \(NCD\). Colorectal Cancer Screening Tests \(210.3\)](#)

[National Coverage Determination \(NCD\). Computed Tomography \(220.1\)](#)

[Local Coverage Determination \(LCD\). Virtual Colonoscopy \(CT Colonoscopy\) \(L33452\)](#)

[Local Coverage Determination \(LCD\). Computed Tomographic \(CT\) Colonography for Diagnostic Uses \(L33562\)](#)

[Local Coverage Determination \(LCD\). Virtual Colonoscopy \(CT Colonoscopy\) \(L34055\)](#)

[Billing and Coding: Virtual Colonoscopy \(CT Colonoscopy\) \(A56772\)](#)

[Billing and Coding: Virtual Colonoscopy \(CT Colonoscopy\) \(A56800\)](#)

[Billing and Coding: Computed \(CT\) Colonography for Diagnostic Uses \(A57026\)](#)

Recommended Clinical Approach

The decision to utilize computed tomography (CT) colonography is determined by stratifying individuals into average, moderate, and high-risk categories. High-risk individuals are advised to undergo an optical

colonoscopy without delay. The procedure should be conducted in a facility compliant with the standards of the American College of Radiology (ACR), and performed by a physician trained in CT colonography. Bowel preparation for CT colonography is akin to an optical colonoscopy.⁶

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Computed Tomography, Colonography. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁷⁻¹⁰
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹¹ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹¹
- CT Colonography is contraindicated for patients with active colonic inflammation, due to a high risk of bowel perforation.¹²
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹³

The clinical benefits of using these criteria include:

- CT Colonography is an effective and minimally invasive imaging scan employed to detect colorectal cancer.⁶
- CT Colonoscopy, unlike stool-based cancer screening tests, can detect precancerous polyps before they become cancerous, and may allow

endoscopic evaluations to be conducted on the same day, if necessary.^{6,14}

- Compared to instrument colonoscopy, CT colonography has a lower risk of complications. Furthermore, CT colonography does not require sedation and is relatively safe for individuals with medical comorbidities that preclude colonoscopy.¹⁴
- CT colonography requires a less frequent testing interval than stool-based screening test.¹⁴
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT) colonography** is considered appropriate if **ALL** of the following are **TRUE**:

◆ Colonoscopy is contraindicated or incomplete for **ANY** of the following reasons:

- Prior optical colonoscopy was incomplete due to secondary conditions such as, but not limited to, **ANY** of the following^{6,15-18}:
 - An obstructing neoplasm; **OR**
 - Intrinsic scarring; **OR**
 - Stricture; **OR**
 - Redundant or tortuous colon; **OR**
 - Spasm; **OR**
 - Obstruction from prior surgery, radiation, or diverticular disease; **OR**

- Extrinsic compression; **OR**
- The patient is at increased risk for complications during an optical colonoscopy when **ANY** of the following is **TRUE**⁶:
 - Anticoagulant use that cannot be safely reversed before the procedure; **OR**
 - Coagulopathy; **OR**
 - Complications from prior optical colonoscopy; **OR**
 - Increased risk of bowel perforation; **OR**
 - Sedation risk as indicated by an American Association of Anesthesiologists (ASA) Physical Status classification of IV or above¹⁹; **OR**
- The patient is 76 to 85 years of age, and medical necessity is determined based on symptoms or risk factors²⁰; **AND**
- ◆ **ANY** of the following is **TRUE**:
 - Evaluation of a submucosal abnormality detected on colonoscopy or another imaging study¹⁵; **OR**
 - Screening for colorectal cancer if **ANY** of the following is **TRUE**:
 - Routine screening for an average-risk individual greater than or equal to 45 years old²⁰⁻²⁴; **OR**
 - Prior CT colonography at least 5 years ago¹⁸⁻²⁴; **OR**
 - An incomplete optical colonoscopy has been attempted⁶; **OR**
 - Optical colonoscopy cannot be performed¹⁹; **OR**
 - Surveillance in moderate and high-risk individuals as defined by **ALL** of the following:
 - Documented discussion with the patient on the inferiority of CT colonography in this setting; **AND**
 - **ANY** of the following is **TRUE**:
 - ◆ Biopsy-proven precancerous polyps on prior colonoscopy and **ANY** of the following is **TRUE**:
 - Evaluation 3 years after resection of newly diagnosed small (less than 5mm diameter) adenomatous polyps when only a single polyp was detected (after 1 negative 3-year follow-up examination, subsequent surveillance intervals may be increased to 5 years^{25,26}; **OR**

- Evaluation at 1 and 4-year intervals after resection of multiple or large (greater than 10mm) adenomatous polyps (subsequent surveillance intervals may then be increased to every 5 years)^{25,26}; **OR**
- Evaluation in 1 year after the removal of multiple adenomas if **ANY** of the following is **TRUE**^{25,26}:
 - If examination proves to be negative, then repeat in 3 years; **OR**
 - After 1 negative 3-year follow-up examination, repeat exam every 5 years; **OR**
- ◆ A first-degree relative before age 60 or two first-degree relatives at any age with CRC or an advanced adenoma every 5 to 10 years starting at age 40 to 50 years of age or 10 years younger than the affected relative's age²⁷; **OR**
- ◆ Prior therapeutic abdominal or pelvic radiation – every 5 years beginning at age 35 for at-risk survivors or 10 years after the completion of radiotherapy (whichever occurs last)²⁸; **OR**
- ◆ Personal or family history (first or second-degree relative) of hereditary syndromes that do NOT cause polyposis, virtual colonography starting as early as age 10 and up to annually depending on clinical indication, including **ANY** of the following:
 - Hereditary nonpolyposis colorectal cancer (HNPCC)²⁹⁻³⁰; **OR**
 - Bloom syndrome; **OR**
 - PTEN hamartoma tumor syndrome (PHTS) when colonoscopy is contraindicated; **OR**
- Diagnostic examination in symptomatic patients with **ALL** of the following⁶:

- Documented discussion with the patient that optical colonoscopy is considered the gold standard in this setting; **AND**
- The patient has signs or symptoms suggesting colorectal cancer, including **ANY** of the following:
 - ◆ The positive test result indicates a relative elevation in risk (e.g., positive fecal immunochemical test, positive fecal occult blood test [FOBT]); **OR**
 - ◆ Iron-deficiency anemia; **OR**
 - ◆ Weight loss; **OR**
- Post-surgical follow-up of a patient for a colonic stoma or after a colectomy⁶; **OR**
- Before colorectal cancer surgery for the identification of synchronous lesions⁶; **OR**
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Computed tomography (CT) colonography** is **NOT** considered appropriate if **ANY** of the following is **TRUE**:
- ◆ The patient has undergone advanced imaging of the same body part and for the same indication within 3 months, without being on treatment; **OR**
 - ◆ If intravenous contrast is used, history of anaphylactic allergic reaction to iodinated contrast media; **OR**
 - ◆ When used for first-time screening in the absence of contraindications to colonoscopy, regardless of family history or

- other risk factors for the development of colonic disease³¹⁻³³; **OR**
- ◆ History of colorectal surgery within 1 month; **OR**
- ◆ History of polypectomy or mucosectomy within 1 week; **OR**
- ◆ Attempted colonoscopy within 48 hours; **OR**
- ◆ Symptomatic colon-containing hernia^{6,34}; **OR**
- ◆ Known or suspected current colon perforation^{6,34}; **OR**
- ◆ High-grade or symptomatic small bowel obstruction^{6,34}; **OR**
- ◆ Routine follow-up of inflammatory bowel disease^{6,34}; **OR**
- ◆ Hereditary polyposis syndromes such as familial adenomatous polyposis (FAP) (applies to virtual colonoscopy as it is unlikely to provide clinical benefit)^{6,34}; **OR**
- ◆ Evaluation of anal canal disease such as peri-anal fissure.^{6,34}

*NOTE: CT Colonography should not be performed if the patient has symptomatic acute conditions such as colitis, diarrhea, or recent acute diverticulitis.^{6,34}

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{35,36}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{35,36}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging

based on clinical evaluation.^{35,36}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{35,36}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
74261	Computed tomography (CT) colonography, diagnostic; without contrast material, with image post-processing
74262	Computed tomography (CT) colonography, diagnostic; with contrast material and non-contrast images, with image post-processing
74263	Computed tomographic (CT) colonography, screening, including image postprocessing
76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Jain et al. (2022) outline the updated colorectal cancer (CRC) screening strategies recommended by the United States Preventive Services Task Force (USPSTF) in 2021. Average-risk individuals should start screening at age 45. The Task Force suggests several screening methods: high-sensitivity guaiac fecal occult blood test (HSgFOBT), fecal immunochemical test (FIT), multi-target stool DNA (mt-sDNA) test, computed tomographic (CT) colonography (virtual colonoscopy), flexible sigmoidoscopy, flexible sigmoidoscopy with FIT, or traditional colonoscopy. Numerous emerging and innovative screening approaches are being researched and are on the horizon for primary screening in average-risk individuals. These include blood-based screening or "liquid biopsy," colon capsule endoscopy, urinary metabolomics, and stool-based microbiome testing to detect colorectal polyps or CRC. Compared to traditional colonoscopy, the advantages of CT colonography include a lower risk of complications, less invasive, sedation not required, and the clinician being able to visualize the entire colon. In addition, CT colonography requires a less frequent testing interval than stool-based modalities and is relatively safe for individuals with medical comorbidities that preclude colonoscopy. Same-day endoscopic evaluation may also be performed if indicated.¹⁴

Gupta et al. (2022) review CRC screening for identifying polyps and cancer within the colon. The sensitivity for detecting lesions greater than or equal to 1 cm varies between 67 and 94%, while specificity ranges from 86 to 98%. Notably, an estimated incidence of potentially significant extracolonic findings necessitating further investigation, ranging from 3.4–26.9%, with 1.3–11.4% possibly requiring follow-up due to incomplete characterization. Several studies have shown superior sensitivity in detecting colorectal cancer compared to colonoscopy, mainly when the endoscopist is unaware of CT colonography results. Repeat screening every 5 years is recommended by the USPSTF.³⁷

Shaukat et al. (2022) discuss CT colonography to facilitate the identification and pinpointing of polyps and cancers within the colon through a reconstructed 3D or 4D visualization. Two extensive trials have evaluated the

diagnostic efficacy of CT colonography against optical colonoscopy conducted on the same day. One study involving 1233 individuals at average risk showcased CT colonography's test characteristics, revealing 92% sensitivity and 96% specificity for adenomas measuring 10mm or larger as detected by optical colonoscopy. Additionally, it demonstrated 86% sensitivity and 80% specificity for adenomas measuring 6mm or larger. The National CT Colonography Trial (NCTC), sponsored by the American College of Radiology Imaging Network (ACRIN), comprised 2600 asymptomatic participants undergoing same-day CT colonography and optical colonoscopy. Results revealed a sensitivity of 84% for adenomas or colorectal cancer (CRC) measuring 10mm or larger, with a specificity of 85%. Furthermore, a sensitivity of 70% was observed for adenomas measuring 6mm or larger, with a specificity of 86%. A notable critique of CT colonography is the failure to report lesions smaller than 6mm, the clinical significance of which remains uncertain.³⁸

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Clinical Guideline Revision History/Information

Original Date: October 24, 2024		
Review History		



Cohere Medicare Advantage Policy – Computed Tomography (CT), Face/Sinus

Clinical Policy for Medical Necessity Review

Version: 2

Cohere Health UMC Approval Date: October 16, 2025

Last Annual Review: October 16, 2025

Revision: Not Applicable

Next Annual Review: October 16, 2026

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

Cohere Health, Inc. ("**Cohere**") has published these clinical guidelines to determine the medical necessity of services (the "**Guidelines**") for informational purposes only, and solely for use by Cohere's authorized "**End Users**". These Guidelines (and any attachments or linked third-party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision-making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice. This policy may be superseded by existing and applicable Centers for Medicare & Medicaid Services (CMS) statutes.

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Computed Tomography (CT), Face/Sinus

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Face/Sinus

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁵

- [National Coverage Determination \(NCD\). Computed tomography \(220.1\).](#)
- [Local Coverage Determination \(LCD\). MRI and CT scans of the head and neck \(L37373\).](#)
 - [Billing and Coding: MRI and CT scans of the head and neck \(A57204\).](#)
- [Local Coverage Determination \(LCD\). MRI and CT scans of the head and neck \(L35175\).](#)
 - [Billing and Coding: MRI and CT scans of the head and neck \(A57215\).](#)

Description

Computed tomography (CT) is a common noninvasive imaging modality that allows for the creation of detailed cross-sectional images of the extracranial structures of the head and neck. It allows for the evaluation of the morphology and pathology of osseous and soft tissue structures. It can be performed both with and without contrast, depending on the structures being visualized.⁶

Medical Necessity Criteria

Indications

Computed tomography (CT), face/sinus (including soft tissues of the extracranial head and neck) is considered appropriate for **ANY** of the following:

- Conditions, known or suspected, including **ANY** of the following⁶:
 - Anatomic abnormalities (e.g., deviated septum), suspected as a cause of patient symptoms, and surgical management is being considered; **OR**
 - Bell's palsy or other facial nerve abnormalities requiring evaluation of the extracranial portion of the nerve (magnetic resonance imaging [MRI] is contraindicated or cannot be performed); **OR**
 - Congenital conditions and craniofacial abnormalities⁷; **OR**
 - Infective sinusitis, and **ANY** of the following⁷⁻¹⁰:
 - Four or more acute episodes per year and surgery/biologic therapy are considered; **OR**
 - Persists following completion of two courses of antibiotics; **OR**
 - Acute or subacute rhinosinusitis with a known or suspected complication (e.g., abscess formation, extension to orbits, cavernous sinus, or intracranial involvement)⁸; **OR**
 - The patient is immunocompromised, and invasive fungal sinusitis is suspected; **OR**
 - Allergic fungal sinusitis (AFS) suspected, with failed medical treatment or when surgery is considered; **OR**
 - Chronic rhinosinusitis, symptomatic (e.g. discharge, congestion, anosmia, pain), severity staging or restaging when management change is considered; **OR**
 - Suspected osteonecrosis when the patient is on bisphosphonates or post radiation treatments; **OR**
 - Osteomyelitis; **OR**
 - Odontogenic infections with suspected complications (e.g., abscess formation, facial swelling, nerve, sinus involvement); **OR**
 - Unexplained facial swelling (e.g., over the mandible); **OR**
 - Foreign body, suspected, clinically or seen on prior imaging; **OR**
 - Neoplastic conditions for initial staging, treatment planning, response assessment, and surveillance; **OR**

- Mass or lymphadenopathy when **ANY** of the following⁷:
 - Has been present for at least 2 weeks; **OR**
 - Not suspected to be due to infection; **OR**
 - Mass does not resolve after treatment with antibiotics for suspected infection; **OR**
 - Lymphadenopathy or mass is greater than 1.5 cm; **OR**
 - Ulceration of skin over the mass; **OR**
- Mass or lesion detected on laryngoscopy; **OR**
- Sinonasal polyposis detected on nasal endoscopy with **ALL** of the following^{8,11}:
 - The patient is symptomatic; **AND**
 - No relief with appropriate medical therapy (e.g., corticosteroids, antihistamines, antibiotics); **AND**
 - Surgical intervention or biologic therapy is being considered; **OR**
- Known sinonasal polyposis with complications suspected, (e.g., involvement of the orbits); **OR**
- Noninfectious inflammatory involvement of the sinus is suspected based on clinical history and symptoms (e.g., history of granulomatosis with polyangiitis)⁶; **OR**
- Salivary stones, suspected, when ultrasound is non-diagnostic or further evaluation is needed¹; **OR**
- Salivary gland inflammation (sialadenitis)⁶; **OR**
- Trigeminal neuralgia with **ANY** of the following¹²:
 - MRI is contraindicated or cannot be performed; **OR**
 - Atypical features present (e.g., symptoms outside of typical short-duration trigeminal nerve distribution pain); **OR**
 - Forty years of age or younger; **OR**
 - Failure of conservative management with failure of at least two concurrent agents (e.g., gabapentin, duloxetine) and surgery is being considered; **OR**
- Vascular malformations (e.g., arteriovenous malformations)^{6,13}; **OR**
- For evaluation of **ANY** of the following:
 - Anosmia with **ANY** of the following¹⁴:
 - Persistent anosmia with nondiagnostic endoscopy; **OR**
 - Abnormal endoscopy with further evaluation needed; **OR**
 - Known or suspected neoplasm; **OR**
 - History of head or facial trauma; **OR**

- Cerebrospinal fluid (CSF) leak, strong clinical history or confirmed on testing (e.g., prior trauma or CSF leak that increases after Valsalva maneuvers)⁸; **OR**
- Epistaxis with failure of conservative management (e.g., nasal packing/tampon, cautery); **OR**
- Epistaxis with detection of mass, polyp, or other pathology on examination that requires further evaluation⁶; **OR**
- Preoperative, postoperative, and pretreatment evaluation for surgery, radiation, or chemotherapy; **OR**
- Maxillofacial trauma based on history, swelling, prior imaging, and need for further evaluation; **OR**
- Repeat imaging (defined as a repeat request following recent imaging of the same anatomic region with the same or similar modality) will be considered reasonable and necessary if **ALL** of the following are **TRUE**:
 - There are no established guidelines; **AND**
 - **ANY** of the following:
 - There are new or worsening symptoms not addressed in the guidelines, such that repeat imaging would influence treatment; **OR**
 - There is need for a one-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

Computed tomography (CT), face/sinus (including soft tissues of the extracranial head and neck) with contrast is not considered appropriate if **ANY** of the following is **TRUE**:¹⁵

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

*NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

**NOTE: CT in patients with claustrophobia should be requested at the

discretion of the ordering provider.

Definitions

^ARhinosinusitis classification by symptom duration:¹⁶

- **Acute:** Symptoms lasting less than 4 weeks
- **Subacute:** Symptoms lasting more than 4 weeks but less than 12 weeks
- **Chronic:** Symptoms lasting more than 12 weeks

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{17,18}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{17,18}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{17,18}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{17,18}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70486	Computed tomography (CT), maxillofacial area; without contrast material
70487	Computed tomography (CT), maxillofacial area; with contrast material(s)
70488	Computed tomography (CT), maxillofacial area; without contrast material, followed by contrast material(s) and further sections
76380	Computed tomography, limited or localized follow-up study

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The clinical benefits of using these criteria for computed tomography of the face and neck include:

- CT scanning is cost-effective as a primary diagnostic tool because it provides a robust, encompassing view of target structures, conceivably reducing downstream tests and reducing healthcare costs overall.¹
- Widespread availability of CT scanners has increased clinical adoption of CT as a preferred diagnostic imaging method.¹⁹
- CT is a faster imaging tool with lower scan duration than similar imaging modalities (e.g., MRI) and decreased imaging processing time.¹⁹
- As an imaging modality, CT is noninvasive – particularly when compared to other modalities, such as endoscopic staging of sinus conditions.²⁰ It is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers.
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

The potential clinical harms of using these criteria for computed tomography of the face and neck may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.²¹⁻²⁴
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.²⁵ Fetal risk includes fetal demise,

intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.^{[25](#)}

- Increased healthcare costs and complications from the inappropriate use of additional interventions.^{[26](#)}

Medical Evidence

Bedernik et al. (2022) conducted a randomized controlled trial (RCT) to assess image quality by comparing single-energy computed tomography (SECT) with automated tube voltage adaptation (TVA) to dual-energy CT (DECT) weighted average images. A total of 80 patients underwent SECT or radiation dose-matched DECT. The effective radiation dose showed no significant difference between the SECT and DECT study groups. Compared to the SECT group, the DECT group exhibited significantly higher contrast-to-noise ratio differences (CNRD) for jugular veins relative to fatty tissue and muscle tissue relative to fatty tissue. However, the CNRD for jugular veins relative to muscle tissue was comparable between groups. Image artifacts were also less pronounced, and overall diagnostic acceptability was higher in the DECT group. Overall, DECT-weighted average images demonstrate superior objective and subjective image quality compared to SECT performed with TVA in head and neck imaging.^{[27](#)}

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Aulino et al. (2018) reported on a clinical trial that focused on an assessment tool for the late effect continuum of lymphedema and fibrosis (LEF) for patients with head and neck cancer (HNC) undergoing CT. The tool evaluates areas of soft tissue damage resulting from tumors, surgical interventions, or radiation therapy. The tool analyzed CT scans taken before and after

treatment in 10 patients with HNC. The finalized tool comprised 11 elements, including the assessment of fat stranding at six specific sites, epiglottic thickness measurement, and measurement of prevertebral soft tissue thickness at C3. A total of 176 CT scans from the 20 patients (with a range of 4-14 scans per patient) were evaluated. The final version of the LEF assessment tool (CT-LEFAT) offers a standardized approach to assess critical sites affected by soft tissue damage. Studies continue to evaluate reliability and validity.^{[29](#)}

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Policy Revision History/Information

Original Date: October 17, 2024		
Review History		
Version 2	10/16/2025	Annual review. No changes to medical necessity criteria or procedure codes. Defined classifications of rhinosinusitis in definitions section. Rearranged bullets for improved usability and organization. Updated Harms and Benefits section. Added reference #14.



Cohere Medicare Advantage Policy – Computed Tomography (CT), Face/Sinus

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 17, 2024

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - CT Face/Sinus

Date of last literature review: 10/15/2024

Document last updated: 10/16/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: *Computed Tomography (CT), Face/Sinus*

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹⁶⁻²⁰

- [National Coverage Determination \(NCD\). Computed Tomography \(220.1\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L37373\).](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L35175\).](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\).](#)
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Recommended Clinical Approach

Computed tomography (CT) of the face/sinus is an advanced imaging modality best utilized per institutional ENT, oncologic, infectious, disease, and radiologic protocols. The specialty guidelines may be consulted before ordering and can direct appropriate contrast utilization patterns.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of CT of the face/sinuses. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.²¹⁻²⁴
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.²⁵ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.²⁵
- Increased healthcare costs and complications from the inappropriate use of additional interventions.²⁶

The clinical benefits of using these criteria include:

- CT scanning is cost-effective as a primary diagnostic tool because it provides a robust, encompassing view of target structures, conceivably reducing downstream tests and reducing healthcare costs overall.¹⁶
- Widespread availability of CT scanners has increased clinical adoption of CT as a preferred diagnostic imaging method.²⁷
- CT is a faster imaging tool with lower scan duration than similar imaging modalities (i.e. – MRI) and decreased imaging processing time.²⁷
- As an imaging modality, CT is noninvasive – particularly when compared to other modalities, such as endoscopic staging of sinus conditions.⁵ It is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), face/sinus (including soft tissues of the extracranial head and neck)** is considered appropriate for **ANY** of the following:

- ◆ Conditions, known or suspected, including **ANY** of the following¹:
 - Anatomic abnormalities (e.g. deviated septum), suspected as a cause of patient symptoms and surgical management is being considered; **OR**
 - Bell's palsy or other facial nerve abnormalities requiring evaluation of the extracranial portion of the nerve (MRI is contraindicated or cannot be performed); **OR**
 - Congenital conditions and craniofacial abnormalities²; **OR**
 - Sinusitis and **ANY** of the following is **TRUE**²⁻⁵:
 - Four or more acute episodes per year and surgery/biologic therapy are contemplated; **OR**
 - Not resolving despite 2 courses of antibiotics; **OR**
 - A complication is suspected (e.g., abscess formation, involvement of adjacent structures such as orbits, cavernous sinus, or intracranial); **OR**
 - The patient is immunocompromised, and invasive fungal sinusitis is suspected; **OR**
 - Allergic fungal sinusitis (AFS) suspected, with failed medical treatment or surgery is contemplated; **OR**
 - Chronic rhinosinusitis, symptomatic (discharge, congestion, anosmia, pain), severity staging or restaging when management change is contemplated; **OR**
 - Suspected osteonecrosis when the patient is on bisphosphonates or has had radiation; **OR**
 - Osteomyelitis; **OR**
 - Odontogenic infections with suspected complications (e.g., abscess formation, facial swelling, nerve, sinus involvement); **OR**

- Unexplained focal facial swelling; **OR**
 - Foreign-body (suspected), clinically or seen on prior imaging; **OR**
 - Neoplastic conditions for initial staging, treatment planning, response assessment, and surveillance; **OR**
 - Lymphadenopathy with failure of conservative management (e.g., antibiotics, anti-inflammatory) that is documented for a period of greater than two weeks; **OR**
 - Sinonasal polyposis detected on nasal endoscopy with **ALL** of the following^{3,6}:
 - The patient is symptomatic; **AND**
 - No relief with appropriate medical therapy (e.g., corticosteroids, antihistamines, antibiotics); **AND**
 - Surgical intervention or biologic therapy is being contemplated; **OR**
 - Known sinonasal polyposis with complications suspected, (e.g., involvement of the orbits); **OR**
 - Non-infectious inflammatory involvement of the sinus is suspected based on clinical history and symptoms (e.g., history of granulomatosis with polyangiitis)¹; **OR**
 - Salivary stones, suspected¹; **OR**
 - Salivary gland inflammation (sialadenitis)¹; **OR**
 - Trigeminal neuralgia with **ANY** of the following⁷:
 - MRI is contraindicated or cannot be performed; **OR**
 - Atypical features present (e.g., symptoms outside of typical short-duration trigeminal nerve distribution pain); **OR**
 - Age less than 40; **OR**
 - Failure of conservative management with failure of at least two concurrent agents (e.g., gabapentin, duloxetine) and surgery is being considered; **OR**
 - Vascular malformations (e.g., arterio-venous malformations)^{1,8}; **OR**
- ◆ For evaluation of **ANY** of the following symptoms when applicable:
- Anosmia with **ANY** of the following⁹:
 - Persistent anosmia with nondiagnostic endoscopy;**OR**

- Abnormal endoscopy with further evaluation needed; **OR**
- Known or suspected neoplasm; **OR**
- History of head or facial trauma; **OR**
- Cerebrospinal fluid (CSF) leak, confirmed on testing or strong clinical history (e.g., prior trauma or CSF leak that increases after Valsalva maneuvers)³; **OR**
- Epistaxis with failure of conservative management (e.g., nasal packing/tampon, cautery, etc); **OR**
- Epistaxis with detection of mass, polyp, or other pathology on examination that requires further evaluation¹; **OR**
- ◆ Preoperative, postoperative, and pre-treatment evaluation for surgery, radiation, or chemotherapy; **OR**
- ◆ Maxillo-facial trauma based on history, swelling, prior imaging, and need for further evaluation; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography (CT), face/sinus (including soft tissues of the extracranial head and neck)** is not considered appropriate if **ANY** of the following is **TRUE**¹⁰:

- ◆ If contrast is used, history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{[11-12](#)}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{[11-12](#)}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{[11-12](#)}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{[11-12](#)}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70486	Computed tomography (CT), maxillofacial area; without contrast material
70487	Computed tomography (CT), maxillofacial area; with contrast material(s)
70488	Computed tomography (CT), maxillofacial area; without contrast material, followed by contrast material(s) and further sections
76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Bedernik et al. (2022) conducted a randomized control trial (RCT) to assess image quality by comparing single-energy computed tomography (SECT) with automated tube voltage adaptation (TVA) to dual-energy CT (DECT) weighted average images. A total of 80 patients underwent SECT or radiation dose-matched DECT. The effective radiation dose (ED) showed no significant difference between the SECT and DECT study groups. Compared to the SECT group, the DECT group exhibited significantly higher contrast-to-noise ratio differences (CNRD) for jugular veins relative to fatty tissue and muscle tissue relative to fatty tissue. However, the CNRD for jugular veins relative to muscle tissue was comparable between groups. Image artifacts were also less pronounced, and overall diagnostic acceptability was higher in the DECT group. Overall, DECT-weighted average images demonstrate superior objective and subjective image quality compared to SECT performed with TVA in head and neck imaging.¹³

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sites affected by soft tissue damage. Studies continue to evaluate reliability and validity.¹⁵

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Clinical Guideline Revision History/Information

Original Date: October 17, 2024		
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Cohere Medicare Advantage Policy – Computed Tomography (CT), Face/Sinus

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 17, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - CT Face/Sinus

Date of last literature review: 10/15/2024

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: *Computed Tomography (CT), Face/Sinus*

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹⁶⁻²⁰

- [National Coverage Determination \(NCD\). Computed Tomography \(220.1\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L37373\).](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L35175\).](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\).](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57204\).](#)

Recommended Clinical Approach

Computed tomography (CT) of the face/sinus is an advanced imaging modality best utilized per institutional ENT, oncologic, infectious, disease, and radiologic protocols. The specialty guidelines may be consulted before ordering and can direct appropriate contrast utilization patterns.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of CT of the face/sinuses. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.²¹⁻²⁴
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.²⁵ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.²⁵
- Increased healthcare costs and complications from the inappropriate use of additional interventions.²⁶

The clinical benefits of using these criteria include:

- CT scanning is cost-effective as a primary diagnostic tool because it provides a robust, encompassing view of target structures, conceivably reducing downstream tests and reducing healthcare costs overall.¹⁶
- Widespread availability of CT scanners has increased clinical adoption of CT as a preferred diagnostic imaging method.²⁷
- CT is a faster imaging tool with lower scan duration than similar imaging modalities (i.e. – MRI) and decreased imaging processing time.²⁷
- As an imaging modality, CT is noninvasive – particularly when compared to other modalities, such as endoscopic staging of sinus conditions.⁵ It is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), face/sinus (including soft tissues of the extracranial head and neck)** is considered appropriate for **ANY** of the following:

- ◆ Conditions, known or suspected, including **ANY** of the following¹:
 - Anatomic abnormalities (e.g. deviated septum), suspected as a cause of patient symptoms and surgical management is being considered; **OR**
 - Bell's palsy or other facial nerve abnormalities requiring evaluation of the extracranial portion of the nerve (MRI is contraindicated or cannot be performed); **OR**
 - Congenital conditions and craniofacial abnormalities²; **OR**
 - Sinusitis and **ANY** of the following is **TRUE**²⁻⁵:
 - Four or more acute episodes per year and surgery/biologic therapy are contemplated; **OR**
 - Not resolving despite 2 courses of antibiotics; **OR**
 - A complication is suspected (e.g., abscess formation, involvement of adjacent structures such as orbits, cavernous sinus, or intracranial); **OR**
 - The patient is immunocompromised, and invasive fungal sinusitis is suspected; **OR**
 - Allergic fungal sinusitis (AFS) suspected, with failed medical treatment or surgery is contemplated; **OR**
 - Chronic rhinosinusitis, symptomatic (discharge, congestion, anosmia, pain), severity staging or restaging when management change is contemplated; **OR**
 - Suspected osteonecrosis when the patient is on bisphosphonates or has had radiation; **OR**
 - Osteomyelitis; **OR**
 - Odontogenic infections with suspected complications (e.g., abscess formation, facial swelling, nerve, sinus involvement); **OR**

- Unexplained focal facial swelling; **OR**
 - Foreign-body (suspected), clinically or seen on prior imaging; **OR**
 - Neoplastic conditions for initial staging, treatment planning, response assessment, and surveillance; **OR**
 - Lymphadenopathy with failure of conservative management (e.g., antibiotics, anti-inflammatory) that is documented for a period of greater than two weeks; **OR**
 - Sinonasal polyposis detected on nasal endoscopy with **ALL** of the following^{3,6}:
 - The patient is symptomatic; **AND**
 - No relief with appropriate medical therapy (e.g., corticosteroids, antihistamines, antibiotics); **AND**
 - Surgical intervention or biologic therapy is being contemplated; **OR**
 - Known sinonasal polyposis with complications suspected, (e.g., involvement of the orbits); **OR**
 - Non-infectious inflammatory involvement of the sinus is suspected based on clinical history and symptoms (e.g., history of granulomatosis with polyangiitis)¹; **OR**
 - Salivary stones, suspected¹; **OR**
 - Salivary gland inflammation (sialadenitis)¹; **OR**
 - Trigeminal neuralgia with **ANY** of the following⁷:
 - MRI is contraindicated or cannot be performed; **OR**
 - Atypical features present (e.g., symptoms outside of typical short-duration trigeminal nerve distribution pain); **OR**
 - Age less than 40; **OR**
 - Failure of conservative management with failure of at least two concurrent agents (e.g., gabapentin, duloxetine) and surgery is being considered; **OR**
 - Vascular malformations (e.g., arterio-venous malformations)^{1,8}; **OR**
- ◆ For evaluation of **ANY** of the following symptoms when applicable:
- Anosmia with **ANY** of the following⁹:
 - Persistent anosmia with nondiagnostic endoscopy; **OR**

- Abnormal endoscopy with further evaluation needed; **OR**
- Known or suspected neoplasm; **OR**
- History of head or facial trauma; **OR**
- Cerebrospinal fluid (CSF) leak, confirmed on testing or strong clinical history (e.g., prior trauma or CSF leak that increases after Valsalva maneuvers)³; **OR**
- Epistaxis with failure of conservative management (e.g., nasal packing/tampon, cautery, etc); **OR**
- Epistaxis with detection of mass, polyp, or other pathology on examination that requires further evaluation¹; **OR**
- ◆ Preoperative, postoperative, and pre-treatment evaluation for surgery, radiation, or chemotherapy; **OR**
- ◆ Maxillo-facial trauma based on history, swelling, prior imaging, and need for further evaluation; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography (CT), face/sinus (including soft tissues of the extracranial head and neck)** is not considered appropriate if **ANY** of the following is **TRUE**¹⁰:

- ◆ If contrast is used, history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{[11-12](#)}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{[11-12](#)}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{[11-12](#)}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{[11-12](#)}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70486	Computed tomography (CT), maxillofacial area; without contrast material
70487	Computed tomography (CT), maxillofacial area; with contrast material(s)
70488	Computed tomography (CT), maxillofacial area; without contrast material, followed by contrast material(s) and further sections
76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Bedernik et al. (2022) conducted a randomized control trial (RCT) to assess image quality by comparing single-energy computed tomography (SECT) with automated tube voltage adaptation (TVA) to dual-energy CT (DECT) weighted average images. A total of 80 patients underwent SECT or radiation dose-matched DECT. The effective radiation dose (ED) showed no significant difference between the SECT and DECT study groups. Compared to the SECT group, the DECT group exhibited significantly higher contrast-to-noise ratio differences (CNRD) for jugular veins relative to fatty tissue and muscle tissue relative to fatty tissue. However, the CNRD for jugular veins relative to muscle tissue was comparable between groups. Image artifacts were also less pronounced, and overall diagnostic acceptability was higher in the DECT group. Overall, DECT-weighted average images demonstrate superior objective and subjective image quality compared to SECT performed with TVA in head and neck imaging.¹³

Smith-Bindman et al. (2020) performed an RCT to study the efficacy of interventions to lower the amount of radiation patients are exposed to. The RCT included 864,080 adults at 100 facilities who underwent a CT scan, including CT Head (n = 1,156,657 scans). The study included two primary measures: the percentage of high-dose CT scans and the average effective dose administered at the facility level. The study's secondary measure included the doses received by specific organs. Outcomes were assessed with respect to the impact of the interventions and outcomes post-intervention. Data were contrasted with pre-intervention data, utilizing hierarchical generalized linear models that accounted for temporal patterns and patient attributes. In conclusion, data regarding CT radiation dosage and practical recommendations may improve quality, including significant dose reductions, especially for organ-specific doses.¹⁴

Aulino et al. (2018) report on a clinical trial that focused on an assessment tool for the late effect continuum of lymphedema and fibrosis (LEF) for patients with head and neck cancer (HNC) undergoing CT. The tool evaluates areas of soft tissue damage resulting from tumors, surgical interventions, or radiation therapy. The tool analyzed CT scans taken before and after treatment in 10 patients with HNC. The finalized tool comprised 11 elements, including the assessment of fat stranding at six specific sites, epiglottic thickness measurement, and measurement of prevertebral soft tissue thickness at C3. A total of 176 CT scans from the 20 patients (with a range of 4-14 scans per patient) were evaluated. The final version of the LEF assessment tool (CT-LEFAT) offers a standardized approach to assess critical

sites affected by soft tissue damage. Studies continue to evaluate reliability and validity.¹⁵

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Clinical Guideline Revision History/Information

Original Date: October 17, 2024		
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Cohere Medicare Advantage Policy – Computed Tomography (CT), Neck (Soft Tissue)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 17, 2024

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Neck (Soft Tissue)

Date of last literature review: 10/15/2024

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Neck (Soft Tissue)

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹⁻⁷

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹⁻⁷

- [National Coverage Determination \(NCD\). Computed Tomography \(220.1\)](#)
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- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L35175\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\)](#)

Recommended Clinical Approach

Computed tomography (CT) is a radiological method for assessing various conditions affecting the head and neck outside the skull. Its utilization should be limited to genuine medical necessities, minimizing radiation exposure while ensuring an effective examination. Supplementary or specialized tests might be warranted. While CT may not identify all abnormalities, adherence to specified criteria enhances the likelihood of their detection. CT is often the first-line advanced imaging modality for many neck disorders due to its speed, availability, and high resolution. CT Neck for soft tissue evaluation is routinely performed with contrast; compared to magnetic resonance imaging (MRI), CT is less sensitive to patient motion.⁸

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Computed Tomography (CT), Neck (Soft Tissue). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁹⁻¹²
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹³ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹³
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹⁴

The clinical benefits of using these criteria include:

- Weighted average head and neck images acquired using dual-energy CT (DECT) demonstrate superior objective and subjective image quality compared to single-energy computed tomography (SECT) performed with tube voltage adaptation (TVA).¹⁵
- CT radiation doses vary across imaging facilities and are often higher than needed. However, detailed feedback on CT radiation dose combined with actionable suggestions and quality improvement education significantly reduces radiation doses, particularly organ doses.¹⁶
- Contrast-enhanced CT is the primary and standard imaging modality of choice for head and neck infections. Intracranial spread of head and

neck infections is better detected by magnetic resonance imaging (MRI). Technological developments in mitigating dental-related artifact on CT have been shown to be effective. Subtraction technique CT has been found to be useful in evaluating skull base invasive nasopharyngeal carcinoma, skull base osteomyelitis, and evaluation of recurrence and spread of middle ear cholesteatoma.¹⁷

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **Computed tomography (CT), neck (soft tissue)** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Initial staging, treatment assessment, and surveillance of known malignant conditions in the neck (e.g., nasopharynx, oropharynx, hypopharynx, larynx, salivary glands, jaw, oral cavity); **OR**
 - ◆ Thyroid masses or goiter when ultrasound is non-diagnostic or requires further work-up; **OR**
 - ◆ Mass or lymphadenopathy when **ANY** of the following is **TRUE**:
 - Unlikely to be due to infection or not resolving despite treatment; **OR**
 - Lymphadenopathy in a patient older than 50 years; **OR**
 - Mass or lesion detected on laryngoscopy; **OR**
 - ◆ Assessment of signs and symptoms, including **ANY** of the following:
 - Odynophagia; **OR**

- Globus sensation or dysphagia when clinical examination, including endoscopy and fluoroscopy, are negative or require further evaluation; **OR**
- Vocal cord paralysis; **OR**
- Cranial neuropathy of cranial nerves (CN) 9–11; **OR**
- Ear pain unexplained by evaluation, and failed trial of conservative therapy (e.g., topical and systemic antibiotics, ear drops); **OR**
- ◆ Infectious conditions (e.g., tonsillitis, epiglottitis, cellulitis, etc.) when **ANY** of the following is **TRUE**:
 - Suspected compromise of the airway; **OR**
 - Surgery is planned; **OR**
 - Not improving with appropriate therapy; **OR**
- ◆ Suspected Ludwig’s angina; **OR**
- ◆ Localization of parathyroid adenoma when lab tests indicate primary hyperparathyroidism and neck ultrasound and Sestamibi scan (nuclear medicine scan) are normal or nondiagnostic¹⁸; **OR**
- ◆ Presurgical evaluation, planning, or guidance, including radiation planning; **OR**
- ◆ Evaluation for **ANY** of the following¹⁹:
 - Trauma that is not related to the cervical spine; **OR**
 - Suspected Eagle’s syndrome when a long styloid process is detected on prior imaging; **OR**
 - Foreign body when initial radiographs are non-diagnostic; **OR**
 - Suspected extracapsular spread of a tumor into the surrounding neck structures; **OR**
 - Suspected recurrent thyroid cancer or rising thyroglobulin, with negative ultrasound and physical exams to detect occult neck nodes; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
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- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography (CT), neck (soft tissue)** is not considered appropriate if **ANY** of the following is **TRUE**:

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*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.²⁰

**NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

***NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

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Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.²¹⁻²²

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.²¹⁻²²

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Level of Care Criteria

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CPT/HCPCS Code	Code Description
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76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Bedernik et al. (2022) conducted a randomized control trial (RCT) to assess image quality by comparing single-energy computed tomography (SECT) with automated tube voltage adaptation (TVA) to dual-energy CT (DECT) weighted average images. A total of 80 patients underwent SECT or radiation dose-matched DECT. The effective radiation dose (ED) showed no significant difference between the SECT and DECT study groups. Compared to the SECT group, the DECT group exhibited significantly higher contrast-to-noise ratio differences (CNRD) for jugular veins relative to fatty tissue and muscle tissue relative to fatty tissue. However, the CNRD for jugular veins relative to muscle tissue was comparable between groups. Image artifacts were also less pronounced, and overall diagnostic acceptability was higher in the DECT group. Overall, DECT-weighted average images demonstrate superior objective and subjective image quality compared to SECT performed with TVA in head and neck imaging.¹⁵

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Clinical Guideline Revision History/Information

Original Date: October 17, 2024		
Review History		



Cohere Medicare Advantage Policy – Computed Tomography (CT), Neck (Soft Tissue)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 17, 2024

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Neck (Soft Tissue)

Date of last literature review: 10/15/2024

Document last updated: 10/16/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Neck (Soft Tissue)

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹⁻⁷

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁷

- [National Coverage Determination \(NCD\). Computed Tomography \(220.1\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L37373\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57204\)](#)
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Recommended Clinical Approach

Computed tomography (CT) is a radiological method for assessing various conditions affecting the head and neck outside the skull. Its utilization should be limited to genuine medical necessities, minimizing radiation exposure while ensuring an effective examination. Supplementary or specialized tests might be warranted. While CT may not identify all abnormalities, adherence to specified criteria enhances the likelihood of their detection. CT is often the first-line advanced imaging modality for many neck disorders due to its speed, availability, and high resolution. CT Neck for soft tissue evaluation is

routinely performed with contrast; compared to magnetic resonance imaging (MRI), CT is less sensitive to patient motion.⁸

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of computed tomography (CT), neck (soft tissue). This process helps prevent incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- The inherent risk of the procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁹⁻¹²
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹³ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹³
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹⁴

The clinical benefits of using these criteria include:

- Weighted average head and neck images acquired using dual-energy CT (DECT) demonstrate superior objective and subjective image quality compared to single-energy computed tomography (SECT) performed with tube voltage adaptation (TVA).¹⁵
- CT radiation doses vary across imaging facilities and are often higher than needed. However, detailed feedback on CT radiation dose combined with actionable suggestions and quality improvement education significantly reduces radiation doses, particularly organ doses.¹⁶

- Contrast-enhanced CT is the primary and standard imaging modality of choice for head and neck infections. Intracranial spread of head and neck infections is better detected by magnetic resonance imaging (MRI). Technological developments in mitigating dental-related artifact on CT have been shown to be effective. Subtraction technique CT has been found to be helpful in evaluating skull base invasive nasopharyngeal carcinoma, skull base osteomyelitis, and evaluation of recurrence and spread of middle ear cholesteatoma.¹⁷
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Cohere Medicare Advantage Policy – Computed Tomography (CT), Orbit/Ear/Sella

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Medical Necessity Criteria

Service: Computed Tomography (CT), Orbit/Ear/Sella

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹⁻⁵

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹⁻⁵

- [National Coverage Determination \(NCD\). Computed Tomography \(220.1\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L37373\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57204\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L35175\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\)](#)

Recommended Clinical Approach

Computed tomography (CT) is often the first-line imaging exam for many disorders of the extracranial head due to its speed, availability, and high resolution. In the setting of trauma and other primary osseous abnormalities, contrast is not routinely employed. For many soft-tissue processes, contrast is preferred. The specific area imaged, reformations performed, and radiation dose depends upon the clinical question being addressed and is deferred to the supervising radiologist.⁶

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Computed Tomography (CT), Orbit/Ear/Sella. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁷⁻¹⁰
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹¹ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹¹
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹²

The clinical benefits of using these criteria include:

- Weighted average head and neck images acquired using dual-energy CT (DECT) demonstrate superior objective and subjective image quality compared to single-energy computed tomography (SECT) performed with tube voltage adaptation (TVA).¹³
- CT radiation doses vary across imaging facilities and are often higher than needed. However, detailed feedback on CT radiation dose combined with actionable suggestions and quality improvement education significantly reduces radiation doses, particularly organ doses.¹⁴
- A CT assessment tool developed to assess soft tissue damage secondary to tumor, surgery, or radiation, in patients with lymphedema

and fibrosis (LEF) following treatment for head and neck cancer provides a standardized method for assessing critical sites affected by LEF.¹⁵

- Cone-beam CT with a large field of view can accurately identify craniofacial anomalies and quantify asymmetries between the nonaffected and affected sides of the face in Goldenhar syndrome, a rare disease with hemifacial microsomia and craniofacial disorders including auricular anomalies, for an efficient maxillofacial treatment planning.¹⁶
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), orbit/ear/fossa** is considered appropriate if **ANY** of the following is **TRUE**⁶:

◆ Orbital indications, including **ANY** of the following:

- Trauma-related conditions, including traumatic visual defect with suspected orbital injury¹⁷; **OR**
- **ANY** of the following if MRI is contraindicated or cannot be performed:
 - Congenital conditions (e.g., capillary hemangioma, optic nerve hypoplasia); **OR**
 - Optic neuritis; **OR**
 - Eye pain, with history or other sign or symptom, indicating non-ischemic pathology; **OR**
 - Ophthalmoplegia; **OR**

- Eye movement abnormality in a child (e.g., strabismus, nystagmus in a child 6 months or older); **OR**
- Vision loss or visual field deficit with history or other signs or symptoms indicating non-ischemic intra-orbital pathology; **OR**
- Conditions, known or suspected, including **ANY** of the following¹⁷:
 - Initial staging, treatment response, surveillance, complication, recurrence, treatment planning, or of an orbital mass (e.g., dermoid, melanoma, lymphoma, metastases)¹⁸; **OR**
 - Orbital pseudotumor or orbital inflammatory disease; **OR**
 - Osseous lesions (e.g., fibrodysplasia, Paget's); **OR**
 - Foreign-body, suspected clinically or seen on prior imaging; **OR**
 - Orbital infectious process, suspected or known, that has failed medical management (e.g., orbital cellulitis not responding appropriately to antibiotics) or patient is pediatric or immunocompromised; **OR**
 - Scleritis confirmed clinically with failure of medical management or with complication suspected¹⁹; **OR**
 - Uveitis, confirmed clinically with complication suspected; **OR**
 - Thyroid orbitopathy; **OR**
 - Venous conditions (e.g., orbital varices); **OR**
- Additional evaluation is needed when etiology remains unclear following a complete eye examination that includes funduscopy, including **ANY** of the following:
 - Diplopia; **OR**
 - Enophthalmos²⁰; **OR**
 - Exophthalmos; **OR**
 - Orbital asymmetry; **OR**
 - Preseptal or post-septal orbital mass, otherwise unexplained; **OR**
 - Proptosis; **OR**
 - Unilateral papilledema; **OR**

- Orbital hemorrhage; **OR**
 - Preoperative, postoperative, or pre-treatment evaluation for surgery, radiation, or chemotherapy; **OR**
- ◆ Temporal bone and inner ear indications including **ANY** of the following:
 - Conditions, known or suspected, including **ANY** of the following²¹; **OR**
 - Aberrant and symptomatic congenital or acquired anatomy (e.g., stenosis of the external auditory canal [EAC] or dehiscence of the superior semicircular canal, facial nerve canal, carotid canal, or jugular bulb); **OR**
 - Cholesteatoma, initial and 9 to 12-month postoperative follow-up; **OR**
 - Tympanosclerosis; **OR**
 - Neoplastic conditions, detection, and follow-up (including tumors of the internal or external auditory canal, inner ear, and mastoid); **OR**
 - Otitis media, recurrent with at least 3 episodes in the past 12 months, with complications suspected (e.g., hearing loss, intracranial extension, mastoiditis)²²; **OR**
 - Malignant otitis externa, unresponsive to antibiotics; **OR**
 - Mastoiditis; **OR**
 - Other infectious processes involving the middle or inner ear, where imaging is needed to direct appropriate management; **OR**
 - Bell's palsy or other facial nerve abnormalities requiring evaluation of the extracranial portion of the nerve (when MRI is contraindicated or cannot be performed); **OR**
 - Tinnitus, unexplained by history or physical examination, and is worsening or affects daily function (when MRI is contraindicated or cannot be performed)²³; **OR**
 - Symptoms or signs evaluated by complete auditory examination, including **ANY** of the following²¹:

- Conductive, mixed-conductive, or congenital hearing loss; **OR**
- Sensorineural hearing loss, acquired or congenital, (when MRI is contraindicated or cannot be performed); **OR**
- Total deafness, otherwise unexplained; **OR**
- Vertigo, unexplained by history or physical examination with **ANY** of the following:
 - ◆ Worsening; **OR**
 - ◆ Affects daily function; **OR**
 - ◆ Associated hearing loss or other neurological deficits; **OR**
 - ◆ History of prior infection (e.g., otitis or meningitis); **OR**
 - ◆ History of prior trauma; **OR**
- Trauma-related conditions related to the ear, including evaluation of cerebrospinal fluid leak²³⁻²⁵; **OR**
- Preoperative, postoperative, or pre-treatment evaluation for surgery, radiation, or chemotherapy (including evaluation for cochlear implant); **OR**
- Vascular conditions, known or suspected, related to the ear or temporal bone, including evaluation of pulsatile tinnitus²⁶; **OR**
- ◆ Sellar and posterior fossa indications, including **ANY** of the following indications related to a sella or posterior fossa:
 - Sellar mass (including pituitary masses) is suspected due to documented clinical or laboratory findings (e.g., prolactinemia); **OR**
 - Visual field deficit (e.g., bitemporal hemianopsia) indicating optic nerve compression; **OR**
 - Other neoplastic conditions, known, suspected, or suggested by prior imaging (e.g., meningioma); **OR**
 - Trauma-related conditions; **OR**
 - Pituitary dysfunction, suggested by documented laboratory or clinical abnormalities (e.g., pituitary failure due to conditions such as pituitary apoplexy); **OR**
 - Vascular conditions, known or suspected, including aberrant anatomy; **OR**

- Preoperative, postoperative, or pre-treatment evaluation for surgery, radiation, or chemotherapy (including pre-operative planning for removal of the pituitary tumor); **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography (CT), orbit/ear/fossa** is not considered appropriate if **ANY** of the following is **TRUE**²⁷:

- ◆ If contrast is used, history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.²⁸⁻²⁹

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.²⁸⁻²⁹

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.²⁸⁻²⁹

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.²⁸⁻²⁹

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70480	Computed tomography (CT), orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material
70481	Computed tomography (CT), orbit, sella, or posterior fossa; with contrast material(s)
70482	Computed tomography (CT), orbit, sella, or posterior fossa; without contrast material, followed by contrast material(s) and further sections

76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Bedernik et al. (2022) conducted a randomized control trial (RCT) to assess image quality by comparing single-energy computed tomography (SECT) with automated tube voltage adaptation (TVA) to dual-energy CT (DECT) weighted average images. A total of 80 patients underwent SECT or radiation dose-matched DECT. The effective radiation dose (ED) showed no significant difference between the SECT and DECT study groups. Compared to the SECT group, the DECT group exhibited significantly higher contrast-to-noise ratio differences (CNRD) for jugular veins relative to fatty tissue and muscle tissue relative to fatty tissue. However, the CNRD for jugular veins relative to muscle tissue was comparable between groups. Image artifacts were also less pronounced, and overall diagnostic acceptability was higher in the DECT group. Overall, DECT-weighted average images demonstrate superior objective and subjective image quality compared to SECT performed with TVA in head and neck imaging.¹³

Smith-Bindman et al. (2020) performed an RCT to study the efficacy of interventions to lower the amount of radiation exposure. The RCT included 864,080 adults at 100 facilities who underwent a CT scan, including head CT scans (n = 1,156,657 scans). The study included two primary measures: the percentage of high-dose CT scans and the average effective dose administered at the facility level. The study's secondary measure included the doses received by specific organs - outcomes assessed for the impact of the interventions and outcomes post-intervention. Data were contrasted with pre-intervention data, utilizing hierarchical generalized linear models that accounted for temporal patterns and patient attributes. In conclusion, data regarding CT radiation dosage and practical recommendations may improve quality, including significant dose reductions, especially for organ-specific doses.¹⁴

Aulino et al. (2018) reported on a clinical trial that focused on an assessment tool for the late effect continuum of lymphedema and fibrosis (LEF) for patients with head and neck cancer (HNC) undergoing CT. The tool evaluates areas of soft tissue damage resulting from tumors, surgical interventions, or radiation therapy. The tool analyzed CT scans taken before and after treatment in 10 patients with HNC. The finalized tool has 11 elements, including assessing fat stranding at six specific sites, measuring epiglottic thickness, and measuring prevertebral soft tissue thickness at C3. The trial includes 176 CT scans from 20 patients (with a range of 4-14 scans per patient). The final version of the LEF assessment tool (CT-LEFAT) offers a standardized approach to assess critical sites affected by soft tissue damage. Studies continue to evaluate reliability and validity.¹⁵

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Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

Cohere Health, Inc. ("**Cohere**") has published these clinical guidelines to determine the medical necessity of services (the "**Guidelines**") for informational purposes only, and solely for use by Cohere's authorized "**End Users**". These Guidelines (and any attachments or linked third-party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision-making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice. This policy may be superseded by existing and applicable Centers for Medicare & Medicaid Services (CMS) statutes.

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Computed Tomography (CT), Orbit/Ear/Sella

Date of last literature review: 10/15/2024

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Orbit/Ear/Sella

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹⁻⁵

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹⁻⁵

- [National Coverage Determination \(NCD\). Computed Tomography \(220.1\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L37373\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57204\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L35175\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\)](#)

Recommended Clinical Approach

Computed tomography (CT) is often the first-line imaging exam for many disorders of the extracranial head due to its speed, availability, and high resolution. In the setting of trauma and other primary osseous abnormalities, contrast is not routinely employed. For many soft-tissue processes, contrast is preferred. The specific area imaged, reformations performed, and radiation dose depends upon the clinical question being addressed and is deferred to the supervising radiologist.⁶

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Computed Tomography (CT), Orbit/Ear/Sella. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁷⁻¹⁰
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹¹ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹¹
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹²

The clinical benefits of using these criteria include:

- Weighted average head and neck images acquired using dual-energy CT (DECT) demonstrate superior objective and subjective image quality compared to single-energy computed tomography (SECT) performed with tube voltage adaptation (TVA).¹³
- CT radiation doses vary across imaging facilities and are often higher than needed. However, detailed feedback on CT radiation dose combined with actionable suggestions and quality improvement education significantly reduces radiation doses, particularly organ doses.¹⁴
- A CT assessment tool developed to assess soft tissue damage secondary to tumor, surgery, or radiation, in patients with lymphedema

and fibrosis (LEF) following treatment for head and neck cancer provides a standardized method for assessing critical sites affected by LEF.¹⁵

- Cone-beam CT with a large field of view can accurately identify craniofacial anomalies and quantify asymmetries between the nonaffected and affected sides of the face in Goldenhar syndrome, a rare disease with hemifacial microsomia and craniofacial disorders including auricular anomalies, for an efficient maxillofacial treatment planning.¹⁶
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), orbit/ear/fossa** is considered appropriate if **ANY** of the following is **TRUE**⁶:

◆ Orbital indications, including **ANY** of the following:

- Trauma-related conditions, including traumatic visual defect with suspected orbital injury¹⁷; **OR**
- **ANY** of the following if MRI is contraindicated or cannot be performed:
 - Congenital conditions (e.g., capillary hemangioma, optic nerve hypoplasia); **OR**
 - Optic neuritis; **OR**
 - Eye pain, with history or other sign or symptom, indicating non-ischemic pathology; **OR**
 - Ophthalmoplegia; **OR**

- Eye movement abnormality in a child (e.g., strabismus, nystagmus in a child 6 months or older); **OR**
 - Vision loss or visual field deficit with history or other signs or symptoms indicating non-ischemic intra-orbital pathology; **OR**
- Conditions, known or suspected, including **ANY** of the following¹⁷:
 - Initial staging, treatment response, surveillance, complication, recurrence, treatment planning, or of an orbital mass (e.g., dermoid, melanoma, lymphoma, metastases)¹⁸; **OR**
 - Orbital pseudotumor or orbital inflammatory disease; **OR**
 - Osseous lesions (e.g., fibrodysplasia, Paget's); **OR**
 - Foreign-body, suspected clinically or seen on prior imaging; **OR**
 - Orbital infectious process, suspected or known, that has failed medical management (e.g., orbital cellulitis not responding appropriately to antibiotics) or patient is pediatric or immunocompromised; **OR**
 - Scleritis confirmed clinically with failure of medical management or with complication suspected¹⁹; **OR**
 - Uveitis, confirmed clinically with complication suspected; **OR**
 - Thyroid orbitopathy; **OR**
 - Venous conditions (e.g., orbital varices); **OR**
- Additional evaluation is needed when etiology remains unclear following a complete eye examination that includes funduscopy, including **ANY** of the following:
 - Diplopia; **OR**
 - Enophthalmos²⁰; **OR**
 - Exophthalmos; **OR**
 - Orbital asymmetry; **OR**
 - Preseptal or post-septal orbital mass, otherwise unexplained; **OR**
 - Proptosis; **OR**
 - Unilateral papilledema; **OR**

- Orbital hemorrhage; **OR**
 - Preoperative, postoperative, or pre-treatment evaluation for surgery, radiation, or chemotherapy; **OR**
- ◆ Temporal bone and inner ear indications including **ANY** of the following:
 - Conditions, known or suspected, including **ANY** of the following²¹; **OR**
 - Aberrant and symptomatic congenital or acquired anatomy (e.g., stenosis of the external auditory canal [EAC] or dehiscence of the superior semicircular canal, facial nerve canal, carotid canal, or jugular bulb); **OR**
 - Cholesteatoma, initial and 9 to 12-month postoperative follow-up; **OR**
 - Tympanosclerosis; **OR**
 - Neoplastic conditions, detection, and follow-up (including tumors of the internal or external auditory canal, inner ear, and mastoid); **OR**
 - Otitis media, recurrent with at least 3 episodes in the past 12 months, with complications suspected (e.g., hearing loss, intracranial extension, mastoiditis)²²; **OR**
 - Malignant otitis externa, unresponsive to antibiotics; **OR**
 - Mastoiditis; **OR**
 - Other infectious processes involving the middle or inner ear, where imaging is needed to direct appropriate management; **OR**
 - Bell's palsy or other facial nerve abnormalities requiring evaluation of the extracranial portion of the nerve (when MRI is contraindicated or cannot be performed); **OR**
 - Tinnitus, unexplained by history or physical examination, and is worsening or affects daily function (when MRI is contraindicated or cannot be performed)²³; **OR**
 - Symptoms or signs evaluated by complete auditory examination, including **ANY** of the following²¹:

- Conductive, mixed-conductive, or congenital hearing loss; **OR**
- Sensorineural hearing loss, acquired or congenital, (when MRI is contraindicated or cannot be performed); **OR**
- Total deafness, otherwise unexplained; **OR**
- Vertigo, unexplained by history or physical examination with **ANY** of the following:
 - ◆ Worsening; **OR**
 - ◆ Affects daily function; **OR**
 - ◆ Associated hearing loss or other neurological deficits; **OR**
 - ◆ History of prior infection (e.g., otitis or meningitis); **OR**
 - ◆ History of prior trauma; **OR**
- Trauma-related conditions related to the ear, including evaluation of cerebrospinal fluid leak²³⁻²⁵; **OR**
- Preoperative, postoperative, or pre-treatment evaluation for surgery, radiation, or chemotherapy (including evaluation for cochlear implant); **OR**
- Vascular conditions, known or suspected, related to the ear or temporal bone, including evaluation of pulsatile tinnitus²⁶; **OR**
- ◆ Sellar and posterior fossa indications, including **ANY** of the following indications related to a sella or posterior fossa:
 - Sellar mass (including pituitary masses) is suspected due to documented clinical or laboratory findings (e.g., prolactinemia); **OR**
 - Visual field deficit (e.g., bitemporal hemianopsia) indicating optic nerve compression; **OR**
 - Other neoplastic conditions, known, suspected, or suggested by prior imaging (e.g., meningioma); **OR**
 - Trauma-related conditions; **OR**
 - Pituitary dysfunction, suggested by documented laboratory or clinical abnormalities (e.g., pituitary failure due to conditions such as pituitary apoplexy); **OR**
 - Vascular conditions, known or suspected, including aberrant anatomy; **OR**

- Preoperative, postoperative, or pre-treatment evaluation for surgery, radiation, or chemotherapy (including pre-operative planning for removal of the pituitary tumor); **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography (CT), orbit/ear/fossa** is not considered appropriate if **ANY** of the following is **TRUE**²⁷:

- ◆ If contrast is used, history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.²⁸⁻²⁹

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.²⁸⁻²⁹

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.²⁸⁻²⁹

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.²⁸⁻²⁹

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70480	Computed tomography (CT), orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material
70481	Computed tomography (CT), orbit, sella, or posterior fossa; with contrast material(s)
70482	Computed tomography (CT), orbit, sella, or posterior fossa; without contrast material, followed by contrast material(s) and further sections

76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Bedernik et al. (2022) conducted a randomized control trial (RCT) to assess image quality by comparing single-energy computed tomography (SECT) with automated tube voltage adaptation (TVA) to dual-energy CT (DECT) weighted average images. A total of 80 patients underwent SECT or radiation dose-matched DECT. The effective radiation dose (ED) showed no significant difference between the SECT and DECT study groups. Compared to the SECT group, the DECT group exhibited significantly higher contrast-to-noise ratio differences (CNRD) for jugular veins relative to fatty tissue and muscle tissue relative to fatty tissue. However, the CNRD for jugular veins relative to muscle tissue was comparable between groups. Image artifacts were also less pronounced, and overall diagnostic acceptability was higher in the DECT group. Overall, DECT-weighted average images demonstrate superior objective and subjective image quality compared to SECT performed with TVA in head and neck imaging.¹³

Smith-Bindman et al. (2020) performed an RCT to study the efficacy of interventions to lower the amount of radiation exposure. The RCT included 864,080 adults at 100 facilities who underwent a CT scan, including head CT scans (n = 1,156,657 scans). The study included two primary measures: the percentage of high-dose CT scans and the average effective dose administered at the facility level. The study's secondary measure included the doses received by specific organs - outcomes assessed for the impact of the interventions and outcomes post-intervention. Data were contrasted with pre-intervention data, utilizing hierarchical generalized linear models that accounted for temporal patterns and patient attributes. In conclusion, data regarding CT radiation dosage and practical recommendations may improve quality, including significant dose reductions, especially for organ-specific doses.¹⁴

Aulino et al. (2018) reported on a clinical trial that focused on an assessment tool for the late effect continuum of lymphedema and fibrosis (LEF) for patients with head and neck cancer (HNC) undergoing CT. The tool evaluates areas of soft tissue damage resulting from tumors, surgical interventions, or radiation therapy. The tool analyzed CT scans taken before and after treatment in 10 patients with HNC. The finalized tool has 11 elements, including assessing fat stranding at six specific sites, measuring epiglottic thickness, and measuring prevertebral soft tissue thickness at C3. The trial includes 176 CT scans from 20 patients (with a range of 4-14 scans per patient). The final version of the LEF assessment tool (CT-LEFAT) offers a standardized approach to assess critical sites affected by soft tissue damage. Studies continue to evaluate reliability and validity.¹⁵

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Clinical Guideline Revision History/Information

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Review History		



Cohere Medicare Advantage Policy – Computed Tomography (CT), Spine (Cervical, Thoracic, and Lumbar)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Spine (Cervical, Thoracic, and Lumbar)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Spine (Cervical, Thoracic, and Lumbar)

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.^{1-3,26-29}

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.^{1-3,26-29}

- [National Coverage Determination \(NCD\) Computed Tomography \(220.1\)](#)
- [Local Coverage Determination \(LCD\) MRI and CT Scans of the Head and Neck \(L37373\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57204\)](#)
- [Local Coverage Determination \(LCD\) MRI and CT Scans of the Head and Neck \(L35175\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\)](#)
- [Local Coverage Determination \(LCD\) Multiple Imaging in Oncology \(L35391\)](#)
- [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Recommended Clinical Approach

Computed tomography (CT) utilizes ionizing radiation to create images based on the varying absorption of X-rays by different tissues. This technology provides detailed cross-sectional views and enables the generation of multidimensional 2-D and 3-D reconstructions. CT scanning is highly valuable in clinical practice, particularly for evaluating spinal structures.⁴ CT scan (non-contrast) is appropriate in the setting of acute trauma or suspected fracture. CT myelogram (CT with contrast) is a two-part

procedure – iodinated contrast is first injected into the spinal canal under fluoroscopic guidance before a CT scan covering the region of concern is performed.

Primary evaluation with CT is typically non-contrasted in the setting of trauma or suspected fracture. While infection and tumor can be evaluated with a contrasted exam, MR is the preferred modality when possible. CT myelogram is an alternative in patients for whom spinal canal evaluation is desired, and MR is not practical (e.g., non-compatible hardware or pacemaker device, unable to cooperate with MR imaging demands).⁵⁻⁷

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Computed Tomography (CT), Spine (Cervical, Thoracic, and Lumbar). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁸
- Potential harm to fetus: Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy. Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁹
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Enhanced diagnostics: CT scanning provides fast, painless, noninvasive and accurate diagnosis. In case of emergency, CT scans can expediently reveal internal injuries and bleeding. Comparative meta-analyses among CT, magnetic resonance imaging (MRI), and

Dual-Energy X-ray Absorptiometry (DEXA) do not distinguish among these modalities in their ability to predict mechanical complications and clinical outcomes in patients with spine surgery.^{10, 24}

- Reproducible imaging of high quality: CT scans of the spine can provide detailed information about spinal vertebrae and soft tissues that cannot be visualized by standard X-rays of the spine. Single-photon emission computed tomography (SPECT) coupled with CT provides complementary information because sites of abnormal radiopharmaceutical uptake on the spine are of diagnostic value.¹⁰
- CT permits evaluation of vertebral body height, architecture, and integrity of the posterior cortex and pedicles before VA, which is critical in patients with cortical disruption, posterior cortex osseous retropulsion, and spinal canal compression.²⁴
- Dual-energy CT may show bone marrow edema with a reasonably high sensitivity and specificity and good concordance to MRI in thoracolumbar vertebral compression fractures (VCFs).^{10, 25}
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), spine (cervical, thoracic, and lumbar)** is considered appropriate if **ANY** of the following is **TRUE**:

◆ Neoplastic conditions for **ANY** of the following¹¹⁻¹²:

- Initial staging; **OR**
- Treatment planning; **OR**
- Response assessment; **OR**

- Surveillance and **ANY** of the following is **TRUE**^{27,28,30-32}:
 - The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6–12 months for an overall duration [e.g., 5 years]); **OR**
 - Suspected recurrence/progression; **OR**
 - Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6–8 weeks since the prior imaging evaluation); **OR**
- ◆ **ALL** of the following indications for infection or an infectious disorder (e.g., discitis, osteomyelitis, epidural abscess):
 - **ANY** of the following¹³⁻¹⁴:
 - Abnormal lab values; **OR**
 - Decubitus ulcer; **OR**
 - New cauda equina syndrome⁵; **OR**
 - New neurologic deficit; **OR**
 - New or worsening back or neck pain; **OR**
 - Recent intervention (e.g., hardware, pain injection, stimulator implantation); **OR**
 - Wound overlying spine; **OR**
 - **ANY** of the following “red flags”:
 - ◆ Cancer; **OR**
 - ◆ Diabetes mellitus; **OR**
 - ◆ Dialysis; **OR**
 - ◆ HIV; **OR**
 - ◆ Immunosuppression; **OR**
 - ◆ IV drug use; **OR**
 - ◆ Prior spinal infections (e.g., abscess, discitis arachnoiditis, osteomyelitis); **AND**
 - Follow-up to abnormal or indeterminate initial imaging; **OR**
- ◆ Trauma-related conditions, including **ANY** of the following¹⁵:
 - Following a traumatic event (e.g., accident, surgery, or intervention), and the patient has **ANY** of the following:
 - Neurological deficit (myelopathy); **OR**
 - Radiculopathy; **OR**

- Follow-up to initial radiographs with positive or indeterminate findings and advanced imaging is needed; **OR**
- High suspicion for fracture; **OR**
- Persistent or worsening pain without acute findings on initial imaging and **ANY** of the following apply to the patient:
 - Chronic steroid use; **OR**
 - Elderly; **OR**
 - Osteoporotic; **OR**
- Follow-up to initial radiographs for a known or suspected vertebral compression fracture (asymptomatic or symptomatic)¹⁰; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Spinal cord infarct; **OR**
 - Vascular malformation; **OR**
- ◆ Autoimmune, collagen vascular diseases, or inflammatory conditions (e.g., inflammatory arthritis, spondyloarthropathy, demyelinating diseases, muscular dystrophies) including **ANY** of the following^{6-7, 16-18}:
 - To assist in the diagnostic work-up; **OR**
 - Initial diagnosis or follow-up to evaluate for progression of disease or response to treatment; **OR**
 - Pain or radiculopathy; **OR**
 - Suspicion of **ANY** of the following:
 - Fracture; **OR**
 - Vertebral body subluxation; **OR**
- ◆ For evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when applicable:
 - Pain or radiculopathy without trauma as indicated by **ALL** of the following⁴⁻⁷:
 - Neurological deficit (myelopathy) or severe radiculopathy and **ANY** of the following⁷:
 - ◆ Abnormal EMG; **OR**
 - ◆ **ANY** of the following new or worsening symptoms:
 - Bladder dysfunction; **OR**
 - Bowel dysfunction; **OR**

- Dermatomal sensory loss; **OR**
- Objective muscle weakness; **OR**
- Radiculopathy (including sciatica); **OR**
- Saddle anesthesia; **OR**
- Sexual dysfunction; **AND**
- Persistent pain or radiculopathy after at least six weeks of conservative treatment; **AND**
- Suspicion of compression of **ANY** of the following:
 - ◆ Cauda equina⁷; **OR**
 - ◆ Nerve root; **AND**
 - ◆ Spinal cord; **AND**
- **ANY** of the following:
 - ◆ Back pain as evidenced by **ANY** of the following⁵:
 - Cauda equina syndrome, suspected; **OR**
 - History of prior lumbar surgery with new or progressing clinical findings; **OR**
 - Osteoporosis; **OR**
 - The patient is a candidate for surgery or intervention and has persistent or progressive symptoms during or following 6 weeks of optimal medical management; **OR**
 - Steroid use, chronic; **OR**
 - Suspicion of **ANY** of the following:
 - Cancer; **OR**
 - Immunosuppression; **OR**
 - Infection; **OR**
 - ◆ Cervical or neck pain as evidenced by **ANY** of the following⁶:
 - Cervicogenic headache with new or increasing non-traumatic cervical or neck pain and no neurologic deficit; **OR**
 - Chronic cervical or neck pain with no neurologic findings and radiographs show degenerative changes; **OR**
 - Chronic cervical or neck pain without or with radiculopathy and radiographs show

- ossification in the posterior longitudinal ligament (OPLL); **OR**
 - Known malignancy with new or increasing non-traumatic cervical or neck pain or radiculopathy; **OR**
 - New or increasing pain or radiculopathy with no “red flags”; **OR**
 - Prior cervical spine surgery with new or increasing non-traumatic cervical or neck pain or radiculopathy; **OR**
 - Suspicion for infection with new or increasing non-traumatic cervical or neck pain or radiculopathy; **OR**
- Plexopathy (traumatic) including **ANY** of the following¹⁹:
 - Brachial; **OR**
 - Lumbosacral; **OR**
- ◆ The patient is post-operative from a spinal surgery with recurrent or worsening symptoms^{4, 20}; **OR**
- ◆ **ANY** of the following indications for congenital or acquired abnormalities of the spine or vertebral bodies (not including specific pediatric indications)²¹:
 - Arnold Chiari malformation; **OR**
 - Neurological symptoms not previously imaged; **OR**
 - Pain that does not improve and imaging previously not performed; **OR**
 - Preoperative assessment needed; **OR**
 - Scoliosis; **OR**
 - Syrinx; **OR**
 - Syringohydromyelia; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**

- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography (CT), spine (cervical, thoracic, or lumbar)** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ History of anaphylactic allergic reaction to iodinated contrast media if contrast is used²²; **OR**
- ◆ Chronic neck pain⁶; **OR**
- ◆ Plexopathy (non-traumatic, with or without malignancy) including **ANY** of the following¹⁹:
 - Brachial; **OR**
 - Lumbosacral.

*NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT myelography is an effective alternative to MRI in patients with pacemakers, metallic implants, extreme obesity, or tremors.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{8, 23}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT,

fluoroscopy, or radiography.^{8, 23}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{8, 23}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{8, 23}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72125	Computed tomography (CT), cervical spine; without contrast material
72126	Computed tomography (CT), cervical spine; with contrast material
72127	Computed tomography (CT), cervical spine; without contrast material, followed by contrast material(s) and further sections
72128	Computed tomography (CT), thoracic spine; without contrast material
72129	Computed tomography (CT), thoracic spine; with contrast material
72130	Computed tomography (CT), thoracic spine; without contrast material, followed by contrast material(s) and further sections
72131	Computed tomography (CT), lumbar spine; without contrast material
72132	Computed tomography (CT), lumbar spine; with contrast material
72133	Computed tomography (CT), lumbar spine; without contrast material, followed by contrast material(s) and further sections
76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Ahmad et al. (2023) conducted a systematic review on the use of computed tomography (CT) and magnetic resonance imaging (MRI) with respect to the correlations between bone mineral density (BMD) derived from scans and Dual-Energy X-ray Absorptiometry (DEXA). A comprehensive analysis of 25 studies was included (15 utilizing CT and 10 utilizing MRI) with a total of 2745 patients. Articles published from 2011 to 2021 were included investigating the associations between CT or MRI measurements, such as CT-derived Hounsfield units (CT-HU) values or MRI parameters, and DEXA-derived BMD, specifically focusing on lumbar spine or hip regions. CT-HU exhibits stronger correlations with DEXA measurements than MRI parameters, however, both CT and MRI demonstrate moderate correlations with DEXA. Additional research is needed within spine surgery cohorts, including inferior correlations in populations with degenerative spine conditions.²⁴

Bäcker et al. (2021) performed a systematic literature review and meta-analysis to assess the sensitivity, specificity, and accuracy of dual-energy computed tomography (DE-CT) in detecting bone marrow edema and disc edema in spinal injuries. Early diagnosis of vertebral injuries is crucial to prevent treatment delays. Imaging modalities such as MRI or DE-CT are necessary to identify bone marrow or disc edemas. The analysis encompassed 13 studies involving 515 patients, 3335 vertebrae, and 926 acute fractures confirmed by MRI, which was used for comparison in 12 publications. DE-CT demonstrated an overall sensitivity of 86.2%, specificity of 91.2%, and accuracy of 89.3%. In addition, five studies reported the accuracy of conventional CT, yielding an overall sensitivity of 81.3%, specificity of 80.7%, and accuracy of 80.9%. Overall, DE-CT shows promise as a diagnostic tool for detecting bone marrow and disc edemas, potentially offering an alternative to MRI, the current gold standard.²⁵

Ghudasara et al. (2019) review the use of postoperative CT following spine surgery. Scans are useful to identify implant locations and integrity, evaluate the efficacy of decompression and intervertebral arthrodesis procedures, and identify associated complications. While metallic implant artifacts may limit postoperative spinal CT scans, advancements in parameter optimization and metal artifact reduction techniques (e.g., iterative reconstruction and monoenergetic extrapolation methods) offer significant improvements in image quality. Furthermore, they are valuable in detecting and characterizing any postoperative irregularities. Complications following spinal surgery and intervertebral arthroplasty range from issues with implant position and integrity to adjacent segment degeneration, collections, fistulas, pseudo meningoceles, cerebrospinal fluid leaks, and surgical site infections.²⁰

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Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		



Cohere Medicare Advantage Policy – Computed Tomography (CT), Spine (Cervical, Thoracic, and Lumbar)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Spine (Cervical, Thoracic, and Lumbar)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Spine (Cervical, Thoracic, and Lumbar)

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.^{1-3,26-29}

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.^{1-3,26-29}

- [National Coverage Determination \(NCD\) Computed Tomography \(220.1\)](#)
- [Local Coverage Determination \(LCD\) MRI and CT Scans of the Head and Neck \(L37373\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57204\)](#)
- [Local Coverage Determination \(LCD\) MRI and CT Scans of the Head and Neck \(L35175\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\)](#)
- [Local Coverage Determination \(LCD\) Multiple Imaging in Oncology \(L35391\)](#)
- [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Recommended Clinical Approach

Computed tomography (CT) utilizes ionizing radiation to create images based on the varying absorption of X-rays by different tissues. This technology provides detailed cross-sectional views and enables the generation of multidimensional 2-D and 3-D reconstructions. CT scanning is highly valuable in clinical practice, particularly for evaluating spinal structures.⁴ CT scan (non-contrast) is appropriate in the setting of acute trauma or suspected fracture. CT myelogram (CT with contrast) is a two-part

procedure – iodinated contrast is first injected into the spinal canal under fluoroscopic guidance before a CT scan covering the region of concern is performed.

Primary evaluation with CT is typically non-contrasted in the setting of trauma or suspected fracture. While infection and tumor can be evaluated with a contrasted exam, MR is the preferred modality when possible. CT myelogram is an alternative in patients for whom spinal canal evaluation is desired, and MR is not practical (e.g., non-compatible hardware or pacemaker device, unable to cooperate with MR imaging demands).⁵⁻⁷

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Computed Tomography (CT), Spine (Cervical, Thoracic, and Lumbar). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁸
- Potential harm to fetus: Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy. Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁹
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Enhanced diagnostics: CT scanning provides fast, painless, noninvasive and accurate diagnosis. In case of emergency, CT scans can expediently reveal internal injuries and bleeding. Comparative meta-analyses among CT, magnetic resonance imaging (MRI), and

Dual-Energy X-ray Absorptiometry (DEXA) do not distinguish among these modalities in their ability to predict mechanical complications and clinical outcomes in patients with spine surgery.^{10, 24}

- Reproducible imaging of high quality: CT scans of the spine can provide detailed information about spinal vertebrae and soft tissues that cannot be visualized by standard X-rays of the spine. Single-photon emission computed tomography (SPECT) coupled with CT provides complementary information because sites of abnormal radiopharmaceutical uptake on the spine are of diagnostic value.¹⁰
- CT permits evaluation of vertebral body height, architecture, and integrity of the posterior cortex and pedicles before VA, which is critical in patients with cortical disruption, posterior cortex osseous retropulsion, and spinal canal compression.²⁴
- Dual-energy CT may show bone marrow edema with a reasonably high sensitivity and specificity and good concordance to MRI in thoracolumbar vertebral compression fractures (VCFs).^{10, 25}
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), spine (cervical, thoracic, and lumbar)** is considered appropriate if **ANY** of the following is **TRUE**:

◆ Neoplastic conditions for **ANY** of the following¹¹⁻¹²:

- Initial staging; **OR**
- Treatment planning; **OR**
- Response assessment; **OR**

- Surveillance and **ANY** of the following is **TRUE**^{27,28,30-32}:
 - The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6–12 months for an overall duration [e.g., 5 years]); **OR**
 - Suspected recurrence/progression; **OR**
 - Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6–8 weeks since the prior imaging evaluation); **OR**
- ◆ **ALL** of the following indications for infection or an infectious disorder (e.g., discitis, osteomyelitis, epidural abscess):
 - **ANY** of the following¹³⁻¹⁴:
 - Abnormal lab values; **OR**
 - Decubitus ulcer; **OR**
 - New cauda equina syndrome⁵; **OR**
 - New neurologic deficit; **OR**
 - New or worsening back or neck pain; **OR**
 - Recent intervention (e.g., hardware, pain injection, stimulator implantation); **OR**
 - Wound overlying spine; **OR**
 - **ANY** of the following “red flags”:
 - ◆ Cancer; **OR**
 - ◆ Diabetes mellitus; **OR**
 - ◆ Dialysis; **OR**
 - ◆ HIV; **OR**
 - ◆ Immunosuppression; **OR**
 - ◆ IV drug use; **OR**
 - ◆ Prior spinal infections (e.g., abscess, discitis arachnoiditis, osteomyelitis); **AND**
 - Follow-up to abnormal or indeterminate initial imaging; **OR**
- ◆ Trauma-related conditions, including **ANY** of the following¹⁵:
 - Following a traumatic event (e.g., accident, surgery, or intervention), and the patient has **ANY** of the following:
 - Neurological deficit (myelopathy); **OR**
 - Radiculopathy; **OR**

- Follow-up to initial radiographs with positive or indeterminate findings and advanced imaging is needed; **OR**
- High suspicion for fracture; **OR**
- Persistent or worsening pain without acute findings on initial imaging and **ANY** of the following apply to the patient:
 - Chronic steroid use; **OR**
 - Elderly; **OR**
 - Osteoporotic; **OR**
- Follow-up to initial radiographs for a known or suspected vertebral compression fracture (asymptomatic or symptomatic)¹⁰; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Spinal cord infarct; **OR**
 - Vascular malformation; **OR**
- ◆ Autoimmune, collagen vascular diseases, or inflammatory conditions (e.g., inflammatory arthritis, spondyloarthropathy, demyelinating diseases, muscular dystrophies) including **ANY** of the following^{6-7, 16-18}:
 - To assist in the diagnostic work-up; **OR**
 - Initial diagnosis or follow-up to evaluate for progression of disease or response to treatment; **OR**
 - Pain or radiculopathy; **OR**
 - Suspicion of **ANY** of the following:
 - Fracture; **OR**
 - Vertebral body subluxation; **OR**
- ◆ For evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when applicable:
 - Pain or radiculopathy without trauma as indicated by **ALL** of the following⁴⁻⁷:
 - Neurological deficit (myelopathy) or severe radiculopathy and **ANY** of the following⁷:
 - ◆ Abnormal EMG; **OR**
 - ◆ **ANY** of the following new or worsening symptoms:
 - Bladder dysfunction; **OR**
 - Bowel dysfunction; **OR**

- Dermatomal sensory loss; **OR**
- Objective muscle weakness; **OR**
- Radiculopathy (including sciatica); **OR**
- Saddle anesthesia; **OR**
- Sexual dysfunction; **AND**
- Persistent pain or radiculopathy after at least six weeks of conservative treatment; **AND**
- Suspicion of compression of **ANY** of the following:
 - ◆ Cauda equina⁷; **OR**
 - ◆ Nerve root; **AND**
 - ◆ Spinal cord; **AND**
- **ANY** of the following:
 - ◆ Back pain as evidenced by **ANY** of the following⁵:
 - Cauda equina syndrome, suspected; **OR**
 - History of prior lumbar surgery with new or progressing clinical findings; **OR**
 - Osteoporosis; **OR**
 - The patient is a candidate for surgery or intervention and has persistent or progressive symptoms during or following 6 weeks of optimal medical management; **OR**
 - Steroid use, chronic; **OR**
 - Suspicion of **ANY** of the following:
 - Cancer; **OR**
 - Immunosuppression; **OR**
 - Infection; **OR**
 - ◆ Cervical or neck pain as evidenced by **ANY** of the following⁶:
 - Cervicogenic headache with new or increasing non-traumatic cervical or neck pain and no neurologic deficit; **OR**
 - Chronic cervical or neck pain with no neurologic findings and radiographs show degenerative changes; **OR**
 - Chronic cervical or neck pain without or with radiculopathy and radiographs show

- ossification in the posterior longitudinal ligament (OPLL); **OR**
 - Known malignancy with new or increasing non-traumatic cervical or neck pain or radiculopathy; **OR**
 - New or increasing pain or radiculopathy with no “red flags”; **OR**
 - Prior cervical spine surgery with new or increasing non-traumatic cervical or neck pain or radiculopathy; **OR**
 - Suspicion for infection with new or increasing non-traumatic cervical or neck pain or radiculopathy; **OR**
- Plexopathy (traumatic) including **ANY** of the following¹⁹:
 - Brachial; **OR**
 - Lumbosacral; **OR**
- ◆ The patient is post-operative from a spinal surgery with recurrent or worsening symptoms^{4, 20}; **OR**
- ◆ **ANY** of the following indications for congenital or acquired abnormalities of the spine or vertebral bodies (not including specific pediatric indications)²¹:
 - Arnold Chiari malformation; **OR**
 - Neurological symptoms not previously imaged; **OR**
 - Pain that does not improve and imaging previously not performed; **OR**
 - Preoperative assessment needed; **OR**
 - Scoliosis; **OR**
 - Syrinx; **OR**
 - Syringohydromyelia; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**

- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography (CT), spine (cervical, thoracic, or lumbar)** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ History of anaphylactic allergic reaction to iodinated contrast media if contrast is used²²; **OR**
- ◆ Chronic neck pain⁶; **OR**
- ◆ Plexopathy (non-traumatic, with or without malignancy) including **ANY** of the following¹⁹:
 - Brachial; **OR**
 - Lumbosacral.

*NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT myelography is an effective alternative to MRI in patients with pacemakers, metallic implants, extreme obesity, or tremors.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{8, 23}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT,

fluoroscopy, or radiography.^{8, 23}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{8, 23}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{8, 23}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72125	Computed tomography (CT), cervical spine; without contrast material
72126	Computed tomography (CT), cervical spine; with contrast material
72127	Computed tomography (CT), cervical spine; without contrast material, followed by contrast material(s) and further sections
72128	Computed tomography (CT), thoracic spine; without contrast material
72129	Computed tomography (CT), thoracic spine; with contrast material
72130	Computed tomography (CT), thoracic spine; without contrast material, followed by contrast material(s) and further sections
72131	Computed tomography (CT), lumbar spine; without contrast material
72132	Computed tomography (CT), lumbar spine; with contrast material
72133	Computed tomography (CT), lumbar spine; without contrast material, followed by contrast material(s) and further sections
76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Ahmad et al. (2023) conducted a systematic review on the use of computed tomography (CT) and magnetic resonance imaging (MRI) with respect to the correlations between bone mineral density (BMD) derived from scans and Dual-Energy X-ray Absorptiometry (DEXA). A comprehensive analysis of 25 studies was included (15 utilizing CT and 10 utilizing MRI) with a total of 2745 patients. Articles published from 2011 to 2021 were included investigating the associations between CT or MRI measurements, such as CT-derived Hounsfield units (CT-HU) values or MRI parameters, and DEXA-derived BMD, specifically focusing on lumbar spine or hip regions. CT-HU exhibits stronger correlations with DEXA measurements than MRI parameters, however, both CT and MRI demonstrate moderate correlations with DEXA. Additional research is needed within spine surgery cohorts, including inferior correlations in populations with degenerative spine conditions.²⁴

Bäcker et al. (2021) performed a systematic literature review and meta-analysis to assess the sensitivity, specificity, and accuracy of dual-energy computed tomography (DE-CT) in detecting bone marrow edema and disc edema in spinal injuries. Early diagnosis of vertebral injuries is crucial to prevent treatment delays. Imaging modalities such as MRI or DE-CT are necessary to identify bone marrow or disc edemas. The analysis encompassed 13 studies involving 515 patients, 3335 vertebrae, and 926 acute fractures confirmed by MRI, which was used for comparison in 12 publications. DE-CT demonstrated an overall sensitivity of 86.2%, specificity of 91.2%, and accuracy of 89.3%. In addition, five studies reported the accuracy of conventional CT, yielding an overall sensitivity of 81.3%, specificity of 80.7%, and accuracy of 80.9%. Overall, DE-CT shows promise as a diagnostic tool for detecting bone marrow and disc edemas, potentially offering an alternative to MRI, the current gold standard.²⁵

Ghudasara et al. (2019) review the use of postoperative CT following spine surgery. Scans are useful to identify implant locations and integrity, evaluate the efficacy of decompression and intervertebral arthrodesis procedures, and identify associated complications. While metallic implant artifacts may limit postoperative spinal CT scans, advancements in parameter optimization and metal artifact reduction techniques (e.g., iterative reconstruction and monoenergetic extrapolation methods) offer significant improvements in image quality. Furthermore, they are valuable in detecting and characterizing any postoperative irregularities. Complications following spinal surgery and intervertebral arthroplasty range from issues with implant position and integrity to adjacent segment degeneration, collections, fistulas, pseudo meningoceles, cerebrospinal fluid leaks, and surgical site infections.²⁰

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Clinical Guideline Revision History/Information

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Review History		



Cohere Medicare Advantage Policy – Computed Tomography (CT), Upper Extremity

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

Important Notices

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Medical Necessity Criteria

Service: Computed Tomography (CT), Upper Extremity

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\). Computed Tomography \(220.1\)](#)

Recommended Clinical Approach

Computed tomography (CT) of the upper extremity for trauma typically does not require contrast. Intravenous (IV) contrast is used if requested by the ordering provider and guided by the radiologist. Common reasons for using contrast include detecting infectious and inflammatory conditions, or suspected malignancy. In cases where internal joint derangement or cartilage loss is suspected but MRI is not feasible (e.g., due to an incompatible implanted device, inability to tolerate an MRI exam or metallic artifacts), intra-articular contrast may be beneficial.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of computed tomography (CT) of the upper extremity. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary

procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- CT imaging uses ionizing radiation in the form of x-rays, and while such routine x-rays use low levels of ionizing radiation, this form of radiation is known to increase the risk of cancer.²
- Young children are more sensitive to radiation than adults and even the low-dose radiation of CT may pose a significant cancer risk to pediatric patients. In growing children, the thyroid gland, breast tissue, and gonads are particularly sensitive to radiation.³⁻⁴
- The contrast agent, or dye, employed in some CT scans of the extremities has been linked to renal dysfunction (contrast-induced nephropathy). Patients undergoing consecutive scans, or patients with cirrhosis, hypotension, or peritoneal carcinomatosis may be predisposed to contrast-induced nephropathy.⁵
- Contrast agents may also produce adverse anaphylactoid or non-anaphylactoid reactions. Women, infants, older adults, and Individuals with medical conditions such as diabetes, asthma, or thyroid disorders may be predisposed to contrast induced allergic reactions.⁶
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- CT may aid in surgical planning following whole-body trauma, by enabling triage through the simultaneous consideration of extremity and intracavitary injuries.⁷
- CT is more sensitive in the detection of fractures in the extremities than conventional radiographic examinations, while delivering an equivalent dose of radiation.⁸
- For patients for whom magnetic resonance imaging (MRI) is unavailable or contraindicated, CT scanning can serve as an alternative when a suspected extremity fracture is not detectable on an x-ray.⁹
- CT is the standard reference imaging modality for visualizing bone damage, including bone erosions in rheumatoid arthritis (RA), but lacks

sensitivity for soft-tissue changes, including synovitis and tenosynovitis.¹⁰

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), upper extremity** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Traumatic upper extremity injury (e.g., fracture, dislocation) that requires additional detail than is available with plain radiographs and **ANY** of the following is **TRUE**¹¹⁻¹³:
 - Bony injury and **ANY** of the following is **TRUE**¹⁴:
 - Fracture (known) and additional detail needed; **OR**
 - Acute injury with occult fracture suspected; **OR**
 - Joint dislocation or instability; **OR**
 - Stress/insufficiency fracture (known) and follow-up imaging needed; **OR**
 - Stress/insufficiency fracture (suspected) with negative radiographs; **OR**
 - Suspected soft tissue injury (e.g., rotator cuff tear), and MRI and ultrasound are contraindicated or cannot be performed^{11,13,15-16}; **OR**

- ◆ Detection, screening, or surveillance of neoplasms, masses, and cysts of an upper extremity, and **ANY** of the following is **TRUE**¹⁷:
 - Malignant or aggressive primary tumor¹⁷; **OR**
 - A bone tumor is suspected with indeterminate or aggressive appearance of an incidental osseous lesion on MRI or radiographs for unrelated indication¹⁸; **OR**
 - Presence of a mass with **ANY** of the following¹⁹:
 - Absence of trauma; **OR**
 - Rapid growth; **OR**
 - Recurrence after prior surgery; **OR**
 - Non-diagnostic ultrasound or other inconclusive imaging; **OR**
 - Known malignancy and **ANY** of the following is required:
 - Monitor response to treatment; **OR**
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 - Follow-up exam to further characterize a bone or soft tissue lesion diagnosed on initial imaging study¹⁸⁻¹⁹; **OR**
- ◆ Infectious disorder, including **ANY** of the following:
 - Septic arthritis is suspected with initial radiographs that are normal or with findings suggestive of joint effusion or soft tissue swelling; **OR**
 - Osteomyelitis suspected²⁰; **OR**
 - Soft tissue infection suspected with **ANY** of the following²⁰:
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 - History of puncture wound with possible retained foreign body; **OR**
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- ◆ Vascular conditions, known or suspected, when ultrasound and MRI are contraindicated or inconclusive; **OR**
- ◆ Evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when applicable:
 - Marrow abnormalities²¹⁻²²; **OR**
 - Pain or weakness of an upper extremity as indicated by **ALL** of the following^{15,23}:

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- Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 3 months; **AND**
- Concern for rupture or high-grade tear based on **ALL** of the following:
 - ◆ Clinical history; **AND**
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 - Screening, surveillance, or follow-up of autoimmune, collagen vascular diseases, or inflammatory conditions (e.g., inflammatory arthritis)²⁴; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
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- **Computed tomography (CT), upper extremity** is not considered appropriate if **ANY** of the following is **TRUE** if contrast is used:
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Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{[25-26](#)}

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The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

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Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		



Cohere Medicare Advantage Policy – Computed Tomography (CT), Upper Extremity

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

Important Notices

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GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Upper Extremity

Date of last literature review: 10/2/2024

Document last updated: 10/3/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Upper Extremity

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\). Computed Tomography \(220.1\)](#)

Recommended Clinical Approach

Computed tomography (CT) of the upper extremity for trauma typically does not require contrast. Intravenous (IV) contrast is used if requested by the ordering provider and guided by the radiologist. Common reasons for using contrast include detecting infectious and inflammatory conditions, or suspected malignancy. In cases where internal joint derangement or cartilage loss is suspected but MRI is not feasible (e.g., due to an incompatible implanted device, inability to tolerate an MRI exam or metallic artifacts), intra-articular contrast may be beneficial.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of computed tomography (CT) of the upper extremity. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary

procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- CT imaging uses ionizing radiation in the form of x-rays, and while such routine x-rays use low levels of ionizing radiation, this form of radiation is known to increase the risk of cancer.²
- Young children are more sensitive to radiation than adults and even the low-dose radiation of CT may pose a significant cancer risk to pediatric patients. In growing children, the thyroid gland, breast tissue, and gonads are particularly sensitive to radiation.³⁻⁴
- The contrast agent, or dye, employed in some CT scans of the extremities has been linked to renal dysfunction (contrast-induced nephropathy). Patients undergoing consecutive scans, or patients with cirrhosis, hypotension, or peritoneal carcinomatosis may be predisposed to contrast-induced nephropathy.⁵
- Contrast agents may also produce adverse anaphylactoid or non-anaphylactoid reactions. Women, infants, older adults, and Individuals with medical conditions such as diabetes, asthma, or thyroid disorders may be predisposed to contrast induced allergic reactions.⁶
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- CT may aid in surgical planning following whole-body trauma, by enabling triage through the simultaneous consideration of extremity and intracavitary injuries.⁷
- CT is more sensitive in the detection of fractures in the extremities than conventional radiographic examinations, while delivering an equivalent dose of radiation.⁸
- For patients for whom magnetic resonance imaging (MRI) is unavailable or contraindicated, CT scanning can serve as an alternative when a suspected extremity fracture is not detectable on an x-ray.⁹
- CT is the standard reference imaging modality for visualizing bone damage, including bone erosions in rheumatoid arthritis (RA), but lacks

sensitivity for soft-tissue changes, including synovitis and tenosynovitis.¹⁰

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), upper extremity** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Traumatic upper extremity injury (e.g., fracture, dislocation) that requires additional detail than is available with plain radiographs and **ANY** of the following is **TRUE**¹¹⁻¹³:
 - Bony injury and **ANY** of the following is **TRUE**¹⁴:
 - Fracture (known) and additional detail needed; **OR**
 - Acute injury with occult fracture suspected; **OR**
 - Joint dislocation or instability; **OR**
 - Stress/insufficiency fracture (known) and follow-up imaging needed; **OR**
 - Stress/insufficiency fracture (suspected) with negative radiographs; **OR**
 - Suspected soft tissue injury (e.g., rotator cuff tear), and MRI and ultrasound are contraindicated or cannot be performed^{11,13,15-16}; **OR**

- ◆ Detection, screening, or surveillance of neoplasms, masses, and cysts of an upper extremity, and **ANY** of the following is **TRUE**¹⁷:
 - Malignant or aggressive primary tumor¹⁷; **OR**
 - A bone tumor is suspected with indeterminate or aggressive appearance of an incidental osseous lesion on MRI or radiographs for unrelated indication¹⁸; **OR**
 - Presence of a mass with **ANY** of the following¹⁹:
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 - Follow-up exam to further characterize a bone or soft tissue lesion diagnosed on initial imaging study¹⁸⁻¹⁹; **OR**
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Clinical Guideline Revision History/Information

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Review History		



Cohere Medicare Advantage Policy – Computed Tomography Angiography (CTA), Abdomen/Pelvis, including Lower Extremity RunOff

Clinical Guidelines for Medical Necessity Review

Version: 1
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Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

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Medical Necessity Criteria

Service: Computed Tomography Angiography (CTA), Abdomen/Pelvis

Benefit Category

Not applicable

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs or LCDs for computed tomography angiography (CTA), abdomen/pelvis.

Recommended Clinical Approach

Computed tomography angiography (CTA) is a preferred imaging test for various aortic conditions because of its excellent spatial resolution, rapid image acquisition, and wide availability. CTA provides a robust tool for planning aortic interventions and diagnosing acute and chronic vascular diseases in the abdomen. CTA is the standard for imaging aneurysms before intervention and evaluating the aorta in the acute setting to assess the traumatic injury, dissection, and aneurysm rupture. Knowledge of the imaging features of these disease processes, inflammatory vasculitis, and occlusive atherosclerotic disease is essential for guiding the surgical and medical management of patients. Computed tomography venography (CTV) is a diagnostic imaging procedure that uses computed tomography (CT) to visualize the veins in the body. CTV can detect deep vein thrombosis (DVT) and evaluate venous insufficiency. Advantages include the ability to capture high-resolution images and are non-invasive and efficient.¹

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of computed tomography angiography (CTA) abdomen/ pelvis, including lower extremity runoff. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks

associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.²⁻⁵
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.⁶ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁶
- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁷

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. Allam et al. (2024) reviewed CTA as a component of multi-modality imaging in vasculitis. They state that CTA is widely accessible and is widely used in large vessel vasculitis, with excellent spatial and temporal resolution. CTA may reveal both early vascular changes as well as late complications, such as stenosis, dissection, or aneurysms.⁸
- Reduction in complications and adverse effects from unnecessary procedures. The ACR-NASCI-SIR-SPR practice parameter for the performance and interpretation of body computed tomography angiography (CTA)(2021) enumerates indications for the modality's use in diagnosis and treatment of vascular aneurysms and dissections, trauma evaluation, and anatomic mapping for organ transplantation and autograft planning.¹
- Enhanced diagnostic accuracy for complex medical conditions. Hansen (2016) reviewed the use of CTA of the abdominal aorta, stating that it has become the preferred method for planning repair, monitoring complications, and follow-up of abdominal aortic aneurysms.⁹

- Enhanced overall patient satisfaction and healthcare experience. Patients may tolerate computed tomography scanning better than magnetic resonance imaging, due to the shorter amount of time involved for the study and lower risk for claustrophobia.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography angiography or venography (CTA/CTV) of the abdomen/pelvis (CPT 74191, 74174)** is considered appropriate when **ANY** of the following is **TRUE**:

- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Suspected renal artery stenosis, when intervention is planned if diagnosed, including **ANY** of the following:
 - Previous imaging (e.g., ultrasound) indicates small kidney or unequal kidney sizes; **OR**
 - Renal artery Doppler ultrasound suggests renal artery stenosis; **OR**
 - Early-onset hypertension (age less than 35, diastolic greater than 110 mmHg)¹⁰; **OR**
 - Late-onset hypertension (age greater than 50)¹⁰; **OR**
 - Renal artery bruit¹⁰; **OR**
 - Malignant or accelerated hypertension¹⁰; **OR**
 - Sudden development or worsening of hypertension¹⁰; **OR**

- Deterioration of renal function in response to angiotensin-converting enzyme inhibitors¹⁰; **OR**
- Hypertension resistant to medication, and the patient must be currently taking **ALL** of the following at maximally tolerated doses¹¹;
 - ◆ Long-acting calcium channel blocker; **AND**
 - ◆ Long-acting ace inhibitor or angiotensin receptor blocker (ARB); **AND**
 - ◆ Diuretic (e.g., loop or thiazide); **OR**
- Mesenteric ischemia or ischemic enteritis/colitis when **ANY** of the following is **TRUE**:
 - High suspicion for ischemic enteritis/colitis or mesenteric/bowel infarct by another imaging study; **OR**
 - Anion-gap metabolic acidosis and/or high lactate in the setting of severe abdominal pain or abdominal pain that is out of proportion to the physical exam; **OR**
 - Known vascular risk factors or known vascular disease (e.g., age greater than 60 years, known coronary artery disease [CAD] or peripheral artery disease [PAD]) with severe abdominal pain or abdominal pain that is out of proportion to the physical exam; **OR**
 - Known vascular risk factors with post-prandial pain that affects daily life (e.g., fear of food, weight loss); **OR**
 - Symptoms or signs indicating lower GI bleeding; **OR**
- Thromboembolic disease; **OR**
- Concern for aneurysm when ultrasound is inconclusive or non-diagnostic, based on documented clinical or imaging findings; **OR**
- Known unrepaired aortic aneurysm over 5.4 cm in size, initial evaluation, if surgical intervention is being planned¹²⁻¹³; **OR**
- Unrepaired aortic aneurysm when ultrasound and non-contrast CT are inconclusive. Follow-up evaluation is based on aneurysm size when **ANY** of the following is **TRUE**¹⁴:

- 3 to 3.9 cm, every 3 years; **OR**
 - 4 to 4.9 cm, annually; **OR**
 - 5 to 5.4 cm, every 6 months; **OR**
- Preoperative planning for thoracoabdominal aortic aneurysm (TAAA) or dissection (with or without symptoms) and **ANY** of the following is **TRUE**¹⁵:
 - CTA of the chest has been performed; **OR**
 - Endovascular repair of thoracoabdominal aortic aneurysm (TAAA); **OR**
 - Open repair of thoracoabdominal aortic aneurysm (TAAA); **OR**
 - Follow-up after **ANY** of the following:
 - ◆ Endovascular repair of thoracoabdominal aortic aneurysm (TAAA); **OR**
 - ◆ Known thoracoabdominal aortic aneurysm (TAAA) or dissection without repair; **OR**
 - ◆ Open repair of thoracoabdominal aortic aneurysm (TAAA); **OR**
- Vascular invasion or displacement by tumor or other process; **OR**
- Assessment of patients with spontaneous coronary artery dissection (SCAD), one-time; **OR**
- Trauma, with concern for solid organ or vascular injury¹¹⁶⁻¹⁷; **OR**
- Vasculitis, initial evaluation, when **ANY** of the following is **TRUE**^{116,18-20}:
 - Biopsy proven; **OR**
 - Rheumatologic panel work-up including but not limited to erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) is suggestive of vasculitis; **OR**
 - The outcome of the imaging is expected to change management and/or treatment plan; **OR**
- Evaluation of hepatic arteries, when ultrasound is inconclusive, nondiagnostic, or abnormal requiring confirmation; **OR**
- Evaluation of other visceral arteries, including, but not limited to, suspected superior mesenteric artery (SMA)

syndrome and median arcuate ligament syndrome (MAL)²¹⁻²²; **OR**

- Evaluation of the portal venous system (hepatic portal system) after Doppler ultrasound has been performed; **OR**
 - Diffuse unexplained lower extremity edema with negative or inconclusive ultrasound; **OR**
 - Suspected venous compression syndrome (e.g., Nutcracker syndrome [renal vein compression], May-Thurner syndrome [iliac vein compression syndrome including pelvic CT venography])²³⁻²⁴; **OR**
 - Large vein thrombosis of the major abdominal or pelvic veins, including inferior vena cava (IVC), iliac, renal, portal, and hepatic veins, when Doppler ultrasound is inconclusive or indicates the presence or complications; **OR**
 - Detailed evaluation for pelvic congestion syndrome; **OR**
 - Other, unspecified vascular findings that were inconclusive on prior imaging; **OR**
- ◆ Preoperative, postoperative, or pre-treatment evaluation for **ANY** of the following:
- Evaluation post-endovascular repair (EVAR) or open repair of abdominal aortic aneurysm (AAA) and **ANY** of the following is **TRUE**¹⁴:
 - Follow-up within one month; **OR**
 - Follow-up within one year; **OR**
 - Type II endoleak, every six months for up to two years after diagnosis; **OR**
 - Type II endoleak, annual followup; **OR**
 - Planning for vascular surgery, interventional procedure; **OR**
 - Other procedures involving arteries (e.g., inferior epigastric arteries for breast reconstruction, ureteropelvic junction [UPJ] obstruction, solid organ transplant, prostate embolization); **OR**
 - Renal transplant rejection/dysfunction, when ultrasound and nuclear medicine (e.g., MAG3, DTPA) scans are inconclusive or are indicative of a vascular cause of rejection or dysfunction²⁵; **OR**
 - Anastomotic integrity or stent patency; **OR**

- Other vascular graft complication (e.g., suspected infection, pseudoaneurysm, or thrombosis)¹⁶; **OR**
- ◆ Gastrointestinal bleeding including **ANY** of the following¹⁴:
 - Lower gastrointestinal tract bleeding with **ANY** of the following²⁶:
 - Active bleeding is clinically observed as hematochezia or melena in a hemodynamically stable patient, where colonoscopy is contraindicated or unavailable; **OR**
 - Active bleeding in a hemodynamically unstable patient or a patient who has required more than 5 units of blood within 24 hours; **OR**
 - Concern for ongoing or recurrent bleeding after treatment (e.g., colonoscopy or transcatheter angiography); **OR**
 - Upper gastrointestinal bleeding (non-variceal) with **ANY** of the following²⁷:
 - High suspicion of an arterial source endoscopy is contraindicated (e.g., post-surgical or traumatic cause), or inconclusive; **OR**
 - Source of bleeding is not identified on endoscopy; **OR**
- ◆ Known or suspected syndromes with increased risk of vascular anomalies including **ANY**, but not limited to, the following:
 - As a one-time screening for syndromes with a vascular component (e.g., fibromuscular dysplasia, Ehlers–Danlos syndrome, Marfan syndrome, neurofibromatosis, William’s syndrome, tuberous sclerosis); **OR**
 - Loeys Dietz (every two years for screening; surveillance as indicated depending on abnormalities found)^{28–29}; **OR**
 - Other syndromes not otherwise specified, follow-up as clinical documentation supports; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**

- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Computed tomography angiogram and/or venography (CTA/CTV) of the abdomen/pelvis with runoff (CPT 74175, 75635)** is considered appropriate when **ANY** of the following is **TRUE**:

- ◆ Lower extremity ischemic symptoms when **ALL** of the following are **TRUE**:
 - **ANY** of the following:
 - Leg pain worsens with activity and relief with rest (claudication); **OR**
 - Non-healing lower extremity ulcers; **AND**
 - **ALL** of the following:
 - Limitation of performance of daily activities; **AND**
 - Expected mobility after treatment warrants revascularization; **AND**
 - Revascularization is planned³⁰; **AND**
 - Abnormal ABI as evidenced by **ANY** of the following:
 - ◆ ABI is inconclusive or nondiagnostic; **OR**
 - ◆ ABI less than 0.9 or greater than 1.4 on at least one leg; **OR**
 - ◆ ABI less than 1.1 in patients with risk factors for atherosclerosis (e.g., personal history of diabetes or known cardiac disease)³¹; **OR**
- ◆ Critical limb ischemia strongly suspected (sudden onset of a cold leg with pain, gangrene, rest pain)³²; **OR**
- ◆ Evidence of severe venous reflux disease, including venous leg ulcer, when pelvic or abdominal etiology is suspected; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**

- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography angiogram and/or venography (CTA/CTV) of the abdomen/pelvis with contrast** is not considered appropriate if **ANY** of the following is **TRUE**³³:

- ◆ The request is for CT/CTA with contrast, and the patient has a history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{4,34}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the

patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{4,34}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{4,34}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{4,34}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72191	Computed tomographic angiography (CTA), pelvis; with contrast material(s) including non-contrast images, if performed, and image postprocessing
74174	Computed tomographic angiography (CTA), abdomen and pelvis; with contrast material(s), including non-contrast images, if performed, and image postprocessing
74175	Computed tomographic angiography (CTA), abdomen; with contrast material(s), including non-contrast images, if performed, and image postprocessing
75635	Computed tomographic angiography (CTA),

	abdominal aorta, and bilateral iliofemoral lower extremity runoff; with contrast material(s), including non-contrast images, if performed, and image postprocessing

Medical Evidence

Allam et al. (2024) review multiple imaging modalities in vasculitis. Advantages of computed tomography angiography (CTA) include its high availability and rapid execution, along with excellent spatial and temporal resolution. Additionally, coronary CTA can be performed simultaneously if there is a suspicion of coronary artery disease (CAD). A prospective study by Lariviere et al. (2016) demonstrates that CTA can identify late complications such as stenosis, dissection, or aneurysms. In another prospective study, CTA showed a sensitivity of 73% and a specificity of 78% for diagnosing giant cell arteritis compared to clinical diagnosis.^{8,35}

Fernando et al. (2022) conducted a meta-analysis to assess the effectiveness of various diagnostic methods, including presenting symptoms, physical examination findings, CTA, and point-of-care ultrasound (PoCUS) in accurately identifying ruptured abdominal aortic aneurysm (rAAA). A total of 2077 patients from 20 studies were included. While classic clinical symptoms related to rAAA may lack sensitivity, their absence does not always exclude the diagnosis. CTA exhibits reasonable accuracy but may still fail to detect some instances of rAAA. PoCUS may be a valuable resource when determining the transfer of suspected rAAA patients to a vascular center.²⁴

Rotzinger et al. (2020) prospectively compared three image acquisition techniques in lower extremity CT angiography. Of the 60 consecutive patients enrolled, each was randomly assigned to one of three groups: the standard anterograde technique (SA), the adaptive anterograde technique (AA), and the retrograde acquisition technique (RA). Quantitative image quality was evaluated by measuring intraluminal attenuation at 536 different levels. Additionally, occlusive or aneurysmal disease was documented for each patient and limb. The RA technique demonstrated lower attenuation compared to the SA and AA techniques. The highest and most consistent attenuation was found with the AA technique. Qualitative analysis revealed that AA had the lowest rate of non-diagnostic vascular segments, followed by SA and RA. Venous contamination was significantly higher with RA, particularly at the aortic level. The presence of stenosis or occlusion did not significantly affect attenuation values across all techniques, whereas aneurysmal disease significantly impacted luminal attenuation in AA.

(increased attenuation) and RA (decreased attenuation) at the iliac and femoral levels.^{[36](#)}

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Clinical Guideline Revision History/Information

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Review History		



Cohere Medicare Advantage Policy – Computed Tomography Angiography (CTA), Abdomen/Pelvis, including Lower Extremity RunOff

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 19, 2024

Important Notices

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Medical Necessity Criteria

Service: Computed Tomography Angiography (CTA), Abdomen/Pelvis

Benefit Category

Not applicable

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs or LCDs for computed tomography angiography (CTA), abdomen/pelvis.

Recommended Clinical Approach

Computed tomography angiography (CTA) is a preferred imaging test for various aortic conditions because of its excellent spatial resolution, rapid image acquisition, and wide availability. CTA provides a robust tool for planning aortic interventions and diagnosing acute and chronic vascular diseases in the abdomen. CTA is the standard for imaging aneurysms before intervention and evaluating the aorta in the acute setting to assess the traumatic injury, dissection, and aneurysm rupture. Knowledge of the imaging features of these disease processes, inflammatory vasculitis, and occlusive atherosclerotic disease is essential for guiding the surgical and medical management of patients. Computed tomography venography (CTV) is a diagnostic imaging procedure that uses computed tomography (CT) to visualize the veins in the body. CTV can detect deep vein thrombosis (DVT) and evaluate venous insufficiency. Advantages include the ability to capture high-resolution images and are non-invasive and efficient.¹

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of computed tomography angiography (CTA) abdomen/ pelvis, including lower extremity runoff. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks

associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.²⁻⁵
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.⁶ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁶
- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁷

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. Allam et al. (2024) reviewed CTA as a component of multi-modality imaging in vasculitis. They state that CTA is widely accessible and is widely used in large vessel vasculitis, with excellent spatial and temporal resolution. CTA may reveal both early vascular changes as well as late complications, such as stenosis, dissection, or aneurysms.⁸
- Reduction in complications and adverse effects from unnecessary procedures. The ACR-NASCI-SIR-SPR practice parameter for the performance and interpretation of body computed tomography angiography (CTA)(2021) enumerates indications for the modality's use in diagnosis and treatment of vascular aneurysms and dissections, trauma evaluation, and anatomic mapping for organ transplantation and autograft planning.¹
- Enhanced diagnostic accuracy for complex medical conditions. Hansen (2016) reviewed the use of CTA of the abdominal aorta, stating that it has become the preferred method for planning repair, monitoring complications, and follow-up of abdominal aortic aneurysms.⁹

- Enhanced overall patient satisfaction and healthcare experience. Patients may tolerate computed tomography scanning better than magnetic resonance imaging, due to the shorter amount of time involved for the study and lower risk for claustrophobia.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography angiography or venography (CTA/CTV) of the abdomen/pelvis (CPT 74191, 74174)** is considered appropriate when **ANY** of the following is **TRUE**:

- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Suspected renal artery stenosis, when intervention is planned if diagnosed, including **ANY** of the following:
 - Previous imaging (e.g., ultrasound) indicates small kidney or unequal kidney sizes; **OR**
 - Renal artery Doppler ultrasound suggests renal artery stenosis; **OR**
 - Early-onset hypertension (age less than 35, diastolic greater than 110 mmHg)¹⁰; **OR**
 - Late-onset hypertension (age greater than 50)¹⁰; **OR**
 - Renal artery bruit¹⁰; **OR**
 - Malignant or accelerated hypertension¹⁰; **OR**
 - Sudden development or worsening of hypertension¹⁰; **OR**

- Deterioration of renal function in response to angiotensin-converting enzyme inhibitors¹⁰; **OR**
- Hypertension resistant to medication, and the patient must be currently taking **ALL** of the following at maximally tolerated doses¹¹;
 - ◆ Long-acting calcium channel blocker; **AND**
 - ◆ Long-acting ace inhibitor or angiotensin receptor blocker (ARB); **AND**
 - ◆ Diuretic (e.g., loop or thiazide); **OR**
- Mesenteric ischemia or ischemic enteritis/colitis when **ANY** of the following is **TRUE**:
 - High suspicion for ischemic enteritis/colitis or mesenteric/bowel infarct by another imaging study; **OR**
 - Anion-gap metabolic acidosis and/or high lactate in the setting of severe abdominal pain or abdominal pain that is out of proportion to the physical exam; **OR**
 - Known vascular risk factors or known vascular disease (e.g., age greater than 60 years, known coronary artery disease [CAD] or peripheral artery disease [PAD]) with severe abdominal pain or abdominal pain that is out of proportion to the physical exam; **OR**
 - Known vascular risk factors with post-prandial pain that affects daily life (e.g., fear of food, weight loss); **OR**
 - Symptoms or signs indicating lower GI bleeding; **OR**
- Thromboembolic disease; **OR**
- Concern for aneurysm when ultrasound is inconclusive or non-diagnostic, based on documented clinical or imaging findings; **OR**
- Known unrepaired aortic aneurysm over 5.4 cm in size, initial evaluation, if surgical intervention is being planned¹²⁻¹³; **OR**
- Unrepaired aortic aneurysm when ultrasound and non-contrast CT are inconclusive. Follow-up evaluation is based on aneurysm size when **ANY** of the following is **TRUE**¹⁴:

- 3 to 3.9 cm, every 3 years; **OR**
 - 4 to 4.9 cm, annually; **OR**
 - 5 to 5.4 cm, every 6 months; **OR**
- Preoperative planning for thoracoabdominal aortic aneurysm (TAAA) or dissection (with or without symptoms) and **ANY** of the following is **TRUE**¹⁵:
 - CTA of the chest has been performed; **OR**
 - Endovascular repair of thoracoabdominal aortic aneurysm (TAAA); **OR**
 - Open repair of thoracoabdominal aortic aneurysm (TAAA); **OR**
 - Follow-up after **ANY** of the following:
 - ◆ Endovascular repair of thoracoabdominal aortic aneurysm (TAAA); **OR**
 - ◆ Known thoracoabdominal aortic aneurysm (TAAA) or dissection without repair; **OR**
 - ◆ Open repair of thoracoabdominal aortic aneurysm (TAAA); **OR**
- Vascular invasion or displacement by tumor or other process; **OR**
- Assessment of patients with spontaneous coronary artery dissection (SCAD), one-time; **OR**
- Trauma, with concern for solid organ or vascular injury¹¹⁶⁻¹⁷; **OR**
- Vasculitis, initial evaluation, when **ANY** of the following is **TRUE**^{116,18-20}:
 - Biopsy proven; **OR**
 - Rheumatologic panel work-up including but not limited to erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) is suggestive of vasculitis; **OR**
 - The outcome of the imaging is expected to change management and/or treatment plan; **OR**
- Evaluation of hepatic arteries, when ultrasound is inconclusive, nondiagnostic, or abnormal requiring confirmation; **OR**
- Evaluation of other visceral arteries, including, but not limited to, suspected superior mesenteric artery (SMA)

syndrome and median arcuate ligament syndrome (MAL)²¹⁻²²; **OR**

- Evaluation of the portal venous system (hepatic portal system) after Doppler ultrasound has been performed; **OR**
 - Diffuse unexplained lower extremity edema with negative or inconclusive ultrasound; **OR**
 - Suspected venous compression syndrome (e.g., Nutcracker syndrome [renal vein compression], May-Thurner syndrome [iliac vein compression syndrome including pelvic CT venography])²³⁻²⁴; **OR**
 - Large vein thrombosis of the major abdominal or pelvic veins, including inferior vena cava (IVC), iliac, renal, portal, and hepatic veins, when Doppler ultrasound is inconclusive or indicates the presence or complications; **OR**
 - Detailed evaluation for pelvic congestion syndrome; **OR**
 - Other, unspecified vascular findings that were inconclusive on prior imaging; **OR**
- ◆ Preoperative, postoperative, or pre-treatment evaluation for **ANY** of the following:
- Evaluation post-endovascular repair (EVAR) or open repair of abdominal aortic aneurysm (AAA) and **ANY** of the following is **TRUE**¹⁴:
 - Follow-up within one month; **OR**
 - Follow-up within one year; **OR**
 - Type II endoleak, every six months for up to two years after diagnosis; **OR**
 - Type II endoleak, annual followup; **OR**
 - Planning for vascular surgery, interventional procedure; **OR**
 - Other procedures involving arteries (e.g., inferior epigastric arteries for breast reconstruction, ureteropelvic junction [UPJ] obstruction, solid organ transplant, prostate embolization); **OR**
 - Renal transplant rejection/dysfunction, when ultrasound and nuclear medicine (e.g., MAG3, DTPA) scans are inconclusive or are indicative of a vascular cause of rejection or dysfunction²⁵; **OR**
 - Anastomotic integrity or stent patency; **OR**

- Other vascular graft complication (e.g., suspected infection, pseudoaneurysm, or thrombosis)¹⁶; **OR**
- ◆ Gastrointestinal bleeding including **ANY** of the following¹⁴:
 - Lower gastrointestinal tract bleeding with **ANY** of the following²⁶:
 - Active bleeding is clinically observed as hematochezia or melena in a hemodynamically stable patient, where colonoscopy is contraindicated or unavailable; **OR**
 - Active bleeding in a hemodynamically unstable patient or a patient who has required more than 5 units of blood within 24 hours; **OR**
 - Concern for ongoing or recurrent bleeding after treatment (e.g., colonoscopy or transcatheter angiography); **OR**
 - Upper gastrointestinal bleeding (non-variceal) with **ANY** of the following²⁷:
 - High suspicion of an arterial source endoscopy is contraindicated (e.g., post-surgical or traumatic cause), or inconclusive; **OR**
 - Source of bleeding is not identified on endoscopy; **OR**
- ◆ Known or suspected syndromes with increased risk of vascular anomalies including **ANY**, but not limited to, the following:
 - As a one-time screening for syndromes with a vascular component (e.g., fibromuscular dysplasia, Ehlers–Danlos syndrome, Marfan syndrome, neurofibromatosis, William’s syndrome, tuberous sclerosis); **OR**
 - Loeys Dietz (every two years for screening; surveillance as indicated depending on abnormalities found)^{28–29}; **OR**
 - Other syndromes not otherwise specified, follow-up as clinical documentation supports; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**

- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Computed tomography angiogram and/or venography (CTA/CTV) of the abdomen/pelvis with runoff (CPT 74175, 75635)** is considered appropriate when **ANY** of the following is **TRUE**:

◆ Lower extremity ischemic symptoms when **ALL** of the following are **TRUE**:

- **ANY** of the following:
 - Leg pain worsens with activity and relief with rest (claudication); **OR**
 - Non-healing lower extremity ulcers; **AND**
- **ALL** of the following:
 - Limitation of performance of daily activities; **AND**
 - Expected mobility after treatment warrants revascularization; **AND**
 - Revascularization is planned³⁰; **AND**
 - Abnormal ABI as evidenced by **ANY** of the following:
 - ◆ ABI is inconclusive or nondiagnostic; **OR**
 - ◆ ABI less than 0.9 or greater than 1.4 on at least one leg; **OR**
 - ◆ ABI less than 1.1 in patients with risk factors for atherosclerosis (e.g., personal history of diabetes or known cardiac disease)³¹; **OR**
- ◆ Critical limb ischemia strongly suspected (sudden onset of a cold leg with pain, gangrene, rest pain)³²; **OR**
- ◆ Evidence of severe venous reflux disease, including venous leg ulcer, when pelvic or abdominal etiology is suspected; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**

- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography angiogram and/or venography (CTA/CTV) of the abdomen/pelvis with contrast** is not considered appropriate if **ANY** of the following is **TRUE**³³:

- ◆ The request is for CT/CTA with contrast, and the patient has a history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{4,34}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the

patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{4,34}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{4,34}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{4,34}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72191	Computed tomographic angiography (CTA), pelvis; with contrast material(s) including non-contrast images, if performed, and image postprocessing
74174	Computed tomographic angiography (CTA), abdomen and pelvis; with contrast material(s), including non-contrast images, if performed, and image postprocessing
74175	Computed tomographic angiography (CTA), abdomen; with contrast material(s), including non-contrast images, if performed, and image postprocessing
75635	Computed tomographic angiography (CTA),

	abdominal aorta, and bilateral iliofemoral lower extremity runoff; with contrast material(s), including non-contrast images, if performed, and image postprocessing

Medical Evidence

Allam et al. (2024) review multiple imaging modalities in vasculitis. Advantages of computed tomography angiography (CTA) include its high availability and rapid execution, along with excellent spatial and temporal resolution. Additionally, coronary CTA can be performed simultaneously if there is a suspicion of coronary artery disease (CAD). A prospective study by Lariviere et al. (2016) demonstrates that CTA can identify late complications such as stenosis, dissection, or aneurysms. In another prospective study, CTA showed a sensitivity of 73% and a specificity of 78% for diagnosing giant cell arteritis compared to clinical diagnosis.^{8,35}

Fernando et al. (2022) conducted a meta-analysis to assess the effectiveness of various diagnostic methods, including presenting symptoms, physical examination findings, CTA, and point-of-care ultrasound (PoCUS) in accurately identifying ruptured abdominal aortic aneurysm (rAAA). A total of 2077 patients from 20 studies were included. While classic clinical symptoms related to rAAA may lack sensitivity, their absence does not always exclude the diagnosis. CTA exhibits reasonable accuracy but may still fail to detect some instances of rAAA. PoCUS may be a valuable resource when determining the transfer of suspected rAAA patients to a vascular center.²⁴

Rotzinger et al. (2020) prospectively compared three image acquisition techniques in lower extremity CT angiography. Of the 60 consecutive patients enrolled, each was randomly assigned to one of three groups: the standard anterograde technique (SA), the adaptive anterograde technique (AA), and the retrograde acquisition technique (RA). Quantitative image quality was evaluated by measuring intraluminal attenuation at 536 different levels. Additionally, occlusive or aneurysmal disease was documented for each patient and limb. The RA technique demonstrated lower attenuation compared to the SA and AA techniques. The highest and most consistent attenuation was found with the AA technique. Qualitative analysis revealed that AA had the lowest rate of non-diagnostic vascular segments, followed by SA and RA. Venous contamination was significantly higher with RA, particularly at the aortic level. The presence of stenosis or occlusion did not significantly affect attenuation values across all techniques, whereas aneurysmal disease significantly impacted luminal attenuation in AA.

(increased attenuation) and RA (decreased attenuation) at the iliac and femoral levels.^{[36](#)}

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Cohere Medicare Advantage Policy – Computed Tomography Angiography (CTA), Chest

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Medical Necessity Criteria

Service: Computed Tomography Angiography (CTA), Chest

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for CTA of the chest

Recommended Clinical Approach

The referring clinician is responsible for indicating the appropriate clinical indication (e.g., Wells criteria for intermediate and high probability for pulmonary embolism) for computed tomography angiogram (CTA), CTA of the aorta, and computed tomography venography (CTV). The patient's pertinent history should justify the exam and select phase(s) of post-contrast imaging. The radiologist should protocol the examination before the patient arrives at the CT scanner.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of CTA of the chest. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.^{[23,30-32](#)}
- Relative Speed: Although generally regarded as a fast method to comprehensively evaluate the chest, the relative speed of CTA is far slower than similar, lower-intensity, less-invasive modalities such as chest radiographs.^{[25,26](#)}
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.^{[28](#)} Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.^{[28](#)}
- Increased healthcare costs and complications from the inappropriate use of additional interventions.^{[29](#)}

The clinical benefits of using these criteria include:

- Accuracy: CTA of the chest is highly accurate and thorough as an imaging modality, which is especially critical in clinical scenarios that carry a high risk of morbidity and mortality, such as acute aortic disease and chest trauma.^{[25,26](#)}
- Cost-Effective: Additionally, CTA as a first- or second-line imaging strategy appears to be a cost-saving measure over other more invasive testing and may also confer a downstream cost savings due to the avoidance of unnecessary, more costly imaging in the workup of stable chest pain, such as ICA (invasive coronary angiography).^{[26](#)}

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography angiography (CTA), chest** is considered appropriate if **ANY** of the following is **TRUE**¹⁻²:

- ◆ Trauma to the chest and cardiovascular injury is suspected³; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Aneurysm, known or suspected by prior imaging (ascending, arch, or other thoracic) for initial diagnosis
 - Aortic disease (non-traumatic) for initial diagnosis based on prior imaging or risk factors, surgical planning, or assessing treatment response or complications with **ANY** of the following^{4,6-7}:
 - Congenital conditions (e.g., vascular anomaly); **OR**
 - Aortic rupture; **OR**
 - Dissection; **OR**
 - Mediastinal hematoma; **OR**
 - Intramural hematoma; **OR**
 - Penetrating atherosclerotic ulcer; **OR**
 - Pseudoaneurysm; **OR**
 - Infectious vasculitis (e.g., syphilis, mycotic aneurysm); **OR**
 - Inflammatory vasculitis; **OR**
 - Large-vessel vasculitis (e.g., Takayasu arteritis, giant cell arteritis, systemic lupus erythematosus)⁵; **OR**
 - Medium-vessel vasculitis (e.g., vasculitis affecting main visceral arteries)⁵; **OR**
 - Neoplasm; **OR**
 - Suspected arterial embolism that impacts **ANY** of the following⁸:
 - Upper or lower extremity; **OR**
 - Mesenteric system; **OR**
 - Renal arterial system; **OR**

- Pulmonary arteriovenous malformation (PAVM), suspected, based on prior imaging or risk factors; **OR**
- Pulmonary embolism (PE), known or suspected, as indicated by **ANY** of the following^{7,9-11}:
 - Evaluation of PE in a pregnant patient; **OR**
 - High-risk with a validated Wells score greater than 6 (D-dimer is not needed); **OR**
 - PE likely based on modified Wells criteria (greater than 4 points); **OR**
 - PE suspected, based on modified Wells criteria (less than or equal to 4 points), with a positive D-dimer; **OR**
- Pulmonary hypertension; **OR**
- Chronic thromboembolic pulmonary hypertension; **OR**
- Subclavian steal syndrome based on history, examination, or Doppler ultrasound¹²; **OR**
- Subclavian artery stenosis¹²; **OR**
- Systemic venous thrombosis or occlusion (includes superior vena cava [SVC] syndrome) based on clinical features or prior imaging; **OR**
- Thoracic outlet syndrome based on clinical features or prior imaging; **OR**
- ◆ For evaluation of hemoptysis when chest radiograph or chest CT is inconclusive or requires further evaluation; **OR**
- ◆ Follow-up evaluation of known thoracic aortic aneurysm (TAA) in a patient without syndromic and non-syndromic hereditary thoracic aneurysm disease and **ANY** of the following:
 - Annual surveillance for aneurysm less than 5.0 cm; **OR**
 - Symptoms suggestive of aneurysmal growth/dissection⁶; **OR**
 - 6-month evaluation for aneurysm for **ANY** of the following:
 - Greater than or equal to 5.0 cm; **OR**
 - Growing more than 0.5 cm/year; **OR**
- ◆ Follow-up evaluation of known TAA in a patient with syndromic and non-syndromic hereditary thoracic aneurysm disease defined as **ANY** of the following:
 - Vascular Ehlers-Danlos syndrome; **OR**
 - Loeys-Dietz syndrome; **OR**
 - Marfan syndrome; **OR**

- Coarctation of the aorta; **OR**
 - Tetralogy of Fallot, transposition of the great vessels, truncus arteriosus; **OR**
 - Turner syndrome; **OR**
 - Familial bicuspid aortic valve; **OR**
 - Known predisposition as defined by the presence of genetic markers; **AND**
 - Surveillance CTA at baseline, then follow up at 6–12 months, then every 6–24 months if stable^{13–14}; **OR**
 - Symptoms suggestive of aneurysmal growth/dissection^{6–7}; **OR**
- ◆ Ongoing monitoring for possible TAA in patients at high-risk of but no prior documented TAA with **ANY** of the following:
- Loeys–Dietz syndrome monitoring annually if the patient is stable and low risk (less than 0.3 cm aneurysm growth/year) and less than 4.0 cm; **OR**
 - Turner syndrome every 5 to 10 years; **OR**
 - Bicuspid aortic valve every 2 years if TTE/TEE inconclusive; **OR**
 - Marfan syndrome every 2 years; **OR**
- ◆ Initial screening CTA for relatives of a patient with thoracic aortic disease with **ANY** of the following:
- First-degree relative (parent, sibling, or child) and **ANY** of the following:
 - Family history of Marfan syndrome, Loeys–Dietz syndrome, or vascular Ehlers–Danlos; **OR**
 - Family history of TAA due to **ANY** of the following:
 - ◆ ACTA2, MYH11, PRKG1, MYLK; **OR**
 - ◆ TAA without identified pathogenic variants in a known gene for HTAD; **OR**
 - ◆ TAA and bicuspid aortic valve; **OR**
 - ◆ Family history of intracranial or peripheral aneurysm; **OR**
 - ◆ Turner syndrome; **OR**
 - ◆ Coarctation of the aorta; **OR**
 - ◆ Congenital heart defects such as tetralogy of Fallot, transposition of the great vessels, truncus arteriosus; **OR**

- ◆ Transcatheter aortic valve replacement (TAVR) pre-intervention planning with an assessment of **ANY** of the following¹⁷:
 - Aortic root and supra-avalvular aorta; **OR**
 - Vascular access; **OR**
- ◆ Pulmonary vein mapping (e.g., prior to atrial fibrillation ablation); **OR**
- ◆ Thoracic endovascular aneurysm repair (TEVAR) for the treatment of thoracic aortic disease and **ANY** of the following is **TRUE**¹⁸⁻²⁰:
 - Pre-repair; **OR**
 - Post-repair; **OR**
- ◆ Post-treatment of acute aortic dissection at **ANY** of the following intervals:
 - 1 month; **OR**
 - 6 months; **OR**
 - Annually; **OR**
- ◆ Chronic dissection, annually; **OR**
- ◆ Re-evaluation of known ascending aortic dilation or history of aortic dissection with a change in clinical status (including cardiac exam or other findings that may alter management); **OR**
- ◆ Non-invasive clinical staging of a tumor to define vascular invasion; **OR**
- ◆ Congenital or acquired conditions as indicated by **ANY** of the following²¹:
 - Pulmonary sequestration; **OR**
 - Heart disease with **ANY** of the following:
 - Known single ventricle physiology and postoperative evaluation needed after stage 3 single ventricle palliation (total cavopulmonary connection); **OR**
 - Known or suspected anomalous pulmonary venous return; **OR**
 - Repaired tetralogy of Fallot or pulmonary valve stenosis with concern for pulmonary valve dysfunction or branch pulmonary artery stenosis; **OR**
 - Suspected aortic coarctation; **OR**
 - Transposition of the great arteries after arterial switch; **OR**

- Transposition of the great arteries after atrial switch;
OR
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Computed tomography angiography (CTA), chest with contrast** is not considered if **ANY** of the following is **TRUE**²²:
 - ◆ History of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for

pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.²³⁻²⁴

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.²³⁻²⁴

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.²³⁻²⁴

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.²³⁻²⁴

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
71275	Computed tomographic angiography (CTA), chest; with contrast material(s), including non-contrast images, if performed, and image postprocessing

Medical Evidence

Ko et al. (2021) review the utilization of chest CT angiography (CTA) to diagnose acute aortic syndromes. To ensure optimal quality of images, the authors address technical parameters of chest CTA, including non-contrast

imaging, timing of contrast-enhanced imaging, volume and type of contrast material used, kilovolt potential, tube-current modulation, and decisions regarding electrocardiographic-gating and ultra-fast imaging. Acute aortic syndromes, especially those involving the ascending aorta, carry high morbidity and mortality rates and encompass conditions such as classic aortic dissection, penetrating atherosclerotic ulcer, and acute intramural hematoma. Recognition of related entities like ulcerated plaque, ulcer-like projections, intramural blood pools, and mimics such as vasculitis and aortic thrombus is crucial to avoid interpretive errors.^{[25](#)}

Carrabba et al. (2019) present the results of a clinical trial that evaluated the efficacy of CTA for diagnosing coronary artery disease (CAD) in patients with new-onset chest pain. The 208 patients included had an unknown CAD diagnosis. Approximately half of the participants received standard testing care and CTA as a secondary investigation (group A), while the other half underwent CTA as their initial investigation (group B). Patients with obstructive CAD (O-CAD) demonstrated greater than 50% stenosis in the principal branch. According to the CTA results, the rates of CAD in group A compared to group B were as follows ($P=0.001$): 31.1% versus 27.4% for normal or minimal CAD; 42.5% versus 63.7% for no O-CAD; and 26.4% versus 8.8% for O-CAD.^{[26](#)}

Baliyan et al. (2018) report on acute aortic syndromes in an emergency setting. CTA is the preferred imaging modality as it can be performed quickly and identify variations in anatomy including coarctation. Incidental findings are often identified (89%) when performing chest CTA. An alternative is MRA when CTA cannot be performed due to allergy to renal dysfunction or iodinated contrast.^{[27](#)}

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Clinical Guideline Revision History/Information

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Review History		



Cohere Medicare Advantage Policy – Computed Tomography Angiography (CTA), Chest

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 12, 2024

Important Notices

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Medical Necessity Criteria

Service: Computed Tomography Angiography (CTA), Chest

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for CTA of the chest

Recommended Clinical Approach

The referring clinician is responsible for indicating the appropriate clinical indication (e.g., Wells criteria for intermediate and high probability for pulmonary embolism) for computed tomography angiogram (CTA), CTA of the aorta, and computed tomography venography (CTV). The patient's pertinent history should justify the exam and select phase(s) of post-contrast imaging. The radiologist should protocol the examination before the patient arrives at the CT scanner.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of CTA of the chest. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.^{[23,30-32](#)}
- Relative Speed: Although generally regarded as a fast method to comprehensively evaluate the chest, the relative speed of CTA is far slower than similar, lower-intensity, less-invasive modalities such as chest radiographs.^{[25,26](#)}
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.^{[28](#)} Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.^{[28](#)}
- Increased healthcare costs and complications from the inappropriate use of additional interventions.^{[29](#)}

The clinical benefits of using these criteria include:

- Accuracy: CTA of the chest is highly accurate and thorough as an imaging modality, which is especially critical in clinical scenarios that carry a high risk of morbidity and mortality, such as acute aortic disease and chest trauma.^{[25,26](#)}
- Cost-Effective: Additionally, CTA as a first- or second-line imaging strategy appears to be a cost-saving measure over other more invasive testing and may also confer a downstream cost savings due to the avoidance of unnecessary, more costly imaging in the workup of stable chest pain, such as ICA (invasive coronary angiography).^{[26](#)}

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography angiography (CTA), chest** is considered appropriate if **ANY** of the following is **TRUE**¹⁻²:

- ◆ Trauma to the chest and cardiovascular injury is suspected³; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Aneurysm, known or suspected by prior imaging (ascending, arch, or other thoracic) for initial diagnosis
 - Aortic disease (non-traumatic) for initial diagnosis based on prior imaging or risk factors, surgical planning, or assessing treatment response or complications with **ANY** of the following^{4,6-7}:
 - Congenital conditions (e.g., vascular anomaly); **OR**
 - Aortic rupture; **OR**
 - Dissection; **OR**
 - Mediastinal hematoma; **OR**
 - Intramural hematoma; **OR**
 - Penetrating atherosclerotic ulcer; **OR**
 - Pseudoaneurysm; **OR**
 - Infectious vasculitis (e.g., syphilis, mycotic aneurysm); **OR**
 - Inflammatory vasculitis; **OR**
 - Large-vessel vasculitis (e.g., Takayasu arteritis, giant cell arteritis, systemic lupus erythematosus)⁵; **OR**
 - Medium-vessel vasculitis (e.g., vasculitis affecting main visceral arteries)⁵; **OR**
 - Neoplasm; **OR**
 - Suspected arterial embolism that impacts **ANY** of the following⁸:
 - Upper or lower extremity; **OR**
 - Mesenteric system; **OR**
 - Renal arterial system; **OR**

- Pulmonary arteriovenous malformation (PAVM), suspected, based on prior imaging or risk factors; **OR**
- Pulmonary embolism (PE), known or suspected, as indicated by **ANY** of the following^{7,9-11}:
 - Evaluation of PE in a pregnant patient; **OR**
 - High-risk with a validated Wells score greater than 6 (D-dimer is not needed); **OR**
 - PE likely based on modified Wells criteria (greater than 4 points); **OR**
 - PE suspected, based on modified Wells criteria (less than or equal to 4 points), with a positive D-dimer; **OR**
- Pulmonary hypertension; **OR**
- Chronic thromboembolic pulmonary hypertension; **OR**
- Subclavian steal syndrome based on history, examination, or Doppler ultrasound¹²; **OR**
- Subclavian artery stenosis¹²; **OR**
- Systemic venous thrombosis or occlusion (includes superior vena cava [SVC] syndrome) based on clinical features or prior imaging; **OR**
- Thoracic outlet syndrome based on clinical features or prior imaging; **OR**
- ◆ For evaluation of hemoptysis when chest radiograph or chest CT is inconclusive or requires further evaluation; **OR**
- ◆ Follow-up evaluation of known thoracic aortic aneurysm (TAA) in a patient without syndromic and non-syndromic hereditary thoracic aneurysm disease and **ANY** of the following:
 - Annual surveillance for aneurysm less than 5.0 cm; **OR**
 - Symptoms suggestive of aneurysmal growth/dissection⁶; **OR**
 - 6-month evaluation for aneurysm for **ANY** of the following:
 - Greater than or equal to 5.0 cm; **OR**
 - Growing more than 0.5 cm/year; **OR**
- ◆ Follow-up evaluation of known TAA in a patient with syndromic and non-syndromic hereditary thoracic aneurysm disease defined as **ANY** of the following:
 - Vascular Ehlers-Danlos syndrome; **OR**
 - Loeys-Dietz syndrome; **OR**
 - Marfan syndrome; **OR**

- Coarctation of the aorta; **OR**
 - Tetralogy of Fallot, transposition of the great vessels, truncus arteriosus; **OR**
 - Turner syndrome; **OR**
 - Familial bicuspid aortic valve; **OR**
 - Known predisposition as defined by the presence of genetic markers; **AND**
 - Surveillance CTA at baseline, then follow up at 6–12 months, then every 6–24 months if stable¹³⁻¹⁴; **OR**
 - Symptoms suggestive of aneurysmal growth/dissection⁶⁻⁷; **OR**
- ◆ Ongoing monitoring for possible TAA in patients at high-risk of but no prior documented TAA with **ANY** of the following:
- Loeys–Dietz syndrome monitoring annually if the patient is stable and low risk (less than 0.3 cm aneurysm growth/year) and less than 4.0 cm; **OR**
 - Turner syndrome every 5 to 10 years; **OR**
 - Bicuspid aortic valve every 2 years if TTE/TEE inconclusive; **OR**
 - Marfan syndrome every 2 years; **OR**
- ◆ Initial screening CTA for relatives of a patient with thoracic aortic disease with **ANY** of the following:
- First-degree relative (parent, sibling, or child) and **ANY** of the following:
 - Family history of Marfan syndrome, Loeys–Dietz syndrome, or vascular Ehlers–Danlos; **OR**
 - Family history of TAA due to **ANY** of the following:
 - ◆ ACTA2, MYH11, PRKG1, MYLK; **OR**
 - ◆ TAA without identified pathogenic variants in a known gene for HTAD; **OR**
 - ◆ TAA and bicuspid aortic valve; **OR**
 - ◆ Family history of intracranial or peripheral aneurysm; **OR**
 - ◆ Turner syndrome; **OR**
 - ◆ Coarctation of the aorta; **OR**
 - ◆ Congenital heart defects such as tetralogy of Fallot, transposition of the great vessels, truncus arteriosus; **OR**

- ◆ Transcatheter aortic valve replacement (TAVR) pre-intervention planning with an assessment of **ANY** of the following¹⁷:
 - Aortic root and supra-avalvular aorta; **OR**
 - Vascular access; **OR**
- ◆ Pulmonary vein mapping (e.g., prior to atrial fibrillation ablation); **OR**
- ◆ Thoracic endovascular aneurysm repair (TEVAR) for the treatment of thoracic aortic disease and **ANY** of the following is **TRUE**¹⁸⁻²⁰:
 - Pre-repair; **OR**
 - Post-repair; **OR**
- ◆ Post-treatment of acute aortic dissection at **ANY** of the following intervals:
 - 1 month; **OR**
 - 6 months; **OR**
 - Annually; **OR**
- ◆ Chronic dissection, annually; **OR**
- ◆ Re-evaluation of known ascending aortic dilation or history of aortic dissection with a change in clinical status (including cardiac exam or other findings that may alter management); **OR**
- ◆ Non-invasive clinical staging of a tumor to define vascular invasion; **OR**
- ◆ Congenital or acquired conditions as indicated by **ANY** of the following²¹:
 - Pulmonary sequestration; **OR**
 - Heart disease with **ANY** of the following:
 - Known single ventricle physiology and postoperative evaluation needed after stage 3 single ventricle palliation (total cavopulmonary connection); **OR**
 - Known or suspected anomalous pulmonary venous return; **OR**
 - Repaired tetralogy of Fallot or pulmonary valve stenosis with concern for pulmonary valve dysfunction or branch pulmonary artery stenosis; **OR**
 - Suspected aortic coarctation; **OR**
 - Transposition of the great arteries after arterial switch; **OR**

- Transposition of the great arteries after atrial switch;
OR
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Computed tomography angiography (CTA), chest with contrast** is not considered if **ANY** of the following is **TRUE**²²:
 - ◆ History of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for

pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.²³⁻²⁴

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.²³⁻²⁴

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.²³⁻²⁴

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.²³⁻²⁴

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
71275	Computed tomographic angiography (CTA), chest; with contrast material(s), including non-contrast images, if performed, and image postprocessing

Medical Evidence

Ko et al. (2021) review the utilization of chest CT angiography (CTA) to diagnose acute aortic syndromes. To ensure optimal quality of images, the authors address technical parameters of chest CTA, including non-contrast

imaging, timing of contrast-enhanced imaging, volume and type of contrast material used, kilovolt potential, tube-current modulation, and decisions regarding electrocardiographic-gating and ultra-fast imaging. Acute aortic syndromes, especially those involving the ascending aorta, carry high morbidity and mortality rates and encompass conditions such as classic aortic dissection, penetrating atherosclerotic ulcer, and acute intramural hematoma. Recognition of related entities like ulcerated plaque, ulcer-like projections, intramural blood pools, and mimics such as vasculitis and aortic thrombus is crucial to avoid interpretive errors.^{[25](#)}

Carrabba et al. (2019) present the results of a clinical trial that evaluated the efficacy of CTA for diagnosing coronary artery disease (CAD) in patients with new-onset chest pain. The 208 patients included had an unknown CAD diagnosis. Approximately half of the participants received standard testing care and CTA as a secondary investigation (group A), while the other half underwent CTA as their initial investigation (group B). Patients with obstructive CAD (O-CAD) demonstrated greater than 50% stenosis in the principal branch. According to the CTA results, the rates of CAD in group A compared to group B were as follows ($P=0.001$): 31.1% versus 27.4% for normal or minimal CAD; 42.5% versus 63.7% for no O-CAD; and 26.4% versus 8.8% for O-CAD.^{[26](#)}

Baliyan et al. (2018) report on acute aortic syndromes in an emergency setting. CTA is the preferred imaging modality as it can be performed quickly and identify variations in anatomy including coarctation. Incidental findings are often identified (89%) when performing chest CTA. An alternative is MRA when CTA cannot be performed due to allergy to renal dysfunction or iodinated contrast.^{[27](#)}

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Cohere Medicare Advantage Policy – Computed Tomography Angiography (CTA), Head

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Medical Necessity Criteria

Service: Computed Tomography Angiography (CTA), Head

Benefit Category

Not applicable.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for CTA Head.

Recommended Clinical Approach

Computed tomography angiography (CTA) and CT venography (CTV) of the head help detect and characterize vascular disease and anatomy relevant to treating extravascular disorders. CTA may be used as the primary modality for detecting disease, as an adjunctive tool for characterizing a known disease, or to assess changes over time.¹ Magnetic resonance angiography (MRA) or magnetic resonance venography (MRV) is the preferred imaging study due to the lack of ionizing radiation.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of CTA of the head. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.²⁻⁵
- Potential danger to pregnancy: CT imaging completed during

pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.⁶ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁶

- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁷

The clinical benefits of using these criteria include:

- Accuracy: CTA of the head is effective in diagnosing acute ischemic stroke. A study assessing acute stroke imaging found that CTA compared to non-contrast CT, increased the diagnosis of acute ischemic stroke.⁸
- Patient outcomes: CTA has a low risk of allergic reaction and contrast-induced neuropathy; adverse patient outcomes are minor.⁹
- Early diagnosis: Improved resolution of CTA may lead to early diagnosis of vascular abnormalities.¹⁰
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography angiography (CTA), head** is indicated if **ANY** of the following is **TRUE**:

- ◆ Neoplastic conditions including surgical and radiation therapy localization, planning, and neuronavigation to delineate the

vascular anatomy (e.g., tumor is in the vicinity or encases a major artery or occludes major vein)¹; **OR**

- ◆ Trauma-related conditions as indicated by **ANY** of the following:
 - Head trauma with suspected intracranial arterial injury due to clinical risk factors or positive findings on prior imaging¹¹; **OR**
 - Blunt cerebrovascular injury (BCVI) is suspected based on the mechanism and location of trauma (CT neck is also indicated with CT head)¹²; **OR**
 - Traumatic vascular injuries¹; **OR**
 - Suspected carotid or vertebral artery dissection secondary to trauma; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Aneurysm with **ANY** of the following¹³⁻¹⁸:
 - Screening for cerebral artery aneurysm when **ANY** of the following is **TRUE**¹⁹⁻²⁷:
 - ◆ Autosomal dominant polycystic kidney disease (adults); **OR**
 - ◆ The patient has two or more first-degree relatives (parent, brother, sister, or child) with a history of intracranial aneurysm; **OR**
 - ◆ The patient is symptomatic with one first-degree relative who has a history of intracranial aneurysm^{13-15,28}; **OR**
 - ◆ Fibromuscular dysplasia; **OR**
 - ◆ Loeys-Dietz syndrome; **OR**
 - ◆ Spontaneous coronary arteries dissection (SCAD); **OR**
 - ◆ Known aortic coarctation (after age 10); **OR**
 - **ANY** of the following:
 - ◆ Diagnosis of intracranial hemorrhage; **OR**
 - ◆ Diagnosis of subarachnoid hemorrhage; **OR**
 - ◆ Intracerebral hemorrhage, known or suspected²⁹; **OR**
 - ◆ The patient has a history of subarachnoid hemorrhages¹⁴; **OR**
 - Cervical bruit or thrill with suspicion of neck carotid stenosis; **OR**

- Headache with **ANY** of the following:
 - Acute onset worst/thunderclap headache³⁰; **OR**
 - New onset or pattern during pregnancy or peripartum period; **OR**
 - Associated with exercise, exertion, Valsalva, or sexual activity; **OR**
- Intracranial arterial dissection, suspected; **OR**
- Intracranial occlusive disease (arterial or venous), suspected³¹; **OR**
- Intracranial hypertension (idiopathic), suspected; **OR**
- Pseudoaneurysm¹; **OR**
- Recent stroke, up to 6 months (remote history is not an indication unless recent TIA episodes)¹; **OR**
- Cranial neuropathy as indicated by **ANY** of the following and prior imaging is suspicious for a vascular pathology (e.g., aneurysm, arteriovenous fistulas [AVF])^{1,16-17}:
 - Lower cranial nerve palsies, weakness or paralysis (CN IX-XII) (i.e., glossopharyngeal neuralgia); **OR**
 - Unilateral isolated weakness or paralysis of the tongue (hypoglossal nerve, CN XII); **OR**
 - Refractory trigeminal neuralgia when done for surgical planning; **OR**
 - Isolated third nerve palsy (oculomotor) with pupil involvement to evaluate for aneurysm; **OR**
 - Any combination or isolated involvement of cranial nerves where prior imaging is suspicious for vascular pathology; **OR**
- Acute or recent unexplained intracranial hemorrhage¹; **OR**
- Atherosclerotic stenosis or occlusive disease, including suspected vasospasm or thromboembolism with **ANY** of the following¹:
 - Patient has documented symptoms suggestive of stroke or TIA; **OR**
 - Based on prior imaging; **OR**
- Vasculopathy that is non-atherosclerotic, non-inflammatory (e.g., radiation vasculopathy) and suspected on prior imaging (e.g., CT, MRI)¹; **OR**
- The patient has **ANY** of the following:
 - Abnormal neurologic signs; **OR**

- Fever; **OR**
 - Visual disturbance; **OR**
 - Vertigo; **OR**
 - Weight loss; **OR**
- Vascular malformation and fistula based on prior imaging¹; **OR**
- Cerebrovascular disease in a patient age 18 or older including **ANY** of the following¹⁸:
 - Acute subarachnoid hemorrhage (SAH), suspected or known on CT; **OR**
 - Central nervous system (CNS) vasculitis, suspected; **OR**
 - Cerebral aneurysm (treated or untreated), known; **OR**
 - Cerebral vasospasm, suspected; **OR**
 - High-flow vascular malformation (AVM/AVF), known; **OR**
 - Aneurysmal SAH in a younger patient who is at-risk of de novo aneurysm formation; **OR**
 - The patient has **ANY** of the following:
 - ◆ Moyamoya disease; **OR**
 - ◆ Bicuspid aortic valve; **OR**
 - ◆ Aortic aneurysm; **OR**
 - ◆ Coarctation of the aorta; **OR**
- Cerebrovascular disease in a patient age 17 or younger and **ANY** of the following is **TRUE**³⁰:
 - Acute stroke is suspected with **ANY** of the following:
 - ◆ Non-sickle-cell related with new focal fixed or worsening neurologic deficit lasting less than 24 hours from last seen normal state and there are no contraindications to emergent intervention; **OR**
 - ◆ Known or suspected arteriopathy or moyamoya¹⁷⁻¹⁸; **OR**
 - ◆ Known or suspected central nervous system vasculitis; **OR**
 - ◆ Known or suspected low- or high-flow vascular anomaly; **OR**
 - ◆ The patient is not a candidate for emergent intervention; **OR**

- Acute subarachnoid hemorrhage (SAH), suspected or known on CT; **OR**
- Spontaneous cervicocranial arterial dissection based on clinical or imaging findings. (CTA head and neck ordered together); **OR**
- Nontraumatic intracranial hemorrhage (hematoma) of unknown etiology found on CT or MRI and additional imaging study is needed; **OR**
- Nontraumatic SAH detected by non-contrast CT; **OR**
- Vertebrobasilar insufficiency (VBI) as indicated by **ANY** of the following^{29,31}:
 - Abnormal neurologic examination is consistent with central vertigo; **OR**
 - Associated with other brainstem neurologic deficits; **OR**
 - HINTS (Head Impulse–Nystagmus–Test of Skew) examination is consistent with central vertigo; **OR**
 - Neurological symptoms (central vertigo); **OR**
- ◆ For evaluation of **ANY** of the following miscellaneous pathologies when prior testing has failed:
 - Headache with an unrevealing MRI and **ANY** of the following is **TRUE**:
 - Persistent in nature; **OR**
 - Undifferentiated; **OR**
 - Unexplained; **OR**
 - Pulsatile tinnitus (unilateral or bilateral) as evidenced by **ANY** of the following^{1,32–33}:
 - Localized to one ear (prior testing not required); **OR**
 - Focal neurological abnormalities (consider MRI brain internal auditory canal [IAC] protocol first); **OR**
 - Asymmetric hearing loss (consider MRI brain internal auditory canal [IAC] protocol first); **OR**
 - Visual impairment including **ANY** of the following³²:
 - Isolated third nerve palsy (oculomotor) with pupil involvement to evaluate for aneurysm; **OR**
 - Suspected venous thrombosis (e.g., dural sinus thrombosis) when MRV is contraindicated or cannot be performed; **OR**
- ◆ Preoperative assessment of vascular anatomy or pathology; **OR**

- ◆ Post-treatment follow-up to monitor treatment result and surveillance of vascular condition; **OR**
- ◆ Congenital conditions or anomalies including vascular abnormality associated with chronic anemic conditions (e.g., sickle cell disease) (MRA head is preferred in pediatric patients)³⁵⁻³⁶; **OR**

→ **Computed tomography venography (CTV), head** is indicated if **ANY** of the following is **TRUE**:

- ◆ Ultrasound and CT venography (CTV) are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to IV contrast reaction, pregnancy, pediatric); **OR**
- ◆ **ANY** of the following is **TRUE**:
 - Vascular conditions, known or suspected, including **ANY** of the following:
 - Venous/dural sinus abnormalities such as **ANY** of the following:
 - ◆ Acquired thrombosis/occlusion; **OR**
 - ◆ Venous sinus stenosis; **OR**
 - Large vein injury secondary to trauma; **OR**
 - Vascular invasion or displacement by tumor; **OR**
 - Headache with **ANY** of the following:
 - New onset or pattern during pregnancy or peripartum period; **OR**
 - Headache with features of intracranial hypertension (e.g., papilledema, pulsatile tinnitus, visual symptoms worse on Valsalva)³⁰; **OR**
 - Initial diagnostic, one-time pre or one-time post-treatment evaluation for treatment planning or evidence of clinical concern for vascular malformation.

→ **Repeat imaging** (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- ◆ New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- ◆ One-time clarifying follow-up of a prior indeterminate finding; **OR**

- ◆ In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography angiography (CTA) or computed tomography venography (CTV), head**, is not considered appropriate if **ANY** of the following is **TRUE**³⁷:

- ◆ If contrast is used, history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{4,38}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{4,38}

Cumulative Dose Monitoring: Implement systems to track cumulative

radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{4,38}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{4,38}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70496	Computed tomographic angiography (CTA), head; with contrast material(s), including non-contrast images, if performed, and image postprocessing

Medical Evidence

Tu et al. (2022) conducted a retrospective review on the utilization of head and neck computed tomography angiography (CTA) in the emergency department (ED). Head and neck CTA in the ED has shown a disproportionate increase compared to other neuroimaging examinations. The study contrasted utilization and the frequency of communicating non-routine results across different patient chief concerns. The study identified the top 50 primary concerns leading to the most CTA examinations. A total of 17903 CTAs for 833 distinct chief concerns were included, which accounts for 2.5% of 708,145 ED visits. The rates of ordering and communication of non-standard results exhibit significant variability across different chief concerns. Approximately half of the non-standard communications made by radiologists pertain to acute indications. Understanding the trends in ordering head and neck CTA and communicating non-standard results can aid in refining patient selection and enhancing radiologist interactions in the ED.³⁹

Schenk et al. (2021) report on a retrospective review of stroke in young adults. The use of CTA head and neck diagnostic yield for anterior circulation ischemic stroke evaluation is discussed. The review included adults aged 18–50 who presented to the Mayo Clinic Rochester ED. Carotid dissection is a predominant cause of anterior circulation ischemic stroke, as evidenced by findings on CTA. Studies found that carotid webs were infrequent in the patients studied, while carotid atherosclerosis was relatively rare – the presence of carotid webs, understanding their potential to trigger recurrent strokes. The authors did not cite a significant disparity in the prevalence of carotid atherosclerosis between the symptomatic and asymptomatic sides. Clinicians can recognize high-risk morphological attributes of carotid plaque observed on CT angiography, even in cases with no discernible stenosis.⁴⁰

Heit et al. (2016) conducted an 11-year single-center retrospective review to analyze the yield of digital subtraction angiography (DSA) in patients with subarachnoid hemorrhage. DSA reveals vascular abnormalities in 13% of patients who initially test negative for subarachnoid hemorrhage (SAH) on CTA. Upon subsequent DSA, aneurysms or pseudoaneurysms are found in 4% of cases. Utilization of DSA may be appropriate for all patients with SAH-negative CT scans. To aid the clinician, the type of SAH pattern observed with DSA may offer clues to the underlying cause of the hemorrhage.⁴¹

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Clinical Guideline Revision History/Information

Original Date: September 19, 2024		
Review History		



Cohere Medicare Advantage Policy – Computed Tomography Angiography (CTA), Lower Extremity

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 19, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography Angiography (CTA), Lower Extremity

Date of last literature review: 9/16/2024

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Computed Tomography Angiography (CTA), Lower Extremity

Benefit Category

None applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for CTA of the lower extremity.

Recommended Clinical Approach

Lower extremity computed tomography angiography (CTA) is indicated for peripheral artery disease (PAD), trauma, assessment of vascular anatomy and congenital malformations, vasculitis, and surgical planning.¹ After the intravenous injection of an iodinated contrast medium, CTA employs a thin-section CT scan timed to capture peak arterial and/or venous enhancement, depending on the targeted vascular structures. The resulting volumetric data set is analyzed using primary transverse reconstructions along with multiplanar reformations and 3-D renderings.¹

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of CTA of the lower extremity. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Nondiagnostic: Up to 8% of post-trauma extremity CTA is ultimately felt to be nondiagnostic.⁵
- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.^{13,18,19,21}
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.²⁰ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.²⁰
- Increased healthcare costs and complications from the inappropriate use of additional interventions.²²

The clinical benefits of using these criteria include:

- Less invasive: CTA of the lower extremity is comparatively less invasive than other similar, more invasive modalities, including the previous gold standard of DSA.¹⁷ Less invasive imaging is generally associated with a better safety profile and improved patient satisfaction.¹⁷
- Versatility: CTA of the lower extremity is a multipurpose, versatile modality which plays a role in the detection of a variety of conditions with similar symptomatology, including congenital vascular anomalies, trauma, peripheral artery disease and other ischemic disease, as well as a range of nonischemic etiologies.¹⁷ Further, it serves both surgical planning purpose and complete characterization of peripheral artery disease and can be employed in surgical planning in other contexts, such as plastic surgery procedures which require detailed preoperative assessment of the lower vasculature for flap or vascular harvest.¹⁷
- Improved trauma triage: Importantly, CTA of the lower extremity represents a rapid method to identify those trauma patients which require emergent operative intervention rather than conservative management.¹⁷
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are

employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **Computed tomography angiography (CTA), lower extremity** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment response, or prognostication); **OR**
 - ◆ Neoplastic invasion of arteries or veins; **OR**
 - ◆ Trauma-related conditions as indicated by **ANY** of the following²:
 - Expanding hematoma³; **OR**
 - Major blunt trauma and the patient is hemodynamically stable⁴; **OR**
 - Neurologic deficit of lower extremity in association with trauma⁵; **OR**
 - Known or suspected knee dislocation*⁶; **OR**
 - Vascular trauma to a lower extremity⁷; **OR**
 - ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Aneurysm, seen on ultrasound or where ultrasound is nondiagnostic; **OR**
 - Intramural hematoma; **OR**
 - Dissection; **OR**
 - Critical limb ischemia strongly suspected (e.g. sudden onset of a cold leg with pain, gangrene, rest pain)⁸; **OR**
 - Lower extremity ischemic symptoms when **ALL** of the following are **TRUE**:
 - **ANY** of the following:

- ◆ Leg pain worsens with activity and is relieved with rest (claudication); **OR**
- ◆ Non-healing lower extremity ulcers; **AND**
- **ALL** of the following:
 - ◆ Limitation of performance of daily activities; **AND**
 - ◆ Expected mobility after treatment warrants revascularization; **AND**
 - ◆ Revascularization is planned⁹; **AND**
 - ◆ Abnormal ABI as evidenced by **ANY** of the following:
 - ABI is inconclusive or nondiagnostic; **OR**
 - ABI less than 0.9 or greater than 1.4 on at least one leg; **OR**
 - ABI less than 1.1 in patients with risk factors for atherosclerosis (e.g., personal history of diabetes or known cardiac disease)¹⁰; **AND**
 - ◆ Either low concern for aortic and iliac artery disease or aorta and iliac arteries previously imaged; **OR**
- Determination of hemorrhage source (including non-surgical, spontaneous)³; **OR**
- Localization and characterization of vascular malformation or fistula (e.g., assessing treatment response, treatment planning) with **ANY** of the following:
 - Duplex ultrasound indeterminate or nondiagnostic; **OR**
 - High flow lesion suspected clinically or by imaging; **OR**
 - Preoperative planning; **OR**
- Vasculitis, initial evaluation, when **ANY** of the following is **TRUE**⁷:
 - Biopsy proven; **OR**
 - Rheumatologic panel work-up including but not limited to erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) is suggestive of vasculitis; **OR**

- The requesting clinician specializes in rheumatology and the outcome of the imaging is expected to change management and/or treatment plan; **OR**
 - Popliteal entrapment syndrome, when ultrasound and MRI/MRA are indeterminate or contraindicated²; **OR**
- ◆ Pre and post-intervention evaluation when **ANY** of the following is **TRUE**:
 - Postoperative evaluation of the effectiveness of arterial or venous reconstruction or bypass; **OR**
 - Characterization of normal and variant vascular anatomy; **OR**
 - Determination of the patency, location, or integrity of grafts and other vascular devices (e.g., stents); **OR**
 - Planning autografts for musculoskeletal reconstruction; **OR**
 - Treatment of popliteal entrapment syndrome; **OR**
- ◆ Hemodialysis access evaluation, when duplex ultrasound is inconclusive and fistulogram cannot be performed, for **ANY** of the following conditions:
 - Arteriovenous fistula (AVF) stenosis; **OR**
 - Occlusion; **OR**
 - Pseudoaneurysm; **OR**
 - Steal syndrome (cool and painful extremity); **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Computed tomography venography (CTV), lower extremity** is considered appropriate for **ANY** of the following is **TRUE**:

- ◆ Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment-response, or prognostication); **OR**
- ◆ Neoplastic invasion of arteries or veins; **OR**
- ◆ Evaluation for known venous leg ulcer after ultrasound has been completed; **OR**
- ◆ Known or suspected acute or chronic deep venous thrombosis, when results would change management and ultrasound has been completed¹¹; **OR**
- ◆ Known severe post-thrombotic changes incompletely evaluated by ultrasound¹¹; **OR**
- ◆ Evidence of severe venous reflux disease and **ALL** of the following¹¹:
 - Duplex ultrasound evaluation indeterminate, incomplete, or non-diagnostic; **AND**
 - Surgical or endovascular intervention planned; **OR**
- ◆ Pre and post-intervention evaluation when **ANY** of the following is **TRUE**:
 - Postoperative evaluation of the effectiveness of arterial or venous reconstruction or bypass; **OR**
 - Characterization of normal and variant vascular anatomy; **OR**
 - Determination of the patency, location, or integrity of grafts and other vascular devices (e.g. stents); **OR**
 - Planning autografts for musculoskeletal reconstruction; **OR**
 - Treatment of popliteal entrapment syndrome; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography angiography (CTA)/computed tomography venography (CTA/CTV), lower extremity with contrast** is not considered appropriate if **ANY** of the following is **TRUE**¹²:

- ◆ The request is for CT/CTA with contrast, and the patient has a history of anaphylactic allergic reaction to iodinated contrast media; **OR**
- ◆ Evaluation of lower extremity arterial perfusion, such as for claudication, when there may be a concern for aorta or iliac disease and aorta and iliac have not been imaged.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.¹³⁻¹⁴

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.¹³⁻¹⁴

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.¹³⁻¹⁴

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.¹³⁻¹⁴

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
73706	Computed tomographic angiography (CTA), lower extremity; with contrast material(s), including non-contrast images, if performed, and image postprocessing

Medical Evidence

Jayaraj et al. (2024) evaluate using CT venography (CTV) to diagnose chronic iliac venous obstruction. Advantages of CTV include acquisition and postprocessing functionalities, including multiplanar reconstruction assessment and image processing techniques (e.g., volume rendering and maximum intensity projection). These serve to ascertain and categorize the features of the lesion. CTV also enables the detection of extravascular structures potentially implicated in compression and obstruction. The identification of congenital anatomical variances was present in 20% of patients with these conditions.¹⁵

Kakkos et al. (2021) discuss the efficacy of CTV as a reliable diagnostic tool for proximal DVT in patients suspected of DVT and pulmonary embolism (PE), exhibiting sensitivity and specificity akin to ultrasound. CTV presents clear advantages over ultrasound in assessing pelvic veins and the inferior vena cava (IVC) while also identifying concurrent medical conditions manifesting as pain and swelling. The superior spatial resolution of CTV facilitates precise vessel measurements and treatment planning when intervention is warranted. Limitations of CTV include the necessity of iodine contrast administration and exposure to radiation – a concern, especially in younger patients.¹⁶

Cook et al. (2016) review CTA of the lower extremities for conditions including peripheral artery disease (PAD), trauma, evaluation of variant anatomy and congenital malformations, vasculitis, and pre-surgical planning. CTA is a crucial and adaptable noninvasive technique with various diagnostic and procedural applications. While it is commonly employed for patients with PAD or lower extremity trauma, the utility of CTA extends to investigating non-ischemic conditions and congenital vascular abnormalities. Tailoring CT scanner protocols to specific clinical inquiries, including adjusting bolus timing and employing multiphasic imaging, is essential. Additionally, the utilization of three-dimensional postprocessing techniques is vital for enhancing visualization and interpretation of the detailed imaging data obtained from these examinations.¹⁷

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Clinical Guideline Revision History/Information

Original Date: September 19, 2024		
Review History		



Cohere Medicare Advantage Policy – Computed Tomography Angiography (CTA), Lower Extremity

Clinical Guidelines for Medical Necessity Review

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Effective Date: September 19, 2024

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography Angiography (CTA), Lower Extremity

Date of last literature review: 9/16/2024

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Computed Tomography Angiography (CTA), Lower Extremity

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Lower extremity computed tomography angiography (CTA) is indicated for peripheral artery disease (PAD), trauma, assessment of vascular anatomy and congenital malformations, vasculitis, and surgical planning.¹ After the intravenous injection of an iodinated contrast medium, CTA employs a thin-section CT scan timed to capture peak arterial and/or venous enhancement, depending on the targeted vascular structures. The resulting volumetric data set is analyzed using primary transverse reconstructions along with multiplanar reformations and 3-D renderings.¹

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of CTA of the lower extremity. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Nondiagnostic: Up to 8% of post-trauma extremity CTA is ultimately felt to be nondiagnostic.⁵
- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.^{13,18,19,21}
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.²⁰ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.²⁰
- Increased healthcare costs and complications from the inappropriate use of additional interventions.²²

The clinical benefits of using these criteria include:

- Less invasive: CTA of the lower extremity is comparatively less invasive than other similar, more invasive modalities, including the previous gold standard of DSA.¹⁷ Less invasive imaging is generally associated with a better safety profile and improved patient satisfaction.¹⁷
- Versatility: CTA of the lower extremity is a multipurpose, versatile modality which plays a role in the detection of a variety of conditions with similar symptomatology, including congenital vascular anomalies, trauma, peripheral artery disease and other ischemic disease, as well as a range of nonischemic etiologies.¹⁷ Further, it serves both surgical planning purpose and complete characterization of peripheral artery disease and can be employed in surgical planning in other contexts, such as plastic surgery procedures which require detailed preoperative assessment of the lower vasculature for flap or vascular harvest.¹⁷
- Improved trauma triage: Importantly, CTA of the lower extremity represents a rapid method to identify those trauma patients which require emergent operative intervention rather than conservative management.¹⁷
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are

employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **Computed tomography angiography (CTA), lower extremity** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment response, or prognostication); **OR**
 - ◆ Neoplastic invasion of arteries or veins; **OR**
 - ◆ Trauma-related conditions as indicated by **ANY** of the following²:
 - Expanding hematoma³; **OR**
 - Major blunt trauma and the patient is hemodynamically stable⁴; **OR**
 - Neurologic deficit of lower extremity in association with trauma⁵; **OR**
 - Known or suspected knee dislocation*⁶; **OR**
 - Vascular trauma to a lower extremity⁷; **OR**
 - ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Aneurysm, seen on ultrasound or where ultrasound is nondiagnostic; **OR**
 - Intramural hematoma; **OR**
 - Dissection; **OR**
 - Critical limb ischemia strongly suspected (e.g. sudden onset of a cold leg with pain, gangrene, rest pain)⁸; **OR**
 - Lower extremity ischemic symptoms when **ALL** of the following are **TRUE**:
 - **ANY** of the following:

- ◆ Leg pain worsens with activity and is relieved with rest (claudication); **OR**
- ◆ Non-healing lower extremity ulcers; **AND**
- **ALL** of the following:
 - ◆ Limitation of performance of daily activities; **AND**
 - ◆ Expected mobility after treatment warrants revascularization; **AND**
 - ◆ Revascularization is planned⁹; **AND**
 - ◆ Abnormal ABI as evidenced by **ANY** of the following:
 - ABI is inconclusive or nondiagnostic; **OR**
 - ABI less than 0.9 or greater than 1.4 on at least one leg; **OR**
 - ABI less than 1.1 in patients with risk factors for atherosclerosis (e.g., personal history of diabetes or known cardiac disease)¹⁰; **AND**
 - ◆ Either low concern for aortic and iliac artery disease or aorta and iliac arteries previously imaged; **OR**
- Determination of hemorrhage source (including non-surgical, spontaneous)³; **OR**
- Localization and characterization of vascular malformation or fistula (e.g., assessing treatment response, treatment planning) with **ANY** of the following:
 - Duplex ultrasound indeterminate or nondiagnostic; **OR**
 - High flow lesion suspected clinically or by imaging; **OR**
 - Preoperative planning; **OR**
- Vasculitis, initial evaluation, when **ANY** of the following is **TRUE**⁷:
 - Biopsy proven; **OR**
 - Rheumatologic panel work-up including but not limited to erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) is suggestive of vasculitis; **OR**

- The requesting clinician specializes in rheumatology and the outcome of the imaging is expected to change management and/or treatment plan; **OR**
 - Popliteal entrapment syndrome, when ultrasound and MRI/MRA are indeterminate or contraindicated²; **OR**
- ◆ Pre and post-intervention evaluation when **ANY** of the following is **TRUE**:
 - Postoperative evaluation of the effectiveness of arterial or venous reconstruction or bypass; **OR**
 - Characterization of normal and variant vascular anatomy; **OR**
 - Determination of the patency, location, or integrity of grafts and other vascular devices (e.g., stents); **OR**
 - Planning autografts for musculoskeletal reconstruction; **OR**
 - Treatment of popliteal entrapment syndrome; **OR**
- ◆ Hemodialysis access evaluation, when duplex ultrasound is inconclusive and fistulogram cannot be performed, for **ANY** of the following conditions:
 - Arteriovenous fistula (AVF) stenosis; **OR**
 - Occlusion; **OR**
 - Pseudoaneurysm; **OR**
 - Steal syndrome (cool and painful extremity); **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Computed tomography venography (CTV), lower extremity** is considered appropriate for **ANY** of the following is **TRUE**:

- ◆ Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment-response, or prognostication); **OR**
- ◆ Neoplastic invasion of arteries or veins; **OR**
- ◆ Evaluation for known venous leg ulcer after ultrasound has been completed; **OR**
- ◆ Known or suspected acute or chronic deep venous thrombosis, when results would change management and ultrasound has been completed¹¹; **OR**
- ◆ Known severe post-thrombotic changes incompletely evaluated by ultrasound¹¹; **OR**
- ◆ Evidence of severe venous reflux disease and **ALL** of the following¹¹:
 - Duplex ultrasound evaluation indeterminate, incomplete, or non-diagnostic; **AND**
 - Surgical or endovascular intervention planned; **OR**
- ◆ Pre and post-intervention evaluation when **ANY** of the following is **TRUE**:
 - Postoperative evaluation of the effectiveness of arterial or venous reconstruction or bypass; **OR**
 - Characterization of normal and variant vascular anatomy; **OR**
 - Determination of the patency, location, or integrity of grafts and other vascular devices (e.g. stents); **OR**
 - Planning autografts for musculoskeletal reconstruction; **OR**
 - Treatment of popliteal entrapment syndrome; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography angiography (CTA)/computed tomography venography (CTA/CTV), lower extremity with contrast** is not considered appropriate if **ANY** of the following is **TRUE**¹²:

- ◆ The request is for CT/CTA with contrast, and the patient has a history of anaphylactic allergic reaction to iodinated contrast media; **OR**
- ◆ Evaluation of lower extremity arterial perfusion, such as for claudication, when there may be a concern for aorta or iliac disease and aorta and iliac have not been imaged.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.¹³⁻¹⁴

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.¹³⁻¹⁴

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.¹³⁻¹⁴

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.¹³⁻¹⁴

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
73706	Computed tomographic angiography (CTA), lower extremity; with contrast material(s), including non-contrast images, if performed, and image postprocessing

Medical Evidence

Jayaraj et al. (2024) evaluate using CT venography (CTV) to diagnose chronic iliac venous obstruction. Advantages of CTV include acquisition and postprocessing functionalities, including multiplanar reconstruction assessment and image processing techniques (e.g., volume rendering and maximum intensity projection). These serve to ascertain and categorize the features of the lesion. CTV also enables the detection of extravascular structures potentially implicated in compression and obstruction. The identification of congenital anatomical variances was present in 20% of patients with these conditions.¹⁵

Kakkos et al. (2021) discuss the efficacy of CTV as a reliable diagnostic tool for proximal DVT in patients suspected of DVT and pulmonary embolism (PE), exhibiting sensitivity and specificity akin to ultrasound. CTV presents clear advantages over ultrasound in assessing pelvic veins and the inferior vena cava (IVC) while also identifying concurrent medical conditions manifesting as pain and swelling. The superior spatial resolution of CTV facilitates precise vessel measurements and treatment planning when intervention is warranted. Limitations of CTV include the necessity of iodine contrast administration and exposure to radiation – a concern, especially in younger patients.¹⁶

Cook et al. (2016) review CTA of the lower extremities for conditions including peripheral artery disease (PAD), trauma, evaluation of variant anatomy and congenital malformations, vasculitis, and pre-surgical planning. CTA is a crucial and adaptable noninvasive technique with various diagnostic and procedural applications. While it is commonly employed for patients with PAD or lower extremity trauma, the utility of CTA extends to investigating non-ischemic conditions and congenital vascular abnormalities. Tailoring CT scanner protocols to specific clinical inquiries, including adjusting bolus timing and employing multiphasic imaging, is essential. Additionally, the utilization of three-dimensional postprocessing techniques is vital for enhancing visualization and interpretation of the detailed imaging data obtained from these examinations.¹⁷

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Clinical Guideline Revision History/Information

Original Date: September 19, 2024		
Review History		



Cohere Medicare Advantage Policy – Computed Tomography Angiography (CTA), Neck

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 19, 2024

Important Notices

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GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy Computed Tomography Angiography (CTA), Neck

Date of last literature review: 9/6/2024

Document last updated: 9/18/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Computed Tomography Angiography (CTA), Neck

Benefit Category

Not applicable.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for CTA Neck.

Recommended Clinical Approach

Cervicocerebral computed tomography angiography (CTA) is a clinically established and valuable procedure for identifying and characterizing vascular diseases, as well as for evaluating vascular anatomy relevant to the management of extravascular disorders. Typically, CTA focuses on evaluating the heart, arteries, or veins and necessitates a thin-section CT scan combined with intravenous injection of iodinated contrast medium. Incorporating three-dimensional rendering and multiplanar reformations are integral components of CTA examinations.¹

CTA can serve as the primary imaging modality for disease detection or as a supplementary tool for characterizing known conditions or monitoring changes over time. Preferentially, magnetic resonance angiography (MRA) should be considered as an alternative to CTA to minimize radiation exposure, particularly in pediatric and vulnerable patient populations. CTA involves exposure to ionizing radiation and should be performed solely for medically necessary reasons and with the lowest radiation dose necessary to achieve diagnostically adequate image quality.¹

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of CTA of the neck. This process helps to

prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.²⁻⁵
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.⁶ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁶
- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁷

The clinical benefits of using these criteria include:

- Accuracy: A retrospective review of 4923 patients with blunt trauma demonstrated that performing CTA of the neck with CT or CTA of the spine identified more injuries compared to spine imaging alone.⁸ CTA is also effective in diagnosing acute ischemic stroke compared to non-contrast CT.⁹
- Rapid evaluation: CTA offers fast evaluation of the vasculature of the head and neck when there is concern of acute onset of neurologic symptoms (including stroke) and blunt trauma.¹⁰
- Non-invasive: CTA provides excellent detail to identify and classify a lesion.¹⁰
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography angiography (CTA), neck** is considered appropriate for **ANY** of the following:

- ◆ Detection, screening, surveillance, and follow-up of vascular neck mass (e.g., paraganglioma, pulsatile neck mass [not parotid region or thyroid])¹¹; **OR**
- ◆ Tumor of vascular origin, with rich vascular supply or involving vascular structures¹²⁻¹³; **OR**
- ◆ Trauma-related conditions as indicated by **ANY** of the following:
 - Trauma of the head with a suspected intracranial arterial injury based on clinical findings or prior imaging¹⁴; **OR**
 - Traumatic and non-traumatic orbital pathology with clinical or imaging findings that indicate vascular involvement¹⁵; **OR**
 - Traumatic injury to cervicocerebral vessels, suspected¹⁶; **OR**
 - Trauma-related spine injuries (cervical and upper thoracic)¹⁷; **OR**
 - Blunt cerebrovascular injury (BCVI) is suspected based on the mechanism and location of trauma (CTA head is also indicated with CTA neck)¹⁷; **OR**
 - Suspected carotid or vertebral artery dissection secondary to trauma or spontaneous due to weakness of vessel wall (CTA head is also indicated with CTA neck); **OR**
 - Traumatic vascular injury^{12,18-20}; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Arterial aneurysm; **OR**
 - Pseudoaneurysm²¹⁻²²; **OR**
 - Atherosclerotic stenosis or occlusive disease (e.g., atherosclerotic plaque localization and characterization)¹; **OR**
 - Cerebrovascular disease, including **ANY** of the following²²:

- Acute ischemic stroke with focal neurologic deficit; **OR**
- Carotid stenosis, asymptomatic; **OR**
- Cervical bruit, asymptomatic; **OR**
- Cervical vascular dissection or injury, known or suspected; **OR**
- Recent ischemic infarct; **OR**
- Collagen vascular disease; **OR**
- Hemorrhage (acute) including **ANY** of the following:
 - Cervical spine²³⁻²⁴; **OR**
 - Head and neck; **OR**
- Ischemic stroke^{12,18-20}; **OR**
- Non-atherosclerotic, non-inflammatory vasculopathy (e.g., radiation vasculopathy); **OR**
- Pulsatile tinnitus for the evaluation of vascular etiology²⁵⁻²⁶; **OR**
- Subclavian artery stenosis; **OR**
- Thromboembolism^{12,18-20}; **OR**
- Transient ischemic attack (TIA)^{12,18-20}; **OR**
- Vasculitis; **OR**
- Vasospasm^{12,18-20}; **OR**
- Vascular anatomic variant²⁷; **OR**
- Vascular fistula; **OR**
- Vascular malformation²⁸; **OR**
- Venous varix; **OR**
- ◆ For evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when applicable:
 - Cranial neuropathy as indicated by **ANY** of the following²⁹:
 - Combined lower cranial nerve syndromes (CN IX–XII); **OR**
 - Multiple different lower cranial nerve palsies; **OR**
 - Unilateral isolated weakness or paralysis of the tongue (hypoglossal nerve, CN XII); **OR**
 - Penetrating neck injury³⁰; **OR**
 - Chronic recurrent vertigo associated with other brainstem neurologic deficits³¹; **OR**
- ◆ Preoperative, postoperative, or pre-treatment evaluation for **ANY** of the following¹:
 - Surgical and radiation therapy localization, planning, and neuronavigation³²⁻³³; **OR**

- Vascular compression or vertebrobasilar insufficiency³⁴; **OR**
- Vascular intervention and follow-up (percutaneous and surgical)^{32,35-36}; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Computed tomography angiography (CTA), neck** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ If contrast is used, history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

***NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for

pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{4,37}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{4,37}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{4,37}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{4,37}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70498	Computed tomographic angiography (CTA), of neck; with contrast material(s), including non-contrast images, if performed, and image post-processing

Medical Evidence

Tu et al. (2022) conducted a retrospective review on the utilization of head and neck computed tomography angiography (CTA) in the emergency department (ED). Head and neck CTA in the ED has shown a disproportionate increase compared to other neuroimaging examinations. The study contrasted utilization and the frequency of communicating non-routine results across different patient chief concerns. The study identified the top 50 primary concerns that led to the most CTA examinations. A total of 17903 CTAs for 833 distinct chief concerns were included, which accounts for 2.5% of 708,145 ED visits. The rates of ordering and communication of non-standard results exhibit significant variability across different chief concerns. Approximately half of the non-standard communications made by radiologists pertain to acute indications. Understanding the trends in ordering head and neck CTA and the communication of non-standard results can aid in refining patient selection and enhancing radiologist interactions in the ED setting.³⁸

Paladino et al. (2021) performed a systematic review to determine the efficacy of CTA Neck in determining vascular or aerodigestive injuries (ADI). CTA covering the entire neck region is now an integral component of the standard diagnostic approach for patients with penetrating neck trauma (PNT) who do not necessitate immediate surgical intervention for ADI. While many studies have highlighted the usefulness of CTA to rule out arterial injuries, consensus is lacking regarding the capability of CTA Neck to detect ADI.³⁹

Schenk et al. (2021) report on a retrospective review of stroke in young adults and the use of CTA Head and Neck diagnostic yield for anterior circulation ischemic stroke evaluation. The review included adults aged 18–50 who presented to the Mayo Clinic Rochester ED. Carotid dissection is a predominant cause of anterior circulation ischemic stroke, as evidenced by findings on CTA. Carotid webs were found to be infrequent in the patients studied, while carotid atherosclerosis was relatively rare. The presence of carotid webs, understanding their potential to trigger recurrent strokes. No significant disparity in the prevalence of carotid atherosclerosis between the symptomatic and asymptomatic sides was identified. Additionally, clinicians can recognize high-risk morphological attributes of carotid plaque observed on CT angiography, even in cases with no discernible stenosis.⁴⁰

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Clinical Guideline Revision History/Information

Original Date: September 19, 2024		
Review History		



Cohere Medicare Advantage Policy – Computed Tomography Angiography (CTA), Neck

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 19, 2024

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy Computed Tomography Angiography (CTA), Neck

Date of last literature review: 9/6/2024

Document last updated: 9/18/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Computed Tomography Angiography (CTA), Neck

Benefit Category

Not applicable.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for CTA Neck.

Recommended Clinical Approach

Cervicocerebral computed tomography angiography (CTA) is a clinically established and valuable procedure for identifying and characterizing vascular diseases, as well as for evaluating vascular anatomy relevant to the management of extravascular disorders. Typically, CTA focuses on evaluating the heart, arteries, or veins and necessitates a thin-section CT scan combined with intravenous injection of iodinated contrast medium. Incorporating three-dimensional rendering and multiplanar reformations are integral components of CTA examinations.¹

CTA can serve as the primary imaging modality for disease detection or as a supplementary tool for characterizing known conditions or monitoring changes over time. Preferentially, magnetic resonance angiography (MRA) should be considered as an alternative to CTA to minimize radiation exposure, particularly in pediatric and vulnerable patient populations. CTA involves exposure to ionizing radiation and should be performed solely for medically necessary reasons and with the lowest radiation dose necessary to achieve diagnostically adequate image quality.¹

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of CTA of the neck. This process helps to

prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.²⁻⁵
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.⁶ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁶
- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁷

The clinical benefits of using these criteria include:

- Accuracy: A retrospective review of 4923 patients with blunt trauma demonstrated that performing CTA of the neck with CT or CTA of the spine identified more injuries compared to spine imaging alone.⁸ CTA is also effective in diagnosing acute ischemic stroke compared to non-contrast CT.⁹
- Rapid evaluation: CTA offers fast evaluation of the vasculature of the head and neck when there is concern of acute onset of neurologic symptoms (including stroke) and blunt trauma.¹⁰
- Non-invasive: CTA provides excellent detail to identify and classify a lesion.¹⁰
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography angiography (CTA), neck** is considered appropriate for **ANY** of the following:

- ◆ Detection, screening, surveillance, and follow-up of vascular neck mass (e.g., paraganglioma, pulsatile neck mass [not parotid region or thyroid])¹¹; **OR**
- ◆ Tumor of vascular origin, with rich vascular supply or involving vascular structures¹²⁻¹³; **OR**
- ◆ Trauma-related conditions as indicated by **ANY** of the following:
 - Trauma of the head with a suspected intracranial arterial injury based on clinical findings or prior imaging¹⁴; **OR**
 - Traumatic and non-traumatic orbital pathology with clinical or imaging findings that indicate vascular involvement¹⁵; **OR**
 - Traumatic injury to cervicocerebral vessels, suspected¹⁶; **OR**
 - Trauma-related spine injuries (cervical and upper thoracic)¹⁷; **OR**
 - Blunt cerebrovascular injury (BCVI) is suspected based on the mechanism and location of trauma (CTA head is also indicated with CTA neck)¹⁷; **OR**
 - Suspected carotid or vertebral artery dissection secondary to trauma or spontaneous due to weakness of vessel wall (CTA head is also indicated with CTA neck); **OR**
 - Traumatic vascular injury^{12,18-20}; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Arterial aneurysm; **OR**
 - Pseudoaneurysm²¹⁻²²; **OR**
 - Atherosclerotic stenosis or occlusive disease (e.g., atherosclerotic plaque localization and characterization)¹; **OR**
 - Cerebrovascular disease, including **ANY** of the following²²:

- Acute ischemic stroke with focal neurologic deficit; **OR**
- Carotid stenosis, asymptomatic; **OR**
- Cervical bruit, asymptomatic; **OR**
- Cervical vascular dissection or injury, known or suspected; **OR**
- Recent ischemic infarct; **OR**
- Collagen vascular disease; **OR**
- Hemorrhage (acute) including **ANY** of the following:
 - Cervical spine²³⁻²⁴; **OR**
 - Head and neck; **OR**
- Ischemic stroke^{12,18-20}; **OR**
- Non-atherosclerotic, non-inflammatory vasculopathy (e.g., radiation vasculopathy); **OR**
- Pulsatile tinnitus for the evaluation of vascular etiology²⁵⁻²⁶; **OR**
- Subclavian artery stenosis; **OR**
- Thromboembolism^{12,18-20}; **OR**
- Transient ischemic attack (TIA)^{12,18-20}; **OR**
- Vasculitis; **OR**
- Vasospasm^{12,18-20}; **OR**
- Vascular anatomic variant²⁷; **OR**
- Vascular fistula; **OR**
- Vascular malformation²⁸; **OR**
- Venous varix; **OR**
- ◆ For evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when applicable:
 - Cranial neuropathy as indicated by **ANY** of the following²⁹:
 - Combined lower cranial nerve syndromes (CN IX–XII); **OR**
 - Multiple different lower cranial nerve palsies; **OR**
 - Unilateral isolated weakness or paralysis of the tongue (hypoglossal nerve, CN XII); **OR**
 - Penetrating neck injury³⁰; **OR**
 - Chronic recurrent vertigo associated with other brainstem neurologic deficits³¹; **OR**
- ◆ Preoperative, postoperative, or pre-treatment evaluation for **ANY** of the following¹:
 - Surgical and radiation therapy localization, planning, and neuronavigation³²⁻³³; **OR**

- Vascular compression or vertebrobasilar insufficiency³⁴; **OR**
- Vascular intervention and follow-up (percutaneous and surgical)^{32,35-36}; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Computed tomography angiography (CTA), neck** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ If contrast is used, history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

***NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for

pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{4,37}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{4,37}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{4,37}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{4,37}

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Cohere Medicare Advantage Policy – Computed Tomography Angiography (CTA), Upper Extremity

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Medical Necessity Criteria

Service: Computed Tomography Angiography (CTA), Upper Extremity

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for CTA

Recommended Clinical Approach

For most indications, ultrasound with Doppler is the initial screening modality except in urgent conditions, including acute trauma or an extremity that is cold or painful. Computed tomography angiography (CTA) is most beneficial for the evaluation of peripheral artery disease (PAD), trauma, assessment of variant anatomy and congenital malformations, vasculitis, and surgical planning. CTA is generally preferred over MRA in urgent situations whereas magnetic resonance angiography (MRA) should be considered in non-urgent conditions, including inflammatory or connective tissue disease.¹⁻⁴

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of CTA of upper extremity. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy,

nephrotoxicity, and contrast extravasation into surrounding tissues.^{9,13,18,19}

- Suboptimal upper extremity imaging: CTA may not adequately characterize small vessel vasculitis, such as Raynaud Syndrome¹⁴, may not sufficiently delineate between acute vasculitis versus atherosclerosis in the absence of other diagnostic systemic symptoms¹⁴, may be poor in examination of hand vasculature among patients with vasoconstriction caused by cold hands or tobacco/cannabis use prior to exam¹⁷, and may be nondiagnostic/inconclusive if artifacts are present – including those caused by retained metal objects.¹⁵
- Nondiagnostic: Up to 8% of post-trauma extremity CTA is ultimately felt to be nondiagnostic.¹⁶
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.²⁰ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.²⁰
- Increased healthcare costs and complications from the inappropriate use of additional interventions.²¹

The clinical benefits of using these criteria include:

- Expedited Diagnosis: CTA represents an accurate, fast, reproducible imaging modality which improves time to hemorrhage control and limb reperfusion.^{15,16}
- Optimal View: CTA is of particular use to visualize extravascular tissue versus other modalities, such as DSA (digital subtraction angiography).^{12,14} CTA also optimally evaluates mycotic aneurysms, as gas within an aneurysm is a characteristic/diagnostic sign that is best seen on CTA.¹⁷
- Streamlined Triage: In the setting of polytrauma and complex acute injury, CTA of the upper extremity can be performed as part of standard whole-body imaging and may improve likelihood of limb salvage among patients with competing multisystem injuries.^{15,16}

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **Computed tomography angiography (CTA), upper extremity** is considered appropriate if **ANY** of the following is **TRUE**¹⁻⁴:
- ◆ Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment response, or prognostication); **OR**
 - ◆ Neoplastic invasion of arteries or veins; **OR**
 - ◆ Trauma-related conditions as indicated by **ANY** of the following³:
 - Expanding hematoma⁴; **OR**
 - Major blunt trauma and the patient is hemodynamically stable⁵; **OR**
 - Neurologic deficit of upper extremity in association with trauma; **OR**
 - Vascular trauma to upper extremity⁶; **OR**
 - Repetitive trauma syndromes with vascular complications (e.g., crutch injury, hypothenar hammer syndrome); **OR**
 - ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Aneurysm, seen on ultrasound or where ultrasound is nondiagnostic; **OR**
 - Intramural hematoma; **OR**
 - Dissection; **OR**
 - Clinical suspicion of acute or chronic limb ischemia, when ultrasound is inconclusive or nondiagnostic, with **ANY** of the following:

- Acute absence of radial or ulnar pulses; **OR**
- Acute changes in motor or sensory function; **OR**
- Symptoms with exercise attributable to vascular etiologies such as muscle pain that resolves with rest, coldness, pallor, or fatigue; **OR**
- Determination of hemorrhage source (including non-surgical, spontaneous)⁴; **OR**
- Localization and characterization of vascular malformation or fistula (e.g., assessing treatment response, treatment planning) with **ANY** of the following:
 - Duplex ultrasound indeterminate or nondiagnostic; **OR**
 - High flow lesion suspected clinically or by imaging; **OR**
 - Pre-operative planning; **OR**
- Vasculitis, initial evaluation, when **ANY** of the following is **TRUE**⁶:
 - Biopsy proven; **OR**
 - Rheumatologic panel work-up including but not limited to erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) is suggestive of vasculitis; **OR**
 - Requesting clinician specializes in rheumatology and outcome of the imaging is expected to change management and/or treatment plan; **OR**
- Non-inflammatory vasculopathy that is symptomatic such as Raynaud's, Buerger's disease, fibromuscular dysplasia, or scleroderma; **OR**
- Arterial entrapment syndrome, when ultrasound and MRI/MRA are inconclusive or contraindicated⁷; **OR**
- Pre and post-intervention evaluation, when ultrasound is inconclusive or non-diagnostic and **ANY** of the following is **TRUE**:
 - Postoperative evaluation of the effectiveness of arterial or venous reconstruction or bypass; **OR**
 - Characterization of normal and variant vascular anatomy; **OR**
 - Determination of the patency, location, or integrity of grafts and other vascular devices (e.g., stents); **OR**

- Planning autografts for musculoskeletal reconstruction; **OR**
- Treatment of arterial entrapment syndrome; **OR**
- Non-healing upper extremity ulcers with abnormal or inconclusive ultrasound results (e.g. arterial Doppler); **OR**
- Vascular steal syndrome of the upper extremity, is suspected, and initial imaging is needed to guide therapy⁶; **OR**
- Hemodialysis access evaluation, when duplex ultrasound inconclusive and fistulogram cannot be performed, for **ANY** of the following conditions:
 - Arteriovenous fistula (AVF) stenosis; **OR**
 - Occlusion; **OR**
 - Pseudoaneurysm; **OR**
 - Steal syndrome (cool and painful extremity); **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Computed tomography venogram (CTV), upper extremity** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment-response, or prognostication); **OR**
- ◆ Neoplastic invasion of arteries or veins; **OR**
- ◆ Initial evaluation for known venous upper extremity ulcer, when ultrasound is indeterminate or nondiagnostic; **OR**
- ◆ Known or suspected acute or chronic deep venous thrombosis, when results would change management and ultrasound has been completed; **OR**

- ◆ Known severe post-thrombotic changes incompletely evaluated by ultrasound²; **OR**
- ◆ Subclavian or central venous obstruction such as subclavian vein thrombosis, Paget-Schroetter syndrome, or thoracic outlet syndrome, either known or suspected clinically (e.g. edema aggravated by exercise/arm position); **OR**
- ◆ Pre- and post-intervention evaluation when **ANY** of the following is **TRUE**:
 - Postoperative evaluation of the effectiveness of arterial or venous reconstruction or bypass; **OR**
 - Characterization of normal and variant vascular anatomy; **OR**
 - Determination of the patency, location, or integrity of grafts and other vascular devices (e.g., stents); **OR**
 - Planning autografts for musculoskeletal reconstruction; **OR**
 - Treatment of popliteal entrapment syndrome; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Computed tomography angiography (CTA), upper extremity** is not considered appropriate if **ANY** of the following is **TRUE**⁸:
- ◆ The request is for CT/CTA with contrast, and the patient has a history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the

ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.⁹⁻¹⁰

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.⁹⁻¹⁰

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.⁹⁻¹⁰

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.⁹⁻¹⁰

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
73206	Computed tomographic angiography (CTA), upper extremity; with contrast material(s), including non-contrast images, if performed, and image postprocessing

Medical Evidence

Ghouri et al. (2019) review the use of computed tomography (CT) and magnetic resonance angiography (MRA) of the upper extremity vasculature. While less frequent than lower extremity vascular abnormalities, upper extremity vascular issues require comprehensive assessment. Color Doppler is more convenient and bedside-accessible however, it suffers from operator variability and lacks central vasculature evaluation. Computed Tomography Angiography (CTA) is the primary imaging tool and allows for optimal results. Contrast enhancement is pivotal in CTA imaging, with adjustments in acquisition methods, contrast injection rates, and patient characteristics like BMI enhancing diagnostic accuracy. Advancements in CTA and MRA, including 3D reconstructions and time-resolved techniques, expand the ability to assess vascular pathologies previously reliant on conventional angiography.²

Nagpal et al. (2017) discuss the advancements in CT and magnetic resonance imaging (MRI) technology. This type of imaging allows for the assessment of upper extremity vascular conditions non-invasively. CT captures a wide field of view and the widespread availability of CT makes it valuable in emergency scenarios and for patients with contraindications to gadolinium-based contrast agents. The capability of MRI provides dynamic imaging through techniques like time-resolved MRA and its superior resolution for soft tissues positions it as the preferred choice for diagnosing vascular malformations, dynamic vascular compression disorders, and issues related to digital arteries. The technology of CT and MR ensures better anatomical and functional assessments for patients with upper extremity vascular symptoms.¹

Dave and Fleischmann (2016) provide an overview of CTA of the upper extremities. While the value of CTA in trauma situations is widely acknowledged, its extensive and diverse clinical applications in subacute settings are equally significant. These include crucial roles in presurgical anatomical mapping, such as identifying variant arterial structures, assessing connective tissue disorders, diagnosing vasculitis, managing overuse syndromes, evaluating arteriovenous fistulae/grfts, diagnosing vascular malformations, recognizing compression syndromes and investigating perivascular pathology.⁴

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Clinical Guideline Revision History/Information

Original Date: September 12, 2024		
Review History		



Cohere Medicare Advantage Policy – Computed Tomography Angiography (CTA), Upper Extremity

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 12, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography Angiography (CTA), Upper Extremity

Date of last literature review: 9/9/2024

Document last updated: 9/11/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Computed Tomography Angiography (CTA), Upper Extremity

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for CTA

Recommended Clinical Approach

For most indications, ultrasound with Doppler is the initial screening modality except in urgent conditions, including acute trauma or an extremity that is cold or painful. Computed tomography angiography (CTA) is most beneficial for the evaluation of peripheral artery disease (PAD), trauma, assessment of variant anatomy and congenital malformations, vasculitis, and surgical planning. CTA is generally preferred over MRA in urgent situations whereas magnetic resonance angiography (MRA) should be considered in non-urgent conditions, including inflammatory or connective tissue disease.¹⁻⁴

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of CTA of upper extremity. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy,

nephrotoxicity, and contrast extravasation into surrounding tissues.^{9,13,18,19}

- Suboptimal upper extremity imaging: CTA may not adequately characterize small vessel vasculitis, such as Raynaud Syndrome¹⁴, may not sufficiently delineate between acute vasculitis versus atherosclerosis in the absence of other diagnostic systemic symptoms¹⁴, may be poor in examination of hand vasculature among patients with vasoconstriction caused by cold hands or tobacco/cannabis use prior to exam¹⁷, and may be nondiagnostic/inconclusive if artifacts are present – including those caused by retained metal objects.¹⁵
- Nondiagnostic: Up to 8% of post-trauma extremity CTA is ultimately felt to be nondiagnostic.¹⁶
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.²⁰ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.²⁰
- Increased healthcare costs and complications from the inappropriate use of additional interventions.²¹

The clinical benefits of using these criteria include:

- Expedited Diagnosis: CTA represents an accurate, fast, reproducible imaging modality which improves time to hemorrhage control and limb reperfusion.^{15,16}
- Optimal View: CTA is of particular use to visualize extravascular tissue versus other modalities, such as DSA (digital subtraction angiography).^{12,14} CTA also optimally evaluates mycotic aneurysms, as gas within an aneurysm is a characteristic/diagnostic sign that is best seen on CTA.¹⁷
- Streamlined Triage: In the setting of polytrauma and complex acute injury, CTA of the upper extremity can be performed as part of standard whole-body imaging and may improve likelihood of limb salvage among patients with competing multisystem injuries.^{15,16}

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **Computed tomography angiography (CTA), upper extremity** is considered appropriate if **ANY** of the following is **TRUE**¹⁻⁴:
- ◆ Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment response, or prognostication); **OR**
 - ◆ Neoplastic invasion of arteries or veins; **OR**
 - ◆ Trauma-related conditions as indicated by **ANY** of the following³:
 - Expanding hematoma⁴; **OR**
 - Major blunt trauma and the patient is hemodynamically stable⁵; **OR**
 - Neurologic deficit of upper extremity in association with trauma; **OR**
 - Vascular trauma to upper extremity⁶; **OR**
 - Repetitive trauma syndromes with vascular complications (e.g., crutch injury, hypothenar hammer syndrome); **OR**
 - ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Aneurysm, seen on ultrasound or where ultrasound is nondiagnostic; **OR**
 - Intramural hematoma; **OR**
 - Dissection; **OR**
 - Clinical suspicion of acute or chronic limb ischemia, when ultrasound is inconclusive or nondiagnostic, with **ANY** of the following:

- Acute absence of radial or ulnar pulses; **OR**
 - Acute changes in motor or sensory function; **OR**
 - Symptoms with exercise attributable to vascular etiologies such as muscle pain that resolves with rest, coldness, pallor, or fatigue; **OR**
- Determination of hemorrhage source (including non-surgical, spontaneous)⁴; **OR**
- Localization and characterization of vascular malformation or fistula (e.g., assessing treatment response, treatment planning) with **ANY** of the following:
 - Duplex ultrasound indeterminate or nondiagnostic; **OR**
 - High flow lesion suspected clinically or by imaging; **OR**
 - Pre-operative planning; **OR**
- Vasculitis, initial evaluation, when **ANY** of the following is **TRUE**⁶:
 - Biopsy proven; **OR**
 - Rheumatologic panel work-up including but not limited to erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) is suggestive of vasculitis; **OR**
 - Requesting clinician specializes in rheumatology and outcome of the imaging is expected to change management and/or treatment plan; **OR**
- Non-inflammatory vasculopathy that is symptomatic such as Raynaud's, Buerger's disease, fibromuscular dysplasia, or scleroderma; **OR**
- Arterial entrapment syndrome, when ultrasound and MRI/MRA are inconclusive or contraindicated⁷; **OR**
- Pre and post-intervention evaluation, when ultrasound is inconclusive or non-diagnostic and **ANY** of the following is **TRUE**:
 - Postoperative evaluation of the effectiveness of arterial or venous reconstruction or bypass; **OR**
 - Characterization of normal and variant vascular anatomy; **OR**
 - Determination of the patency, location, or integrity of grafts and other vascular devices (e.g., stents); **OR**

- Planning autografts for musculoskeletal reconstruction; **OR**
- Treatment of arterial entrapment syndrome; **OR**
- Non-healing upper extremity ulcers with abnormal or inconclusive ultrasound results (e.g. arterial Doppler); **OR**
- Vascular steal syndrome of the upper extremity, is suspected, and initial imaging is needed to guide therapy⁶; **OR**
- Hemodialysis access evaluation, when duplex ultrasound inconclusive and fistulogram cannot be performed, for **ANY** of the following conditions:
 - Arteriovenous fistula (AVF) stenosis; **OR**
 - Occlusion; **OR**
 - Pseudoaneurysm; **OR**
 - Steal syndrome (cool and painful extremity); **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Computed tomography venogram (CTV), upper extremity** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment-response, or prognostication); **OR**
- ◆ Neoplastic invasion of arteries or veins; **OR**
- ◆ Initial evaluation for known venous upper extremity ulcer, when ultrasound is indeterminate or nondiagnostic; **OR**
- ◆ Known or suspected acute or chronic deep venous thrombosis, when results would change management and ultrasound has been completed; **OR**

- ◆ Known severe post-thrombotic changes incompletely evaluated by ultrasound²; **OR**
- ◆ Subclavian or central venous obstruction such as subclavian vein thrombosis, Paget-Schroetter syndrome, or thoracic outlet syndrome, either known or suspected clinically (e.g. edema aggravated by exercise/arm position); **OR**
- ◆ Pre- and post-intervention evaluation when **ANY** of the following is **TRUE**:
 - Postoperative evaluation of the effectiveness of arterial or venous reconstruction or bypass; **OR**
 - Characterization of normal and variant vascular anatomy; **OR**
 - Determination of the patency, location, or integrity of grafts and other vascular devices (e.g., stents); **OR**
 - Planning autografts for musculoskeletal reconstruction; **OR**
 - Treatment of popliteal entrapment syndrome; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Computed tomography angiography (CTA), upper extremity** is not considered appropriate if **ANY** of the following is **TRUE**⁸:
- ◆ The request is for CT/CTA with contrast, and the patient has a history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the

ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.⁹⁻¹⁰

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.⁹⁻¹⁰

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.⁹⁻¹⁰

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.⁹⁻¹⁰

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
73206	Computed tomographic angiography (CTA), upper extremity; with contrast material(s), including non-contrast images, if performed, and image postprocessing

Medical Evidence

Ghouri et al. (2019) review the use of computed tomography (CT) and magnetic resonance angiography (MRA) of the upper extremity vasculature. While less frequent than lower extremity vascular abnormalities, upper extremity vascular issues require comprehensive assessment. Color Doppler is more convenient and bedside-accessible however, it suffers from operator variability and lacks central vasculature evaluation. Computed Tomography Angiography (CTA) is the primary imaging tool and allows for optimal results. Contrast enhancement is pivotal in CTA imaging, with adjustments in acquisition methods, contrast injection rates, and patient characteristics like BMI enhancing diagnostic accuracy. Advancements in CTA and MRA, including 3D reconstructions and time-resolved techniques, expand the ability to assess vascular pathologies previously reliant on conventional angiography.²

Nagpal et al. (2017) discuss the advancements in CT and magnetic resonance imaging (MRI) technology. This type of imaging allows for the assessment of upper extremity vascular conditions non-invasively. CT captures a wide field of view and the widespread availability of CT makes it valuable in emergency scenarios and for patients with contraindications to gadolinium-based contrast agents. The capability of MRI provides dynamic imaging through techniques like time-resolved MRA and its superior resolution for soft tissues positions it as the preferred choice for diagnosing vascular malformations, dynamic vascular compression disorders, and issues related to digital arteries. The technology of CT and MR ensures better anatomical and functional assessments for patients with upper extremity vascular symptoms.¹

Dave and Fleischmann (2016) provide an overview of CTA of the upper extremities. While the value of CTA in trauma situations is widely acknowledged, its extensive and diverse clinical applications in subacute settings are equally significant. These include crucial roles in presurgical anatomical mapping, such as identifying variant arterial structures, assessing connective tissue disorders, diagnosing vasculitis, managing overuse syndromes, evaluating arteriovenous fistulae/grfts, diagnosing vascular malformations, recognizing compression syndromes and investigating perivascular pathology.⁴

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Clinical Guideline Revision History/Information

Original Date: September 12, 2024		
Review History		



Cohere Medicare Advantage Policy – Coronary Artery Atherectomy

Clinical Guidelines for Medical Necessity Review

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medicare Advantage Policy - Coronary Artery Atherectomy and Intracoronary Lithotripsy

Date of last literature review: 6/3/2024

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Type: ☒ Adult (18+ yo) | ☐ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Coronary Artery Atherectomy

Benefit Category

Not applicable.

Recommended Clinical Approach

Coronary artery atherectomy is a percutaneous interventional technique that removes or ablates coronary plaque. Three atherectomy devices are FDA-approved: 1) rotational (RotaPro, Boston Scientific); 2) orbital (Diamondback, CSI); and 3) excimer laser (ELCA, Phillips). These devices are typically used as adjuncts to balloon angioplasty and stenting procedures and rarely used as stand-alone treatment. They improve procedural success in patients with fibrotic and/or moderate to severely calcified lesions and in lesions that are unable to be crossed or adequately expanded with a balloon.¹⁻⁷ Atherectomy may also be useful to improve procedural success in lesions that are eccentric, lesions that are due to in-stent restenosis (rotational or laser)⁸⁻¹¹, aorto-ostial or branch ostial (bifurcation) lesions, and in under-expanded stents (rotational or laser).¹¹⁻¹³ Additional procedures sometimes used with atherectomy or to treat similar lesions include atherotomy devices (cutting and scoring balloons) and intracoronary lithotripsy.¹⁴⁻¹⁷

Medical Necessity Criteria

Indications

→ **Coronary artery atherectomy** is considered appropriate if **ALL** of the following are **TRUE**¹⁹⁻²⁰:

- ◆ Patient has an indication for a percutaneous coronary intervention; **AND**
- ◆ **ANY** of the following:
 - Rotational atherectomy may be used to treat patients undergoing PCI of fibrotic or heavily calcified lesions (see Note below) in order to achieve plaque modification to improve procedural success^{2-3,7,10-11}; **OR**
 - Orbital atherectomy may be used to treat patients undergoing PCI of fibrotic or heavily calcified lesions (see

Note below) to achieve plaque modification in order to improve procedural success^{1,4-6,18}

NOTE: Heavy (severe) calcification is most commonly defined by invasive angiography as radiopacities seen without cardiac motion before contrast injection, usually affecting both sides of the arterial lumen.

Intravascular ultrasound (IVUS) or optical coherence tomography (OCT) criteria may predict non-dilatable lesions or impaired stent delivery and expansion (e.g., calcium thickness greater than 670 um by OCT or greater than 270 degree arc of calcium by IVUS or OCT or other proposed scoring system that predicts stent underexpansion).²¹⁻²²

Non-Indications

None

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

HCPCS Code	Code Description/Definition
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch
+92925	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; each additional branch of a major coronary artery
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
+92934	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary

	artery
92941	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel
+92944	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)
C1724	Catheter, transluminal atherectomy, rotational
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
+C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and

	angioplasty; single vessel
+C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)

Medical Evidence

Lawton et al. (2022) published a clinical practice guideline for the American College of Cardiology, the American Heart Association, and the Society for Cardiovascular Angiography and Interventions for coronary artery revascularization. It was recommended that in patients with significant left main disease, surgical revascularization is indicated. Percutaneous revascularization is a reasonable option to improve survival compared with medical therapy in selected patients with low to medium anatomic complexity of coronary artery disease and left main disease that is suitable for revascularization. In patients with stable ischemic heart disease, normal left ventricular ejection fraction, and triple vessel coronary artery disease, surgical revascularization may be reasonable, and percutaneous revascularization survival benefit is uncertain.¹

Mehanna et al. (2018) discuss the use of optical coherence tomography (OCT) in guiding percutaneous coronary intervention (PCI) for calcified lesions. The authors highlight the challenges associated with treating calcified coronary lesions, which can lead to suboptimal stent deployment and increased risk of adverse cardiovascular events. They emphasize the importance of understanding lesion morphology and composition to improve procedural outcomes. The utility of OCT is reviewed, a high-resolution imaging modality, in assessing lesion characteristics such as calcium distribution, thickness, and morphology. By providing detailed visualization of the vessel wall, OCT enables better lesion assessment and facilitates optimal stent selection and deployment. The authors discuss the role of atherectomy devices in modifying calcified plaques prior to stent placement. They argue that OCT-guided atherectomy can improve procedural success by optimizing lesion preparation and ensuring adequate stent expansion. The group overall advocates for the integration of OCT into routine clinical practice for PCI in calcified lesions, citing its potential to enhance procedural outcomes and reduce the risk of complications.²¹

Whiteside and colleagues (2019), present evidence regarding the use of rotational atherectomy (RA) for the treatment of underexpanded and undilatable coronary stents. The authors address the clinical challenge of managing stent underexpansion, a condition associated with increased risk of adverse cardiovascular events. They propose RA as a potential solution to

improve stent expansion and optimize procedural outcomes. The study reviews the outcomes of patients undergoing stent ablation with RA, focusing on procedural success rates, safety, and long-term efficacy. By analyzing data from a cohort of patients with under expanded or undilatable stents, the authors evaluate the effectiveness of RA in achieving adequate stent expansion and restoring optimal coronary flow. Key findings from the study include improvements in angiographic parameters such as minimal lumen diameter and percent diameter stenosis following RA. Additionally, the authors report favorable clinical outcomes with low rates of major adverse cardiovascular events during follow-up. The importance of appropriate patient selection and meticulous procedural technique in achieving successful stent ablation with RA is emphasized. Potential challenges and complications associated with the technique are discussed, emphasizing the need for careful risk assessment and management strategies. Overall, the evidence presented in the article suggests that RA represents a valuable therapeutic option for the management of underexpanded and undilatable coronary stents, offering the potential to improve clinical outcomes and reduce the need for repeat revascularization procedures.¹³

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Clinical Guideline Revision History/Information

Original Date: June 3, 2024		
Review History		



Cohere Medicare Advantage Policy – Coronary Artery Atherectomy

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: June 11, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medicare Advantage Policy - Coronary Artery Atherectomy and Intracoronary Lithotripsy

Date of last literature review: 6/11/2024

Document last updated: 6/11/2024

Type: ☒ Adult (18+ yo) | ☐ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Coronary Artery Atherectomy

Benefit Category

Not applicable.

Recommended Clinical Approach

Coronary artery atherectomy is a percutaneous interventional technique that removes or ablates coronary plaque. Three atherectomy devices are FDA-approved: 1) rotational (RotaPro, Boston Scientific); 2) orbital (Diamondback, CSI); and 3) excimer laser (ELCA, Phillips). These devices are typically used as adjuncts to balloon angioplasty and stenting procedures and are rarely used as a stand-alone treatment. They improve procedural success in patients with fibrotic and/or moderate to severely calcified lesions and in lesions that are unable to be crossed or adequately expanded with a balloon.¹⁻⁷ Atherectomy may also be useful to improve procedural success in lesions that are eccentric, lesions that are due to in-stent restenosis (rotational or laser)⁸⁻¹¹, aorto-ostial or branch ostial (bifurcation) lesions, and in under-expanded stents (rotational or laser).¹¹⁻¹³ Additional procedures sometimes used with atherectomy or to treat similar lesions include atherotomy devices (cutting and scoring balloons) and intracoronary lithotripsy.¹⁴⁻¹⁷

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of coronary artery atherectomy procedures. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Adverse effects from delayed or denied treatment: Delays or denials in the use of coronary artery atherectomy can lead to increased

symptoms and complications, especially in patients with severe calcified coronary lesions. The 2021 ACC/AHA/SCAI Coronary Artery Revascularization guideline emphasizes the importance of timely intervention to prevent adverse outcomes in patients with significant heart conditions.¹

- Risks with inappropriate surgical procedures: This includes infection, bleeding, injury to neurovascular structures, anesthetic risk, and the need for repeat or additional procedures due to complications. The ROTAXUS trial highlights the importance of appropriate patient selection to minimize surgical risks and enhance the benefits of coronary artery atherectomy.²
- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. Proper use of coronary artery atherectomy criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. The guidelines for the management of coronary artery disease support the necessity of appropriate diagnostic and treatment procedures to prevent unnecessary healthcare utilization.¹

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to coronary artery atherectomy procedures for the patients selected for best outcomes. The goal is to provide accurate diagnostics and effective treatment planning, reducing the risk of complications and improving overall patient health. The guidelines for the management of coronary artery disease revascularization emphasize the diagnostic accuracy of imaging and monitoring procedures in managing patients with heart conditions.¹
- Enhanced diagnostic accuracy: This is crucial for complex cardiovascular conditions where traditional diagnostic methods may pose additional risks. Advanced imaging and monitoring techniques offer the advantage of detailed vascular assessment, aiding in decision-making regarding interventions.⁵
- Reduction in complications and adverse effects: Proper use of coronary artery atherectomy criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. Studies on

the use of coronary artery atherectomy procedures emphasize the importance of accurate diagnostics in preventing complications.⁶

- Enhanced overall patient satisfaction: Ensuring that coronary artery atherectomy procedures are used appropriately leads to better procedural outcomes in certain clinical settings and higher satisfaction rates due to effective treatment and reduced complications.⁷

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and to ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Coronary artery atherectomy** is considered appropriate if **ALL** of the following are **TRUE**¹⁹⁻²⁰:

- ◆ The patient has an indication for a percutaneous coronary intervention; **AND**
- ◆ **ANY** of the following:
 - Rotational atherectomy may be used to treat patients undergoing PCI of fibrotic or heavily calcified lesions (see Note below) in order to achieve plaque modification to improve procedural success^{2-3,7,10-11}; **OR**
 - Orbital atherectomy may be used to treat patients undergoing PCI of fibrotic or heavily calcified lesions (see Note below) to achieve plaque modification in order to improve procedural success^{1,4-6,18}

NOTE: Heavy (severe) calcification is most commonly defined by invasive angiography as radiopacities seen without cardiac

motion before contrast injection, usually affecting both sides of the arterial lumen.

Intravascular ultrasound (IVUS) or optical coherence tomography (OCT) criteria may predict non-dilatable lesions or impaired stent delivery and expansion (e.g., calcium thickness greater than 670 um by OCT or greater than 270-degree arc of calcium by IVUS or OCT or other proposed scoring system that predicts stent underexpansion).²¹⁻²²

Non-Indications

→ **Coronary Artery Atherectomy** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ There are no current non-indications in the literature.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

HCPCS Code	Code Description/Definition
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch
+92925	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; each additional branch of a major coronary artery
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
+92934	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery
92941	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft,

	any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel
+92944	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)
C1724	Catheter, transluminal atherectomy, rotational
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
+C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel
+C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of

	drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)

Medical Evidence

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Clinical Guideline Revision History/Information

Original Date: June 3, 2024		
Review History		
Version 2	6/11/2024	422.101 Disclaimer Added



Cohere Medicare Advantage Policy – Coronary Computed Tomography Angiography (CCTA), With or Without Fractional Flow Reserve (FFR)

Clinical Policy for Medical Necessity Review

Version: 2.1

Policy Number: CHP-183-2.1

Cohere Health UMC Approval Date: September 11, 2025

Last Annual Review: September 11, 2025

Revision: February 3, 2026

Next Annual Review: September 11, 2026

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medicare Advantage Policy - Coronary Computed Tomography Angiography (CCTA)

Policy Number: CHP-183-2.1

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Coronary Computed Tomography Angiography (CCTA), With or Without Fractional Flow Reserve (FFR)

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻²¹

- [Local Coverage Determination \(LCD\). Cardiac Computed tomography and angiography \(CCTA\) \(L33423\)](#)
 - [Billing and Coding: Cardiac computed tomography and angiography \(CCTA\) \(A56691\)](#)
- [Local Coverage Determination \(LCD\). Cardiac computed tomography \(CCT\) and Coronary computed tomography angiography \(CCTA\) \(L33559\)](#)
 - [Billing and Coding: Cardiac computed tomography \(CCT\) and coronary computed tomography angiography \(CCTA\) \(A56737\)](#)
- [Local Coverage Determination \(LCD\). Cardiac computed tomography \(CCT\) and coronary computed tomography angiography \(CCTA\) \(L33947\)](#)
 - [Billing and Coding: Cardiac computed tomography \(CCT\) and coronary computed tomography angiography \(CCTA\) \(A56451\)](#)
- [Local Coverage Determination \(LCD\). Coronary computed tomography angiography \(CCTA\) \(L35121\)](#)
 - [Billing and Coding: Artificial intelligence enabled CT-based quantitative coronary topography \(AI-QCT\)/coronary plaque analysis \(AI-CPA\) \(A59813\)](#)
 - [Billing and Coding: Coronary computed tomography angiography \(CCTA\) \(A57552\)](#)
- [Local Coverage Determination \(LCD\). Non-invasive fractional flow reserve \(FFR\) for stable ischemic heart disease \(L38278\)](#)
 - [Billing and Coding: Non-invasive fractional flow reserve \(FFR\) for stable ischemic heart disease \(A58406\)](#)

- [Local Coverage Determination \(LCD\). Non-invasive fractional flow reserve \(FFR\) for ischemic heart disease \(L38613\)](#)
 - [Billing and Coding: Non-invasive fractional flow reserve \(FFR\) for ischemic heart disease \(A58095\)](#)
- [Local Coverage Determination \(LCD\). Non-invasive fractional flow reserve \(FFR\) for ischemic heart disease \(L38615\)](#)
 - [Billing and Coding: Non-invasive fractional flow reserve \(FFR\) for ischemic heart disease \(A58097\)](#)
- [Local Coverage Determination \(LCD\). Non-invasive fractional flow reserve \(FFR\) for ischemic heart disease \(L38771\)](#)
 - [Billing and Coding: Non-invasive fractional flow reserve \(FFR\) for ischemic heart disease \(A58359\)](#)
- [Local Coverage Determination \(LCD\). Non-invasive fractional flow reserve \(FFR\) for ischemic heart disease \(L38839\)](#)
 - [Billing and Coding: Non-invasive fractional flow reserve \(FFR\) for ischemic heart disease \(A58473\)](#)
- [Local Coverage Determination \(LCD\). Non-invasive fractional flow reserve \(FFR\) for ischemic heart disease \(L39075\)](#)
 - [Billing and Coding: Non-invasive fractional flow reserve \(FFR\) for ischemic heart disease \(A58814\)](#)

Description

Computed tomography coronary angiography (CCTA) is a non-invasive imaging alternative to cardiac catheterization performed with X-rays and an iodinated contrast. The radiologist may consider additional phases, dynamic sequences, positioning of the patient, and the use of markers. Following a positive CCTA, a non-invasive fractional flow reserve (FFR) test may be medically necessary to guide decisions about invasive coronary angiography in patients with intermediate or high-risk coronary anatomy on imaging.¹¹⁻¹⁵

Medical Necessity Criteria

Indications

Computed tomography coronary angiography (CCTA) with or without fractional flow reserve (FFR) is considered appropriate if **ANY** of the following is **TRUE**^{1,3,5,7}:

- Symptomatic coronary artery disease (CAD) in **ANY** of the following^{1,3,5,7}:
 - Evaluation of acute chest pain, unexplained dyspnea, or symptoms suggesting angina pectoris (such as jaw pain) with **ANY** of the following^{1,3,5,7}:
 - Intermediate pre-test probability of CAD (see the [Pre-Test Probability of CAD](#) published by the CAD Consortium), no changes in electrocardiogram (EKG) to suggest acute myocardial injury or ischemia, and normal initial cardiac markers¹; **OR**
 - Patients with intermediate risk and a discordant clinical situation (e.g., ongoing ischemic symptoms or normal stress test)^{1,3,5,7}; **OR**
 - Evaluation of patients with prior bypass surgery or intracoronary artery stent placement who present with chest pain or dyspnea^{3,5,7}; **OR**
 - The patient presents to the emergency room with complaints consistent with cardiac ischemia, but without diagnostic ECG or enzymes^{3,5,7}; **OR**
 - The patient status is post-revascularization procedures who presents with recurrent symptoms not identifiable as ischemic^{3,5}; **OR**
 - The patient has known CAD with recurrence of symptoms, which may be related to progression and exacerbation of underlying disease⁵; **OR**
- Surveillance of cardiac allograft vasculopathy (CAV) in heart transplant patients, typically every 1-2 years unless the patient is at high-risk (e.g., known moderate CAD or prior coronary intervention)²²; **OR**
- The patient will undergo non-coronary artery cardiac surgery and may need a preoperative invasive coronary angiogram^{3,5,7}; **OR**
- The assessment of coronary or pulmonary venous anatomy^{5,7}; **OR**
- CCTA is an alternative when cardiac catheterization is impossible or carries a high risk⁷; **OR**
- CCTA screening to clarify unclear findings after invasive angiography⁷; **OR**
- Atrial fibrillation or atrial flutter with planned ablation therapy.⁷

Fractional flow reserve (FFR) is considered appropriate for **ANY** of the following^{10,12,14,16,18,20}:

- Intermediate risk patients with acute or stable chest pain and with no known history of coronary artery stenosis with finding of 40–90% in proximal or middle coronary artery on CCTA^{10,12,14,16,18,20}; **OR**
- Intermediate risk patients with acute chest pain and known non-obstructive (less than 50%) coronary artery disease (CAD), coronary artery stenosis with finding of 40–90% stenosis on CCTA^{10,12,14,16,18,20}; **OR**
- Stable nonobstructive CAD (less than 50% stenosis) with persistent symptoms requiring further test, and finding of 40–90% stenosis on CCTA.^{10,12,14,16,18,20}

Non-Indications

Computed tomography coronary angiography (CCTA) is not considered appropriate if **ANY** of the following is **TRUE**^{1,3,5,7}:

- Performed for asymptomatic patients,^{3,5,7} for risk stratification, or quantitative evaluation of coronary calcium^{1,7}; **OR**
- Ultrafast CT scan of the heart, electron-beam tomography (EBT) or electron-beam computed tomography (EBCT)^{1,7}; **OR**
- A simultaneous exclusion of obstructive CAD, pulmonary embolism, and aortic dissection (“triple rule-out” CT scan) in the emergency department¹; **OR**
- CCTA screening performed on patients with elevated quantitative calcium scores that preclude accurate assessment of coronary anatomy^{1,3}; **OR**
- It is anticipated that the patient would require invasive cardiac angiography for further diagnosis or therapeutic intervention. (e.g., angina decubitus, unstable angina, Prinzmetal angina, etc.)^{3,5,7}; **OR**
- CCTA screening is performed for cardiac evaluation when there is pre-test knowledge of sufficiently extensive calcification of the suspected coronary segment that would diminish the interpretive value^{3,5}; **OR**
- CCTA screening is not performed under the direct supervision of a physician^{3,5,7}; **OR**
- Atrial fibrillation or atrial flutter alone without planned ablation⁷; **OR**
- If FFR is performed, it is not considered appropriate for **ANY** of the following^{10,12,14,16,18,20}:

- CCTA in conjunction with stress testing, unless CCTA was not of sufficient quality for non-invasive FFR, and an alternative study is needed; **OR**
- Prior placement of prosthetic valves; **OR**
- Prior placement of grafts in coronary bypass surgery; **OR**
- Suspicion of acute coronary syndrome (where myocardial infarction (MI) or unstable angina have not been ruled out); **OR**
- Intracoronary metallic stent is present; **OR**
- Status is post-heart transplantation; **OR**
- Recent MI (30 days or less); **OR**
- Prior pacemaker or defibrillator lead placement; **OR**
- Newly diagnosed systolic heart failure, with no prior left heart catheterization; **OR**
- Left main CAD with intermediated coronary stenosis (lumen reduction less than or equal to 40%); **OR**
- Non-obstructing stenosis (less than 50% of all major epicardial vessels) on CTA or catheterization in the past 12 months, in the absence of a new symptom complex; **OR**
- The patient has unstable coronary symptoms; **OR**
- The CCTA base study has not yet been completed and interpreted; **OR**
- High-grade stenoses greater than 90% are present; **OR**
- Low-grade stenoses of less than 40% are present.

Definitions

Acceptable levels of competence: As defined by the American College of Cardiology (ACC)/American Heart Association (AHA) Clinical Competence Statement on Cardiac Imaging with Computed Tomography and Magnetic Resonance (2005) and the American College of Radiology (ACR) Clinical Statement on Noninvasive Cardiac Imaging (2005).^{23,24}

Intermediate risk patients: Intermediate and high-risk and stress test as defined in the 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain.²⁵

Persistent symptoms: Unacceptable ischemia-related symptoms despite maximally tolerated medical therapy.¹⁰

Intermediate pretest probability: The probability of CAD by age, sex, and symptoms is between 10% and 90%.²⁶

Disclaimer on Radiation Exposure in Pediatric Populations

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{27,28}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{27,28}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{27,28}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{27,28}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
75574	Computed tomographic angiography (CTA), heart, coronary arteries and bypass grafts (when present); with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation).
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified healthcare professional.

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

Clinical coverage criteria for coronary computed tomography angiography (CCTA), with or without fractional flow reserve (FFR) were fully defined and established by NCDs and/or LCDs. Cohere Health did not supplement this policy with any additional criteria or interpretations.

Medical Evidence

In a recent review, Sandoval et al. (2025) provided insights and agreed viewpoints from a scientific roundtable regarding applying CCTA to guide subsequent invasive coronary angiography and percutaneous coronary intervention (PCI) strategy. CCTA utilization has increasingly become a first-line diagnostic test for patients with chest pain, and its use before PCI is expanding, facilitating preprocedural preparation for a wider range of patients. This method presents a significant chance to improve the efficiency, safety, and effectiveness of revascularization.²⁹

In the 2021 chest pain guideline for the American College of Cardiology, Gulati et al. gave several recommendations for the use of CCTA, including for intermediate-risk patients with acute chest pain and no known CAD who require diagnostic testing following a negative evaluation for acute coronary syndrome. Additionally, CCTA is a proven approach for evaluating patients with stable chest pain with a strong (Class 1) strength of recommendation. The writers stated that CCTA helps exclude atherosclerotic plaque and obstructive CAD. A recommendation was given for CCTA to diagnose obstructive CAD in patients at intermediate risk with acute pain and mildly abnormal previous stress testing. When evaluating patients in the emergency department with acute chest pain, CCTA may reduce the time to diagnosis and possibly lead to earlier safe discharge.²⁵

Taylor et al. (2010) developed appropriate use criteria for cardiac computed tomography. The use of CCTA in low or intermediate-risk patients with pretest probability for CAD may be considered. Testing in high-risk patients, routinely repeated testing, and use for general cardiac screening were not viewed favorably. Lowest appropriateness ratings were assigned in urgent presentations with acute symptoms with suspicion of acute coronary syndrome, such as in definite myocardial infarction (MI), persistent ST-segment elevation on ECG (when MI excluded), and acute chest pain of uncertain cause prompting rule out of pulmonary embolism, aortic dissection, and acute coronary syndrome.²⁶

Driessen and colleagues (2019) published post hoc single-center study results comparing CCTA, FFR, and perfusion imaging for ischemia diagnosis for the American College of Cardiology. The 208 patients were enrolled with suspicion of CAD and underwent CCTA, single-photon emission computed tomography (SPECT), and positron emission tomography (PET) scans with a routine FFR study of all major coronary arteries. All patients were prospectively tested noninvasively and invasively with FFR within 2 weeks, regardless of their results. Of the 208 patients, the CCTA images of 75% of patients were entirely sufficient for evaluation by noninvasive FFR. The group concluded that noninvasive FFR showed high diagnostic performance for vessel-specific ischemia, provided that the CCTA images were adequate for FFR evaluation. PET scanning yielded the highest diagnostic performance due to the often high rejection rate of the noninvasive FFR.³⁰

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Policy Revision History/Information

Original Date: September 12, 2024		
Review History		
Version 1.1	03/27/2025	Updated policy per CMS revisions for 11/24/24.
Version 1.2	04/22/2025	Updated policy per CMS revisions for 03/13/2025.
Version 1.3	05/15/2025	Updated policy per CMS revisions for 04/17/2025.
Version 2	09/11/2025	Annual review. Superseded LCD links and references for L33423, L33947, L35121, and L38278 were updated to the new versions. All indications and non-Indications were revised to focus solely on CMS documents. All criteria were referenced to the appropriate LCDs. Included the CAD Consortium's Pre-Test Probability of CAD calculator in the indications section. Added indication for "surveillance of cardiac allograft vasculopathy (CAV) in heart transplant patients, typically every 1-2 years unless the patient is at high-risk (e.g., known moderate CAD or prior coronary intervention)."
Version 2.1	02/03/2026	Revision. Per CMS revisions, updated links and references for L35121, A59813, A57552, A58406, A58095, A58097.



Cohere Medicare Advantage Policy – Coronary Computed Tomography Angiography (CCTA), with or without Fractional Flow Reserve (FFR)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 12, 2024

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Coronary Computed Tomography Angiography (CCTA), with or without Fractional Flow Reserve (FFR)

Date of last literature review: 9/11/2024

Document last updated: 9/11/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Coronary Computed Tomography Angiogram (CCTA) with or without Fractional Flow Reserve (FFR)

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service. [36-45](#)

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- [LCD Non-Invasive Fractional Flow Reserve \(FFR\) for Ischemic Heart Disease \(L38839\)](#)
- [LCD Non-Invasive Fractional Flow Reserve \(FFR\) for Stable Ischemic Heart Disease \(L38278\)](#)
- [LCD Non-Invasive Fractional Flow Reserve \(FFR\) for Ischemic Heart Disease \(L38613\)](#)
- [LCD Non-Invasive Fractional Flow Reserve \(FFR\) for Ischemic Heart Disease \(L38615\)](#)
- [LCD Non-Invasive Fractional Flow Reserve \(FFR\) for Ischemic Heart Disease \(L39075\)](#)
- [LCD Non-Invasive Fractional Flow Reserve \(FFR\) for Ischemic Heart Disease \(L38771\)](#)
- [LCD Cardiac Computed Tomography & Angiography \(CCTA\) \(L33423\)](#)
- [LCD Cardiac Computed Tomography \(CCT\) and Coronary Computed Tomography Angiography \(CCTA\) \(L33947\)](#)
- [LCD Coronary Computed Tomography Angiography \(CCTA\) \(L35121\)](#)
- [LCD Cardiac Computed Tomography \(CCT\) and Coronary Computed Tomography Angiography \(CCTA\) \(L33559\)](#)
- [Billing and Coding: Non-Invasive Fractional Flow Reserve \(FFR\) for Ischemic Heart Disease \(A58473\)](#)
- [Billing and Coding: Category III Codes \(A56902\)](#)
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- [Billing and Coding: Non-Invasive Fractional Flow Reserve \(FFR\) for Ischemic Heart Disease \(A58095\)](#)
- [Billing and Coding: Non-Invasive Fractional Flow Reserve \(FFR\) for Ischemic Heart Disease \(A58814\)](#)
- [Billing and Coding: Non-Invasive Fractional Flow Reserve \(FFR\) for Ischemic Heart Disease \(A58359\)](#)
- [Billing and Coding: Cardiac Computed Tomography & Angiography \(CCTA\) \(A56691\)](#)
- [Billing and Coding: Cardiac Computed Tomography \(CCT\) and Coronary Computed Tomography Angiography \(CCTA\) \(A56737\)](#)
- [Billing and Coding: Cardiac Computed Tomography \(CCT\) and Coronary Computed Tomography Angiography \(CCTA\) \(A56451\)](#)
- [Billing and Coding: Artificial Intelligence Enabled CT Based Quantitative Coronary Topography \(AI-QCT\)/Coronary Plaque Analysis \(AI-CPA\) \(DA59813\)](#)
- [Billing and Coding: Coronary Computed Tomography Angiography \(CCTA\) \(A57552\)](#)

Recommended Clinical Approach

Computed tomography coronary angiography (CCTA) is a non-invasive alternative to cardiac catheterization performed with iodinated contrast. The radiologist may consider additional phases, dynamic sequences, positioning of the patient, and the use of markers. The referring clinician is responsible for the appropriate clinical indication in consultation with a cardiac imaging expert. The patient's pertinent medical history should justify the exam. The physician laboratory director should choose the scanning protocol for the study before the patient's arrival. Following a positive CCTA, non-invasive fractional flow reserve (FFR) may be medically necessary to guide decisions about invasive coronary angiography in patients with intermediate or high-risk coronary anatomy on imaging.¹⁻⁵ CT-FFR is not recommended in patients with complex congenital heart disease.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of computed tomography coronary angiography (CCTA). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.^{[24,29-31](#)}
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.^{[32](#)} Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.^{[32](#)}
- Increased healthcare costs and complications from the inappropriate use of additional interventions.^{[26](#)}

The clinical benefits of using these criteria include:

- Accuracy: CCTA has exceptional diagnostic accuracy, with a high degree of sensitivity (91%) and specificity (92%) for the detection of coronary artery disease.^{[1](#)} Further, CCTA in conjunction with FFR holds increased sensitivity and specificity of diagnostic accuracy than standard CCTA alone.^{[9,21](#)}
- Noninvasive: As a cardiac imaging modality, CCTA is relatively noninvasive when compared to other modalities, such as invasive cardiac angiography (ICA).^{[1](#)} It is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers.^{[27,28](#)}
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography coronary angiography (CCTA) with or without fractional flow reserve (FFR)** is considered appropriate if **ANY** of the following is **TRUE**^{3,6-12}:

- ◆ There is a suspicion of cardiac anomaly¹² including **ANY** of the following^{36,37}:
 - Evaluation of cardiac mass (suspected tumor or thrombus)
 - Evaluation of pericardial conditions (mass, constrictive pericarditis or complications of cardiac surgery)
 - Complex congenital heart disease (e.g., anomalies of coronary or pulmonary circulation, great vessels and cardiac chamber and valves); OR
- ◆ Possible acute coronary syndrome where standard diagnostic testing including EKG and cardiac enzymes are nondiagnostic or indeterminate for myocardial injury³⁶⁻³⁹; **OR**
- ◆ No known coronary artery disease (CAD) with an intermediate or high pre-test probability of obstructive CAD (based on the [CAD Consortium Calculator](#))³³ and **ANY** of the following^{3,12}:
 - Chest pain (or ischemic equivalent, including dyspnea) after an inconclusive or abnormal exercise ECG or stress imaging study; **OR**
 - Chest pain (or ischemic equivalent, including dyspnea) after a negative stress test but with high clinical suspicion of CAD; **OR**
 - Chest pain (or ischemic equivalent, including dyspnea); **OR**
- ◆ CAD is known and previously determined to be non-obstructive (less than 70%), but there has been a clinical change that suggests CAD in the native coronary arteries has progressed¹³; **OR**
- ◆ Previous coronary revascularization with bypass or percutaneous intervention was performed and there is a clinical change in cardiac status³⁸; **OR**
- ◆ New or unexplained cardiomyopathy with an ejection fraction less than 40%^{5,36}; **OR**

- ◆ Fractional Flow Reserve (FFR) is for **ANY** of the following^{20,21,40-45}:
 - For functional evaluation of coronary CTA lesions, which are 40–90% stenosed in a proximal to a middle coronary segment on CCTA^{3,20}; **OR**
 - For evaluating multivessel disease and identifying culprit lesions seen on CCTA that may be causing symptoms; **OR**
 - For evaluating the physiologic severity of multiple lesions in a single vessel³; **OR**
- ◆ Preoperative evaluation when **ANY** of the following is **TRUE**:
 - Valve or other cardiac surgery
 - High risk vascular surgery (e.g., aneurysm repair)
 - Renal transplant or other solid organ transplant; **OR**
- ◆ Annual surveillance post-cardiac transplant^{34,35}; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Computed tomography coronary angiography (CCTA)** is not considered appropriate if **ANY** of the following is **TRUE**^{5,11}:
- ◆ If **ANY** of the following is **TRUE** if contrast is used:
 - History of anaphylactic allergic reaction to iodinated contrast media; **OR**
 - Renal insufficiency with no provided detailed guidelines; **OR**
 - ◆ Normal coronary angiogram or CCTA with no stenosis or plaque within the last two years and stable symptoms; **OR**
 - ◆ Normal stress test within the previous year (given adequate stress) with stable symptoms; **OR**
 - ◆ If FFR is performed, it is not considered appropriate if **ANY** of the following conditions is **TRUE**^{3,21}:

- The original CCTA was of suboptimal quality; **OR**
- The patient is not a candidate for revascularization; **OR**
- Coronary anatomy seen on CCTA is non-obstructive²⁰.

*NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{24,25}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{24,25}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{24,25}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{24,25}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
75574	Computed tomographic angiography (CTA), heart, coronary arteries and bypass grafts (when present); with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation)
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified healthcare professional

Medical Evidence

In the 2021 chest pain guideline for the American College of Cardiology, Gulati et al. give several recommendations for the use of coronary computed tomography angiography (CCTA), including for intermediate-risk patients with acute chest pain and no known coronary artery disease (CAD) who require diagnostic testing following a negative evaluation for acute coronary syndrome. Additionally, CCTA is a proven approach for evaluating patients with stable chest pain with a strong (Class 1) strength of recommendation³. The writers state that CCTA helps exclude atherosclerotic plaque and obstructive CAD. A recommendation was given for CCTA to diagnose obstructive CAD in patients at intermediate risk with acute pain and mildly abnormal previous stress testing. When evaluating patients in the emergency department with acute chest pain, CCTA may reduce the time to diagnosis and possible earlier safe discharge.³

Taylor et al. (2010) developed appropriate use criteria for cardiac computed tomography. The use of CCTA in low or intermediate-risk patients with pretest probability for CAD may be considered. Testing in high-risk patients, routinely repeating testing, and use for general cardiac screening were not viewed favorably. Lowest appropriateness ratings were assigned in urgent presentations with acute symptoms with suspicion of acute coronary syndrome, such as in definite myocardial infarction (MI), persistent ST-segment elevation on ECG (when MI excluded), and acute chest pain of uncertain cause prompting rule out of pulmonary embolism, aortic dissection and acute coronary syndrome.⁶

Driessen and colleagues (2019) published post hoc single-center study results comparing CCTA, FFR, and perfusion imaging for ischemia diagnosis for the American College of Cardiology. The 208 patients were enrolled with suspicion of CAD and underwent CCTA, SPECT, and PET scans with routine FFR study of all major coronary arteries. All patients were prospectively tested noninvasively and invasively with FFR within 2 weeks, regardless of their results. Of the 208 patients, the CCTA images of 75% of patients were entirely sufficient for evaluation by FFR_{CT}. The group concluded that FFR_{CT} showed high diagnostic performance for vessel-specific ischemia, provided that the CCTA images were adequate for FFR evaluation. PET scanning yielded the highest diagnostic performance due to the often high rejection rate of the FFR_{CT}.⁹

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Clinical Guideline Revision History/Information

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Review History		

Cohere Medicare Advantage Policy – Coronary Computed Tomography Angiography (CCTA), With or Without Fractional Flow Reserve (FFR) or Artificial Intelligence (AI) Plaque Analysis

Clinical Policy for Medical Necessity Review

CHP-183-3 Version 3

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Specialty: Diagnostic Imaging

Population Type: Adult (18+ years old), Pediatric (0-17 years old)

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Procedure Codes (CPT/HCPCS)

Service: Coronary Computed Tomography Angiography (CCTA)

Code	Description
75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)

Service: Fractional Flow Reserve (FFR)

Code	Description
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional

Service: Artificial Intelligence (AI) Plaque Analysis

Code	Description
75577	Quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, derived from augmentative software analysis of the data set from a coronary computed tomographic angiography, with interpretation and report by a physician or other qualified health care professional

Service: Repeat Imaging

Code	Description
75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)
75577	Quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, derived from augmentative software analysis of the data set from a coronary computed tomographic angiography, with interpretation and report by a physician or other qualified health care professional
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Service: Coronary Computed Tomography Angiography (CCTA), With or Without Fractional Flow Reserve (FFR) or Artificial Intelligence (AI) Plaque Analysis - Description

Computed tomography coronary angiography (CCTA) is a non-invasive alternative to cardiac catheterization performed with iodinated contrast. The radiologist may consider additional phases, dynamic sequences, positioning of the patient, and the use of markers. The physician laboratory director may choose a scanning protocol for the study prior to imaging. CCTA creates detailed images of the coronary arteries using CT technology, which is augmented by the intravenous injection of contrast dye.¹⁸⁻²²

Service: Coronary Computed Tomography Angiography (CCTA) - Medical Necessity Criteria

Related Centers for Medicare & Medicaid Services (CMS) Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Cohere defines CMS coverage criteria as follows¹:

- Fully established: Applicable LCD or NCD is comprehensive and does not require additional criteria to determine medical necessity consistently.
- Not fully established: Additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently. The additional Cohere criteria will provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

For each jurisdiction, Cohere's internal coverage criteria will only be applied when CMS guidance is not fully established and additional guidelines are needed to support consistent and appropriate decision-making.

Cohere Health's position on NCDs or LCDs related to *Cohere Medicare Advantage Policy - Coronary Computed Tomography Angiography (CCTA), With or Without Fractional Flow Reserve (FFR) or Artificial Intelligence (AI) Plaque Analysis* is reflected in Table 1 below. For the LCDs that are defined as not fully established, please refer to the far right column as a guide for the application of Cohere Medicare Advantage criteria.

Table 1 - Related CMS Policies (NCDs or LCDs)²⁻¹⁷

Type	Title	Number	Cohere Definition of CMS Policy Establishment	Indications not fully established by CMS policy (refer to Cohere Health MA medical necessity criteria for these topics):
NCD	Computed Tomography	220.1	Not fully established	- No coronary computed tomography angiography (CCTA), fractional flow reserve (FFR), or artificial intelligence (AI) plaque analysis criteria.
LCD	Cardiac Computed Tomography and Angiography (CCTA)	L33423	Fully established	- Not applicable
LCD	Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA)	L33559	Fully established	- Not applicable
LCD	Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA)	L33947	Fully established	- Not applicable

LCD	Coronary Computed Tomography Angiography (CCTA)	L35121	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38278	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38613	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38615	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38771	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38839	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L39075	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39840	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39851	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39863	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-	L39881	Fully established	- Not applicable

	QCT)/ Coronary Plaque Analysis (AI-CPA)			
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39913	Fully established	- Not applicable
LCD	Not Applicable - No LCD Available for Jurisdiction	N/A	N/A	- Use Cohere Medicare Advantage internal coverage criteria

Indications

- **Computed tomography coronary angiography (CCTA)** is considered appropriate if **ANY** of the following is **TRUE**:

- Initial evaluation of stable chest pain (or ischemic equivalent) in patients with intermediate or higher pre-test probability of coronary artery disease (CAD) (See the [Pre-Test Probability of CAD Calculator](#) published by the CAD Consortium) without known CAD²⁰⁻²⁴; **OR**
- Stable chest pain (or ischemic equivalent) in patients with intermediate or higher pre-test probability of CAD (See the [Pre-Test Probability of CAD Calculator](#) published by the CAD Consortium) following an inconclusive or abnormal exercise ECG or stress imaging study, if such imaging will influence subsequent patient care²⁰⁻²⁴; **OR**
- Stable chest pain (or ischemic equivalent) after a negative stress test but with high pre-test probability of CAD (See the [Pre-Test Probability of CAD Calculator](#) published by the CAD Consortium)²⁰⁻²⁴; **OR**
- Worsening clinical symptoms suggestive of angina and CAD is known and previously determined to be non-obstructive (less than 50%)²⁰⁻²⁴; **OR**
- Anginal symptoms in a patient with previous coronary revascularization if revascularization was performed with bypass grafts or stented vessels with a diameter greater than 3 mm²⁰⁻²⁴; **OR**
- Possible acute coronary syndrome (ACS) or unstable angina²⁰⁻²⁴; **OR**
- Acute chest pain with suspected aortic or coronary dissection²⁰⁻²⁴; **OR**
- Newly diagnosed cardiomyopathy or unexplained congestive heart failure and **ALL** of the following^{24,25}:
 - No known history of CAD²⁴; **AND**
 - Left ventricular ejection fraction (LVEF) is less than 50%; **AND**
 - No prior cardiac catheterization, single photon emission computed tomography (SPECT), cardiac positron emission tomography (PET), or stress echocardiogram²⁴; **OR**
- There is a suspicion of congenital coronary artery anomalies²⁰⁻²⁴; **OR**
- Evaluation of patients suspected of having large, medium, or variable vessel vasculitis involving the coronary arteries (including giant cell arteritis, Takayasu's arteritis, polyarteritis nodosum, or Behçet's disease)^{20-24,26}; **OR**
- Pre-operative evaluation of coronary artery disease as an equivalent alternative to catheter-based angiography prior to **ANY** of the following^{24,27-29}:
 - Non-coronary cardiac surgery in patients with low-intermediate probability of CAD²⁴; **OR**
 - Re-do cardiac bypass surgery with the need to visualize grafts or other structures²⁴; **OR**
 - Transcatheter aortic valve implantation/replacement (TAVI/TAVR)²⁷; **OR**
 - Aortic dissection or aneurysm repair²⁸; **OR**
 - Liver or renal transplant surgery.²⁹

Non-Indications

- **Computed tomography coronary angiography (CCTA)** is not considered appropriate if **ANY** of the following is **TRUE**²⁰⁻²⁴.
 - The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms; **OR**
 - The patient has uncontrolled rapid atrial fibrillation; **OR**
 - Normal coronary angiogram or CCTA with no stenosis or plaque was performed within the last two years with stable symptoms; **OR**
 - Normal stress test was performed within the previous year (given adequate stress) with stable symptoms.

Service: Fractional Flow Reserve (FFR) - Medical Necessity Criteria

Related Centers for Medicare & Medicaid Services (CMS) Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Cohere defines CMS coverage criteria as follows¹:

- Fully established: Applicable LCD or NCD is comprehensive and does not require additional criteria to determine medical necessity consistently.
- Not fully established: Additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently. The additional Cohere criteria will provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

For each jurisdiction, Cohere's internal coverage criteria will only be applied when CMS guidance is not fully established and additional guidelines are needed to support consistent and appropriate decision-making.

Cohere Health's position on NCDs or LCDs related to *Cohere Medicare Advantage Policy - Coronary Computed Tomography Angiography (CCTA), With or Without Fractional Flow Reserve (FFR) or Artificial Intelligence (AI) Plaque Analysis* is reflected in Table 1 below. For the LCDs that are defined as not fully established, please refer to the far right column as a guide for the application of Cohere Medicare Advantage criteria.

Table 1 - Related CMS Policies (NCDs or LCDs)²⁻¹⁷

Type	Title	Number	Cohere Definition of CMS Policy Establishment	Indications not fully established by CMS policy (refer to Cohere Health MA medical necessity criteria for these topics):
NCD	Computed Tomography	220.1	Not fully established	- No coronary computed tomography angiography (CCTA), fractional flow reserve (FFR), or artificial intelligence (AI) plaque analysis criteria.
LCD	Cardiac Computed Tomography and Angiography (CCTA)	L33423	Fully established	- Not applicable
LCD	Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA)	L33559	Fully established	- Not applicable
LCD	Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA)	L33947	Fully established	- Not applicable

LCD	Coronary Computed Tomography Angiography (CCTA)	L35121	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38278	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38613	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38615	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38771	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38839	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L39075	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39840	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39851	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39863	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-	L39881	Fully established	- Not applicable

	QCT)/ Coronary Plaque Analysis (AI-CPA)			
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39913	Fully established	- Not applicable
LCD	Not Applicable - No LCD Available for Jurisdiction	N/A	N/A	- Use Cohere Medicare Advantage internal coverage criteria

Indications

- **Fractional flow reserve computed tomography (FFR CT)** is considered appropriate if **ALL** of the following are **TRUE**^{20,30,31}:
 - FFR CT is performed only after the CCTA has been completed and interpreted; **AND**
 - Functional evaluation of patients with chest pain (or ischemic equivalent) with coronary CTA lesions that are 40-90% stenosed in a proximal or middle coronary segment²⁰; **AND**
 - CCTA was performed within 90 days prior to FFR CT.

Non-Indications

- **Fractional flow reserve computed tomography (FFR CT)** is not considered appropriate if **ANY** of the following is **TRUE**^{30,31}:
 - The original CCTA was of suboptimal quality; **OR**
 - The patient is not a candidate for revascularization; **OR**
 - The patient has a metal intracoronary stent in the vessel to be studied^{33,34}; **OR**
 - There is a suspicion of acute coronary syndrome³⁰; **OR**
 - The patient has complex congenital heart disease; **OR**
 - Prior placement of prosthetic valves; **OR**
 - Prior placement of grafts in coronary bypass surgery; **OR**
 - Suspicion of ACS (where myocardial infarction [MI] or unstable angina has not been ruled out)³⁰; **OR**
 - Status post-heart transplantation; **OR**
 - Recent MI (30 days or less)³⁰; **OR**
 - Prior pacemaker or defibrillator lead placement; **OR**
 - Newly diagnosed systolic heart failure, with no prior left heart catheterization; **OR**
 - Non-obstructing stenosis (less than 50% of all major epicardial vessels) on CTA or catheterization in the past 12 months, in the absence of a new symptom complex; **OR**
 - Coronary anatomy seen on CCTA demonstrates stenoses less than 30% or greater than 90%^{30,31}; **OR**
 - When turnaround times may impact prompt clinical care decisions.

Service: Artificial Intelligence (AI) Plaque Analysis - Medical Necessity Criteria

Related Centers for Medicare & Medicaid Services (CMS) Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Cohere defines CMS coverage criteria as follows¹:

- Fully established: Applicable LCD or NCD is comprehensive and does not require additional criteria to determine medical necessity consistently.
- Not fully established: Additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently. The additional Cohere criteria will provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

For each jurisdiction, Cohere's internal coverage criteria will only be applied when CMS guidance is not fully established and additional guidelines are needed to support consistent and appropriate decision-making.

Cohere Health's position on NCDs or LCDs related to *Cohere Medicare Advantage Policy - Coronary Computed Tomography Angiography (CCTA), With or Without Fractional Flow Reserve (FFR) or Artificial Intelligence (AI) Plaque Analysis* is reflected in Table 1 below. For the LCDs that are defined as not fully established, please refer to the far right column as a guide for the application of Cohere Medicare Advantage criteria.

Table 1 - Related CMS Policies (NCDs or LCDs)²⁻¹⁷

Type	Title	Number	Cohere Definition of CMS Policy Establishment	Indications not fully established by CMS policy (refer to Cohere Health MA medical necessity criteria for these topics):
NCD	Computed Tomography	220.1	Not fully established	- No coronary computed tomography angiography (CCTA), fractional flow reserve (FFR), or artificial intelligence (AI) plaque analysis criteria.
LCD	Cardiac Computed Tomography and Angiography (CCTA)	L33423	Fully established	- Not applicable
LCD	Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA)	L33559	Fully established	- Not applicable
LCD	Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA)	L33947	Fully established	- Not applicable

LCD	Coronary Computed Tomography Angiography (CCTA)	L35121	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38278	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38613	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38615	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38771	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38839	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L39075	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39840	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39851	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39863	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-	L39881	Fully established	- Not applicable

	QCT)/ Coronary Plaque Analysis (AI-CPA)			
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39913	Fully established	- Not applicable
LCD	Not Applicable - No LCD Available for Jurisdiction	N/A	N/A	- Use Cohere Medicare Advantage internal coverage criteria

Indications

- **Artificial intelligence (AI)-enabled computed tomography (CT)-based quantitative coronary topography or coronary plaque analysis** is considered appropriate if **ALL** of the following are **TRUE**:
 - The request is for a recent CCTA study in which the results are available and should include CAD-RAD scoring; **AND**
 - CCTA results are of adequate quality (i.e., not CAD-RADS N^B) to perform AI plaque analysis; **AND**
 - Results from the completed CCTA indicate **ANY** of the following risk categories:
 - Intermediate risk^{A,20}; **OR**
 - CAD-RADS 1^{B,32}; **OR**
 - CAD-RADS 2^{B,32}; **OR**
 - CAD-RADS 3^{B,32}; **AND**
 - Acute or stable chest pain with no known CAD²⁰; **AND**
 - Cardiac evaluation is negative or inconclusive for acute coronary syndrome (ACS).²⁰

Non-Indications

- **Artificial intelligence (AI)-enabled computed tomography (CT)-based quantitative coronary topography or coronary plaque analysis** is not considered appropriate if **ANY** of the following is **TRUE**:
 - CAD-RADS 4^B; **OR**
 - CAD-RADS 5^B; **OR**
 - Disease surveillance; **OR**
 - High-grade stenosis (greater than or equal to 70%); **OR**
 - In conjunction with invasive coronary catheterization; **OR**
 - Normal CCTA results (i.e., CAD-RADS 0^B or no plaque disease); **OR**
 - Screening in the absence of signs, symptoms, or disease; **OR**
 - The request is in conjunction with a CCTA study, as CCTA must be complete prior to plaque analysis; **OR**
 - Unstable coronary symptoms; **OR**
 - Within 30 days of an MI.

Definitions and Notes

^A**Intermediate risk:** Pre-test probability of 15-50%, to be calculated with the [Pre-Test Probability of CAD Calculator](#) published by the CAD Consortium.²⁰

^B**CAD-RADS 2.0** categories include³²:

- CAD-RADS 0: Absence of CAD (0%), no plaque or stenosis
- CAD-RADS 1: Minimal stenosis (1–24%), plaque with no stenosis, or presence of plaque with positive remodeling and no evidence of stenosis
- CAD-RADS 2: Mild stenosis (25–49%)
- CAD-RADS 3: Moderate stenosis (50–69%)
- CAD-RADS 4: Severe stenosis (70–99%), left main 50% stenosis, or 3-vessel obstructive (70%) disease
- CAD-RADS 5: Total occlusion or sub-total occlusion (100%)
- CAD-RADS N (Non-diagnostic): Uninterpretable scan

Service: Repeat Imaging - Medical Necessity Criteria

Related Centers for Medicare & Medicaid Services (CMS) Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

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- Fully established: Applicable LCD or NCD is comprehensive and does not require additional criteria to determine medical necessity consistently.
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For each jurisdiction, Cohere's internal coverage criteria will only be applied when CMS guidance is not fully established and additional guidelines are needed to support consistent and appropriate decision-making.

Cohere Health's position on NCDs or LCDs related to *Cohere Medicare Advantage Policy - Coronary Computed Tomography Angiography (CCTA), With or Without Fractional Flow Reserve (FFR) or Artificial Intelligence (AI) Plaque Analysis* is reflected in Table 1 below. For the LCDs that are defined as not fully established, please refer to the far right column as a guide for the application of Cohere Medicare Advantage criteria.

Table 1 - Related CMS Policies (NCDs or LCDs)²⁻¹⁷

Type	Title	Number	Cohere Definition of CMS Policy Establishment	Indications not fully established by CMS policy (refer to Cohere Health MA medical necessity criteria for these topics):
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LCD	Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA)	L33559	Fully established	- Not applicable
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LCD	Coronary Computed Tomography Angiography (CCTA)	L35121	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38278	Fully established	- Not applicable
LCD	Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	L38613	Fully established	- Not applicable
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LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39840	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39851	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39863	Fully established	- Not applicable
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-	L39881	Fully established	- Not applicable

	QCT)/ Coronary Plaque Analysis (AI-CPA)			
LCD	Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/ Coronary Plaque Analysis (AI-CPA)	L39913	Fully established	- Not applicable
LCD	Not Applicable - No LCD Available for Jurisdiction	N/A	N/A	- Use Cohere Medicare Advantage internal coverage criteria

Indications

- **Repeat imaging** is considered appropriate when **ALL** of the following are **TRUE**:
 - Repeat request following recent imaging within the past 3 months of the same anatomic region with the same or similar modality; **AND**
 - No established guidelines for repeat imaging; **AND**
 - **ANY** of the following:
 - Need for a one-time clarifying follow-up of a prior indeterminate finding; **OR**
 - New or worsening symptoms not addressed in the guidelines, such that repeat imaging would influence treatment; **OR**
 - No change in symptoms and a well-established clinical need for ongoing monitoring that will influence management.

Non-Indications

- **Computed tomography coronary angiography (CCTA)** is not considered appropriate if **ANY** of the following is **TRUE**²⁰⁻²⁴:
 - The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms; **OR**
 - The patient has uncontrolled rapid atrial fibrillation; **OR**
 - Normal coronary angiogram or CCTA with no stenosis or plaque was performed within the last two years with stable symptoms; **OR**
 - Normal stress test was performed within the previous year (given adequate stress) with stable symptoms.
- **Fractional flow reserve computed tomography (FFR CT)** is not considered appropriate if **ANY** of the following is **TRUE**^{30,31}:
 - The original CCTA was of suboptimal quality; **OR**
 - The patient is not a candidate for revascularization; **OR**
 - The patient has a metal intracoronary stent in the vessel to be studied^{33,34}; **OR**
 - There is a suspicion of acute coronary syndrome³⁰; **OR**
 - The patient has complex congenital heart disease; **OR**
 - Prior placement of prosthetic valves; **OR**
 - Prior placement of grafts in coronary bypass surgery; **OR**
 - Suspicion of ACS (where myocardial infarction [MI] or unstable angina has not been ruled out)³⁰; **OR**
 - Status post-heart transplantation; **OR**

- Recent MI (30 days or less)³⁰; **OR**
- Prior pacemaker or defibrillator lead placement; **OR**
- Newly diagnosed systolic heart failure, with no prior left heart catheterization; **OR**
- Non-obstructing stenosis (less than 50% of all major epicardial vessels) on CTA or catheterization in the past 12 months, in the absence of a new symptom complex; **OR**
- Coronary anatomy seen on CCTA demonstrates stenoses less than 30% or greater than 90%^{30,31}; **OR**
- When turnaround times may impact prompt clinical care decisions.
- **Artificial intelligence (AI)-enabled computed tomography (CT)-based quantitative coronary topography or coronary plaque analysis** is not considered appropriate if **ANY** of the following is **TRUE**:
 - CAD-RADS 4 B; **OR**
 - CAD-RADS 5 B; **OR**
 - Disease surveillance; **OR**
 - High-grade stenosis (greater than or equal to 70%); **OR**
 - In conjunction with invasive coronary catheterization; **OR**
 - Normal CCTA results (i.e., CAD-RADS 0 or no plaque disease); **OR**
 - Screening in the absence of signs, symptoms, or disease; **OR**
 - The request is in conjunction with a CCTA study, as CCTA must be complete prior to plaque analysis; **OR**
 - Unstable coronary symptoms; **OR**
 - Within 30 days of an MI.

Disclaimer on Radiation Exposure in Pediatric Populations

Cohere Health is committed to ensuring that every patient has access to appropriate and safe imaging studies in accordance with established guidelines. While radiographic studies, such as computed tomography (CT), can provide critical clinical information, exposure to ionizing radiation has the potential to increase lifetime cancer risk. Risk is higher in pediatric patients due to their greater radiosensitivity and longer expected lifespan.

Radiation-induced risks can be reduced by ensuring that imaging is medically necessary and by optimizing procedures to use the lowest dose necessary to achieve diagnostic quality images, consistent with ALARA (As Low As Reasonably Achievable) principles. Alternative modalities that do not involve ionizing radiation should be considered when clinically feasible, such as ultrasound or magnetic resonance imaging (MRI). Providers should adjust equipment and dose to pediatric body sizes and track cumulative radiation exposure for patients requiring multiple imaging studies.

These measures align with guidance from the US Food and Drug Administration (FDA) initiative to reduce unnecessary radiation exposure, the National Cancer Institute pediatric CT risk guidelines, and the Image Gently Alliance and Image Wisely Alliance recommendations for pediatric radiation safety.³⁵⁻³⁹

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established." When clinical coverage criteria are "not fully established," Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.¹

The potential clinical harms of using these criteria for coronary computed tomography angiography (CCTA), with or without fractional flow reserve (FFR) or artificial intelligence (AI) plaque analysis may include:

- Adverse effects from delayed or denied treatment, such as major adverse cardiac events (MACE).⁴⁰
- Errors or biased interpretations of artificial intelligence (AI)-enabled plaque analysis of CCTA scans, which may occur if algorithms are trained on non-representative populations or flawed inputs.^{41,42}

The clinical benefits of using these criteria for CCTA, with or without FFR or AI plaque analysis may include:

- Improved patient selection, resulting in better long-term outcomes, such as those with intermediate pre-test probability or ambiguous symptoms.²⁰
- Maintenance of rigorous patient safety standards aligned to best available evidence.
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

In the 2021 chest pain guideline for the American College of Cardiology, Gulati et al. gave several recommendations for the use of coronary computed tomography angiography (CCTA), including for intermediate-risk patients with acute chest pain and no known coronary artery disease (CAD) who require diagnostic testing following a negative evaluation for acute coronary syndrome. Additionally, CCTA was confirmed as a proven approach for evaluating patients with stable chest pain with a strong (Class 1) strength of recommendation. The authors state that CCTA helps exclude atherosclerotic plaque and obstructive CAD. A recommendation was given for CCTA to diagnose obstructive CAD in patients at intermediate risk with acute pain and mildly abnormal previous stress testing.²⁰

Chen et al. (2021) reviewed the current status of fractional flow reserve-computed tomography (FFR CT). Studies validating the technology included the DEFER trial (2001), which concluded that patients with an FFR greater than 0.75 did not benefit from percutaneous intervention. The FAME trial (2009) found an 18% reduction in the 1-year composite endpoint of myocardial infarction (MI), death, and repeat revascularization with FFR of 0.80 compared to visual interpretation when planning stent placement. The review included evidence that supports the diagnostic accuracy of FFR CT from a number of large-scale multicenter trials of 50 to 5083 patients between 2011 and 2019.³³

Driessen et al. (2019) published post hoc results from a single-center study comparing CCTA, FFR, and perfusion imaging for ischemia diagnosis. The 208 patients were enrolled with suspicion of CAD and underwent CCTA, single-photon emission computed tomography (SPECT), and positron emission tomography (PET) scans with a routine FFR study of all major coronary arteries. All patients were prospectively tested noninvasively and invasively with FFR within 2 weeks, regardless of their results. CCTA images of 75% of patients were sufficient for noninvasive FFR evaluation. The authors concluded that noninvasive FFR showed high diagnostic performance for vessel-specific ischemia, provided that the CCTA images were adequate for FFR evaluation.⁴³

Taylor et al. (2010) developed appropriate use criteria for cardiac computed tomography. The use of CCTA in low- or intermediate-risk patients with a pretest probability of CAD may be considered. Testing in high-risk patients, routine retesting, and use for general cardiac screening were not viewed favorably. Lowest appropriateness ratings were assigned in urgent presentations with acute symptoms with suspicion of acute coronary syndrome, such as in definite MI, persistent ST-segment elevation on ECG (MI excluded), and acute chest pain of uncertain cause, prompting the test to rule out pulmonary embolism, aortic dissection, and acute coronary syndrome.³⁴

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Policy Revision History/Information

Clinical Policy Version	Date	Review History
Version 1	09/12/2024	Original Date.
Version 1.1	03/27/2025	Updated policy per CMS revisions for 11/24/24.
Version 1.2	04/22/2025	Updated policy per CMS revisions for 03/13/2025.
Version 1.3	05/15/2025	Updated policy per CMS revisions for 04/17/2025.
Version 2	09/11/2025	Annual review. Superseded LCD links and references for L33423, L33947, L35121, and L38278 were updated to the new versions. All indications and non-Indications were revised to focus solely on CMS documents. All criteria were referenced to the appropriate LCDs. Included the CAD Consortium's Pre-Test Probability of CAD calculator in the indications section. Added indication for "surveillance of cardiac allograft vasculopathy (CAV) in heart transplant patients, typically every 1-2 years unless the patient is at high-risk (e.g., known moderate CAD or prior coronary intervention)."
Version 3	02/26/2026	Revision. Policy name changed. Formerly "Cohere Medicare Advantage Policy - Coronary Computed Tomography Angiography (CCTA), With or Without Fractional Flow Reserve (FFR)." Added CPT 75577. Updated template, including addition of "Table 1 - Related CMS Policies" that describes Cohere definition of which LCDs/NCDs are not fully established. Cohere MA criteria updated for internal alignment across policies. Added NCD 220.1 and LCDs L39840, L39851, L39863, L39881, and L39913. Added indications and non-indications for "Artificial intelligence (AI)-enabled computed tomography (CT)-based quantitative coronary topography or coronary plaque analysis." Added Definitions. Updated Harms and Benefits (added references 40–42). Updated Disclaimer on Radiation Exposure in Pediatric Populations (added references 35–39).



Cohere Medicare Advantage Policy – Computed Tomography (CT), Brain

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 29, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Brain

Date of last literature review: 10/29/2024

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Brain

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹⁻⁴

- [National Coverage Determination \(NCD\). Computed Tomography \(220.1\)](#)
- [Local Coverage Determination \(LCD\). CT of the Head \(L34417\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L37373\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L35175\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57204\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\)](#)

Recommended Clinical Approach

Computed tomography (CT) of the brain is often appropriate when MRI is unavailable or contraindicated. The clinical request form for a CT Head should be initiated by the referring physician or any appropriate allied healthcare professional familiar with the patient's clinical problem or question and consistent with the state scope of practice requirements. CT Head will often be the initial screening examination to evaluate for acute, life-threatening conditions but will be commonly supplemented by MRI evaluation subsequently.⁵

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of computed tomography (CT), brain. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁶⁻¹⁰
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.⁹ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹⁰
- Compared to adults, children are more sensitive to radiation. CT exposure among children may increase their risk of leukemia and brain cancer.¹¹
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹²

The clinical benefits of using these criteria include:

- Compared to other neuroimaging modalities, CT is widely available and can be performed quickly and at relatively low cost.¹³
- Computed tomography can be particularly useful in the evaluation of patients unable to tolerate magnetic resonance imaging (MRI).¹⁴
- Compared to MRI, CT can provide clearer depictions of calcification, a particularly salient advantage in evaluations of populations at risk for calcified lesions or vascular or cavernous malfunctions.¹⁴
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), brain** is considered appropriate if **ANY** of the following is **TRUE**:

◆ **ALL** of the following are **TRUE**:

- MRI is contraindicated or cannot be performed; **AND**
- **ANY** of the following:
 - Syncope with clinical concern for seizure or associated neurological signs and symptoms; **OR**
 - For evaluation of cranial nerve abnormalities; **OR**
 - For evaluation of visual abnormalities; **OR**
 - Mental status change, including but not limited to cognitive impairment^{15,16}; **OR**
 - Developmental delay in a child less than 18 years of age¹⁵; **OR**
 - Pediatric population with persistent headaches for **ANY** of the following:
 - ◆ Occipital location; **OR**
 - ◆ Severe headache in a child with an underlying disease that predisposes them to intracranial pathology, including but not limited to immune deficiency, sickle cell disease, neurofibromatosis, hypertension; **OR**
 - Focal abnormality present³⁻⁴; **OR**
 - The patient has experienced a significant change in symptoms³⁻⁴; **OR**

- Movement disorders including **ANY** of the following neurodegenerative diseases²⁴:
 - ◆ Acute onset of a movement disorder with concern for stroke or hemorrhage; **OR**
 - ◆ Evaluation of Parkinson's disease with atypical features or other movement disorders, including but not limited to suspected Huntington's disease, chorea, hemiballismus, and atypical dystonia, to exclude an underlying structural lesion; **OR**
- Acute neurologic deficit, including but not limited to ataxia or cranial nerve dysfunction^{15,21}; **OR**
- Vertigo, acute or recurrent with **ANY** of the following^{25,26}:
 - ◆ Signs and symptoms suggestive of a central nervous system lesion; **OR**
 - ◆ Progressive unilateral hearing loss; **OR**
 - ◆ Risk factors for cerebrovascular disease with concern for stroke; **OR**
 - ◆ After a full neurological examination and vestibular testing with concern for central vertigo; **OR**
- ◆ Congenital skull and brain lesions, including but not limited to craniosynostosis, macrocephaly, and microcephaly¹⁵; **OR**
- ◆ Patients whose condition requires the visualization of fine bone detail or calcification; **OR**
- ◆ The patient has **ANY** of the following:
 - Acute central nervous system hemorrhage^{3,4}; **OR**
 - Cerebrovascular accident or encephalomalacia²⁻⁴; **OR**
 - New onset seizures, including but not limited to focal onset seizures^{3,4}; **OR**
 - Headache or dizziness and **ANY** of the following¹⁵⁻²³:
 - Focal abnormality on neurologic exam^{3,4}; **OR**
 - A significant change in symptoms³⁻⁴; **OR**
 - Head injury and intracranial bleeding is suspected^{3,4,15-19}; **OR**
 - Duration of headache is greater than 2 weeks and unresponsive to medical therapy^{3,4}; **OR**

- Sudden onset of severe headache with concern for aneurysm, bleeding, or arteriovenous malformation^{3,4}; **OR**
- With features of intracranial hypertension, including but not limited to papilledema, pulsatile tinnitus, visual symptoms worse on Valsalva); **OR**
- Fever; **OR**
- History of cancer or immunocompromised; **OR**
- Increasing frequency or severity (during a course of physician-directed treatment); **OR**
- Related to activity or event (including, but not limited to, sexual activity, exertion, Valsalva, positional) with new or progressively worsening symptoms; **OR**
- Older age (over 50 years) at onset; **OR**
- Sudden onset of the worst headache of life; **OR**
- Intractable vomiting; **OR**
- ◆ Neoplastic conditions for **ANY** of the following is **TRUE**:²⁷⁻³¹
 - Initial staging; **OR**
 - Treatment planning; **OR**
 - Surveillance and **ANY** of the following is **TRUE**:²⁷⁻³¹
 - The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - Suspected recurrence/progression; **OR**
 - Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6-8 weeks since the prior imaging evaluation); **OR**
- ◆ Preoperative, postoperative, or pretreatment or post-treatment evaluation; **OR**
- ◆ Congenital conditions (e.g., hydrocephalus), and **ANY** of the following is **TRUE**:^{15,32,33}
 - Perioperatively if indicated based on the underlying disease and preoperative radiographic findings; **OR**
 - 6-12 months after placement of ventriculoperitoneal shunt; **OR**

- With neurologic symptoms that suggest shunt malfunction;
OR
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography (CT), brain** is not considered appropriate if **ANY** of the following is **TRUE**³⁴:

- ◆ Absence of symptoms of brain involvement, and **ANY** of the following is **TRUE**:
 - Esophagus cancer; **OR**
 - Oropharynx cancer; **OR**
 - Prostate cancer; **OR**
 - Non-melanoma skin cancer; **OR**
- ◆ History of anaphylactic allergic reaction to iodinated contrast media.³⁵

*For malignancies that commonly metastasize to the brain, staging in the absence of neurological findings may be appropriate.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{[36,37](#)}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{[36,37](#)}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{[36,37](#)}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{[36,37](#)}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70450	Computed tomography (CT), head or brain; without contrast material
70460	Computed tomography (CT), head or brain; with contrast material(s)
70470	Computed tomography (CT), head or brain; without contrast material, followed by contrast material(s) and further sections

76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Bedernik et al. (2022) conducted a randomized control trial (RCT) to assess image quality by comparing single-energy computed tomography (SECT) with automated tube voltage adaptation (TVA) to dual-energy CT (DECT) weighted average images. A total of 80 patients underwent SECT or radiation dose-matched DECT. The effective radiation dose (ED) showed no significant difference between the SECT and DECT study groups. Compared to the SECT group, the DECT group exhibited significantly higher contrast-to-noise ratio differences (CNRD) for jugular veins relative to fatty tissue and muscle tissue relative to fatty tissue. However, the CNRD for jugular veins relative to muscle tissue was comparable between groups. Image artifacts were also less pronounced, and overall diagnostic acceptability was higher in the DECT group. Overall, DECT-weighted average images demonstrate superior objective and subjective image quality compared to SECT performed with TVA in head and neck imaging.¹³

Smith-Bindman et al. (2020) performed an RCT to study the efficacy of interventions to lower the amount of radiation patients are exposed to. The RCT included 864,080 adults at 100 facilities who underwent a CT scan, including CT Head (1,156,657 total scans). The study included two primary measures: the percentage of high-dose CT scans and the average effective dose administered at the facility level. The study's secondary measure included the doses received by specific organs. Outcomes were assessed concerning the impact of the interventions and outcomes post-intervention. Data were contrasted with pre-intervention data, utilizing hierarchical generalized linear models that accounted for temporal patterns and patient attributes. In conclusion, data regarding CT radiation dosage and practical recommendations may improve quality, including significant dose reductions, especially for organ-specific doses.¹¹

Tranvinh et al. (2019) examined the evidence backing the utilization of neuroimaging in adult patients experiencing a new-onset seizure. In the acute setting, unenhanced CT serves as the primary imaging modality for adults encountering their first unprovoked seizure, prioritizing the exclusion of urgent or emergent conditions. An initial unenhanced head CT scan may rule out treatable intracranial abnormalities promptly. If the CT findings are negative but clinical suspicion persists for a structural cause of the seizure, MRI should be considered, particularly in acute cases. MRI offers supplementary advantages and is helpful for patients with negative initial CT findings in acute scenarios and those experiencing new-onset seizures in nonacute circumstances.¹⁴

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Clinical Guideline Revision History/Information

Original Date: October 29, 2024		
Review History		



Cohere Medicare Advantage Policy – Computed Tomography (CT), Brain

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 29, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography (CT), Brain

Date of last literature review: 10/29/2024

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Brain

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁴

- [National Coverage Determination \(NCD\). Computed Tomography \(220.1\)](#)
- [Local Coverage Determination \(LCD\). CT of the Head \(L34417\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L37373\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L35175\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57204\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\)](#)

Recommended Clinical Approach

Computed tomography (CT) of the brain is often appropriate when MRI is unavailable or contraindicated. The clinical request form for a CT Head should be initiated by the referring physician or any appropriate allied healthcare professional familiar with the patient's clinical problem or question and consistent with the state scope of practice requirements. CT Head will often be the initial screening examination to evaluate for acute, life-threatening conditions but will be commonly supplemented by MRI evaluation subsequently.⁵

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of computed tomography (CT), brain. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- The inherent risk of the procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁶⁻¹⁰
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.⁹ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.¹⁰
- Compared to adults, children are more sensitive to radiation. CT exposure among children may increase their risk of leukemia and brain cancer.¹¹
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹²

The clinical benefits of using these criteria include:

- Compared to other neuroimaging modalities, CT is widely available and can be performed quickly and at relatively low cost.¹³
- Computed tomography can be particularly useful in the evaluation of patients unable to tolerate magnetic resonance imaging (MRI).¹⁴
- Compared to MRI, CT can provide clearer depictions of calcification, a particularly salient advantage in evaluations of populations at risk for calcified lesions or vascular or cavernous malfunctions.¹⁴
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), brain** is considered appropriate if **ANY** of the following is **TRUE**:

◆ **ALL** of the following are **TRUE**:

- MRI is contraindicated or cannot be performed; **AND**
- **ANY** of the following:
 - Syncope with clinical concern for seizure or associated neurological signs and symptoms; **OR**
 - For evaluation of cranial nerve abnormalities; **OR**
 - For evaluation of visual abnormalities; **OR**
 - Mental status change, including but not limited to cognitive impairment¹⁵⁻¹⁶; **OR**
 - Developmental delay in a child less than 18 years of age¹⁵; **OR**
 - Pediatric population with persistent headaches for **ANY** of the following:
 - ◆ Occipital location; **OR**
 - ◆ Severe headache in a child with an underlying disease that predisposes them to intracranial pathology, including but not limited to immune deficiency, sickle cell disease, neurofibromatosis, hypertension; **OR**
 - ◆ Focal abnormality present³⁻⁴; **OR**
 - ◆ The patient has experienced a significant change in symptoms³⁻⁴; **OR**

- Movement disorders including **ANY** of the following neurodegenerative diseases⁴:
 - ◆ Acute onset of a movement disorder with concern for stroke or hemorrhage; **OR**
 - ◆ Evaluation of Parkinson's disease with atypical features or other movement disorders, including but not limited to suspected Huntington's disease, chorea, hemiballismus, and atypical dystonia, to exclude an underlying structural lesion; **OR**
- Acute neurologic deficit, including but not limited to ataxia or cranial nerve dysfunction^{15,18}; **OR**
- Vertigo, acute or recurrent with **ANY** of the following¹⁹⁻²⁰:
 - ◆ Signs and symptoms suggestive of a central nervous system lesion; **OR**
 - ◆ Progressive unilateral hearing loss; **OR**
 - ◆ Risk factors for cerebrovascular disease with concern for stroke; **OR**
 - ◆ After a full neurological examination and vestibular testing with concern for central vertigo; **OR**
- ◆ Congenital skull and brain lesions, including but not limited to craniosynostosis, macrocephaly, and microcephaly¹⁵; **OR**
- ◆ Patients whose condition requires the visualization of fine bone detail or calcification; **OR**
- ◆ The patient has **ANY** of the following:
 - Acute central nervous system hemorrhage³⁻⁴; **OR**
 - Cerebrovascular accident or encephalomalacia²⁻⁴; **OR**
 - New onset seizures, including but not limited to focal onset seizures³⁻⁴; **OR**
 - Headache or dizziness and **ANY** of the following^{3,15}:
 - Focal abnormality on neurologic exam³⁻⁴; **OR**
 - A significant change in symptoms³⁻⁴; **OR**
 - Head injury and intracranial bleeding is suspected^{3-4,15}; **OR**
 - Duration of headache is greater than 2 weeks and unresponsive to medical therapy³⁻⁴; **OR**

- Sudden onset of severe headache with concern for aneurysm, bleeding, or arteriovenous malformation³⁻⁴; **OR**
- With features of intracranial hypertension, including but not limited to papilledema, pulsatile tinnitus, visual symptoms worse on Valsalva); **OR**
- Fever; **OR**
- History of cancer or immunocompromised; **OR**
- Increasing frequency or severity (during a course of physician-directed treatment); **OR**
- Related to activity or event (including, but not limited to, sexual activity, exertion, Valsalva, positional) with new or progressively worsening symptoms; **OR**
- Older age (over 50 years) at onset; **OR**
- Sudden onset of the worst headache of life; **OR**
- Intractable vomiting; **OR**
- ◆ Neoplastic conditions for **ANY** of the following is **TRUE**:^{15-18,21}
 - Initial staging; **OR**
 - Treatment planning; **OR**
 - Surveillance and **ANY** of the following is **TRUE**:^{15-18,21}
 - The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - Suspected recurrence/progression; **OR**
 - Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6-8 weeks since the prior imaging evaluation); **OR**
- ◆ Preoperative, postoperative, or pretreatment or post-treatment evaluation; **OR**
- ◆ Congenital conditions (e.g., hydrocephalus), and **ANY** of the following is **TRUE**:^{15,22-23}:
 - Perioperatively if indicated based on the underlying disease and preoperative radiographic findings; **OR**
 - 6-12 months after placement of ventriculoperitoneal shunt; **OR**

- With neurologic symptoms that suggest shunt malfunction;
OR
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Computed tomography (CT), brain** is not considered appropriate if **ANY** of the following is **TRUE**²⁴:

- ◆ Absence of symptoms of brain involvement, and **ANY** of the following is **TRUE**:
 - Esophagus cancer; **OR**
 - Oropharynx cancer; **OR**
 - Prostate cancer; **OR**
 - Non-melanoma skin cancer; **OR**
- ◆ History of anaphylactic allergic reaction to iodinated contrast media.²⁵

*For malignancies that commonly metastasize to the brain, staging in the absence of neurological findings may be appropriate.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure. [26-27](#)

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography. [26-27](#)

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation. [26-27](#)

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images. [26-27](#)

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70450	Computed tomography (CT), head or brain; without contrast material
70460	Computed tomography (CT), head or brain; with contrast material(s)
70470	Computed tomography (CT), head or brain; without contrast material, followed by contrast material(s) and further sections
76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Bedernik et al. (2022) conducted a randomized control trial (RCT) to assess image quality by comparing single-energy computed tomography (SECT) with automated tube voltage adaptation (TVA) to dual-energy CT (DECT) weighted average images. A total of 80 patients underwent SECT or radiation dose-matched DECT. The effective radiation dose (ED) showed no significant difference between the SECT and DECT study groups. Compared to the SECT group, the DECT group exhibited significantly higher contrast-to-noise ratio differences (CNRD) for jugular veins relative to fatty tissue and muscle tissue relative to fatty tissue. However, the CNRD for jugular veins relative to muscle tissue was comparable between groups. Image artifacts were also less pronounced, and overall diagnostic acceptability was higher in the DECT group. Overall, DECT-weighted average images demonstrate superior objective and subjective image quality compared to SECT performed with TVA in head and neck imaging.¹³

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Cohere Medicare Advantage Policy – Computed Tomography (CT), Lower Extremity

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Medical Necessity Criteria

Service: Computed Tomography (CT), Lower Extremity

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\) 220.1. Computed Tomography](#)

Recommended Clinical Approach

Computed tomography (CT) of the lower extremity for trauma and fracture generally does not require contrast. IV contrast should be used at the request of the ordering provider with guidance from the radiologist. Common indications for administering contrast include infectious and inflammatory conditions, as well as fractures, tumors, palpable abnormalities, and concern for malignancy of the soft tissues. CT scan coverage can be modified to include the region of clinical suspicion. Intra-articular contrast may be useful in patients for whom internal joint derangement or cartilage loss is suspected, but in whom MR is not possible (e.g., incompatible pacemaker, unable to tolerate MR exam, metallic artifact).

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of CT of the lower extremity. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals

reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Computed tomography imaging employs ionizing radiation in the form of x-rays, and while such routine x-rays use low levels of ionizing radiation, this form of radiation is known to increase the risk of cancer.²
- Young children are more sensitive to radiation than adults and even the low-dose radiation of CT may pose a significant cancer risk to pediatric patients. In growing children, the thyroid gland, breast tissue, and gonads are particularly sensitive to radiation.^{3,4}
- The contrast agent, or dye, employed in some lower extremity CT scans has been linked to a renal dysfunction called contrast-induced nephropathy. Patients undergoing consecutive scans, or patients with cirrhosis, hypotension, or peritoneal carcinomatosis may be predisposed to contrast-induced nephropathy.⁵
- Contrast agents may also produce adverse anaphylactoid or nonanaphylactoid reactions. Women, infants, older adults, and Individuals with medical conditions such as diabetes, asthma, or thyroid disorders may be predisposed to contrast induced allergic reactions.⁶
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- As a component of a whole-body trauma study, CT may aid in surgical planning by enabling triage through the simultaneous consideration of extremity and intracavitary injuries.⁷
- Computed tomography is more sensitive to lower extremity fractures than conventional radiographic examinations, while delivering an equivalent dose of radiation.⁸
- For patients for whom magnetic resonance imaging is unavailable or contraindicated, CT can serve as an alternative when an occult proximal femoral fracture is suspected.⁹
- Computed tomography scans can visualize anatomical structures, including the posterior cruciate ligament, allowing for better soft tissue protection in surgical procedures such as total knee arthroplasty.¹⁰

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Computed tomography (CT), lower extremity** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Neoplastic conditions (including masses and mass-like conditions) requiring evaluation (e.g., for treatment planning, treatment response, or prognostication) and **ANY** of the following is **TRUE**¹⁰⁻¹³:

- Malignant or aggressive primary bone tumor¹¹; **OR**
- Malignant or aggressive primary soft tissue tumor¹¹; **OR**
- Metastatic lesions of the lower extremity; **OR**
- Nonsuperficial (deep) soft tissue mass¹²; **OR**
- Soft tissue mass and MRI or ultrasound is unable to be performed or is contraindicated¹²; **OR**
- A primary bone tumor is suspected, and radiographs indicate **ANY** of the following¹³:
 - Radiograph is negative; **OR**
 - Benign features (osteoid osteoma is not suspected); **OR**
 - Osteoid osteoma is suspected; **OR**
 - Lesion is present on plain radiographs; **OR**
 - Indeterminate or aggressive appearance for malignancy; **OR**

- “Incidental” osseous lesion on MRI or CT scan for unrelated indication; **OR**
- Presence of a mass with **ANY** of the following¹²:
 - Absence of trauma; **OR**
 - Rapid growth; **OR**
 - Recurrence after prior surgery; **OR**
 - Non-diagnostic ultrasound or other inconclusive imaging; **OR**
- Follow-up exam to further characterize a bone or soft tissue lesion diagnosed on the initial radiologic exam, including radiograph, ultrasound, magnetic resonance (MR), and nuclear medicine studies¹³; **OR**
- Known malignancy with unexpected, localized lower extremity pain or swelling; **OR**
- Persistent palpable abnormality with non-diagnostic imaging (e.g., radiograph, ultrasound); **OR**
- Routine surveillance of known malignancy; **OR**
- ◆ Acute traumatic lower extremity injury (e.g., fracture, dislocation) that requires additional detail than is available with plain radiographs and **ANY** of the following is **TRUE**^{14,15}:
 - Bony injury and **ANY** of the following is **TRUE**¹⁴:
 - Fracture (known) and additional detail needed; **OR**
 - Acute injury with occult fracture suspected; **OR**
 - Joint dislocation or instability; **OR**
 - Stress/insufficiency fracture (known) and follow-up imaging needed; **OR**
 - Stress/insufficiency fracture (suspected) with negative radiographs; **OR**
 - Suspected soft tissue injury (e.g., peroneal tendon injury) and MRI or ultrasound is unable to be performed or is contraindicated; **OR**
- ◆ Chronic injury with ongoing symptoms and **ALL** of the following is **TRUE**^{16,17}:
 - The patient has failed conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 6 weeks; **AND**

- Radiographs are negative for osseous injury, an alignment abnormality is suspected based on physical examination, or the injury requires additional detail than is available with plain radiographs and **ALL** of the following are **TRUE**:
 - MRI and/or ultrasound are contraindicated or cannot be performed; **AND**
 - Radiographs that suggest **ANY** of the following:
 - ◆ Dislocation; **OR**
 - ◆ Syndesmotic injury; **OR**
 - ◆ Other ligamentous injury; **OR**
- ◆ The patient requires a CT with arthrogram for a knee meniscal tear, and **ALL** of the following is **TRUE**:
 - Concern for rupture or high-grade tear based on clinical history, imaging, or physical exam; **AND**
 - Joint-specific orthopedic evaluation and maneuvers suggest a tear; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Detection, screening, surveillance, and follow-up of autoimmune, collagen vascular diseases, or inflammatory conditions (e.g., inflammatory arthritis)¹⁸; **OR**
 - Osteonecrosis, known or suspected, with negative radiographs¹⁹; **OR**
 - MRI and/or ultrasound are contraindicated or cannot be performed, and the patient requires evaluation for vascular malformation (with or without pain) due to **ANY** of the following findings²⁰:
 - Diffuse or focal enlargement; **OR**
 - Discoloration; **OR**
 - Soft-tissue mass; **OR**
 - Ulceration; **OR**
 - Vascular bruit or thrill; **OR**
- ◆ Pre and post-intervention evaluation (including the diagnosis of postoperative complications) when **ANY** of the following is **TRUE**:
 - Imaging after hip arthroplasty and **ANY** of the following is **TRUE**²¹:
 - Hardware fracture; **OR**
 - History of acute injury; **OR**

- Metal-on-metal prosthesis with an adverse reaction to metal debris; **OR**
- Trunnionosis (corrosion or metallosis), suspected; **OR**
- Pain with **ANY** of the following (infection excluded):
 - ◆ Aseptic loosening; **OR**
 - ◆ Instability; **OR**
 - ◆ Osteolysis; **OR**
- Periprosthetic fracture; **OR**
- Imaging after knee arthroplasty and **ANY** of the following are suspected (with or without pain)²²:
 - Hardware fracture; **OR**
 - Infection; **OR**
 - Pain with **ANY** of the following (infection excluded):
 - ◆ Aseptic loosening; **OR**
 - ◆ Instability; **OR**
 - ◆ Osteolysis; **OR**
 - Periprosthetic fracture; **OR**
 - Concern for injury to extensor mechanism; **OR**
- ◆ Infection or an infectious disorder including **ANY** of the following:
 - Septic arthritis with **ANY** of the following:
 - Elevated laboratory markers (e.g., ESR/CRP, white blood cell count); **OR**
 - Findings are suggestive of joint effusion or soft tissue swelling²³; **OR**
 - Clinical history of **ANY** of the following:
 - ◆ Adjacent infection; **OR**
 - ◆ Diabetes; **OR**
 - ◆ IV drug use; **OR**
 - ◆ Previous surgery on the suspected joint of concern (e.g., joint replacement/ ligament, labral, meniscus repair); **OR**
 - Physical exam that supports suspicion of septic arthritis; **OR**
 - Positive joint aspiration; **OR**
 - Septic arthritis is suspected with normal initial radiographs²³; **OR**
 - Osteomyelitis, suspected^{22,23}; **OR**

- Soft tissue infection suspected with a history of puncture wound with possible retained foreign body (radiographs normal)²³; **OR**
- Soft tissue infection suspected with high clinical suspicion of necrotizing fasciitis²³; **OR**
- ◆ Evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when MRI is contraindicated or cannot be performed, and the patient requires evaluation²⁴:
 - Marrow abnormalities²⁴; **OR**
 - Pain or weakness of a lower extremity as indicated by **ALL** of the following:
 - Nondiagnostic or indeterminate imaging (e.g. radiographs, US); **AND**
 - Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 3 months; **AND**
 - Concern for rupture or high-grade tear based on **ALL** of the following:
 - ◆ Clinical history; **AND**
 - ◆ Physical exam; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Computed tomography (CT), lower extremity** is not considered appropriate if **ANY** of the following is **TRUE**²⁵:
 - ◆ If contrast is used, history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.

**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{[26,27](#)}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{[26,27](#)}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{[26,27](#)}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{[26,27](#)}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description/Definition
73700	Computed tomography (CT), lower extremity; without contrast material
73701	Computed tomography (CT), lower extremity; with contrast material
73702	Computed tomography (CT), lower extremity; without contrast material, followed by contrast material(s) and further sections
76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Dreizin et al. (2022) review the role of computed tomography (CT) and computed tomography angiography (CTA) in trauma and salvaging a threatened or mangled extremity. When reviewing CT scans to assess complications around the amputation site, attention should focus on signs such as surgical wound opening, ulceration, infection, post-surgical blood collections, lingering bone fragments, abnormal bone growth, excessive scarring, and the maintenance of vascular function. Damage control techniques involve swift actions to manage bleeding and restore blood circulation. Early implementation of fasciotomies may be required, along with immediate temporary realignment and stabilization using splints, traction, or external fixation. The measures aim to safeguard the repaired blood vessels and ensure a smooth connection without tension.⁷

Allen et al. (2020) performed an observational study to evaluate the incidence of fractures and ligament injuries among patients presenting with an acute ankle injury and normal findings on radiographic examination while also exploring optimal examination protocols. A total of 100 patients were enrolled in the study – 19 were diagnosed with major fractures, and 42 had small avulsion fractures. Further, 42 patients exhibited ankle effusions, alongside a notable occurrence of soft tissue injuries. CT scans and ultrasound can identify fractures and soft tissue injuries yet may be utilized less frequently in standard clinical practice. The authors also discuss advances in imaging techniques. Research indicates that cone beam CT surpasses ultrasound examination and the traditional combination of clinical assessment and radiography in fracture detection sensitivity. Despite this heightened sensitivity, cone beam CT maintains a radiation exposure level comparable to conventional radiography, suggesting it is a safer and more precise imaging alternative.⁸

Kellock et al. (2019) conducted a meta-analysis on the diagnostic accuracy of CT to identify occult proximal femoral fractures. The authors report 13 studies of varied reporting quality that included 1248 patients (496 with hip fractures, 752 without) with MRI or clinical follow-up serving as the reference standard. Fifty false-negative examinations were identified. The pooled sensitivity estimate was 94%, with specificity reaching 100%. The authors conclude that when clinical suspicion arises for occult proximal femoral fracture, and MRI is either contraindicated or inaccessible, CT represents a viable option. In cases where clinical concern persists despite normal CT results, MRI may be indicated.⁹

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Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Fetal/Placental

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Fetal/Placental

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)

Recommended Clinical Approach

Magnetic Resonance Imaging (MRI) of a fetus/placenta is a diagnostic tool used to provide a detailed view of suspected or known fetal anomalies while the fetus is still in-utero; in addition, it provides a view of the placenta, which is critical for diagnosing and planning the treatment of placenta accreta spectrum disorders (PAS).²⁻³³ Fetal anomalies of interest include neural tube defects (such as spina bifida), cardiovascular abnormalities, pulmonary differences, and certain complications associated with high-risk multiple-gestation pregnancies, including twin-to-twin transfusion syndrome. Because MRI does not use ionizing radiation, it is one of the imaging modalities of choice for pregnant patients. There are no precautions or specific contraindications for the use of MRI in pregnant patients. There are theoretical risks to the fetus – though at present, there is no evidence of actual harm. Because of the theoretical fetal risk, MRI is reserved for only those clinical situations where the diagnostic benefits of MRI outweigh those theoretical risks, which include teratogenesis, tissue heating, and acoustic damage. Tissue heating appears to be negligible due to the proportional distance of the uterus from the scanner, and studies have not demonstrated any evidence of fetal acoustic damage. Teratogenesis has not occurred in

animal studies, and the limited available human literature has not demonstrated an association between fetal MRI imaging and later teratogenesis.^{31,32} Certain conditions require in-utero invasive treatment (including fetal surgery), which relies upon adequate intrapartum imaging. Fetal MRI is of additional use in the advance planning of technically difficult deliveries, such as fetuses with compromised airways who may require complex, assisted delivery methods, like the EXIT (ex utero intrapartum treatment) procedure, to maintain oxygen and blood flow. In general, fetal/placental MRI is considered when the resulting information would be critical in diagnosing a condition, planning the delivery, counseling the pregnant patient, or selecting appropriate surgical or nonsurgical treatment.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Fetal/Placental MRI. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.³⁴⁻³⁶
- The use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.³⁴⁻³⁶
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for magnetic resonance imaging (MRI) in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.³⁷
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.³⁸

The clinical benefits of using these criteria include:

- MRI demonstrates superior visibility and detail of conditions not sufficiently imaged on other conventional imaging, such as congenital anomalies.
- Because MRI does not use ionizing radiation, it is a safer peripartum alternative to computed tomography (CT) when ultrasonography, the traditional first-line imaging modality of pregnancy, is not adequate.
- MRI, as an adjunct to ultrasonography, can help to counsel patients, guide physicians in selecting the appropriate course of management, and plan for delivery.
- MRI is a noninvasive method of diagnosing a fetus with congenital anomalies or placental abnormality which may impact the course of – and management of – a pregnancy.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Fetal/Placental MRI** is considered appropriate if **ALL** of the following are **TRUE**:

- ◆ Ultrasonography has been performed and is indeterminate, technically inadequate, nondiagnostic, or provides an incomplete clinical evaluation; **AND**
- ◆ Per the treating physician, the benefits are felt to outweigh the theoretical risks; **AND**
- ◆ **ANY** of the following is true:

- Evaluation of known or suspected fetal anomaly, including but not limited to **ANY** of the following^{2,3}:
 - Anatomical anomaly (brain, spine, facial, neck, oropharyngeal, thoracoabdominal, cardiac, vascular, pulmonary, gastrointestinal, genitourinary, musculoskeletal, etc.); **OR**
 - Diaphragmatic hernia; **OR**
 - Other tumor or mass; **OR**
 - Other anatomical obstruction; **OR**
- Assessment of the fetal airway²; **OR**
- Evaluation of known or suspected fetal infection³; **OR**
- Evaluation of fetus in the setting of abnormal amniotic fluid, including **ANY** of the following^{4,5}:
 - Polyhydramnios; **OR**
 - Oligohydramnios; **OR**
 - Anhydramnios; **OR**
- Planning or evaluation of candidacy for fetal surgery or other in-utero intervention²; **OR**
- Planning or evaluation of candidacy for complex assisted delivery (e.g., – EXIT procedure)^{2,3,3}; **OR**
- Planning or evaluation of candidacy for post-delivery neonatal surgery²; **OR**
- Complications related to a multiple-gestation pregnancy²; **OR**
- Assessment of fetal morbidity of remaining fetus following in-utero death of a co-twin or co-multiple²; **OR**
- Maternal placental complication as indicated by **ANY** of the following^{6,7,8}:
 - For cesarean section delivery planning/peripartum hysterectomy planning among patients with **ANY** of the following:
 - ◆ Known or suspected placenta accreta spectrum disorder (PAS: placenta increta, placenta percreta, placenta accreta); **OR**
 - ◆ At high risk of PAS, including **ANY** of the following:
 - History of cesarean section; **OR**
 - Prior uterine surgery; **OR**
 - Prior or current placenta previa; **OR**
 - Prior placenta accreta spectrum disorder; **OR**
 - Known adenomyosis; **OR**
 - Pregnancy was conceived with assisted reproductive technology (in vitro fertilization [IVF], frozen embryo transfer,

- Intracytoplasmic sperm injection [ICSI]);
 - OR**
 - Advanced maternal age (greater than or equal to 35 years); **OR**
 - Asherman's syndrome; **OR**
 - Prior curettage; **OR**
 - Multiparity; **OR**
 - Known or suspected posterior placenta previa; **OR**
 - Known or suspected placental abruption; **OR**
 - Known or suspected gestational trophoblastic disease; **OR**
 - Known or suspected adnexal lesions; **OR**
- Evaluation, during pregnancy, of known maternal leiomyoma at high risk of degeneration or rupture, including **ANY** of the following¹⁶:
 - Submucosal leiomyoma; **OR**
 - Retroplacental leiomyoma; **OR**
 - Leiomyoma which enlarges in the first trimester; **OR**
- Screening if **ANY** of the following are true²:
 - Family risk for inheritable brain abnormalities, including but not limited to tuberous sclerosis, corpus callosal dysgenesis, or lissencephaly; **OR**
 - Volumetric assessment of fetal lung parenchyma among fetuses at risk for pulmonary hypoplasia; **OR**
- Repeat imaging with fetal/placental MRI is indicated if **ANY** of the following is true²:
 - In-utero fetal surgery or in-utero intervention has been performed and necessitates follow-up imaging; **OR**
 - Serial antepartum imaging is necessary for ongoing planning, management, or evaluation of the fetal or placental condition; **OR**
 - The initial study was limited, incomplete, or of poor quality due to **ANY** of the following:
 - ◆ Insufficient gestational age; **OR**
 - ◆ Small fetal size; **OR**
 - ◆ Atypical fetal position; **OR**
 - ◆ Fetal movement that degraded the image of the region of interest.

Non-Indications

→ **Fetal/Placental MRI** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; **OR**
- ◆ When complete diagnostic information can be obtained by ultrasonography; **OR**
- ◆ When used solely to evaluate preterm premature rupture of membranes (PPROM) in the absence of any other indication.

*NOTE: Gadolinium-based contrast is considered to hold unknown risk and potential harm to a fetus and is not recommended for routine administration with fetal/placental MRIs. The decision to use gadolinium in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider. [2,15](#)

**NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
74712	Magnetic resonance (e.g., proton) imaging, fetal, including placental and maternal pelvic imaging when performed; single or first gestation
74713	Magnetic resonance (e.g., proton) imaging, fetal, including placental and maternal pelvic imaging when performed; each additional gestation (List separately in addition to code for primary procedure)

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Magnetic resonance imaging (MRI) is used to diagnose anomalies and disorders of the gravid uterus, fetus, and placenta. Because of the detail and enhanced accuracy of MRI, indicated uses in this setting include known or suspected congenital abnormalities, as well as placental disorders and some complications that are present in multiple-gestation pregnancies. MRI during pregnancy is generally reserved for clinical scenarios in which the diagnostic benefit outweighs the theoretical risks to the fetus and pregnant patient.

With regard to the placenta, the primary indication for MRI is clinical suspicion for placenta accreta spectrum (PAS) disorder, which encompasses placenta increta, placenta percreta, and placenta accreta – a series of clinical entities in which the placenta grows abnormally into the wall of the uterus. Prenatal diagnosis of these conditions is critical due to the high morbidity and mortality associated with delivery, which can result in severe blood loss and death. MRI allows for better visualization of the placenta and subsequent planning for delivery, including peripartum hysterectomy.

Prenatal diagnosis of fetal anomalies is also critical due to the expanding roles of fetal surgery or in-utero intervention for some congenital conditions. Congenital diaphragmatic hernia, for example, can be successfully treated in-utero with fetoscopic endoluminal tracheal occlusion to facilitate the growth of the fetus's pulmonary system. Where fetal surgery is not indicated, fetal MRI still provides valuable clinical information when planning a complex delivery, strategizing for neonatal management, and counseling patients. Prenatal diagnosis has been associated with improved outcomes and decreased perioperative mortality for certain congenital anomalies, including congenital heart disease.²⁸

In 2020, the American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR) published practice parameters to guide the use of fetal and placental MRI.² These guidelines formally support the use of MRI imaging of known or suspected fetal anomalies of numerous body systems – including the central nervous system, cardiopulmonary system, and genitourinary system, as well as complications associated with multiparity, assessment for

fetal in-utero intervention, and evaluation of placental disorders. Other medical societies – including the American Heart Association, with respect to fetal cardiac disease – similarly endorse these indications.

The American College of Obstetricians & Gynecologists issued a recommendation that MRI not be used for *initial* evaluation of placenta accreta spectrum disorders, favoring the use of ultrasonography for primary evaluation – a sentiment that is shared by every other medical society cited within this guideline. A 2016 practice overview was published by investigators at Harvard Medical School, which more strongly recommended MRI for evaluation of placenta accreta spectrum disorders – even in cases where ultrasound evaluation was equivocal – in order to plan for peripartum hysterectomy and reduce both maternal and fetal risk for morbidity and mortality.⁷ Other maternal indications for fetal/placental MRI include the evaluation of specific leiomyomas (uterine fibroids) that are at high risk of degeneration and rupture, a medical emergency that would endanger both the fetus and maternal patient due to the possibility of hemorrhage or blood flow occlusion. Abnormal levels of amniotic fluid (paucity or excess) are also an indication for fetal MRI when ultrasonography is technically inadequate to image the fetus in these circumstances. A 2023 study at the Cleveland Clinic found that fetal MRI – when used in addition to standard ultrasonography – identified fetal anomalies in more than a quarter of patients, allowing for improved diagnosis and perinatal management.⁵

In answer to the suggestion that fetal/placental MRI be contraindicated for patients with viable pregnancies, several points bear noting. First, according to both the American College of Obstetricians & Gynecologists (ACOG) and the American College of Radiology, MRI is safe for use in pregnant patients across all trimesters with no specific precautions or contraindications.^{2,15} The risk to the fetus is theoretical; no evidence of actual harm has been documented, and indeed, numerous studies argue there are no risks of tissue heating and acoustic damage, with an additional growing body of evidence suggesting that teratogenesis is not as significant a risk as previously thought.^{2,15,31,32} Importantly, fetal/placental MRI is not performed routinely, and if ordered, these theoretical risks would be outweighed by the greater benefit of increased visualization. Secondly, the concept of fetal viability is evolving, ever-shifting, and imprecise.^{9,10} It can refer to two discrete ideas: the fetus's predicted ability to survive outside of the uterus if delivered before

development is complete, which is often tied to a specific gestational age, or the idea that a pregnancy will continue to develop “normally,” versus a pregnancy likely to end in early loss or miscarriage.^{9,10} There is no one clear clinical definition of “viability” that is formally recognized, nor is there a definitive diagnostic test.^{9,10}

Thirdly, there are valid indications for fetal/placental MRI that are entirely separate from the health of the fetus. For example, a pregnant patient who is carrying a healthy fetus and who has suspected placenta accreta spectrum disorder that is not optimally visualized on ultrasound is, based on the current medical evidence, indicated to undergo MRI imaging to better plan delivery and possible peripartum hysterectomy.² Inadvertent delivery of the fetus through placenta previa, for instance, can lead to hemorrhage and subsequent fetal-maternal death. Regardless of fetal viability in this specific clinical scenario, it is in the pregnant patient’s best interest to obtain optimal prenatal images of the placenta through fetal/placental MRI. As another example, early detection of a fetus with an oropharyngeal teratoma is critical in mitigating the high mortality risk associated with congenital airway obstructions.² In this scenario, fetal MRI is crucial to prenatally characterize the lesion, plan for complex delivery, and prepare to secure the airway (often surgically) immediately after delivery in order to reduce the risk of asphyxiation and demise. Although such anomalies may be visualized on ultrasonography, an MRI is often better able to elucidate the degree – if any – of central nervous system involvement which could ultimately render the pregnancy nonviable. In this case, any assessment of viability is ultimately dependent on the images obtained from fetal MRI. Another example is the use of MRI in multiple gestation pregnancies, where it is indicated for assessment of the remaining twin’s morbidity after decline/demise of a co-twin.² This pregnancy could be considered viable for one twin, and yet nonviable for the other.

Such clinical scenarios begin to exemplify the dynamic, unpredictable, multifaceted nature of viability and human development, and the role advanced imaging plays in our assessment of viability and understanding of the best clinical path forward – as well as the numerous clinical situations wherein fetal/placental MRI would be indicated for reasons unrelated to the fetus itself.

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Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Fetal/Placental

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Fetal/Placental

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)

Recommended Clinical Approach

Magnetic Resonance Imaging (MRI) of a fetus/placenta is a diagnostic tool used to provide a detailed view of suspected or known fetal anomalies while the fetus is still in-utero; in addition, it provides a view of the placenta, which is critical for diagnosing and planning the treatment of placenta accreta spectrum disorders (PAS).²⁻³³ Fetal anomalies of interest include neural tube defects (such as spina bifida), cardiovascular abnormalities, pulmonary differences, and certain complications associated with high-risk multiple-gestation pregnancies, including twin-to-twin transfusion syndrome. Because MRI does not use ionizing radiation, it is one of the imaging modalities of choice for pregnant patients. There are no precautions or specific contraindications for the use of MRI in pregnant patients. There are theoretical risks to the fetus – though at present, there is no evidence of actual harm. Because of the theoretical fetal risk, MRI is reserved for only those clinical situations where the diagnostic benefits of MRI outweigh those theoretical risks, which include teratogenesis, tissue heating, and acoustic damage. Tissue heating appears to be negligible due to the proportional distance of the uterus from the scanner, and studies have not demonstrated any evidence of fetal acoustic damage. Teratogenesis has not occurred in

animal studies, and the limited available human literature has not demonstrated an association between fetal MRI imaging and later teratogenesis.^{31,32} Certain conditions require in-utero invasive treatment (including fetal surgery), which relies upon adequate intrapartum imaging. Fetal MRI is of additional use in the advance planning of technically difficult deliveries, such as fetuses with compromised airways who may require complex, assisted delivery methods, like the EXIT (ex utero intrapartum treatment) procedure, to maintain oxygen and blood flow. In general, fetal/placental MRI is considered when the resulting information would be critical in diagnosing a condition, planning the delivery, counseling the pregnant patient, or selecting appropriate surgical or nonsurgical treatment.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Fetal/Placental MRI. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.³⁴⁻³⁶
- The use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.³⁴⁻³⁶
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for magnetic resonance imaging (MRI) in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.³⁷
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.³⁸

The clinical benefits of using these criteria include:

- MRI demonstrates superior visibility and detail of conditions not sufficiently imaged on other conventional imaging, such as congenital anomalies.
- Because MRI does not use ionizing radiation, it is a safer peripartum alternative to computed tomography (CT) when ultrasonography, the traditional first-line imaging modality of pregnancy, is not adequate.
- MRI, as an adjunct to ultrasonography, can help to counsel patients, guide physicians in selecting the appropriate course of management, and plan for delivery.
- MRI is a noninvasive method of diagnosing a fetus with congenital anomalies or placental abnormality which may impact the course of – and management of – a pregnancy.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Fetal/Placental MRI** is considered appropriate if **ALL** of the following are **TRUE**:

- ◆ Ultrasonography has been performed and is indeterminate, technically inadequate, nondiagnostic, or provides an incomplete clinical evaluation; **AND**
- ◆ Per the treating physician, the benefits are felt to outweigh the theoretical risks; **AND**
- ◆ **ANY** of the following is true:

- Evaluation of known or suspected fetal anomaly, including but not limited to **ANY** of the following^{2,3}:
 - Anatomical anomaly (brain, spine, facial, neck, oropharyngeal, thoracoabdominal, cardiac, vascular, pulmonary, gastrointestinal, genitourinary, musculoskeletal, etc.); **OR**
 - Diaphragmatic hernia; **OR**
 - Other tumor or mass; **OR**
 - Other anatomical obstruction; **OR**
- Assessment of the fetal airway²; **OR**
- Evaluation of known or suspected fetal infection³; **OR**
- Evaluation of fetus in the setting of abnormal amniotic fluid, including **ANY** of the following^{4,5}:
 - Polyhydramnios; **OR**
 - Oligohydramnios; **OR**
 - Anhydramnios; **OR**
- Planning or evaluation of candidacy for fetal surgery or other in-utero intervention²; **OR**
- Planning or evaluation of candidacy for complex assisted delivery (e.g., - EXIT procedure)^{2,3,3}; **OR**
- Planning or evaluation of candidacy for post-delivery neonatal surgery²; **OR**
- Complications related to a multiple-gestation pregnancy²; **OR**
- Assessment of fetal morbidity of remaining fetus following in-utero death of a co-twin or co-multiple²; **OR**
- Maternal placental complication as indicated by **ANY** of the following^{6,7,8}:
 - For cesarean section delivery planning/peripartum hysterectomy planning among patients with **ANY** of the following:
 - ◆ Known or suspected placenta accreta spectrum disorder (PAS: placenta increta, placenta percreta, placenta accreta); **OR**
 - ◆ At high risk of PAS, including **ANY** of the following:
 - History of cesarean section; **OR**
 - Prior uterine surgery; **OR**
 - Prior or current placenta previa; **OR**
 - Prior placenta accreta spectrum disorder; **OR**
 - Known adenomyosis; **OR**
 - Pregnancy was conceived with assisted reproductive technology (in vitro fertilization [IVF], frozen embryo transfer,

- Intracytoplasmic sperm injection [ICSI]); **OR**
 - Advanced maternal age (greater than or equal to 35 years); **OR**
 - Asherman's syndrome; **OR**
 - Prior curettage; **OR**
 - Multiparity; **OR**
 - Known or suspected posterior placenta previa; **OR**
 - Known or suspected placental abruption; **OR**
 - Known or suspected gestational trophoblastic disease; **OR**
 - Known or suspected adnexal lesions; **OR**
- Evaluation, during pregnancy, of known maternal leiomyoma at high risk of degeneration or rupture, including **ANY** of the following¹⁶:
 - Submucosal leiomyoma; **OR**
 - Retroplacental leiomyoma; **OR**
 - Leiomyoma which enlarges in the first trimester; **OR**
- Screening if **ANY** of the following are true²:
 - Family risk for inheritable brain abnormalities, including but not limited to tuberous sclerosis, corpus callosal dysgenesis, or lissencephaly; **OR**
 - Volumetric assessment of fetal lung parenchyma among fetuses at risk for pulmonary hypoplasia; **OR**
- Repeat imaging with fetal/placental MRI is indicated if **ANY** of the following is true²:
 - In-utero fetal surgery or in-utero intervention has been performed and necessitates follow-up imaging; **OR**
 - Serial antepartum imaging is necessary for ongoing planning, management, or evaluation of the fetal or placental condition; **OR**
 - The initial study was limited, incomplete, or of poor quality due to **ANY** of the following:
 - ◆ Insufficient gestational age; **OR**
 - ◆ Small fetal size; **OR**
 - ◆ Atypical fetal position; **OR**
 - ◆ Fetal movement that degraded the image of the region of interest.

Non-Indications

→ **Fetal/Placental MRI** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; **OR**
- ◆ When complete diagnostic information can be obtained by ultrasonography; **OR**
- ◆ When used solely to evaluate preterm premature rupture of membranes (PPROM) in the absence of any other indication.

*NOTE: Gadolinium-based contrast is considered to hold unknown risk and potential harm to a fetus and is not recommended for routine administration with fetal/placental MRIs. The decision to use gadolinium in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider. [215](#)

**NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
74712	Magnetic resonance (e.g., proton) imaging, fetal, including placental and maternal pelvic imaging when performed; single or first gestation
74713	Magnetic resonance (e.g., proton) imaging, fetal, including placental and maternal pelvic imaging when performed; each additional gestation (List separately in addition to code for primary procedure)

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Magnetic resonance imaging (MRI) is used to diagnose anomalies and disorders of the gravid uterus, fetus, and placenta. Because of the detail and enhanced accuracy of MRI, indicated uses in this setting include known or suspected congenital abnormalities, as well as placental disorders and some complications that are present in multiple-gestation pregnancies. MRI during pregnancy is generally reserved for clinical scenarios in which the diagnostic benefit outweighs the theoretical risks to the fetus and pregnant patient.

With regard to the placenta, the primary indication for MRI is clinical suspicion for placenta accreta spectrum (PAS) disorder, which encompasses placenta increta, placenta percreta, and placenta accreta – a series of clinical entities in which the placenta grows abnormally into the wall of the uterus. Prenatal diagnosis of these conditions is critical due to the high morbidity and mortality associated with delivery, which can result in severe blood loss and death. MRI allows for better visualization of the placenta and subsequent planning for delivery, including peripartum hysterectomy.

Prenatal diagnosis of fetal anomalies is also critical due to the expanding roles of fetal surgery or in-utero intervention for some congenital conditions. Congenital diaphragmatic hernia, for example, can be successfully treated in-utero with fetoscopic endoluminal tracheal occlusion to facilitate the growth of the fetus's pulmonary system. Where fetal surgery is not indicated, fetal MRI still provides valuable clinical information when planning a complex delivery, strategizing for neonatal management, and counseling patients. Prenatal diagnosis has been associated with improved outcomes and decreased perioperative mortality for certain congenital anomalies, including congenital heart disease.²⁸

In 2020, the American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR) published practice parameters to guide the use of fetal and placental MRI.² These guidelines formally support the use of MRI imaging of known or suspected fetal anomalies of numerous body systems – including the central nervous system, cardiopulmonary system, and genitourinary system, as well as complications associated with multiparity, assessment for

fetal in-utero intervention, and evaluation of placental disorders. Other medical societies – including the American Heart Association, with respect to fetal cardiac disease – similarly endorse these indications.

The American College of Obstetricians & Gynecologists issued a recommendation that MRI not be used for *initial* evaluation of placenta accreta spectrum disorders, favoring the use of ultrasonography for primary evaluation – a sentiment that is shared by every other medical society cited within this guideline. A 2016 practice overview was published by investigators at Harvard Medical School, which more strongly recommended MRI for evaluation of placenta accreta spectrum disorders – even in cases where ultrasound evaluation was equivocal – in order to plan for peripartum hysterectomy and reduce both maternal and fetal risk for morbidity and mortality.⁷ Other maternal indications for fetal/placental MRI include the evaluation of specific leiomyomas (uterine fibroids) that are at high risk of degeneration and rupture, a medical emergency that would endanger both the fetus and maternal patient due to the possibility of hemorrhage or blood flow occlusion. Abnormal levels of amniotic fluid (paucity or excess) are also an indication for fetal MRI when ultrasonography is technically inadequate to image the fetus in these circumstances. A 2023 study at the Cleveland Clinic found that fetal MRI – when used in addition to standard ultrasonography – identified fetal anomalies in more than a quarter of patients, allowing for improved diagnosis and perinatal management.⁵

In answer to the suggestion that fetal/placental MRI be contraindicated for patients with viable pregnancies, several points bear noting. First, according to both the American College of Obstetricians & Gynecologists (ACOG) and the American College of Radiology, MRI is safe for use in pregnant patients across all trimesters with no specific precautions or contraindications.^{2,15} The risk to the fetus is theoretical; no evidence of actual harm has been documented, and indeed, numerous studies argue there are no risks of tissue heating and acoustic damage, with an additional growing body of evidence suggesting that teratogenesis is not as significant a risk as previously thought.^{2,15,31,32} Importantly, fetal/placental MRI is not performed routinely, and if ordered, these theoretical risks would be outweighed by the greater benefit of increased visualization. Secondly, the concept of fetal viability is evolving, ever-shifting, and imprecise.^{9,10} It can refer to two discrete ideas: the fetus's predicted ability to survive outside of the uterus if delivered before

development is complete, which is often tied to a specific gestational age, or the idea that a pregnancy will continue to develop “normally,” versus a pregnancy likely to end in early loss or miscarriage.^{9,10} There is no one clear clinical definition of “viability” that is formally recognized, nor is there a definitive diagnostic test.^{9,10}

Thirdly, there are valid indications for fetal/placental MRI that are entirely separate from the health of the fetus. For example, a pregnant patient who is carrying a healthy fetus and who has suspected placenta accreta spectrum disorder that is not optimally visualized on ultrasound is, based on the current medical evidence, indicated to undergo MRI imaging to better plan delivery and possible peripartum hysterectomy.² Inadvertent delivery of the fetus through placenta previa, for instance, can lead to hemorrhage and subsequent fetal-maternal death. Regardless of fetal viability in this specific clinical scenario, it is in the pregnant patient’s best interest to obtain optimal prenatal images of the placenta through fetal/placental MRI. As another example, early detection of a fetus with an oropharyngeal teratoma is critical in mitigating the high mortality risk associated with congenital airway obstructions.² In this scenario, fetal MRI is crucial to prenatally characterize the lesion, plan for complex delivery, and prepare to secure the airway (often surgically) immediately after delivery in order to reduce the risk of asphyxiation and demise. Although such anomalies may be visualized on ultrasonography, an MRI is often better able to elucidate the degree – if any – of central nervous system involvement which could ultimately render the pregnancy nonviable. In this case, any assessment of viability is ultimately dependent on the images obtained from fetal MRI. Another example is the use of MRI in multiple gestation pregnancies, where it is indicated for assessment of the remaining twin’s morbidity after decline/demise of a co-twin.² This pregnancy could be considered viable for one twin, and yet nonviable for the other.

Such clinical scenarios begin to exemplify the dynamic, unpredictable, multifaceted nature of viability and human development, and the role advanced imaging plays in our assessment of viability and understanding of the best clinical path forward – as well as the numerous clinical situations wherein fetal/placental MRI would be indicated for reasons unrelated to the fetus itself.

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Clinical Guideline Revision History/Information

Original Date: November 21, 2024		
Review History		



Cohere Medicare Advantage Policy – Low-Dose Computed Tomography (LDCT), Chest, for Lung Cancer Screening

Clinical Policy for Medical Necessity Review

Version: 2

Cohere Health UMC Approval Date: November 13, 2025

Last Annual Review: November 13, 2025

Revision: Not Applicable

Next Annual Review: November 13, 2026

Important Notices

Notices & Disclaimers:

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Low-Dose Computed Tomography (LDCT), Chest, for Lung Cancer Screening

Type: ☒ Adult (18+ yo) | ☐ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Low-Dose Computed Tomography (LDCT), Chest, for Lung Cancer Screening

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\). Lung cancer screening with low dose computed tomography \(LDCT\) \(210.14\)](#)

Description

Low-dose CT of the chest (LDCT) is offered to certain patients considered to be at high-risk of acquiring lung cancer, who, at the same time, would be inclined to pursue oncologic treatment if a lung cancer diagnosis were rendered after a full diagnostic evaluation. A well-developed lung cancer screening program is essential to realizing the population-level promise of the same, the components of which are not limited to the following:

- Shared decision-making between the requesting provider and the patient
- Tobacco cessation counseling, support, and pharmacologic therapy as needed
- LDCT.

LDCT screening for lung cancer increases the odds of detecting lung cancer at an early stage, when there is a better chance of effectively treating/curing the newly diagnosed cancer.² It is properly performed in serial fashion on an annual basis for patients who are participating in a guideline-directed screening program.

Multiple chest images are taken while the patient lies flat on the X-ray table. The images are combined to reconstruct detailed internal organ images, with a particular focus on the lungs. This advanced imaging technology allows the detection of very small lung nodules that can signal early-stage lung cancer.³ According to medical literature, LDCT can lower the mortality rate from lung cancer by as much as 20%.

Medical Necessity Criteria

Indications

Low-dose computed tomography, chest, for lung cancer screening is considered appropriate when **ALL** of the following are **TRUE**¹⁻¹⁰:

- Adults aged 50 to 77 years; **AND**
- Asymptomatic (no signs of lung cancer); **AND**
- Tobacco smoking history of at least 20 pack-years*; **AND**
- Screening may occur no more often than annually; **AND**
- **ANY** of the following:
 - The patient is a current smoker; **OR**
 - The patient has quit smoking within the past 15 years.

Definitions

- One pack-year equals smoking one pack of cigarettes per day for one year (20 cigarettes in one pack).⁴

Non-Indications

Low-dose computed tomography, chest, for lung cancer screening is not considered appropriate if **ANY** of the following is **TRUE**⁴:

- Screening for a patient who has quit smoking more than 15 years ago.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
71271	Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for low-dose computed tomography (LDCT) for lung cancer screening may include:

- Adverse effects from delayed or denied imaging include progression of disease and no longer meeting criteria for some treatment options.
- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.^{[11](#)}
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.^{[12](#)} Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.^{[12](#)}
- Increased healthcare costs and complications from the inappropriate use of additional interventions.^{[13](#)}

The clinical benefits of using these criteria for LDCT for lung cancer screening include:

- Improved patient outcomes through timely and appropriate access to the procedure. Due to the high incidence, particularly of non-small cell lung cancer, morbidity, and mortality of lung cancer, early diagnosis may improve patient outcomes.

- Reduction in complications and adverse effects from unnecessary procedures. Use of low-dose computed tomography (LDCT) is preferred as it is a less invasive procedure.¹⁰
- Enhanced diagnostic accuracy for complex medical conditions. Studies using LDCT have shown a relative reduction of 16% in lung cancer mortality among high-risk patients. LDCT exhibits precision in the identification of smaller nodules.¹⁴
- Enhanced overall patient satisfaction and healthcare experience.
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

The National Comprehensive Cancer Network (NCCN) (2025) lung cancer screening guideline discussed risks and benefits. Risks included false-positive or false-negative results, radiation exposure, cost, and finding of incidental lesions. Benefits included decreased mortality from lung cancer, improvement in anxiety and healthy lifestyles, and the potential for the discovery of other undiagnosed health risks, including thyroid nodules and breast cancer. The screening recommendation by NCCN is in agreement with other societies (high-risk greater than or equal to 50 years of age with a greater than or equal to 20 pack-year cigarette smoking history).⁶

Jonas et al. (2021) analyzed the recommendations by the United States Preventive Services Task Force (USPSTF) for low-dose computed tomography (LDCT) for lung cancer. Seven randomized controlled trials (RCTs) were reviewed, including the National Lung Screening Trial (NLST) with 53,454 participants and the Netherlands-Leuven Longkanker Screenings Onderzoek (NELSON) trial with 15,792 participants. Overall, the authors found that while screening can reduce lung cancer mortality, LDCT can cause false positives.⁷

Aberle et al. (2011) reported on the National Lung Screening Trial (NLST) (NCT00047385), which had 53,454 individuals with a high-risk of lung cancer. Participants were randomly assigned to either the low-dose CT group (26,722) or the single-view posteroanterior chest radiography group (26,732). Positive results were found in 24.2% of the participants, and were higher among the LDCT group by a factor of more than three. Adherence rates were high overall. The authors noted that a main limitation of the study was the advances in technology that have occurred since the study was conducted, which have further reduced the rate of lung cancer deaths. Lower death rates were also attributed to other ongoing LCDT screening not originally in the NLST data, and thus, death rates may be higher.¹⁵

The National Cancer Institute (2024) stated that LDCT was shown to be more sensitive than chest radiography; based on the Early Lung Cancer Action Project, LDCT detected nearly six times more Stage I lung cancers compared to chest radiography, with most of the tumors less than 1 cm in size.³

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Policy Revision History/Information

Original Date: November 21, 2024		
Review History		
Version 2	11/13/2025	Clarified description, indications, and non-indications to align with guideline-directed cigarette smoking history requirement. Updated age range from “50 to 80” to “50 to 77” based on CMS NCD 210.14. Expanded the Medical Evidence section; added one citation.



Cohere Medicare Advantage Policy – Low-Dose Computed Tomography (LDCT), Chest, for Lung Cancer Screening

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: November 21, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Low-Dose Computed Tomography (LDCT), Chest, for Lung Cancer Screening

Date of last literature review: 11/14/2024

Document last updated: 11/20/2024

Type: ☒ Adult (18+ yo) | ☐ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Low-Dose Computed Tomography (LDCT), Chest, for Lung Cancer Screening

Benefit Category

Additional Preventive Services

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\). Lung cancer screening with low dose computed tomography \(LDCT\)\(210.14\)](#)

Recommended Clinical Approach

Lung cancer has historically had a low survival rate due to the frequency of diagnosis at later stages.² Screening for lung cancer using low-dose computed tomography (LDCT) has been found to be more sensitive than traditional chest x-ray in the diagnosis of early-stage lung cancers.³ LDCT provides appropriate visualization with a lower dose of ionizing radiation compared to standard computed tomography. The benefit of such early detection outweighs the incidence of false positive results found with this radiological testing modality.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of low-dose computed tomography (LDCT), chest, for lung cancer screening. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁴⁻⁷
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.⁸ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁸
- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁹

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. Due to the high incidence, particularly of non-small cell lung cancer, morbidity, and mortality of lung cancer, early diagnosis may improve patient outcomes.¹⁰
- Reduction in complications and adverse effects from unnecessary procedures. Use of low-dose computed tomography (LDCT) is preferred as it is a less invasive procedure.¹¹
- Enhanced diagnostic accuracy for complex medical conditions. Studies using LDCT have shown a relative reduction of 16% in lung cancer mortality among high-risk patients. LDCT exhibits precision in the identification of smaller nodules.¹²
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Low-dose computed tomography, chest, for lung cancer screening** is considered appropriate when **ALL** of the following are **TRUE**¹³⁻¹⁶:

- ◆ Asymptomatic adults between the ages of 50 to 80 years; **AND**
- ◆ Screening may occur no more than annually; **AND**
- ◆ **ANY** of the following is **TRUE**:
 - The patient is a current or former smoker with a 20 pack-year* cigarette smoking history; **OR**
 - The patient has quit smoking cigarettes within the past 15 years.

***NOTE:** One pack-year equals smoking one pack of cigarettes per day for one year (20 cigarettes in one pack)

Non-Indications

→ **Low-dose computed tomography, chest, for lung cancer screening** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The patient has not smoked for more than 15 years; **OR**
- ◆ There is limited life expectancy due to another health problem; **OR**
- ◆ The patient is unable or unwilling to have curative lung surgery.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
71271	Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)

Medical Evidence

The National Cancer Institute (2024) updated its PDQ guideline for lung cancer screening (Health Professionals Version), in which evidence of the benefit of LDCT is discussed. They state that low-dose computed tomography (LDCT) was shown to be more sensitive than chest radiography, and based upon the Early Lung Cancer Action Project, nearly six times more stage I lung cancers were detected compared to chest radiography, with most of the tumors less than 1 cm in size. Several large-scale studies have been conducted in recent years, including the National Lung Screening Trial in 2011, with 53,454 enrolled individuals, resulting in 3.6% of individuals found to have lung cancer. The NELSON trial in Europe (2020) resulted in 2.1% of the 13,105 men and 2594 women being diagnosed by LDCT. The reviewers state that smaller, randomized trials are currently being conducted or completed in several countries.²

The US Preventive Services Task Force (USPSTF) published a recommendation in 2021 to update their 2013 recommendation. A systematic review was conducted on the accuracy of using LDCT to screen for lung cancer as well as determining the benefits and harms of such screening. The resulting recommendation is for an annual LDCT screening for lung cancer in adults 50 to 80 years of age who have a 20-pack-year history of smoking currently or have quit in the past 15 years. After 15 years of non-smoking, screening is no longer necessary. The former recommendation from 2013 required a 30-pack year smoking history in adults aged 55–80.³

The National Comprehensive Cancer Network (NCCN) (2025 update) lung cancer screening guideline discusses the risks and benefits of lung cancer screening. Risks include false-positive or false-negative results, radiation exposure, cost, and finding of incidental lesions. Benefits were stated as decreased mortality from lung cancer, improvement in anxiety and healthy lifestyles, and the potential of discovery of other undiagnosed health risks, including thyroid nodules and breast cancer. The screening recommendation by NCCN is in agreement with other societies (high-risk greater than or equal to 50 years of age with a greater than or equal to 20 pack-year cigarette smoking history).¹⁴

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Clinical Guideline Revision History/Information

Original Date: November 21, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance (MR) Elastography

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 17, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance (MR) Elastography

Date of last literature review: 10/15/2024

Document last updated: 10/16/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance (MR) Elastography

Benefit Category

Not applicable.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻²

- There are no applicable NCDs and/or LCDs for MR Elastography.

Recommended Clinical Approach

Magnetic resonance elastography (MRE) is a non-invasive imaging technique that measures the mechanical properties of tissues, particularly stiffness, which can indicate the presence of fibrosis and other pathologies. This technique is primarily used in the assessment of liver diseases, but it also has applications in diagnosing conditions affecting the brain, muscles, and other organs. MRE provides a quantitative measure of tissue elasticity, which is valuable in evaluating the extent of disease, monitoring disease progression, and guiding treatment decisions.³

The clinical journey leading to MRE typically starts with the detection of risk factors or symptoms suggestive of liver fibrosis, such as elevated liver enzymes or clinical signs of chronic liver disease. Initial imaging studies like ultrasound or CT may indicate abnormalities, prompting further evaluation with MRE to assess the degree of fibrosis. MRE is particularly useful in patients for whom a liver biopsy is contraindicated or who require a non-invasive method to monitor treatment response over time.⁴

MRE is a valuable tool in tumor diagnosis by measuring tissue stiffness across various cancers. MRE can detect changes in tissue stiffness before clinical symptoms appear, making it essential for early tumor detection, treatment planning, and assessing resistance to chemoradiotherapy.⁵

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of MR Elastography. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁶⁻⁷
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁶⁻⁷
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁸
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁹

The clinical benefits of using these criteria include:

- MRE is a safe, non-invasive alternative to liver biopsy to detect and stage liver fibrosis. One study included patients with chronic hepatitis B, chronic hepatitis C, metabolic dysfunction-associated steatotic liver disease, autoimmune liver disease, or iron overload. The success rate following MRE was 98%. For patients that required additional evaluation, a biopsy was still recommended for 22% of the patients. Of this percentage, 12.5% MRE showed minimal fibrosis, and biopsy allowed for

further evaluation (e.g., steatohepatitis, to identify the origin of abnormal transaminase levels.^{3-4,10}

- Technology advances have demonstrated the precision of MRE as well as the use of biomarkers to differentiate various diagnoses (e.g., fibrosis vs inflammation or hepatic venous congestion).¹¹
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance elastography (MRE)** is considered appropriate if **ANY** of the following is **TRUE**^{3-5,10}:

- ◆ The patient has metabolic dysfunction-associated steatotic liver disease (MASLD), and hepatic fibrosis or cirrhosis known or suspected; **OR**
- ◆ **ALL** of the following are **TRUE**:
 - The patient has a chronic liver disease (e.g., chronic hepatitis C virus infection, chronic hepatitis B virus infection) and hepatic fibrosis or cirrhosis is known or suspected; **AND**
 - Ultrasound elastography cannot be performed or is nondiagnostic; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**

- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance elastography (MRE)** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
75565	Cardiac magnetic resonance imaging for velocity flow mapping (List separately in addition to code for primary procedure)
76391	Magnetic resonance (eg, vibration) elastography

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Feuille et al. (2024) analyzed clinical situations where magnetic resonance elastography (MRE) of the liver is indicated. A total of 96 MRE exams and respective follow-ups were included over 14 months. The primary indication for all MREs was non-invasive assessment of liver fibrosis, with one additional indication identified in every case. Liver biopsy decreased after MRE however, when liver biopsy was indicated, the patient was very likely to undergo the procedure. MRE is a safe alternative for patients however, rare but serious risks may occur.⁴

Yang et al. (2021) review the advances of MRE as a non-invasive method to diagnose tumors. Tissue stiffness due to pathological changes may be visible sooner with MRE than with other imaging modalities. MRE is often utilized for tumors of the brain, breast, colon, gallbladder, liver, prostate, and uterus. Early detection of tumor changes and resistance to chemoradiotherapy are noted benefits of MRE.⁵

Venkatesh et al. (2013) review the utilization of MRE of the liver. While adequate to detect and stage liver fibrosis, its use is for additional applications. The authors note that future research is needed to improve three-dimensional imaging quality and resolution to aid in characterizing liver lesions and fibrosis. MRE also shows promise for evaluating patient response to antifibrotic treatments.³

The diagnostic performance of MRE for advanced ($\geq$ F3) fibrosis is excellent, with most studies reporting greater than 80% sensitivity and greater than 90% specificity.⁵

In a large meta-analysis by Singh et al including 12 studies and 697 individual patients with different chronic liver diseases from Europe and the United States, the area under the receiver operating characteristic curve values for discriminating any ($\geq$ F1), significant ($\geq$ F2), or advanced fibrosis ($\geq$ F3) or cirrhosis ($\geq$ F4) were 0.84, 0.88, 0.93, and 0.92, respectively.¹⁰

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Clinical Guideline Revision History/Information

Original Date: October 17, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance (MR) Elastography

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 17, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance (MR) Elastography

Date of last literature review: 10/15/2024

Document last updated: 10/16/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance (MR) Elastography

Benefit Category

Not applicable.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻²

- There are no applicable NCDs and/or LCDs for MR Elastography.

Recommended Clinical Approach

Magnetic resonance elastography (MRE) is a non-invasive imaging technique that measures the mechanical properties of tissues, particularly stiffness, which can indicate the presence of fibrosis and other pathologies. This technique is primarily used in the assessment of liver diseases, but it also has applications in diagnosing conditions affecting the brain, muscles, and other organs. MRE provides a quantitative measure of tissue elasticity, which is valuable in evaluating the extent of disease, monitoring disease progression, and guiding treatment decisions.³

The clinical journey leading to MRE typically starts with the detection of risk factors or symptoms suggestive of liver fibrosis, such as elevated liver enzymes or clinical signs of chronic liver disease. Initial imaging studies like ultrasound or CT may indicate abnormalities, prompting further evaluation with MRE to assess the degree of fibrosis. MRE is particularly useful in patients for whom a liver biopsy is contraindicated or who require a non-invasive method to monitor treatment response over time.⁴

MRE is a valuable tool in tumor diagnosis by measuring tissue stiffness across various cancers. MRE can detect changes in tissue stiffness before clinical symptoms appear, making it essential for early tumor detection, treatment planning, and assessing resistance to chemoradiotherapy.⁵

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of MR Elastography. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁶⁻⁷
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁶⁻⁷
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁸
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁹

The clinical benefits of using these criteria include:

- MRE is a safe, non-invasive alternative to liver biopsy to detect and stage liver fibrosis. One study included patients with chronic hepatitis B, chronic hepatitis C, metabolic dysfunction-associated steatotic liver disease, autoimmune liver disease, or iron overload. The success rate following MRE was 98%. For patients that required additional evaluation, a biopsy was still recommended for 22% of the patients. Of this percentage, 12.5% MRE showed minimal fibrosis, and biopsy allowed for

further evaluation (e.g., steatohepatitis, to identify the origin of abnormal transaminase levels.^{3-4,10}

- Technology advances have demonstrated the precision of MRE as well as the use of biomarkers to differentiate various diagnoses (e.g., fibrosis vs inflammation or hepatic venous congestion).¹¹
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance elastography (MRE)** is considered appropriate if **ANY** of the following is **TRUE**^{3-5,10}:

- ◆ The patient has metabolic dysfunction-associated steatotic liver disease (MASLD), and hepatic fibrosis or cirrhosis known or suspected; **OR**
- ◆ **ALL** of the following are **TRUE**:
 - The patient has a chronic liver disease (e.g., chronic hepatitis C virus infection, chronic hepatitis B virus infection) and hepatic fibrosis or cirrhosis is known or suspected; **AND**
 - Ultrasound elastography cannot be performed or is nondiagnostic; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**

- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance elastography (MRE)** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
75565	Cardiac magnetic resonance imaging for velocity flow mapping (List separately in addition to code for primary procedure)
76391	Magnetic resonance (eg, vibration) elastography

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Feuille et al. (2024) analyzed clinical situations where magnetic resonance elastography (MRE) of the liver is indicated. A total of 96 MRE exams and respective follow-ups were included over 14 months. The primary indication for all MREs was non-invasive assessment of liver fibrosis, with one additional indication identified in every case. Liver biopsy decreased after MRE however, when liver biopsy was indicated, the patient was very likely to undergo the procedure. MRE is a safe alternative for patients however, rare but serious risks may occur.⁴

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The diagnostic performance of MRE for advanced ($\geq F3$) fibrosis is excellent, with most studies reporting greater than 80% sensitivity and greater than 90% specificity.⁵

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Clinical Guideline Revision History/Information

Original Date: October 17, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance (MR) Spectroscopy

Clinical Policy for Medical Necessity Review

Version: 2

Cohere Health UMC Approval Date: September 18, 2025

Last Annual Review: September 18, 2025

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Next Annual Review: September 18, 2026

Important Notices

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medicare Advantage Policy - Magnetic Resonance (MR) Spectroscopy

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance (MR) Spectroscopy

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no applicable NCDs and/or LCDs for MR Spectroscopy.

Description

Magnetic resonance spectroscopy (MRS) is a noninvasive diagnostic test that measures biochemical changes in the brain, muscles, and other organs. It primarily evaluates metabolic disorders, tumors, and other lesions. MRS provides additional information to conventional MRI by measuring the concentration of specific metabolites, such as N-acetylaspartate (NAA), choline (Cho), creatine (Cr), and myoinositol (mI).^{1,2}

MRS is particularly valuable in grading and assessing types of brain tumors and in assessing metabolic changes associated with tumor progression or response to therapy. For example, high choline levels can indicate increased cell membrane turnover associated with tumor growth, while reduced NAA levels may suggest neuronal loss or dysfunction.² Additionally, MRS can help differentiate between tumor recurrence, abscess, and radiation necrosis, aiding in treatment planning and monitoring.²

Medical Necessity Criteria

Indications

Magnetic resonance spectroscopy (MRS) is considered appropriate if **ANY** of the following is **TRUE**:

- **ALL** of the following:
 - Conventional imaging by magnetic resonance imaging (MRI) or computed tomography (CT) is inconclusive; **AND**
 - **ANY** of the following:
 - Neoplastic conditions (including masses or mass-like conditions) and **ANY** of the following:
 - Grading of primary glial neoplasm, particularly high-grade versus low-grade glioma³⁻⁵; **OR**
 - Evaluation of brain tumors, including differentiation between tumor recurrence and radiation necrosis³⁻⁵; **OR**
 - Intraaxial brain tumors, including primary neoplasms and metastatic disease⁵; **OR**
 - Post-treatment surveillance in a patient with a known history of brain tumor⁵; **OR**
 - Neonatal hypoxic ischemic encephalopathy⁶; **OR**
 - Congenital conditions as indicated by **ANY** of the following:
 - Diagnosis and evaluation of metabolic disorders such as mitochondrial diseases and inborn errors of metabolism⁷; **OR**
 - Inherited metabolic disorders (e.g., Canavan disease, mitochondrial encephalopathies, and other leukodystrophies)⁸; **OR**
- Repeat imaging (defined as a repeat request following recent imaging of the same anatomic region with the same or similar modality) will be considered reasonable and necessary if **ALL** of the following are **TRUE**:
 - There are no established guidelines; **AND**
 - **ANY** of the following:
 - There are new or worsening symptoms not addressed in the guidelines, such that repeat imaging would influence treatment; **OR**
 - There is need for a one-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

Magnetic resonance spectroscopy (MRS) is not considered appropriate if **ANY** of the following is **TRUE**:

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms⁹.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
76390	Magnetic resonance spectroscopy

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for magnetic resonance spectroscopy (MRS) may include:

- Adverse effects from delayed disease detection and diagnosis, including increased treatment delays.
- Malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.¹⁰
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹¹

The clinical benefits of using these criteria for magnetic resonance spectroscopy (MRS) may include:

- Specificity: MRS is uniquely able to differentiate between primary brain tumors and clinical mimics; it can also predict the clinical course of a brain tumor by diagnosing high-grade versus low-grade tumors.² In addition, MRS plays a unique role following treatment by serving as one of the few imaging modalities that can delineate radiation necrosis from tumor tissue, thereby allaying a common diagnostic challenge.²
- Noninvasive: As an imaging modality, MR spectroscopy is noninvasive; it is widely accepted that noninvasive procedures are less costly, associated

with fewer complications, and preferred by both patients and providers. It also utilizes no injected contrast agent and no ionizing radiation, conferring an inherent safety benefit.

- Enhanced overall patient satisfaction and healthcare experience.
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Weinberg et al. (2021) conducted a systematic review of the literature regarding the clinical applications of magnetic resonance spectroscopy (MRS) in brain tumors. The writers stated that MRS is utilized in clinical practice as well as research applications. The diagnostic clinical relevance of MRS includes its use as a type of virtual biopsy, as well as distinguishing gliomas from other types of diagnoses such as edema, necrosis, infection, or lymphoma. The group recommended using MRS in conjunction with conventional MRI due to occasional overlap in the appearance of different conditions. In tumor grading, the distinction between high and low-grade gliomas can be achieved with MRS. Limitations of MRS use in brain tumor imaging include similarities in the appearance of different diseases despite the differentiation of tissue types. Image quality may be affected by equipment variability and artifacts.²

In a 2022 systematic review of the literature, Germano et al. updated the 2014 Congress of Neurological Surgeons evidence-based guidelines on the management of progressive glioblastoma (pGBM) in adults. The literature search range was between 2012 to 2019, with 237 full-text articles extracted from 8786 total abstracts. The group made two new level II recommendations based on this review, with an additional 21 level III recommendations. The level II recommendations included the use of diffusion-weighted images included with magnetic resonance images with and without contrast in the diagnosis of patients with GBM as well as for surveillance. The other new level II recommendation is related to surgical procedures.⁴

Feldmann and colleagues (2022) examined MR-spectroscopy in metachromatic leukodystrophy (MLD) in a controlled cohort study consisting of 29 patients (10 infants, 19 juveniles) and 12 controls in 53 MRS datasets. MLD spectra were found to differ from the control group. White matter revealed the greatest differences compared to gray matter. Infant patients were found to have more severe changes when compared to later-onset patients in N-acetylaspartate (NAA), aspartate, glutamine, and choline intervals. It was concluded that NAA was the most clinically meaningful biomarker correlating with urine measurements obtained during the study.⁸

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Policy Revision History/Information

Original Date: September 15, 2024		
Review History		
Version 2	09/18/2025	Annual review. Added indications on intraaxial tumors and post-treatment surveillance.



Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Spinal Canal

Clinical Policy for Medical Necessity Review

Version: 2

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Last Annual Review: October 16, 2025

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Important Notices

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Magnetic Resonance Angiography (MRA), Spinal Canal

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Angiography (MRA), Spinal Canal

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁵

- [National Coverage Determination \(NCD\). Magnetic Resonance Imaging \(220.2\).](#)¹
- [Local Coverage Determination \(LCD\). Magnetic Resonance Angiography \(MRA\) \(L33633\).](#)²
 - [Billing and Coding: Magnetic Resonance Angiography \(MRA\) \(A56747\).](#)³
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34424\).](#)⁴
 - [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56775\).](#)⁵

Description

Magnetic resonance angiography (MRA), spinal canal is a diagnostic technique that allows for the visualization of blood vessels in the spinal canal. Typically used as an adjunct to conventional magnetic resonance imaging (MRI), it aids in diagnosing and evaluating vascular conditions, such as aneurysms, stenosis, occlusions, and vascular malformations. Unlike computed tomography angiography (CTA), MRA does not use ionizing radiation yet provides detailed images of blood vessels and surrounding tissues. It also provides an alternative for patients who do not tolerate the iodinated contrast used in CTA. MRA is less invasive than conventional radiographic digital subtraction angiography.⁶

Medical Necessity Criteria

Indications

Magnetic resonance angiography (MRA), spinal canal is considered appropriate if **ANY** of the following is **TRUE**:

- Evaluation and characterization of suspected vascular lesions when detected on prior imaging, including **ANY** of the following:
 - Spinal arteriovenous fistula (AVF), including vascular flow voids on magnetic resonance imaging (MRI) of the spine that are suspicious for spinal AVF⁷; **OR**
 - Spinal arteriovenous malformation (AVM)⁷⁻¹²; **OR**
- Diagnosis and evaluation of known or suspected vascular conditions involving the spinal vessels, including **ANY** of the following^{8,13}:
 - Thrombosis; **OR**
 - Dissection; **OR**
 - Embolism; **OR**
- Preoperative, postoperative, or pretreatment evaluation for **ANY** of the following:
 - To localize the spinal arteries before complex spinal surgery or aortic aneurysm repair; **OR**
 - To characterize suspected vascular lesions, including tumors or masses of the spinal canal and its contents¹⁴; **OR**
 - To assess progressive myelopathy when MRI suggests an underlying vascular cause, such as an AVM¹⁵; **OR**
 - To guide a subsequent digital subtraction angiography meant to assess for a spinal AVM or AVF; **OR**
- For further evaluation of a previously inconclusive finding on prior imaging (e.g., MRI, digital substance angiography) that necessitates additional clarification; **OR**
- As a follow-up study for **ANY** of the following as needed to assess progression or response to treatment:
 - Known AVM^{16,17}; **OR**
 - Known AVF⁷; **OR**
- Repeat imaging (defined as a repeat request following recent imaging of the same anatomic region with the same or similar modality) will be considered reasonable and necessary if **ALL** of the following are **TRUE**:
 - There are no established guidelines; **AND**

- **ANY** of the following:
 - There are new or worsening symptoms not addressed in the guidelines, such that repeat imaging would influence treatment; **OR**
 - There is need for a one-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

Magnetic resonance angiography (MRA), spinal canal is not considered appropriate if **ANY** of the following is **TRUE**:

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms¹⁸.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72159	Magnetic resonance angiography (MRA) of spinal canal and contents with contrast material
C8931	Magnetic resonance angiography with contrast, spinal canal and contents
C8932	Magnetic resonance angiography without contrast, spinal canal and contents
C8933	Magnetic resonance angiography without contrast followed by with contrast, spinal canal and contents

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for MRA, spinal canal may include:

- Risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- Allergic reactions to contrast material if used in the study.^{[19-21](#)}
- The use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.^{[19-21](#)}
- Risk of over-sedation if used for the study (for anxiety or claustrophobia).
- Risk to the developing fetus in a pregnant patient. The decision to image a pregnant patient should be made in consultation with the patient's obstetric provider.^{[22](#)}
- Increased healthcare costs and complications from the inappropriate use of additional interventions.^{[23](#)}
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria for MRA of the spinal canal may include:

- Avoidance of more invasive imaging modalities. MRA is a non-invasive examination that does not require sedation, catheterization, or ionized radiation, yet can be more accurate than conventional venography, offering an alternative imaging technique for patients with contrast allergies or renal dysfunction.^{[24-26](#)} The non-invasive nature of MRA, which allows for examinations of vessel anatomy without ionizing radiation,

makes the imaging technique particularly suited to preoperative imaging.^{[24](#)}

- Quick and accurate images. Magnetic resonance angiography can produce timely and highly accurate assessments of arterial disease in the lower extremity, with high levels of clarity and fidelity.^{[27](#)} Compared to conventional angiography, MRA provides more sensitive visualizations of blood vessel pathology.^{[26](#)}
- Enhanced overall patient satisfaction and healthcare experience.

Medical Evidence

Khalafallah et al. (2024) compared the diagnostic accuracy of 3D contrast-enhanced MRA to digital subtraction angiography (DSA) in the diagnosis of surgically-confirmed spinal dural arteriovenous fistulas in 27 patients.²⁸ They reported that both detection sensitivity and accuracy were higher for MRA compared to DSA, with reported sensitivities of 100% and 85.7% and reported accuracies of 73.3% and 69.2% for MRA and DSA, respectively. However, DSA did have a higher positive predicted value (PPV) compared to MRA (78.3% vs. 73.3%). The authors concluded that MRA may be preferable to the more invasive, riskier, and more technically difficult DSA in diagnosing SDAVFs.

Raman et al. (2022) performed a systematic review comparing DSA with MRA for the evaluation of cerebral arteriovenous malformations (AVMs). In brain AVMs, there is aberrant communication between arteries and veins, resulting in the formation of a nidus, a complex network of intertwined blood vessels. DSA is generally the preferred method due to its superior spatial resolution and hemodynamic properties, representing the current gold standard. There is a need for further research to determine whether MR studies alone could serve as a diagnostic imaging alternative to the current gold standard, DSA, for AVM diagnosis. Numerous studies have highlighted the combined use of both imaging modalities, and some have suggested that specific MR imaging techniques closely resemble the outcomes of invasive conventional scans.²⁸

Sharma et al. (2019) compared computed tomography angiography (CTA) and MRA for traumatic vertebral artery injury (TVAI). The primary diagnostic approach for patients with trauma and meeting screening criteria for potential cervical vascular injury is CTA. At the same time, MRA, DSA, and Doppler duplex ultrasound have supportive roles as complementary imaging modalities. The authors also reviewed anatomic variations and potential mimics. Early detection is crucial, and prompt initiation of therapy can significantly reduce the risk of associated strokes.²⁹

Mathur et al. (2017) evaluated the effectiveness of first-pass contrast-enhanced MRA in diagnosing and localizing spinal epidural AVFs with intradural venous reflux, as well as differentiating them from other types of spinal AVFs. Of the 42 patients with suspected spinal AVF, 7 patients received a diagnosis. The authors conclude that MRA can identify lesions associated with spinal dural AVFs.⁷

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Policy Revision History/Information

Original Date: October 29, 2024		
Review History		
Version 1.1	05/01/2025	Revised per CMS update for 03/27/2025. Updated Revision Date. Updated Links and References for L34424, A56775.
Version 2	10/16/2025	Annual review. Updated references to LCDs and Billing and Coding Articles. Refined description for clarity. Updated in accordance with commercial policy. Removed nonindications for contrast allergies, metallic foreign bodies, and implantable devices. No changes to procedure codes. Expanded the Medical Evidence section; added 1 citation.



Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Abdomen/Pelvis

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 24, 2024

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Angiography (MRA), Abdomen/Pelvis

Date of last literature review: 10/22/2024

Document last updated: 10/23/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Angiography (MRA), Abdomen/Pelvis

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹²⁻²⁰

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\).](#)
- [Local Coverage Determination \(LCD\) Magnetic resonance angiography \(MRA\) \(L33633\).](#)
- [Local Coverage Determination \(LCD\) Magnetic resonance angiography \(MRA\) \(L34865\).](#)
- [Local Coverage Determination \(LCD\) Magnetic resonance angiography \(MRA\) \(L34424\).](#)
- [Local Coverage Determination \(LCD\) Magnetic resonance angiography \(MRA\) \(L34372\).](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A57779\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56747\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56775\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56805\)](#)

Recommended Clinical Approach

Magnetic resonance angiography (MRA) visualizes the blood vessels in the abdomen and pelvis. It aids in diagnosing and evaluating vascular conditions such as aneurysms, stenosis, occlusions, and vascular malformations. Unlike CT angiography, MRA does not use ionizing radiation yet provides detailed images of blood vessels and surrounding tissues. Magnetic resonance venography (MRV) of the abdomen and pelvis is a non-invasive imaging technique that uses magnetic resonance imaging (MRI) to visualize the veins in these regions. This method is particularly useful for evaluating venous

disorders without exposing patients to ionizing radiation. MRA and MRV are less invasive than conventional X-ray digital subtraction angiography.¹

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of MRA of the abdomen and pelvis. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.²¹⁻²³
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.²¹⁻²³
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.²⁴
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.²⁵

The clinical benefits of using these criteria include:

- As MR imaging techniques evolve, the scan time of MR angiography of the pelvis and abdomen have significantly shortened, leading to an overall better patient experience.²⁶
- MRA produces images with high spatial resolution and wide fields of view, resulting in improved visualization of hard-to-image structures, such as the abdominal vasculature.
- Radiation avoidance: MRA images approach the quality of CTA images while sparing the patient from radiation.²⁶ Patients avoid risks

associated with CTA, including risks of contrast media, end-organ damage, or arterial injury.¹²

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance angiography (MRA), abdomen/pelvis** is considered appropriate if **ANY** of the following is **TRUE**¹⁻²:

◆ **ALL** of the following:

- **ANY** of the following is **TRUE**:

- Conventional (catheter) angiography has not been performed; **OR**
- Conventional (catheter) angiography has been performed, and the results are inconclusive or require further evaluation¹⁶; **AND**

- **ANY** of the following is **TRUE**:

- Evaluation of the renal arteries and the aortoiliac arteries if **ANY** of the following are true:
 - ◆ Evaluation for surgical planning prior to AAA repair; **OR**
 - ◆ When standard testing (history, physical examination, etc.) provides insufficient information for patient management; **OR**
 - ◆ Evaluation of possible renal artery stenosis with evidence of renovascular hypertension, including but not limited to **ANY** of the following

- History of early or late onset of hypertension; **OR**
- Hypertension refractory to medication; **OR**
- Worsening renal function; **OR**
- Renal artery bruit; **OR**
- Abnormal diagnostic laboratory tests (elevated serum renins, increasing creatinine); **OR**
- Other radiologic tests (ultrasound, captopril scintigraphy, or other imaging showing small kidney or unequal kidney sizes); **OR**
- Other abdominopelvic vascular evaluation, including **ANY** of the following:
 - ◆ Vascular injury; **OR**
 - ◆ Portal and hepatic veins; **OR**
 - ◆ Thromboembolic disease; **OR**
 - ◆ Suspected vascular invasion of malignancy; **OR**
- Surgery or invasive procedure is anticipated and may be found to be appropriate based upon MRA results for conditions including, but not limited to, the following: tumor, aneurysms, vascular malformations, or thrombosis; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Magnetic resonance venography (MRV), abdomen/pelvis** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Diffuse unexplained lower extremity edema with negative or inconclusive ultrasound; **OR**
 - May-Thurner syndrome (iliac vein compression syndrome including pelvic CT venography)⁹; **OR**
 - Retroperitoneal hematoma or hemorrhage; **OR**
 - Large vein injury secondary to trauma; **OR**
 - Large vein thrombosis of the major abdominal or pelvic veins, including IVC, iliac, renal, portal, hepatic, and mesenteric veins, when Doppler ultrasound is inconclusive or indicates presence or complications; **OR**
 - Vascular invasion or displacement by tumor; **OR**
 - Detailed evaluation for Pelvic Congestion Syndrome; **OR**
- ◆ Vascular mapping for organ donation; **OR**
- ◆ Initial diagnostic, one-time pre or one-time post-treatment evaluation for treatment planning or evidence of clinical concern for **ANY** of the following:
 - Anastomotic integrity or stent patency; **OR**
 - Portal venous system (hepatic portal system) after Doppler ultrasound has been performed; **OR**
 - Vascular malformation; **OR**
 - Vascular mapping for organ donation or before procedure/surgery for planning purposes (including TIPS); **OR**
- ◆ Repeat imaging of a specific area or structure using the same imaging modality (in the absence of an existing follow-up guideline) is considered appropriate when **ALL** of the following is **TRUE**:
 - There is documented clinical necessity; **AND**
 - Prior imaging results of the specific area or structure, obtained using the same imaging modality, must be documented and available for comparison; **AND**
 - **ANY** of the following is **TRUE**:
 - A change in clinical status, such as worsening symptoms or the emergence of new symptoms, that may influence the treatment approach; **OR**
 - The requirement for interval reassessment, which

- may alter the treatment plan; **OR**
- One-time follow-up of a prior indeterminate finding to assess for interval change; **OR**
- The need for re-imaging either before or after performing an invasive procedure.

Non-Indications

- **Magnetic resonance angiography (MRA), abdomen/pelvis** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Used in conjunction with conventional contrast angiography when the criteria listed in the Indications section above have not been met¹²⁻¹⁶; **OR**
 - ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
 - ◆ The patient has metallic clips on vascular aneurysms; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; **OR**

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72198	Magnetic resonance angiography (MRA) of pelvis, with contrast material
74185	Magnetic resonance angiography (MRA) of abdomen, with contrast material
C8900	Magnetic resonance angiography with contrast, abdomen

C8901	Magnetic resonance angiography without contrast, abdomen
C8902	Magnetic resonance angiography without contrast followed by with contrast, abdomen
C8918	Magnetic resonance angiography with contrast, pelvis
C8919	Magnetic resonance angiography without contrast, pelvis
C8920	Magnetic resonance angiography without contrast followed by with contrast, pelvis

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Roditi et al. (2022) performed a review on abdominal and pelvic magnetic resonance angiography (MRA). The topics discussed include MRA for assessing renal vasculature in potential kidney donors and hypertensive patients, hepatic and mesenteric MRA for evaluating liver donors, individuals with portal hypertension, and those with chronic mesenteric ischemia. Pelvic MRA is also mentioned for pre-treatment planning in uterine fibroid embolization and patients with pelvic congestion syndrome. Abdominal wall MRA is also highlighted for planning breast reconstructive surgery.¹⁰

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Zucker et al. (2016) review noninvasive diagnostic imaging for assessing venous compression syndromes, including magnetic resonance venography (MRV). While the exam typically takes longer than CT scans, MRV offers the advantage of reducing ionizing radiation risks. Optimal timing is more easily achieved for venous contrast. Additionally, MRI enables non-contrast exams, which are safer for patients with renal insufficiency, who face a higher risk of nephrogenic systemic fibrosis with gadolinium contrast.¹¹

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Clinical Guideline Revision History/Information

Original Date: October 24, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Abdomen/Pelvis

Clinical Guidelines for Medical Necessity Review

Version: 1.1
Revision Date: April 21, 2025

Important Notices

Notices & Disclaimers:

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Angiography (MRA), Abdomen/Pelvis

Date of last literature review: 10/22/2024

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Medical Necessity Criteria

Service: Magnetic Resonance Angiography (MRA), Abdomen/Pelvis

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹²⁻²⁰

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)
- [Local Coverage Determination \(LCD\) Magnetic resonance angiography \(MRA\) \(L33633\)](#)
- [Local Coverage Determination \(LCD\) Magnetic resonance angiography \(MRA\) \(L34865\)](#)
- [Local Coverage Determination \(LCD\) Magnetic resonance angiography \(MRA\) \(L34424\)](#)
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Recommended Clinical Approach

Magnetic resonance angiography (MRA) visualizes the blood vessels in the abdomen and pelvis. It aids in diagnosing and evaluating vascular conditions such as aneurysms, stenosis, occlusions, and vascular malformations. Unlike CT angiography, MRA does not use ionizing radiation yet provides detailed images of blood vessels and surrounding tissues. Magnetic resonance venography (MRV) of the abdomen and pelvis is a non-invasive imaging technique that uses magnetic resonance imaging (MRI) to visualize the veins in these regions. This method is particularly useful for evaluating venous

disorders without exposing patients to ionizing radiation. MRA and MRV are less invasive than conventional X-ray digital subtraction angiography.¹

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of MRA of the abdomen and pelvis. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.²¹⁻²³
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.²¹⁻²³
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.²⁴
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.²⁵

The clinical benefits of using these criteria include:

- As MR imaging techniques evolve, the scan time of MR angiography of the pelvis and abdomen have significantly shortened, leading to an overall better patient experience.²⁶
- MRA produces images with high spatial resolution and wide fields of view, resulting in improved visualization of hard-to-image structures, such as the abdominal vasculature.
- Radiation avoidance: MRA images approach the quality of CTA images while sparing the patient from radiation.²⁶ Patients avoid risks

associated with CTA, including risks of contrast media, end-organ damage, or arterial injury.¹²

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance angiography (MRA), abdomen/pelvis** is considered appropriate if **ANY** of the following is **TRUE**¹⁻²:

◆ **ALL** of the following:

- **ANY** of the following is **TRUE**:

- Conventional (catheter) angiography has not been performed; **OR**
- Conventional (catheter) angiography has been performed, and the results are inconclusive or require further evaluation¹⁶; **AND**

- **ANY** of the following is **TRUE**:

- Evaluation of the renal arteries and the aortoiliac arteries if **ANY** of the following are true:
 - ◆ Evaluation for surgical planning prior to AAA repair; **OR**
 - ◆ When standard testing (history, physical examination, etc.) provides insufficient information for patient management; **OR**
 - ◆ Evaluation of possible renal artery stenosis with evidence of renovascular hypertension, including but not limited to **ANY** of the following

- History of early or late onset of hypertension; **OR**
- Hypertension refractory to medication; **OR**
- Worsening renal function; **OR**
- Renal artery bruit; **OR**
- Abnormal diagnostic laboratory tests (elevated serum renins, increasing creatinine); **OR**
- Other radiologic tests (ultrasound, captopril scintigraphy, or other imaging showing small kidney or unequal kidney sizes); **OR**
- Other abdominopelvic vascular evaluation, including **ANY** of the following:
 - ◆ Vascular injury; **OR**
 - ◆ Portal and hepatic veins; **OR**
 - ◆ Thromboembolic disease; **OR**
 - ◆ Suspected vascular invasion of malignancy; **OR**
- Surgery or invasive procedure is anticipated and may be found to be appropriate based upon MRA results for conditions including, but not limited to, the following: tumor, aneurysms, vascular malformations, or thrombosis; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Magnetic resonance venography (MRV), abdomen/pelvis** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Diffuse unexplained lower extremity edema with negative or inconclusive ultrasound; **OR**
 - May-Thurner syndrome (iliac vein compression syndrome including pelvic CT venography)⁹; **OR**
 - Retroperitoneal hematoma or hemorrhage; **OR**
 - Large vein injury secondary to trauma; **OR**
 - Large vein thrombosis of the major abdominal or pelvic veins, including IVC, iliac, renal, portal, hepatic, and mesenteric veins, when Doppler ultrasound is inconclusive or indicates presence or complications; **OR**
 - Vascular invasion or displacement by tumor; **OR**
 - Detailed evaluation for Pelvic Congestion Syndrome; **OR**
- ◆ Vascular mapping for organ donation; **OR**
- ◆ Initial diagnostic, one-time pre or one-time post-treatment evaluation for treatment planning or evidence of clinical concern for **ANY** of the following:
 - Anastomotic integrity or stent patency; **OR**
 - Portal venous system (hepatic portal system) after Doppler ultrasound has been performed; **OR**
 - Vascular malformation; **OR**
 - Vascular mapping for organ donation or before procedure/surgery for planning purposes (including TIPS); **OR**
- ◆ Repeat imaging of a specific area or structure using the same imaging modality (in the absence of an existing follow-up guideline) is considered appropriate when **ALL** of the following is **TRUE**:
 - There is documented clinical necessity; **AND**
 - Prior imaging results of the specific area or structure, obtained using the same imaging modality, must be documented and available for comparison; **AND**
 - **ANY** of the following is **TRUE**:
 - A change in clinical status, such as worsening symptoms or the emergence of new symptoms, that may influence the treatment approach; **OR**
 - The requirement for interval reassessment, which

- may alter the treatment plan; **OR**
- One-time follow-up of a prior indeterminate finding to assess for interval change; **OR**
- The need for re-imaging either before or after performing an invasive procedure.

Non-Indications

- **Magnetic resonance angiography (MRA), abdomen/pelvis** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Used in conjunction with conventional contrast angiography when the criteria listed in the Indications section above have not been met¹²⁻¹⁶; **OR**
 - ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
 - ◆ The patient has metallic clips on vascular aneurysms; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; **OR**

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Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Chest

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 29, 2024

Important Notices

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Medical Necessity Criteria

Service: Magnetic Resonance Angiography (MRA), Chest

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻¹⁰

- [National Coverage Determination \(NCD\) 220.2. Magnetic Resonance Imaging](#)
- [Local Coverage Determination \(LCD\) L33633. Magnetic Resonance Angiography \(MRA\)](#)
- [Local Coverage Determination \(LCD\) L34372. Magnetic Resonance Angiography \(MRA\)](#)
- [Local Coverage Determination \(LCD\) L34424. Magnetic Resonance Angiography \(MRA\)](#)
- [Local Coverage Determination \(LCD\) L34865. Magnetic Resonance Angiography \(MRA\)](#)
- [Billing and Coding: Independent Diagnostic Testing Facility \(IDTF\) \(A53252\)](#)
- [Billing and Coding: Independent Diagnostic Testing Facility \(IDTF\) \(A57807\)](#)
- [Billing and Coding: Magnetic Resonance Angiography \(MRA\) \(A56747\)](#)
- [Billing and Coding: Magnetic Resonance Angiography \(MRA\) \(A56805\)](#)
- [Billing and Coding: Magnetic Resonance Angiography \(MRA\) \(A57779\)](#)

Recommended Clinical Approach

Magnetic resonance angiography (MRA) of the chest allows for visualizing blood vessels, including the arteries and veins. MRA evaluates vascular diseases, aortic pathologies, congenital heart conditions, venous pathologies, pulmonary artery diseases, and other pathologies (e.g., vasculitis, extrinsic compression). A computed tomography angiogram (CTA) can be performed faster than an MRA and uses different contrast materials. Radiation exposure occurs during a CTA, whereas MRA does not. Magnetic resonance venography (MRV) is a noninvasive technique used to evaluate the central venous system in the chest, and it can help diagnose and stage central venous obstruction.¹¹

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of MRA of the chest. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.¹¹⁻¹²
- The use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.¹¹⁻¹²
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is an uncertain risk for MR imaging in pregnant patients. The decision to image a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.¹³
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.¹⁴

The clinical benefits of using these criteria include:

- MRA provides high-resolution imaging for a range of vascular territories and disorders.¹⁵
- The patient is not exposed to ionizing radiation or contrast agents.¹⁵⁻¹⁶
- MRA is useful during procedures such as stent placement to help guide physicians to visualize blood flow.
- Non-contrast MRA is safe for patients with renal impairment, pediatric patients, and pregnant patients.¹⁶
- MRA yields hemodynamic information regarding arterial flow and can aid in diagnosing aneurysms and narrowing or blockages of blood vessels. Functional information, like renal hemodynamics, is also provided by MRA.¹⁶
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **Magnetic resonance angiography (MRA), chest** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Trauma (e.g., dissection, post-traumatic pseudoaneurysm); **OR**
 - ◆ Congenital or acquired conditions (e.g., pulmonary sequestration, heart disease)¹⁷; **OR**
 - ◆ Vascular conditions, known or suspected, including **ANY** of the following:

- Abnormality of the thoracic aorta (seen on prior imaging)¹⁸; **OR**
 - Aneurysm or vascular malformation; **OR**
 - Suspicion for acute aortic dissection in the presence of sudden, intense pain in the chest or back¹⁹⁻²⁰; **OR**
 - Pulmonary hypertension when CTA is contraindicated or cannot be performed²¹; **OR**
 - Evaluation or diagnosis of pulmonary embolism if CTA or ventilation/perfusion (V/Q) scan is contraindicated or cannot be performed²²⁻²⁸; **OR**
 - Superior vena cava (SVC) syndrome²⁹; **OR**
 - Subclavian steal syndrome following a positive or inconclusive ultrasound³⁰; **OR**
 - Takayasu's arteritis³¹; **OR**
 - Thoracic outlet syndrome³²⁻³⁷; **OR**
 - Vascular stenosis or occlusion due to atherosclerosis, vasculitis, or thromboembolic phenomena; **OR**
 - Vascular supply to, or involvement by, tumor; **OR**
 - Venous or arterial anatomy (e.g., congenital abnormalities, extrinsic compression, or causes of intrinsic stenosis or obstruction)^{18,38-39}; **OR**
- ◆ Follow-up evaluation with an established thoracic aortic aneurysm (TAA) and **ANY** of the following is **TRUE**:
- Without syndromic and non-syndromic hereditary thoracic aneurysm disease and **ANY** of the following:
 - Annual surveillance for aneurysm less than 5.0 cm; **OR**
 - Symptoms suggestive of aneurysmal growth/dissection⁴⁰; **OR**
 - 6-month evaluation for aneurysm for **ANY** of the following:
 - ◆ Greater than or equal to 5.0 cm; **OR**
 - ◆ Growing more than 0.5 cm per year; **OR**
 - With syndromic and non-syndromic hereditary thoracic aneurysm disease (e.g., Ehlers-Danlos syndrome, Loeys-Dietz syndrome, Marfan syndrome, coarctation of the aorta) defined as **ANY** of the following:

- Known predisposition as defined by the presence of genetic markers; **OR**
 - Surveillance MRA at baseline, then follow-up at 6 months, then annually if stable or more frequently if growth is noted)⁴¹; **OR**
 - Symptoms suggestive of aneurysmal growth/dissection^{40,42}; **OR**
- ◆ **ANY** of the following:
- Transcatheter aortic valve replacement (TAVR) pre-intervention planning with an assessment of **ANY** of the following⁴³:
 - Aortic root; **OR**
 - Supravalvular aorta and vascular access; **OR**
 - Pulmonary vein mapping (e.g., prior to atrial fibrillation ablation); **OR**
 - Thoracic endovascular repair (TEVAR) for the treatment of thoracic aortic disease (pre- or post-repair)^{20,44-45}; **OR**
 - Chronic dissection, annually¹; **OR**
 - Re-evaluation of known ascending aortic dilation or history of aortic dissection with a change in clinical status (including cardiac exam or other findings that may alter management); **OR**
 - Non-invasive clinical staging of a tumor to define vascular invasion; **OR**
 - Post-treatment of acute aortic dissection (e.g., 1 month, 6 months, annually)¹; **OR**
 - Ongoing monitoring for possible TAA in patients at high-risk (e.g., Loeys-Dietz syndrome, Turner syndrome, Marfan syndrome, bicuspid aortic valve); **OR**
 - Initial screening MRA for a first-degree relative (parent, sibling, or child) of a patient with thoracic aortic disease with **ANY** of the following:
 - Family history of Marfan syndrome, Loeys-Dietz syndrome, or vascular Ehlers-Danlos; **OR**
 - Family history of TAA due to **ANY** of the following:
 - ◆ ACTA2, MYH11, PRKG1, MYLK; **OR**
 - ◆ TAA without identified pathogenic variants in a known gene for HTAD; **OR**

- ◆ TAA and bicuspid aortic valve; **OR**
- ◆ Family history of intracranial or peripheral aneurysm; **OR**
- ◆ Turner syndrome; **OR**
- ◆ Coarctation of the aorta; **OR**
- ◆ Congenital heart defects such as tetralogy of Fallot, transposition of the great vessels, truncus arteriosus; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Magnetic resonance angiography (MRA), chest** may not be considered appropriate if **ANY** of the following is **TRUE**:
- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
 - ◆ The patient has incompatible metallic clips on vascular aneurysms¹; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
71555	Magnetic resonance angiography (MRA), chest (excluding myocardium), with or without contrast material(s)
C8909	Magnetic resonance angiography (MRA) with contrast, chest (excluding myocardium)
C8910	Magnetic resonance angiography (MRA) without contrast, chest (excluding myocardium)
C8911	Magnetic resonance angiography (MRA) without contrast followed by with contrast, chest (excluding myocardium)

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Londono et al. (2021) performed a retrospective review to evaluate the image quality of the entire thoracic aorta by comparing 3D radial respiratory self-navigated native magnetic resonance angiography (native-SN-MRA) based on a bSSFP sequence with traditional Cartesian 3D contrast-enhanced MRA (CE-MRA) that uses navigator-gated respiration control. Thirty-one aortic native-SN-MRA scans (average age 63.9 years) to 61 CE-MRA scans (average age 63.1 years) were used as a reference. The image quality was evaluated at the aortic root/ascending aorta, aortic arch, and descending aorta. For the 10 patients who underwent both MRA sequences, aortic pathologies were assessed, and both normal and pathological aortic diameters were measured. The study found that native-SN-MRA provides superior image quality for the entire thoracic aorta, especially in areas prone to motion artifacts, while also achieving shorter acquisition times compared to conventional techniques.⁴⁶

Shimohira et al. (2015) present the results of a multicenter study on reperfusion rates of pulmonary arteriovenous malformations (PAVMs) following coil embolization. The study used time-resolved MRA or pulmonary angiography and included patients diagnosed with PAVM who underwent embolization. Sixteen patients in the study cohort underwent coil embolization (24 untreated or reperfused PAVMs). Among these, sac embolization was performed in 12 untreated PAVMs. Primary feeding artery embolization was performed in each of the 12 reperfused PAVMs. Additionally, five PAVMs required 2 to 4 treatments due to reperfusion. The overall study encompassed 32 coil embolizations. Reperfusion rates were examined at 3, 6, 12, and 24 months for both primary embolization (untreated PAVMs) and repeat embolization (reperfused PAVMs). The rates for primary embolization were 8%, 27%, 36%, and 49%, respectively, while for repeat embolization, they were 50%, 50%, 92%, and 100%, respectively. Upon assessment through time-resolved MR angiography or pulmonary angiography, reperfusion rates following coil embolization for pulmonary arteriovenous malformations (PAVMs) were notably elevated, especially in cases of repeat embolization.⁴⁷

Poretti et al. (2015) reviewed using MRA to evaluate thoracic outlet syndrome (TOS). The protocol enables an independent review of veins and arteries by

employing a single, simultaneous, and bilateral (SB-MRA) contrast injection, applicable for both abduction and adduction acquisitions. Between 2009 and 2013, 38 MRA studies were conducted for individuals with clinically suspected TOS. The study cohort comprised 13 males and 25 females, with a mean age of 35.9 years (standard deviation equal to 11.13). Out of the total participants, 45% (17 patients) were diagnosed with predominant venous TOS (VTOS), 24% (nine patients) with predominant arterial TOS (ATOS), and 32% (12 patients) exhibited an indeterminate or nonvascular condition. Group A radiologists identified Significantly more VTOS cases than Group B ($p = 0.049$). The interobserver agreement was exceptionally high. The employment of the simultaneous bilateral MRA (SB-MRA) protocol proves to be a secure and dependable method for investigating TOS. The protocol, offering an early acquisition phase allowing separate assessment of veins and arteries, enables the examination of collateral venous flow through a single contrast material injection and enhances diagnostic accuracy, particularly for VTOS. SB-MRA emerges as a valuable tool in diagnosing TOS of vascular origin.³⁶

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Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Chest

Clinical Guidelines for Medical Necessity Review

Version: 1.1
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Important Notices

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Medical Necessity Criteria

Service: Magnetic Resonance Angiography (MRA), Chest

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻¹⁰

- [National Coverage Determination \(NCD\) 220.2. Magnetic Resonance Imaging](#)
- [Local Coverage Determination \(LCD\) L33633. Magnetic Resonance Angiography \(MRA\)](#)
- [Local Coverage Determination \(LCD\) L34372. Magnetic Resonance Angiography \(MRA\)](#)
- [Local Coverage Determination \(LCD\) L34424. Magnetic Resonance Angiography \(MRA\)](#)
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- [Billing and Coding: Independent Diagnostic Testing Facility \(IDTF\) \(A53252\)](#)
- [Billing and Coding: Independent Diagnostic Testing Facility \(IDTF\) \(A57807\)](#)
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- [Billing and Coding: Magnetic Resonance Angiography \(MRA\) \(A56805\)](#)
- [Billing and Coding: Magnetic Resonance Angiography \(MRA\) \(A57779\)](#)

Recommended Clinical Approach

Magnetic resonance angiography (MRA) of the chest allows for visualizing blood vessels, including the arteries and veins. MRA evaluates vascular diseases, aortic pathologies, congenital heart conditions, venous pathologies, pulmonary artery diseases, and other pathologies (e.g., vasculitis, extrinsic compression). A computed tomography angiogram (CTA) can be performed faster than an MRA and uses different contrast materials. Radiation exposure occurs during a CTA, whereas MRA does not. Magnetic resonance venography (MRV) is a noninvasive technique used to evaluate the central venous system in the chest, and it can help diagnose and stage central venous obstruction.¹¹

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of MRA of the chest. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.¹¹⁻¹²
- The use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.¹¹⁻¹²
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is an uncertain risk for MR imaging in pregnant patients. The decision to image a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.¹³
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.¹⁴

The clinical benefits of using these criteria include:

- MRA provides high-resolution imaging for a range of vascular territories and disorders.¹⁵
- The patient is not exposed to ionizing radiation or contrast agents.¹⁵⁻¹⁶
- MRA is useful during procedures such as stent placement to help guide physicians to visualize blood flow.
- Non-contrast MRA is safe for patients with renal impairment, pediatric patients, and pregnant patients.¹⁶
- MRA yields hemodynamic information regarding arterial flow and can aid in diagnosing aneurysms and narrowing or blockages of blood vessels. Functional information, like renal hemodynamics, is also provided by MRA.¹⁶
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **Magnetic resonance angiography (MRA), chest** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Trauma (e.g., dissection, post-traumatic pseudoaneurysm); **OR**
 - ◆ Congenital or acquired conditions (e.g., pulmonary sequestration, heart disease)¹⁷; **OR**
 - ◆ Vascular conditions, known or suspected, including **ANY** of the following:

- Abnormality of the thoracic aorta (seen on prior imaging)¹⁸; **OR**
- Aneurysm or vascular malformation; **OR**
- Suspicion for acute aortic dissection in the presence of sudden, intense pain in the chest or back¹⁹⁻²⁰; **OR**
- Pulmonary hypertension when CTA is contraindicated or cannot be performed²¹; **OR**
- Evaluation or diagnosis of pulmonary embolism if CTA or ventilation/perfusion (V/Q) scan is contraindicated or cannot be performed^{1,22-28}; **OR**
- Superior vena cava (SVC) syndrome²⁹; **OR**
- Subclavian steal syndrome following a positive or inconclusive ultrasound³⁰; **OR**
- Takayasu's arteritis³¹; **OR**
- Thoracic outlet syndrome³²⁻³⁷; **OR**
- Vascular stenosis or occlusion due to atherosclerosis, vasculitis, or thromboembolic phenomena; **OR**
- Vascular supply to, or involvement by, tumor; **OR**
- Venous or arterial anatomy (e.g., congenital abnormalities, extrinsic compression, or causes of intrinsic stenosis or obstruction)^{18,38-39}; **OR**
- ◆ Follow-up evaluation with an established thoracic aortic aneurysm (TAA) and **ANY** of the following is **TRUE**:
 - Without syndromic and non-syndromic hereditary thoracic aneurysm disease and **ANY** of the following:
 - Annual surveillance for aneurysm less than 5.0 cm; **OR**
 - Symptoms suggestive of aneurysmal growth/dissection⁴⁰; **OR**
 - 6-month evaluation for aneurysm for **ANY** of the following:
 - ◆ Greater than or equal to 5.0 cm; **OR**
 - ◆ Growing more than 0.5 cm per year; **OR**
 - With syndromic and non-syndromic hereditary thoracic aneurysm disease (e.g., Ehlers-Danlos syndrome, Loeys-Dietz syndrome, Marfan syndrome, coarctation of the aorta) defined as **ANY** of the following:

- Known predisposition as defined by the presence of genetic markers; **OR**
 - Surveillance MRA at baseline, then follow-up at 6 months, then annually if stable or more frequently if growth is noted)⁴¹; **OR**
 - Symptoms suggestive of aneurysmal growth/dissection^{40,42}; **OR**
- ◆ **ANY** of the following:
- Transcatheter aortic valve replacement (TAVR) pre-intervention planning with an assessment of **ANY** of the following⁴³:
 - Aortic root; **OR**
 - Supravalvular aorta and vascular access; **OR**
 - Pulmonary vein mapping (e.g., prior to atrial fibrillation ablation); **OR**
 - Thoracic endovascular repair (TEVAR) for the treatment of thoracic aortic disease (pre- or post-repair)^{20,44-45}; **OR**
 - Chronic dissection, annually¹; **OR**
 - Re-evaluation of known ascending aortic dilation or history of aortic dissection with a change in clinical status (including cardiac exam or other findings that may alter management); **OR**
 - Non-invasive clinical staging of a tumor to define vascular invasion; **OR**
 - Post-treatment of acute aortic dissection (e.g., 1 month, 6 months, annually)¹; **OR**
 - Ongoing monitoring for possible TAA in patients at high-risk (e.g., Loeys-Dietz syndrome, Turner syndrome, Marfan syndrome, bicuspid aortic valve); **OR**
 - Initial screening MRA for a first-degree relative (parent, sibling, or child) of a patient with thoracic aortic disease with **ANY** of the following:
 - Family history of Marfan syndrome, Loeys-Dietz syndrome, or vascular Ehlers-Danlos; **OR**
 - Family history of TAA due to **ANY** of the following:
 - ◆ ACTA2, MYH11, PRKG1, MYLK; **OR**
 - ◆ TAA without identified pathogenic variants in a known gene for HTAD; **OR**

- ◆ TAA and bicuspid aortic valve; **OR**
- ◆ Family history of intracranial or peripheral aneurysm; **OR**
- ◆ Turner syndrome; **OR**
- ◆ Coarctation of the aorta; **OR**
- ◆ Congenital heart defects such as tetralogy of Fallot, transposition of the great vessels, truncus arteriosus; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Magnetic resonance angiography (MRA), chest** may not be considered appropriate if **ANY** of the following is **TRUE**:
- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
 - ◆ The patient has incompatible metallic clips on vascular aneurysms¹; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
71555	Magnetic resonance angiography (MRA), chest (excluding myocardium), with or without contrast material(s)
C8909	Magnetic resonance angiography (MRA) with contrast, chest (excluding myocardium)
C8910	Magnetic resonance angiography (MRA) without contrast, chest (excluding myocardium)
C8911	Magnetic resonance angiography (MRA) without contrast followed by with contrast, chest (excluding myocardium)

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Londono et al. (2021) performed a retrospective review to evaluate the image quality of the entire thoracic aorta by comparing 3D radial respiratory self-navigated native magnetic resonance angiography (native-SN-MRA) based on a bSSFP sequence with traditional Cartesian 3D contrast-enhanced MRA (CE-MRA) that uses navigator-gated respiration control. Thirty-one aortic native-SN-MRA scans (average age 63.9 years) to 61 CE-MRA scans (average age 63.1 years) were used as a reference. The image quality was evaluated at the aortic root/ascending aorta, aortic arch, and descending aorta. For the 10 patients who underwent both MRA sequences, aortic pathologies were assessed, and both normal and pathological aortic diameters were measured. The study found that native-SN-MRA provides superior image quality for the entire thoracic aorta, especially in areas prone to motion artifacts, while also achieving shorter acquisition times compared to conventional techniques.⁴⁶

Shimohira et al. (2015) present the results of a multicenter study on reperfusion rates of pulmonary arteriovenous malformations (PAVMs) following coil embolization. The study used time-resolved MRA or pulmonary angiography and included patients diagnosed with PAVM who underwent embolization. Sixteen patients in the study cohort underwent coil embolization (24 untreated or reperfused PAVMs). Among these, sac embolization was performed in 12 untreated PAVMs. Primary feeding artery embolization was performed in each of the 12 reperfused PAVMs. Additionally, five PAVMs required 2 to 4 treatments due to reperfusion. The overall study encompassed 32 coil embolizations. Reperfusion rates were examined at 3, 6, 12, and 24 months for both primary embolization (untreated PAVMs) and repeat embolization (reperfused PAVMs). The rates for primary embolization were 8%, 27%, 36%, and 49%, respectively, while for repeat embolization, they were 50%, 50%, 92%, and 100%, respectively. Upon assessment through time-resolved MR angiography or pulmonary angiography, reperfusion rates following coil embolization for pulmonary arteriovenous malformations (PAVMs) were notably elevated, especially in cases of repeat embolization.⁴⁷

Poretti et al. (2015) reviewed using MRA to evaluate thoracic outlet syndrome (TOS). The protocol enables an independent review of veins and arteries by

employing a single, simultaneous, and bilateral (SB-MRA) contrast injection, applicable for both abduction and adduction acquisitions. Between 2009 and 2013, 38 MRA studies were conducted for individuals with clinically suspected TOS. The study cohort comprised 13 males and 25 females, with a mean age of 35.9 years (standard deviation equal to 11.13). Out of the total participants, 45% (17 patients) were diagnosed with predominant venous TOS (VTOS), 24% (nine patients) with predominant arterial TOS (ATOS), and 32% (12 patients) exhibited an indeterminate or nonvascular condition. Group A radiologists identified Significantly more VTOS cases than Group B ($p = 0.049$). The interobserver agreement was exceptionally high. The employment of the simultaneous bilateral MRA (SB-MRA) protocol proves to be a secure and dependable method for investigating TOS. The protocol, offering an early acquisition phase allowing separate assessment of veins and arteries, enables the examination of collateral venous flow through a single contrast material injection and enhances diagnostic accuracy, particularly for VTOS. SB-MRA emerges as a valuable tool in diagnosing TOS of vascular origin.³⁶

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Review History		
		• Updated policy per CMS revisions for 03/27/2025 • Updated Effective Date • Updated Links and References



Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Head

Clinical Guidelines for Medical Necessity Review

Version: 1.1
Revision Date: May 1, 2025

Important Notices

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Medical Necessity Criteria

Service: Magnetic Resonance Angiography (MRA), Head

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service. [37-43](#), [50-51](#)

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L33633\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56747\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34865\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56805\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34372\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A57779\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34424\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56775\)](#)

Recommended Clinical Approach

Imaging analysis utilizing magnetic resonance angiography (MRA) of the head can be performed alone or in conjunction with MRA of the neck.

Contrast and concurrent exams should be guided by clinical suspicion of disease presence or exclusion to direct value-based care. Staging,

pre-surgical planning, and screening are also recommendations of a clinical approach. MRA plays a crucial role in the routine assessment of patients experiencing stroke syndrome, specifically for the evaluation of both cervical and intracranial vessels, enabling the identification and diagnosis of vascular anomalies. In conjunction with MRI, MRA enhances the examination by providing a comprehensive analysis of the cerebral parenchyma. MRA also serves as a viable alternative to CT angiography when using iodinated contrast material is not feasible.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance angiography (MRA), head. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.^{1 44-45}
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.^{1 44-45}
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁴⁶
- There is a risk of increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.⁴⁷

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. The non-invasive nature of MRA of the head and neck, particularly in the Medicare population, has increased accessibility and appropriate usage compared to conventional invasive angiography.⁴⁸
- Reduction in complications and adverse effects from unnecessary procedures. According to the 2020 ACR-NASCI-SPR practice parameter for the performance of body magnetic resonance angiography (MRA), the procedure is stated to be much less invasive than standard catheter-based invasive angiography, reducing the risk of vascular injury. For patients who are unable to receive gadolinium-based contrast agents, non-contrast study techniques are available. There is no associated ionizing radiation exposure as with computed tomography studies. MRA is stated to be useful in diagnosis of vascular disease in pediatric patients, although sedation or general anesthesia may be required.¹
- Enhanced diagnostic accuracy for complex medical conditions. Contrast-enhanced MRA of the head is accurate for detecting aneurysms and dissections as well as disease within the vertebrobasilar circulation, and can evaluate the head and neck in a single study.⁴⁹
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance angiography (MRA), head** is considered appropriate if **ANY** of the following is **TRUE**³⁷⁻⁴³:

◆ **ALL** of the following are **TRUE**:

● **ANY** of the following is **TRUE**:

- Conventional (catheter) angiography has not been performed; **OR**
- Conventional (catheter) angiography has been performed, and the results are inconclusive or require further evaluation⁴²; **AND**

● **ANY** of the following is **TRUE**:

- The patient requires post-procedure or post-treatment follow-up; **OR**
- The patient is a candidate for surgery or other intervention, which may be found to be appropriate based upon MRA results for conditions including **ANY** of the following:

◆ Stenosis; **OR**

◆ Tumors; **OR**

◆ Aneurysms; **OR**

◆ Vascular malformations; **OR**

◆ Dissections; **OR**

◆ Thrombosis; **OR**

◆ Other vascular conditions, not specified; **OR**

◆ Ultrasound-confirmed cervical bruit or thrill with suspicion of neck carotid stenosis for surgical planning when ordered in conjunction with MRA neck; **OR**

◆ Intracranial hypertension (idiopathic), suspected; **OR**

◆ Evaluation of **ANY** of the following:

- Circle of Willis; **OR**
- Anterior, middle, or posterior cerebral arteries; **OR**
- Basilar arteries; **OR**
- Venous sinuses³⁷⁻³⁸; **OR**

- ◆ Headache with **ANY** of the following:
 - Clinically-significant finding of blood in the cerebrospinal fluid^{38,40}; **OR**
 - Signs and symptoms strongly suggesting an unruptured intracranial aneurysm and/or intracranial hemorrhage (e.g., acute onset worst/thunderclap headache, new onset or pattern during pregnancy or peripartum period, or headache associated with exercise, exertion, Valsalva, or sexual activity); **OR**^{38,40}
- ◆ For evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when applicable:
 - Massive epistaxis; **OR**
 - Neurological deficit(s) (focal or lateralizing); **OR**
 - Nontraumatic orbital asymmetry, exophthalmos, or enophthalmos⁵; **OR**
 - Ptosis (new-onset); **OR**
 - Pulsatile tinnitus (subjective or objective); **OR**
 - Visual changes (e.g., visual loss, optic nerve symptoms, chiasm symptoms (including pre- or post chiasm, ophthalmoplegia, diplopia)⁵; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance angiography (MRA), head** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Used in conjunction with conventional contrast angiography when the criteria listed in the Indications section above have not been met^{37-38,40}; **OR**
- ◆ For screening asymptomatic patients for intracranial aneurysms^{38,40}; **OR**
- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/ HCPCS Code	Code Description
70544	Magnetic resonance angiography (MRA), head; without contrast material(s)
70545	Magnetic resonance angiography (MRA), head; with contrast material(s)
70546	Magnetic resonance angiography (MRA), head; without contrast material(s), followed by contrast material(s) and further sequences

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Amin et al. (2023) present a scientific statement from the American Heart Association regarding the diagnosis, workup, and risk reduction of transient ischemic attack in the emergency department. Computed tomography angiography (CTA) demonstrates superior sensitivity and positive predictive value compared to magnetic resonance angiography (MRA) in detecting intracranial stenosis and occlusion. As a result, CTA is the recommended imaging modality over time-of-flight (without contrast) MRA. If there is a concern regarding administering iodinated contrast, expedited magnetic resonance imaging (MRI) with MRA is a viable alternative. Time-of-flight MRA may result in images of lower quality as there is a tendency to overestimate cervical carotid stenosis compared to gadolinium-enhanced MRA. However, this type of MRA may be suitable for screening purposes. Gadolinium-enhanced MRA of the neck is the preferred choice for patients who can safely receive gadolinium contrast.²²

AbuRahma et al. (2022) review clinical guidelines for managing extracranial cerebrovascular disease published by the Society for Vascular Surgery. Contrast-enhanced MRA can produce three-dimensional images that rival those from a formal arteriography. A key advantage of MRA is less radiation exposure to the individual, and the use of iodinated-based contrast materials is not needed. Further, MRA allows for the integration of MRI of the brain, enabling the identification of clinically silent cerebral infarction. It also facilitates the assessment of plaque morphology, focusing on detecting intraplaque hemorrhage. The severity of carotid stenosis is more identifiable with MRA than CTA. While MRA excels in various aspects, it is unsuitable for screening carotid artery disease due to its substantial cost.²³

Cummins et al. (2022) discuss the role of TOF MRA for pulsatile tinnitus (PT) and the identification of vascular causes of PT, including dural arteriovenous fistulas (DAVFs). The annual intracranial hemorrhage risk of DAVFs is over 24%. TOF-MRA is considered one of the most sensitive and specific noninvasive methods for diagnosing DAVF. The diagnosis of arterial aneurysms is aided by the use of TOF MRA, with a sensitivity greater than 90% and specificity over 80%. Stenoses are also detected by MRA (a sensitivity of 95.5% and specificity of 87.2%). When severe carotid artery stenosis is a cause of PT, the sensitivity

and specificity of TOF MRA is nearly 100%. Advantages of MRA include a greater pooled sensitivity for diagnosis than CT as well as excellent spatial resolution and is the most powerful sequence for DAVF diagnosis. In addition, MRA can diagnose intracranial and high cervical arterial etiologies (e.g., fibromuscular dysplasia, carotid stenosis, variant anatomy). Disadvantages include high cost, scanning time, and the dephasing of tortuous vessels.²⁴

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Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Head

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 24, 2024

Important Notices

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Medical Necessity Criteria

Service: Magnetic Resonance Angiography (MRA), Head

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service. [37-43](#)

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L33633\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56747\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34865\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56805\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34372\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A57779\)](#)

Recommended Clinical Approach

Imaging analysis utilizing magnetic resonance angiography (MRA) of the head can be performed alone or in conjunction with MRA of the neck. Contrast and concurrent exams should be guided by clinical suspicion of disease presence or exclusion to direct value-based care. Staging, pre-surgical planning, and screening are also recommendations of a clinical approach. MRA plays a crucial role in the routine assessment of patients experiencing stroke syndrome, specifically for the evaluation of both cervical

and intracranial vessels, enabling the identification and diagnosis of vascular anomalies. In conjunction with MRI, MRA enhances the examination by providing a comprehensive analysis of the cerebral parenchyma. MRA also serves as a viable alternative to CT angiography when using iodinated contrast material is not feasible.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance angiography (MRA), head. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.^{[1](#) [44-45](#)}
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.^{[1](#) [44-45](#)}
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.^{[46](#)}
- There is a risk of increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.^{[47](#)}

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. The non-invasive nature of MRA of the head and neck, particularly in the Medicare population, has increased accessibility and appropriate usage compared to conventional invasive angiography.⁴⁸
- Reduction in complications and adverse effects from unnecessary procedures. According to the 2020 ACR-NASCI-SPR practice parameter for the performance of body magnetic resonance angiography (MRA), the procedure is stated to be much less invasive than standard catheter-based invasive angiography, reducing the risk of vascular injury. For patients who are unable to receive gadolinium-based contrast agents, non-contrast study techniques are available. There is no associated ionizing radiation exposure as with computed tomography studies. MRA is stated to be useful in diagnosis of vascular disease in pediatric patients, although sedation or general anesthesia may be required.¹
- Enhanced diagnostic accuracy for complex medical conditions. Contrast-enhanced MRA of the head is accurate for detecting aneurysms and dissections as well as disease within the vertebrobasilar circulation, and can evaluate the head and neck in a single study.⁴⁹
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance angiography (MRA), head** is considered appropriate if **ANY** of the following is **TRUE**³⁷⁻⁴³:

◆ **ALL** of the following are **TRUE**:

- **ANY** of the following is **TRUE**:
 - Conventional (catheter) angiography has not been performed; **OR**
 - Conventional (catheter) angiography has been performed, and the results are inconclusive or require further evaluation⁴²; **AND**
- **ANY** of the following is **TRUE**:
 - The patient requires post-procedure or post-treatment follow-up; **OR**
 - The patient is a candidate for surgery or other intervention, which may be found to be appropriate based upon MRA results for conditions including **ANY** of the following:
 - ◆ Stenosis; **OR**
 - ◆ Tumors; **OR**
 - ◆ Aneurysms; **OR**
 - ◆ Vascular malformations; **OR**
 - ◆ Dissections; **OR**
 - ◆ Thrombosis; **OR**
 - ◆ Other vascular conditions, not specified; **OR**
 - ◆ Ultrasound-confirmed cervical bruit or thrill with suspicion of neck carotid stenosis for surgical planning when ordered in conjunction with MRA neck; **OR**
 - ◆ Intracranial hypertension (idiopathic), suspected; **OR**
 - ◆ Evaluation of **ANY** of the following:
 - Circle of Willis; **OR**
 - Anterior, middle, or posterior cerebral arteries; **OR**
 - Basilar arteries; **OR**
 - Venous sinuses³⁷⁻³⁸; **OR**

- ◆ Headache with **ANY** of the following:
 - Clinically-significant finding of blood in the cerebrospinal fluid^{38,40}; **OR**
 - Signs and symptoms strongly suggesting an unruptured intracranial aneurysm and/or intracranial hemorrhage (e.g., acute onset worst/thunderclap headache, new onset or pattern during pregnancy or peripartum period, or headache associated with exercise, exertion, Valsalva, or sexual activity); **OR**^{38,40}
- ◆ For evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when applicable:
 - Massive epistaxis; **OR**
 - Neurological deficit(s) (focal or lateralizing); **OR**
 - Nontraumatic orbital asymmetry, exophthalmos, or enophthalmos⁵; **OR**
 - Ptosis (new-onset); **OR**
 - Pulsatile tinnitus (subjective or objective); **OR**
 - Visual changes (e.g., visual loss, optic nerve symptoms, chiasm symptoms (including pre- or post chiasm, ophthalmoplegia, diplopia)⁵; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance angiography (MRA), head** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Used in conjunction with conventional contrast angiography when the criteria listed in the Indications section above have not been met^{37-38,40}; **OR**
- ◆ For screening asymptomatic patients for intracranial aneurysms^{38,40}; **OR**
- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/ HCPCS Code	Code Description
70544	Magnetic resonance angiography (MRA), head; without contrast material(s)
70545	Magnetic resonance angiography (MRA), head; with contrast material(s)
70546	Magnetic resonance angiography (MRA), head; without contrast material(s), followed by contrast material(s) and further sequences

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Amin et al. (2023) present a scientific statement from the American Heart Association regarding the diagnosis, workup, and risk reduction of transient ischemic attack in the emergency department. Computed tomography angiography (CTA) demonstrates superior sensitivity and positive predictive value compared to magnetic resonance angiography (MRA) in detecting intracranial stenosis and occlusion. As a result, CTA is the recommended imaging modality over time-of-flight (without contrast) MRA. If there is a concern regarding administering iodinated contrast, expedited magnetic resonance imaging (MRI) with MRA is a viable alternative. Time-of-flight MRA may result in images of lower quality as there is a tendency to overestimate cervical carotid stenosis compared to gadolinium-enhanced MRA. However, this type of MRA may be suitable for screening purposes. Gadolinium-enhanced MRA of the neck is the preferred choice for patients who can safely receive gadolinium contrast.²²

AbuRahma et al. (2022) review clinical guidelines for managing extracranial cerebrovascular disease published by the Society for Vascular Surgery. Contrast-enhanced MRA can produce three-dimensional images that rival those from a formal arteriography. A key advantage of MRA is less radiation exposure to the individual, and the use of iodinated-based contrast materials is not needed. Further, MRA allows for the integration of MRI of the brain, enabling the identification of clinically silent cerebral infarction. It also facilitates the assessment of plaque morphology, focusing on detecting intraplaque hemorrhage. The severity of carotid stenosis is more identifiable with MRA than CTA. While MRA excels in various aspects, it is unsuitable for screening carotid artery disease due to its substantial cost.²³

Cummins et al. (2022) discuss the role of TOF MRA for pulsatile tinnitus (PT) and the identification of vascular causes of PT, including dural arteriovenous fistulas (DAVFs). The annual intracranial hemorrhage risk of DAVFs is over 24%. TOF-MRA is considered one of the most sensitive and specific noninvasive methods for diagnosing DAVF. The diagnosis of arterial aneurysms is aided by the use of TOF MRA, with a sensitivity greater than 90% and specificity over 80%. Stenoses are also detected by MRA (a sensitivity of 95.5% and specificity of 87.2%). When severe carotid artery stenosis is a cause of PT, the sensitivity

and specificity of TOF MRA is nearly 100%. Advantages of MRA include a greater pooled sensitivity for diagnosis than CT as well as excellent spatial resolution and is the most powerful sequence for DAVF diagnosis. In addition, MRA can diagnose intracranial and high cervical arterial etiologies (e.g., fibromuscular dysplasia, carotid stenosis, variant anatomy). Disadvantages include high cost, scanning time, and the dephasing of tortuous vessels.²⁴

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Clinical Guideline Revision History/Information

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Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Lower Extremity

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Medical Necessity Criteria

Service: Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Lower Extremity

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.^{1-4, 36-37}

- [National Coverage Determination \(NCD\). Magnetic Resonance Imaging \(MRI\) 220.2](#)
- [Local Coverage Determination \(LCD\). Magnetic Resonance Angiography \(MRA\) L33633](#)
- [Local Coverage Determination \(LCD\). Magnetic Resonance Angiography \(MRA\) L34865](#)
- [Local Coverage Determination \(LCD\). Magnetic Resonance Angiography \(MRA\) L34372](#)
- [Billing and Coding: Magnetic Resonance Angiography \(MRA\)\(A56747\)](#)
- [Billing and Coding: Magnetic Resonance Angiography \(MRA\)\(A56805\)](#)
- [Billing and Coding: Magnetic Resonance Angiography \(MRA\)\(A57779\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34424\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56775\)](#)

Recommended Clinical Approach

Magnetic resonance angiography (MRA) is a noninvasive alternative to catheter angiography for evaluating vascular structures in the lower extremities. Magnetic resonance venography (MRV) images veins instead of arteries. MRA and MRV are less invasive than conventional X-ray digital subtraction angiography.¹

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance angiography (MRA), lower extremity. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁵⁻⁸
- Despite not requiring radiation, MRA is relatively expensive compared to other imaging modalities and its use may be difficult to justify when cost-effective alternatives are available.⁹
- MRA exams may use gadolinium-based contrast agents to improve the quality of the images. Such agents must be used with caution when imaging patients with moderate to severe renal failure, who may be at risk of nephrogenic systemic fibrosis.¹⁰
- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- Use of gadolinium-based contrast is not recommended in patients with acute or chronic kidney injury or disease.¹¹⁻¹³
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.¹⁴
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.¹⁵

The clinical benefits of using these criteria include:

- Non-Invasive: An MRA is a non-invasive examination that does not require sedation, catheterization, or ionized radiation, yet can be more accurate than conventional venography, offering an alternative imaging technique for patients with contrast allergies or renal dysfunction.^{9,10,16} The non-invasive nature of MRA, which allows for examinations of vessel anatomy without ionizing radiation, makes the imaging technique particularly suited to preoperative imaging.⁹
- Quick And accurate: Magnetic resonance angiography can produce timely and highly accurate assessments of arterial disease in the lower extremity, with high levels of clarity and fidelity.¹⁷ Compared to conventional angiography, MRA provides more sensitive visualizations of blood vessel pathology.¹⁶
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **Magnetic resonance angiography (MRA), lower extremity** is considered appropriate if **ANY** of the following is **TRUE**¹⁷:
- ◆ MRA-preferred indications including **ANY** of the following:
 - Arterial entrapment syndrome, when ultrasound is indeterminate or for pre-treatment planning; **OR**
 - Adventitial cystic disease¹⁷; **OR**
 - When catheter angiography was unable to identify a viable run-off vessel for bypass; **OR**

- ◆ Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment response, or prognostication); **OR**
- ◆ Neoplastic invasion of arteries or veins; **OR**
- ◆ Trauma-related conditions including, but not limited to, **ANY** of the following¹⁸:
 - Expanding hematoma¹⁹; **OR**
 - Major blunt trauma and the patient is hemodynamically stable²⁰; **OR**
 - Neurologic deficit of lower extremity in association with trauma²¹; **OR**
 - Known or suspected knee dislocation²²; **OR**
 - Vascular trauma to a lower extremity²³; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Aneurysm; **OR**
 - Intramural hematoma; **OR**
 - Dissection; **OR**
 - Critical limb ischemia strongly suspected (e.g., sudden onset of a cold leg with pain, gangrene, rest pain)²⁴; **OR**
 - Lower extremity ischemic symptoms; **OR**
 - Determination of hemorrhage source (including non-surgical, spontaneous)²⁵; **OR**
 - Localization and characterization of vascular malformation or fistula (e.g., assessing treatment response, treatment planning); **OR**
 - Vasculitis; **OR**
 - Pre and post-intervention evaluation; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**

- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Magnetic resonance venography (MRV), lower extremity** is

considered appropriate if **ANY** of the following are **TRUE**:

- ◆ MRV-preferred indications, including venous entrapment syndrome, when ultrasound is indeterminate or for pre-treatment planning; **OR**
- ◆ Ultrasound and CT/CTV are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to IV contrast reaction, pregnancy, pediatric) with **ANY** of the following:
 - Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment-response, or prognostication); **OR**
 - Neoplastic invasion of arteries or veins; **OR**
 - Initial evaluation for a known venous leg ulcer, when ultrasound is indeterminate or non-diagnostic²⁷; **OR**
 - Known or suspected acute or chronic deep venous thrombosis, when results would change management and ultrasound has been completed; **OR**
 - Known severe post-thrombotic changes incompletely evaluated by ultrasound²⁷; **OR**
 - Evidence of severe venous reflux disease and **ALL** of the following²⁸:
 - Duplex ultrasound evaluation indeterminate, incomplete, or non-diagnostic; **AND**
 - Surgical or endovascular intervention planned; **OR**
- ◆ Pre and post-intervention evaluation when **ANY** of the following is **TRUE**:
 - Postoperative evaluation of the effectiveness of arterial or venous reconstruction or bypass; **OR**
 - Characterization of normal and variant vascular anatomy; **OR**
 - Determination of the patency, location, or integrity of grafts and other vascular devices (e.g., stents); **OR**
 - Planning autografts for musculoskeletal reconstruction; **OR**

- Treatment of popliteal entrapment syndrome; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Magnetic resonance angiography (MRA), lower extremity** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Catheter angiography has been previously performed and demonstrated conclusive findings; **OR**
 - ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
 - ◆ The patient has metallic clips on vascular aneurysms; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
73725	Magnetic resonance angiography (MRA), lower extremity, with or without contrast material(s)
C8912	Magnetic resonance angiography (MRA) with contrast, lower extremity
C8913	Magnetic resonance angiography (MRA) without contrast, lower extremity
C8914	Magnetic resonance angiography (MRA) without contrast followed by with contrast, lower extremity

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Nassar et al. (2022) reviewed imaging modalities for preoperative planning. Computed tomography angiography (CTA) and magnetic resonance angiography (MRA) can generate detailed 3D images of vascular structures and surrounding anatomy, with applications in preoperative planning for breast, head, neck, and extremity reconstructions. While MRA eliminates the need for radiation exposure, it is less precise than CTA in detecting perforators smaller than 1 mm and contraindicated in specific patient groups. For assessing venous anatomy, the most effective modalities include duplex ultrasound, MRV, and the outflow phase of conventional angiography. While MR scanners and software continue to advance, the general preference is for strength 1.5-T scanners in reconstructive applications. Lower-strength scanners allow enhanced fat suppression, contributing to more precise imaging of vascular structures.¹²

Tamura and Nakahara (2014) conducted a retrospective study to assess pelvic and deep vein thrombosis (DVT) in the lower extremities with magnetic resonance venography (MRV) before surgical intervention for varicose veins. Time-of-flight MRV evaluated the 72 patients enrolled in the study before stripping varicose veins of the lower extremities. A total of 63.9% were female, with a mean age of 65.2 plus or minus 10.2 years; 55.6% of patients had bilateral varicose leg veins; 2.8% of patients had DVT; and 4.2% were diagnosed with iliac vein thrombosis. The remaining patients could undergo the stripping procedure in the saphenous veins. The study concluded that non-contrast MRV helps evaluate the lower extremity venous system.¹³

Koelemay et al. (2001) conducted a meta-analysis of 34 studies (1090 patients) that reports a high accuracy for assessing arteries in the lower extremities using MRA. Three-dimensional (3D) gadolinium-enhanced MRA demonstrated enhanced diagnostic accuracy compared to 2D MRA. The estimated thresholds for equal sensitivity and specificity were 94% and 90% for 3D gadolinium-enhanced MRA and 2D MRA, respectively. Recent investigations specifically examined the diagnostic capabilities of lower extremity 3D gadolinium-enhanced MRA compared to digital subtraction angiography.¹⁴

Ersoy et al. (2008) report on the precision of 3D MRA in assessing bypass grafts and detecting recurrent issues within the graft lumen is comparable to its accuracy in native arteries. Foot and calf MRA exhibit sensitivity and

specificity exceeding 80% and 90%, respectively. In contrast to digital subtraction angiography, gadolinium-enhanced MRA generates a 3D dataset that can create displays reminiscent of multilane digital subtraction angiography after reformatting. These displays emphasize pertinent information for prognosis and treatment planning, such as arterial wall inflammation, plaque composition, and mural and intramural thrombus formation.¹⁵

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Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Lower Extremity

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Medical Necessity Criteria

Service: Cohere Medicare Advantage Policy - Magnetic Resonance Angiography (MRA), Lower Extremity

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹⁻⁴

- [National Coverage Determination \(NCD\). Magnetic Resonance Imaging \(MRI\) 220.2](#)
- [Local Coverage Determination \(LCD\). Magnetic Resonance Angiography \(MRA\) L33633](#)
- [Local Coverage Determination \(LCD\). Magnetic Resonance Angiography \(MRA\) L34865](#)
- [Local Coverage Determination \(LCD\). Magnetic Resonance Angiography \(MRA\) L34372](#)
- [Billing and Coding: Magnetic Resonance Angiography \(MRA\)\(A56747\)](#)
- [Billing and Coding: Magnetic Resonance Angiography \(MRA\)\(A56805\)](#)
- [Billing and Coding: Magnetic Resonance Angiography \(MRA\)\(A57779\)](#)

Recommended Clinical Approach

Magnetic resonance angiography (MRA) is a noninvasive alternative to catheter angiography for evaluating vascular structures in the lower extremities. Magnetic resonance venography (MRV) images veins instead of arteries. MRA and MRV are less invasive than conventional X-ray digital subtraction angiography.¹

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Magnetic Resonance Angiography (MRA), Lower Extremity. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.⁵⁻⁸
- Despite not requiring radiation, MRA is relatively expensive compared to other imaging modalities and its use may be difficult to justify when cost-effective alternatives are available.⁹
- MRA exams may use gadolinium-based contrast agents to improve the quality of the images. Such agents must be used with caution when imaging patients with moderate to severe renal failure, who may be at risk of nephrogenic systemic fibrosis.¹⁰
- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- Use of gadolinium-based contrast is not recommended in patients with acute or chronic kidney injury or disease.¹¹⁻¹³
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.¹⁴
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.¹⁵

The clinical benefits of using these criteria include:

- Non-Invasive: An MRA is a non-invasive examination that does not require sedation, catheterization, or ionized radiation, yet can be more accurate than conventional venography, offering an alternative imaging technique for patients with contrast allergies or renal dysfunction.^{9,10,16} The non-invasive nature of MRA, which allows for examinations of vessel anatomy without ionizing radiation, makes the imaging technique particularly suited to preoperative imaging.⁹
- Quick And accurate: Magnetic resonance angiography can produce timely and highly accurate assessments of arterial disease in the lower extremity, with high levels of clarity and fidelity.¹⁷ Compared to conventional angiography, MRA provides more sensitive visualizations of blood vessel pathology.¹⁶
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance angiography (MRA), lower extremity** is considered appropriate if **ANY** of the following is **TRUE**¹⁷:

- ◆ MRA-preferred indications including **ANY** of the following:
 - Arterial entrapment syndrome, when ultrasound is indeterminate or for pre-treatment planning; **OR**
 - Adventitial cystic disease¹⁷; **OR**
 - When catheter angiography was unable to identify a viable run-off vessel for bypass; **OR**

- ◆ Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment response, or prognostication); **OR**
- ◆ Neoplastic invasion of arteries or veins; **OR**
- ◆ Trauma-related conditions including, but not limited to, **ANY** of the following¹⁸:
 - Expanding hematoma¹⁹; **OR**
 - Major blunt trauma and the patient is hemodynamically stable²⁰; **OR**
 - Neurologic deficit of lower extremity in association with trauma²¹; **OR**
 - Known or suspected knee dislocation²²; **OR**
 - Vascular trauma to a lower extremity²³; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Aneurysm; **OR**
 - Intramural hematoma; **OR**
 - Dissection; **OR**
 - Critical limb ischemia strongly suspected (e.g., sudden onset of a cold leg with pain, gangrene, rest pain)²⁴; **OR**
 - Lower extremity ischemic symptoms; **OR**
 - Determination of hemorrhage source (including non-surgical, spontaneous)²⁶; **OR**
 - Localization and characterization of vascular malformation or fistula (e.g., assessing treatment response, treatment planning); **OR**
 - Vasculitis; **OR**
 - Pre and post-intervention evaluation; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**

- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Magnetic resonance venography (MRV), lower extremity** is

considered appropriate if **ANY** of the following are **TRUE**:

- ◆ MRV-preferred indications, including venous entrapment syndrome, when ultrasound is indeterminate or for pre-treatment planning; **OR**
- ◆ Ultrasound and CT/CTV are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to IV contrast reaction, pregnancy, pediatric) with **ANY** of the following:
 - Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment-response, or prognostication); **OR**
 - Neoplastic invasion of arteries or veins; **OR**
 - Initial evaluation for a known venous leg ulcer, when ultrasound is indeterminate or non-diagnostic²⁷; **OR**
 - Known or suspected acute or chronic deep venous thrombosis, when results would change management and ultrasound has been completed; **OR**
 - Known severe post-thrombotic changes incompletely evaluated by ultrasound²⁷; **OR**
 - Evidence of severe venous reflux disease and **ALL** of the following²⁸:
 - Duplex ultrasound evaluation indeterminate, incomplete, or non-diagnostic; **AND**
 - Surgical or endovascular intervention planned; **OR**
- ◆ Pre and post-intervention evaluation when **ANY** of the following is **TRUE**:
 - Postoperative evaluation of the effectiveness of arterial or venous reconstruction or bypass; **OR**
 - Characterization of normal and variant vascular anatomy; **OR**
 - Determination of the patency, location, or integrity of grafts and other vascular devices (e.g., stents); **OR**
 - Planning autografts for musculoskeletal reconstruction; **OR**

- Treatment of popliteal entrapment syndrome; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Magnetic resonance angiography (MRA), lower extremity** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Catheter angiography has been previously performed and demonstrated conclusive findings; **OR**
 - ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
 - ◆ The patient has metallic clips on vascular aneurysms; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
73725	Magnetic resonance angiography (MRA), lower

	extremity, with or without contrast material(s)
C8912	Magnetic resonance angiography (MRA) with contrast, lower extremity
C8913	Magnetic resonance angiography (MRA) without contrast, lower extremity
C8914	Magnetic resonance angiography (MRA) without contrast followed by with contrast, lower extremity

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Nassar et al. (2022) reviewed imaging modalities for preoperative planning. Computed tomography angiography (CTA) and magnetic resonance angiography (MRA) can generate detailed 3D images of vascular structures and surrounding anatomy, with applications in preoperative planning for breast, head, neck, and extremity reconstructions. While MRA eliminates the need for radiation exposure, it is less precise than CTA in detecting perforators smaller than 1 mm and contraindicated in specific patient groups. For assessing venous anatomy, the most effective modalities include duplex ultrasound, MRV, and the outflow phase of conventional angiography. While MR scanners and software continue to advance, the general preference is for strength 1.5-T scanners in reconstructive applications. Lower-strength scanners allow enhanced fat suppression, contributing to more precise imaging of vascular structures.¹²

Tamura and Nakahara (2014) conducted a retrospective study to assess pelvic and deep vein thrombosis (DVT) in the lower extremities with magnetic resonance venography (MRV) before surgical intervention for varicose veins. Time-of-flight MRV evaluated the 72 patients enrolled in the study before stripping varicose veins of the lower extremities. A total of 63.9% were female, with a mean age of 65.2 plus or minus 10.2 years; 55.6% of patients had bilateral varicose leg veins; 2.8% of patients had DVT; and 4.2% were diagnosed with iliac vein thrombosis. The remaining patients could undergo the stripping procedure in the saphenous veins. The study concluded that non-contrast MRV helps evaluate the lower extremity venous system.¹³

Koelemay et al. (2001) conducted a meta-analysis of 34 studies (1090 patients) that reports a high accuracy for assessing arteries in the lower extremities using MRA. Three-dimensional (3D) gadolinium-enhanced MRA demonstrated enhanced diagnostic accuracy compared to 2D MRA. The estimated thresholds for equal sensitivity and specificity were 94% and 90% for 3D gadolinium-enhanced MRA and 2D MRA, respectively. Recent investigations specifically examined the diagnostic capabilities of lower extremity 3D gadolinium-enhanced MRA compared to digital subtraction angiography.¹⁴

Ersoy et al. (2008) report on the precision of 3D MRA in assessing bypass grafts and detecting recurrent issues within the graft lumen is comparable to its accuracy in native arteries. Foot and calf MRA exhibit sensitivity and specificity exceeding 80% and 90%, respectively. In contrast to digital

subtraction angiography, gadolinium-enhanced MRA generates a 3D dataset that can create displays reminiscent of multilane digital subtraction angiography after reformatting. These displays emphasize pertinent information for prognosis and treatment planning, such as arterial wall inflammation, plaque composition, and mural and intramural thrombus formation.¹⁵

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Clinical Guideline Revision History/Information

Original Date: October 17, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Neck

Clinical Guidelines for Medical Necessity Review

Version: 1.1
Revision Date: May 1, 2025

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Magnetic Resonance Angiography (MRA), Neck

Date of last literature review: 10/22/2024

Document last updated: 04/29/2025

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Angiography (MRA), Neck

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service. [33-39, 46-47](#)

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L33633\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56747\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34865\)](#)
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- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34424\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56775\)](#)

Recommended Clinical Approach

Magnetic resonance angiography (MRA) of the neck is advanced imaging that is best utilized per institutional neurological, neurosurgical, and radiologic protocols. Ordering providers may consult specialty guidelines before ordering.¹ Imaging analysis utilizing MRA of the head can be performed alone or in conjunction with MRA of the head or magnetic resonance imaging (MRI)

of the head. Contrast and concurrent exams should be guided by clinical suspicion of disease presence or exclusion to direct value-based care. Staging, pre-surgical planning, and screening are also recommendations of a clinical approach. MRA plays a crucial role in the routine assessment of patients experiencing stroke syndrome, specifically for the evaluation of both cervical and intracranial vessels, enabling the identification and diagnosis of vascular anomalies. In conjunction with MRI, MRA enhances the examination by comprehensively analyzing the cerebral parenchyma. MRA is also a viable alternative to computed tomography angiography (CTA) when using iodinated contrast material is not feasible.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance angiography (MRA), neck. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.^{1, 40-41}
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.^{1, 40-41}
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁴²

- There is a risk of increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.⁴³

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. The non-invasive nature of MRA of the neck, particularly in the Medicare population, has increased accessibility and appropriate usage compared to conventional invasive angiography.⁴⁴
- Reduction in complications and adverse effects from unnecessary procedures. According to the 2020 ACR-NASCI-SPR practice parameter for the performance of body magnetic resonance angiography (MRA), the procedure is stated to be much less invasive than standard catheter-based invasive angiography, reducing the risk of vascular injury. For patients who are unable to receive gadolinium-based contrast agents, non-contrast study techniques are available. There is no associated ionizing radiation exposure as with computed tomography studies. MRA is stated to be useful in diagnosis of vascular disease in pediatric patients, although sedation or general anesthesia may be required.¹
- Enhanced diagnostic accuracy for complex medical conditions. Contrast-enhanced MRA of the neck is accurate for detecting aneurysms and dissections as well as carotid vessel stenoses and occlusions.⁴⁵
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance angiography (MRA), neck** is considered appropriate if **ANY** of the following is **TRUE**³³⁻³⁹:

◆ **ALL** of the following are **TRUE**:

• **ANY** of the following is **TRUE**:

- Conventional (catheter) angiography has not been performed; **OR**
- Conventional (catheter) angiography has been performed, and the results are inconclusive or require further evaluation³⁸; **AND**

• **ANY** of the following is **TRUE**:

- The patient requires post-procedure or post-treatment follow-up; **OR**
- The patient is a candidate for surgery or other intervention, which may be found to be appropriate based upon MRA results for conditions including **ANY** of the following:

◆ Stenosis; **OR**

◆ Tumors; **OR**

◆ Aneurysms; **OR**

◆ Vascular malformations; **OR**

◆ Dissections; **OR**

◆ Thrombosis; **OR**

◆ Other vascular conditions, not specified; **OR**

◆ Ultrasound-confirmed cervical bruit or thrill with suspicion of neck carotid stenosis for surgical planning (e.g., carotid angioplasty with stent insertion) when ordered in conjunction with MRA neck^{34,36}; **OR**

◆ Evaluation of **ANY** of the following:

• Carotid arteries; **OR**

• Vertebral arteries³³⁻³⁴; **OR**

◆ Headache, sudden and severe^{34,36}; **OR**

◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in

the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance angiography (MRA), neck** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Used in conjunction with conventional contrast angiography when the criteria listed in the Indications section above have not been met^{33-34,38}; **OR**
- ◆ For screening asymptomatic patients for intracranial aneurysms^{34,36}; **OR**
- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70547	Magnetic resonance angiography (MRA), neck; without contrast material(s)
70548	Magnetic resonance angiography (MRA), neck; with contrast material(s)
70549	Magnetic resonance angiography (MRA), neck; without contrast material(s), followed by contrast material(s) and further sequences

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Amin et al. (2023) present a scientific statement from the American Heart Association regarding the diagnosis, workup, and risk reduction of transient ischemic attack in the emergency department. Computed tomography angiography (CTA) demonstrates superior sensitivity and positive predictive value compared to magnetic resonance angiography (MRA) in detecting intracranial stenosis and occlusion. As a result, CTA is the recommended imaging modality over time-of-flight (TOF) (without contrast) MRA. If there is a concern regarding administering iodinated contrast, expedited magnetic resonance imaging (MRI) with MRA is a viable alternative. TOF MRA may result in images of lower quality as there is a tendency to overestimate cervical carotid stenosis compared to gadolinium-enhanced MRA. However, this type of MRA may be suitable for screening purposes. Gadolinium-enhanced MRA of the neck is the preferred choice for patients who can safely receive gadolinium contrast.³⁰

AbuRahma et al. (2022) review clinical guidelines for managing extracranial cerebrovascular disease published by the Society for Vascular Surgery. Contrast-enhanced MRA can produce three-dimensional images that rival those from a formal arteriography. A key advantage of MRA is less radiation exposure to the individual, and the use of iodinated-based contrast materials is not needed. Further, MRA allows for the integration of MRI of the brain, enabling the identification of clinically silent cerebral infarction. It also facilitates the assessment of plaque morphology, focusing on detecting intraplaque hemorrhage. The severity of carotid stenosis is more identifiable with MRA than CTA. While MRA excels in various aspects, it is unsuitable for screening carotid artery disease due to its substantial cost.³¹

Cummins et al. (2022) discuss the role of TOF MRA for pulsatile tinnitus (PT) and the identification of vascular causes of PT, including dural arteriovenous fistulas (DAVFs). The annual intracranial hemorrhage risk of DAVFs is over 24%. TOF-MRA is one of the most sensitive and specific noninvasive methods for diagnosing DAVF. The diagnosis of arterial aneurysms is aided by the use of TOF MRA, with a sensitivity greater than 90% and specificity over 80%. MRA also detects stenoses (a sensitivity of 95.5% and specificity of 87.2%). When severe carotid artery stenosis is a cause of PT, the sensitivity and specificity of TOF

MRA is nearly 100%. The advantages of MRA include a greater pooled sensitivity for diagnosis than CT and excellent spatial resolution and the most powerful sequence for DAVF diagnosis. In addition, MRA can diagnose intracranial and high cervical arterial etiologies (e.g., fibromuscular dysplasia, carotid stenosis, variant anatomy). Disadvantages include high cost, scanning time, and the dephasing of tortuous vessels.^{[32](#)}

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Clinical Guideline Revision History/Information

Original Date: October 24, 2024		
Review History		
Version 1.1	05/01/2025	• Revised per CMS update for 03/27/2025 • Updated Revision Date • Updated Links and References for L34424, A56775



Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Neck

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 24, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Magnetic Resonance Angiography (MRA), Neck

Date of last literature review: 10/22/2024

Document last updated: 10/24/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Angiography (MRA), Neck

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service. [33-39](#)

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L33633\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56747\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34865\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56805\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34372\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A57779\)](#)

Recommended Clinical Approach

Magnetic resonance angiography (MRA) of the neck is advanced imaging that is best utilized per institutional neurological, neurosurgical, and radiologic protocols. Ordering providers may consult specialty guidelines before ordering.¹ Imaging analysis utilizing MRA of the head can be performed alone or in conjunction with MRA of the head or magnetic resonance imaging (MRI) of the head. Contrast and concurrent exams should be guided by clinical suspicion of disease presence or exclusion to direct value-based care. Staging, pre-surgical planning, and screening are also recommendations of a

clinical approach. MRA plays a crucial role in the routine assessment of patients experiencing stroke syndrome, specifically for the evaluation of both cervical and intracranial vessels, enabling the identification and diagnosis of vascular anomalies. In conjunction with MRI, MRA enhances the examination by comprehensively analyzing the cerebral parenchyma. MRA is also a viable alternative to computed tomography angiography (CTA) when using iodinated contrast material is not feasible.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance angiography (MRA), neck. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.^{1 40-41}
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.^{1 40-41}
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁴²
- There is a risk of increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.⁴³

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. The non-invasive nature of MRA of the neck, particularly in the Medicare population, has increased accessibility and appropriate usage compared to conventional invasive angiography.⁴⁴
- Reduction in complications and adverse effects from unnecessary procedures. According to the 2020 ACR-NASCI-SPR practice parameter for the performance of body magnetic resonance angiography (MRA), the procedure is stated to be much less invasive than standard catheter-based invasive angiography, reducing the risk of vascular injury. For patients who are unable to receive gadolinium-based contrast agents, non-contrast study techniques are available. There is no associated ionizing radiation exposure as with computed tomography studies. MRA is stated to be useful in diagnosis of vascular disease in pediatric patients, although sedation or general anesthesia may be required.¹
- Enhanced diagnostic accuracy for complex medical conditions. Contrast-enhanced MRA of the neck is accurate for detecting aneurysms and dissections as well as carotid vessel stenoses and occlusions.⁴⁵
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance angiography (MRA), neck** is considered appropriate if **ANY** of the following is **TRUE**³³⁻³⁹:

◆ **ALL** of the following are **TRUE**:

- **ANY** of the following is **TRUE**:
 - Conventional (catheter) angiography has not been performed; **OR**
 - Conventional (catheter) angiography has been performed, and the results are inconclusive or require further evaluation³⁸; **AND**
- **ANY** of the following is **TRUE**:
 - The patient requires post-procedure or post-treatment follow-up; **OR**
 - The patient is a candidate for surgery or other intervention, which may be found to be appropriate based upon MRA results for conditions including **ANY** of the following:
 - ◆ Stenosis; **OR**
 - ◆ Tumors; **OR**
 - ◆ Aneurysms; **OR**
 - ◆ Vascular malformations; **OR**
 - ◆ Dissections; **OR**
 - ◆ Thrombosis; **OR**
 - ◆ Other vascular conditions, not specified; **OR**
 - ◆ Ultrasound-confirmed cervical bruit or thrill with suspicion of neck carotid stenosis for surgical planning (e.g., carotid angioplasty with stent insertion) when ordered in conjunction with MRA neck^{34,36}; **OR**
 - ◆ Evaluation of **ANY** of the following:
 - Carotid arteries; **OR**
 - Vertebral arteries³³⁻³⁴; **OR**
 - ◆ Headache, sudden and severe ^{34,36}; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in

the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance angiography (MRA), neck** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Used in conjunction with conventional contrast angiography when the criteria listed in the Indications section above have not been met^{33-34,38}; **OR**
- ◆ For screening asymptomatic patients for intracranial aneurysms^{34,36}; **OR**
- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description

70547	Magnetic resonance angiography (MRA), neck; without contrast material(s)
70548	Magnetic resonance angiography (MRA), neck; with contrast material(s)
70549	Magnetic resonance angiography (MRA), neck; without contrast material(s), followed by contrast material(s) and further sequences

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Amin et al. (2023) present a scientific statement from the American Heart Association regarding the diagnosis, workup, and risk reduction of transient ischemic attack in the emergency department. Computed tomography angiography (CTA) demonstrates superior sensitivity and positive predictive value compared to magnetic resonance angiography (MRA) in detecting intracranial stenosis and occlusion. As a result, CTA is the recommended imaging modality over time-of-flight (TOF) (without contrast) MRA. If there is a concern regarding administering iodinated contrast, expedited magnetic resonance imaging (MRI) with MRA is a viable alternative. TOF MRA may result in images of lower quality as there is a tendency to overestimate cervical carotid stenosis compared to gadolinium-enhanced MRA. However, this type of MRA may be suitable for screening purposes. Gadolinium-enhanced MRA of the neck is the preferred choice for patients who can safely receive gadolinium contrast.³⁰

AbuRahma et al. (2022) review clinical guidelines for managing extracranial cerebrovascular disease published by the Society for Vascular Surgery. Contrast-enhanced MRA can produce three-dimensional images that rival those from a formal arteriography. A key advantage of MRA is less radiation exposure to the individual, and the use of iodinated-based contrast materials is not needed. Further, MRA allows for the integration of MRI of the brain, enabling the identification of clinically silent cerebral infarction. It also facilitates the assessment of plaque morphology, focusing on detecting intraplaque hemorrhage. The severity of carotid stenosis is more identifiable with MRA than CTA. While MRA excels in various aspects, it is unsuitable for screening carotid artery disease due to its substantial cost.³¹

Cummins et al. (2022) discuss the role of TOF MRA for pulsatile tinnitus (PT) and the identification of vascular causes of PT, including dural arteriovenous fistulas (DAVFs). The annual intracranial hemorrhage risk of DAVFs is over 24%. TOF-MRA is one of the most sensitive and specific noninvasive methods for diagnosing DAVF. The diagnosis of arterial aneurysms is aided by the use of TOF MRA, with a sensitivity greater than 90% and specificity over 80%. MRA also detects stenoses (a sensitivity of 95.5% and specificity of 87.2%). When severe carotid artery stenosis is a cause of PT, the sensitivity and specificity of TOF

MRA is nearly 100%. The advantages of MRA include a greater pooled sensitivity for diagnosis than CT and excellent spatial resolution and the most powerful sequence for DAVF diagnosis. In addition, MRA can diagnose intracranial and high cervical arterial etiologies (e.g., fibromuscular dysplasia, carotid stenosis, variant anatomy). Disadvantages include high cost, scanning time, and the dephasing of tortuous vessels.^{[32](#)}

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Clinical Guideline Revision History/Information

Original Date: October 24, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Spinal Canal

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 29, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Angiography (MRA), Spinal Canal

Date of last literature review: 10/23/2024

Document last updated: 10/28/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Angiography (MRA), Spinal Canal

Benefit Category

Not Applicable

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻²

- [National Coverage Determination \(NCD\). Magnetic Resonance \(220.2\)](#)
- [Local Coverage Determination \(LCD\). Magnetic Resonance Angiography \(MRA\) \(L33633\)](#)
- [Billing and Coding: Magnetic Resonance Angiography \(MRA\) \(A56747\)](#)

Recommended Clinical Approach

Contrast-enhanced 3D time of flight techniques and contrast-enhanced CT angiography (CTA) is used to evaluate the spinal arteries, veins, and related pathology as a non-invasive alternative to the gold standard catheter angiography. The Adamkiewicz artery's (AKA) detection rate by MRA is 69% – 100%, but with modern equipment, both MRA and CTA detection rates should approach 100%. Magnetic resonance angiography (MRA) may be appropriate when CTA is contraindicated. CTA has the advantage over MRA in providing greater spatial resolution, imaging the entire spine during one contrast bolus, and providing a faster exam time and less prone to motion artifact. A limitation of MRA is a finite field of view, typically less than or equal to 50 cm. MRI has the advantage over CT in detecting areas of ischemia via diffusion-weighted imaging. Mathur et al. showed a 100% sensitivity in detecting recurrent spinal arteriovenous fistulas post-treatment.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance angiography (MRA), spinal canal. This process helps prevent incorrect denials and

inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.³⁻⁵
- The use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.³⁻⁵
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is a certain risk for MR imaging in pregnant patients. The decision to image a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁶
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁷
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Non-Invasive: An MRA is a non-invasive examination that does not require sedation, catheterization, or ionized radiation, yet can be more accurate than conventional venography, offering an alternative imaging technique for patients with contrast allergies or renal dysfunction.⁸⁻¹⁰ The non-invasive nature of MRA, which allows for examinations of vessel anatomy without ionizing radiation, makes the imaging technique particularly suited to preoperative imaging.⁸
- Quick and Accurate: Magnetic resonance angiography can produce timely and highly accurate assessments of arterial disease in the lower extremity, with high levels of clarity and fidelity.¹¹ Compared to

conventional angiography, MRA provides more sensitive visualizations of blood vessel pathology.¹⁰

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance angiography (MRA), spinal canal** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Initial assessment of a previously inconclusive finding on a prior imaging report that necessitates additional clarification; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Thrombosis of spinal arteries is suspected on prior imaging or clinically and would change management; **OR**
 - For the evaluation of known or suspected vertebral artery injury when there is also a concern for vascular compromise to the spinal canal and its contents (otherwise, neck MRA or CTA is sufficient to evaluate vertebral artery injury)³⁻⁵; **OR**
- ◆ Preoperative, postoperative, or pre-treatment evaluation for **ANY** of the following:
 - Localization of the spinal arteries before complex spinal surgery; **OR**
 - Aortic aneurysm repair; **OR**
 - For characterization of suspected vascular lesions, including tumors or masses of the spinal canal and its

- contents⁵; **OR**
- To guide a subsequent digital subtraction angiography meant to assess for a spinal arteriovenous malformation or fistula; **OR**
- ◆ As a follow-up study for **ANY** of the following:
 - Known arteriovenous malformation (AVM)⁶⁻⁷; **OR**
 - Known spinal arteriovenous fistula (AVF)⁸; **OR**
 - To evaluate the patient's post-treatment, post-procedure, or post-surgical progress⁸; **OR**
 - A single follow-up examination for a prior MR/CT finding initially deemed indeterminate, aimed at ensuring no suspicious interval changes have occurred; **OR**
- ◆ For evaluation of **ANY** of the following congenital or acquired conditions:
 - Myelopathy when MRI demonstrates an underlying vascular malformation as a follow-up to demonstrate abnormal vasculature (may be used to guide spinal arteriography and intervention)⁹; **OR**
 - Spinal arteriovenous malformation (AVM)^{5,8,10-13}; **OR**
 - Spinal arteriovenous fistula (AVF), including vascular flow voids on MRI Spine that are suspicious for spinal AVF; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Magnetic resonance angiography (MRA), spinal canal** is not considered appropriate if **ANY** of the following is **TRUE**:
 - ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**

- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72159	Magnetic resonance angiography (MRA) of spinal canal and contents with contrast material material
C8931	Magnetic resonance angiography with contrast, spinal canal and contents
C8932	Magnetic resonance angiography without contrast, spinal canal and contents
C8933	Magnetic resonance angiography without contrast followed by with contrast, spinal canal and contents

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Raman et al. (2022) performed a systematic review comparing digital subtraction angiography (DSA) with magnetic resonance angiography (MRA) for the evaluation of cerebral arteriovenous malformations (AVMs). In brain AVMs, there is aberrant communication between arteries and veins, resulting in the formation of a nidus, a complex network of intertwined blood vessels. DSA is generally the preferred method due to its superior spatial resolution and hemodynamic properties, representing the current gold standard. There is a need for further research to determine whether MR studies alone could serve as a diagnostic imaging alternative to the current gold standard, DSA, for AVM diagnosis. Numerous studies have highlighted the combined use of both imaging modalities, and some have suggested that specific MR imaging techniques closely resemble the outcomes of invasive conventional scans.¹⁴

Sharma et al. (2019) compare computed tomography angiography (CTA) and MRA for traumatic vertebral artery injury (TVAI). The primary diagnostic approach for patients with trauma and meeting screening criteria for potential cervical vascular injury is CTA. At the same time, MRA, DSA, and Doppler duplex ultrasound have supportive roles as complementary imaging modalities. The authors also review anatomic variations and potential mimics. Early detection is crucial, and prompt initiation of therapy can significantly reduce the risk of associated strokes.¹⁵

Mathur et al. (2017) evaluated the effectiveness of first-pass contrast-enhanced MRA in diagnosing and localizing spinal epidural AVFs with intradural venous reflux, as well as differentiating them from other types of spinal AVFs. Of the 42 patients with suspected spinal AVF, 7 patients received a diagnosis. The authors conclude that MRA can identify lesions associated with spinal dural AVFs.¹⁶

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Clinical Guideline Revision History/Information

Original Date: October 29, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Spinal Canal

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 29, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Angiography (MRA), Spinal Canal

Date of last literature review: 10/23/2024

Document last updated: 10/28/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Angiography (MRA), Spinal Canal

Benefit Category

Not Applicable

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻²

- [National Coverage Determination \(NCD\). Magnetic Resonance \(220.2\)](#)
- [Local Coverage Determination \(LCD\). Magnetic Resonance Angiography \(MRA\) \(L33633\)](#)
- [Billing and Coding: Magnetic Resonance Angiography \(MRA\) \(A56747\)](#)

Recommended Clinical Approach

Contrast-enhanced 3D time of flight techniques and contrast-enhanced CT angiography (CTA) is used to evaluate the spinal arteries, veins, and related pathology as a non-invasive alternative to the gold standard catheter angiography. The Adamkiewicz artery's (AKA) detection rate by MRA is 69% – 100%, but with modern equipment, both MRA and CTA detection rates should approach 100%. Magnetic resonance angiography (MRA) may be appropriate when CTA is contraindicated. CTA has the advantage over MRA in providing greater spatial resolution, imaging the entire spine during one contrast bolus, and providing a faster exam time and less prone to motion artifact. A limitation of MRA is a finite field of view, typically less than or equal to 50 cm. MRI has the advantage over CT in detecting areas of ischemia via diffusion-weighted imaging. Mathur et al. showed a 100% sensitivity in detecting recurrent spinal arteriovenous fistulas post-treatment.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance angiography (MRA), spinal canal. This process helps prevent incorrect denials and

inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.³⁻⁵
- The use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.³⁻⁵
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is a certain risk for MR imaging in pregnant patients. The decision to image a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁶
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁷
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Non-Invasive: An MRA is a non-invasive examination that does not require sedation, catheterization, or ionized radiation, yet can be more accurate than conventional venography, offering an alternative imaging technique for patients with contrast allergies or renal dysfunction.⁸⁻¹⁰ The non-invasive nature of MRA, which allows for examinations of vessel anatomy without ionizing radiation, makes the imaging technique particularly suited to preoperative imaging.⁸
- Quick and Accurate: Magnetic resonance angiography can produce timely and highly accurate assessments of arterial disease in the lower extremity, with high levels of clarity and fidelity.¹¹ Compared to

conventional angiography, MRA provides more sensitive visualizations of blood vessel pathology.¹⁰

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance angiography (MRA), spinal canal** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Initial assessment of a previously inconclusive finding on a prior imaging report that necessitates additional clarification; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:
 - Thrombosis of spinal arteries is suspected on prior imaging or clinically and would change management; **OR**
 - For the evaluation of known or suspected vertebral artery injury when there is also a concern for vascular compromise to the spinal canal and its contents (otherwise, neck MRA or CTA is sufficient to evaluate vertebral artery injury)³⁻⁵; **OR**
- ◆ Preoperative, postoperative, or pre-treatment evaluation for **ANY** of the following:
 - Localization of the spinal arteries before complex spinal surgery; **OR**
 - Aortic aneurysm repair; **OR**
 - For characterization of suspected vascular lesions, including tumors or masses of the spinal canal and its

- contents⁵; **OR**
- To guide a subsequent digital subtraction angiography meant to assess for a spinal arteriovenous malformation or fistula; **OR**
- ◆ As a follow-up study for **ANY** of the following:
 - Known arteriovenous malformation (AVM)⁶⁻⁷; **OR**
 - Known spinal arteriovenous fistula (AVF)⁸; **OR**
 - To evaluate the patient's post-treatment, post-procedure, or post-surgical progress⁸; **OR**
 - A single follow-up examination for a prior MR/CT finding initially deemed indeterminate, aimed at ensuring no suspicious interval changes have occurred; **OR**
- ◆ For evaluation of **ANY** of the following congenital or acquired conditions:
 - Myelopathy when MRI demonstrates an underlying vascular malformation as a follow-up to demonstrate abnormal vasculature (may be used to guide spinal arteriography and intervention)⁹; **OR**
 - Spinal arteriovenous malformation (AVM)^{5,8,10-13}; **OR**
 - Spinal arteriovenous fistula (AVF), including vascular flow voids on MRI Spine that are suspicious for spinal AVF; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Magnetic resonance angiography (MRA), spinal canal** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**

- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72159	Magnetic resonance angiography (MRA) of spinal canal and contents with contrast material material
C8931	Magnetic resonance angiography with contrast, spinal canal and contents
C8932	Magnetic resonance angiography without contrast, spinal canal and contents
C8933	Magnetic resonance angiography without contrast followed by with contrast, spinal canal and contents

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Raman et al. (2022) performed a systematic review comparing digital subtraction angiography (DSA) with magnetic resonance angiography (MRA) for the evaluation of cerebral arteriovenous malformations (AVMs). In brain AVMs, there is aberrant communication between arteries and veins, resulting in the formation of a nidus, a complex network of intertwined blood vessels. DSA is generally the preferred method due to its superior spatial resolution and hemodynamic properties, representing the current gold standard. There is a need for further research to determine whether MR studies alone could serve as a diagnostic imaging alternative to the current gold standard, DSA, for AVM diagnosis. Numerous studies have highlighted the combined use of both imaging modalities, and some have suggested that specific MR imaging techniques closely resemble the outcomes of invasive conventional scans.¹⁴

Sharma et al. (2019) compare computed tomography angiography (CTA) and MRA for traumatic vertebral artery injury (TVAI). The primary diagnostic approach for patients with trauma and meeting screening criteria for potential cervical vascular injury is CTA. At the same time, MRA, DSA, and Doppler duplex ultrasound have supportive roles as complementary imaging modalities. The authors also review anatomic variations and potential mimics. Early detection is crucial, and prompt initiation of therapy can significantly reduce the risk of associated strokes.¹⁵

Mathur et al. (2017) evaluated the effectiveness of first-pass contrast-enhanced MRA in diagnosing and localizing spinal epidural AVFs with intradural venous reflux, as well as differentiating them from other types of spinal AVFs. Of the 42 patients with suspected spinal AVF, 7 patients received a diagnosis. The authors conclude that MRA can identify lesions associated with spinal dural AVFs.¹⁶

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Clinical Guideline Revision History/Information

Original Date: October 29, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Upper Extremity

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Magnetic Resonance Angiography (MRA), Upper Extremity

Date of last literature review: 9/16/2024

Document last updated: 04/29/2025

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Angiography (MRA), Upper Extremity

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.^{1-7, 19-20}

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L33633\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56747\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34865\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56805\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34372\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A57779\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34424\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56775\)](#)

Recommended Clinical Approach

Magnetic resonance angiography (MRA) of the upper extremity is typically performed without and with gadolinium contrast. Although contrast-enhanced MRA (CE-MRA) is generally preferred, non-contrast-enhanced techniques are increasingly available. These may be a good option for patients with impaired renal function or who cannot tolerate gadolinium-

based contrast agents. A broad spectrum of upper extremity vascular disorders can be assessed accurately using MRA of the upper extremity.⁸

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance angiography (MRA), upper extremity. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁸⁻⁹
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁸⁻⁹
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.
- There is a risk of increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.¹⁸

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. Ghouri et al (2019) describe the procedural benefits of MRA of the upper extremity, including increasing use for semi-urgent

conditions where computed tomography was previously preferred. MRA is stated to allow better soft tissue characterization without ionizing radiation exposure, as well as high accuracy and reproducibility, and simultaneous assessment of central vessels and soft tissues.¹⁰

- Reduction in complications and adverse effects from unnecessary procedures. According to the 2020 ACR-NASCI-SPR practice parameter for the performance of body magnetic resonance angiography (MRA), the procedure is stated to be much less invasive than standard catheter-based invasive angiography, reducing the risk of vascular injury. For patients who are unable to receive gadolinium-based contrast agents, non-contrast study techniques are available. There is no associated ionizing radiation exposure as with computed tomography studies. MRA is stated to be useful in diagnosis of vascular disease in pediatric patients, although sedation or general anesthesia may be required.⁸
- Enhanced diagnostic accuracy for complex medical conditions. Bode et al. (2012) evaluated MRA use in upper extremity vascular access planning. They stated that MRA allows examination of the entire upper extremity vascular tree compared to discrete locations from duplex ultrasound testing.¹¹
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **Magnetic resonance angiography (MRA), upper extremity** is considered appropriate if **ALL** of the following are **TRUE**⁸:

- ◆ MRA-preferred indications including **ANY** of the following:
 - Arterial entrapment syndrome, when ultrasound is indeterminate or for pre-treatment planning; **OR**
 - Adventitial cystic disease; **OR**
 - Intimal hyperplasia evaluation within vascular devices such as stents; **AND**
- ◆ Ultrasound and CT/CTA are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to IV contrast reaction, pregnancy, pediatric) with **ANY** of the following:
 - Clinical suspicion of acute or chronic limb ischemia, when ultrasound is inconclusive or nondiagnostic, with **ANY** of the following:
 - Acute absence of radial or ulnar pulses; **OR**
 - Acute changes in motor or sensory function; **OR**
 - Symptoms with exercise attributable to vascular; **OR** etiologies such as muscle pain that resolves with rest, coolness, pallor, or fatigue; **OR**
 - Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment response, or prognostication); **OR**
 - Neoplastic invasion of arteries or veins; **OR**
 - Trauma-related conditions as indicated by **ANY** of the following¹²:
 - Expanding hematoma; **OR**
 - Major blunt trauma and the patient is hemodynamically stable¹³; **OR**
 - Neurologic deficit of upper extremity in association with trauma¹⁴; **OR**
 - Vascular trauma to an upper extremity¹⁵; **OR**
 - Vascular conditions, known or suspected, including **ANY** of the following:
 - Aneurysm, seen on ultrasound or when ultrasound is nondiagnostic; **OR**
 - Intramural hematoma; **OR**
 - Dissection; **OR**
 - Non-healing upper extremity ulcers with abnormal or inconclusive ultrasound results (e.g. arterial Doppler); **OR**

- Determination of hemorrhage source (including non-surgical, spontaneous); **OR**
- Localization and characterization of vascular malformation (e.g., assessing treatment response, treatment planning) with **ANY** of the following:
 - ◆ Duplex ultrasound indeterminate or nondiagnostic; **OR**
 - ◆ High flow lesion suspected clinically or by imaging; **OR**
 - ◆ Preoperative planning; **OR**
- Vasculitis, initial evaluation, when **ANY** of the following is **TRUE**¹⁵:
 - ◆ Biopsy proven; **OR**
 - ◆ Rheumatologic panel work-up including but not limited to erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) is suggestive of vasculitis; **OR**
 - ◆ The requesting clinician specializes in rheumatology and the outcome of the imaging is expected to change management and/or treatment plan; **OR**
- Non-inflammatory vasculopathies that are symptomatic such as Raynaud's, Buerger's disease, fibromuscular dysplasia, or scleroderma; **OR**
- Vascular steal syndrome of the upper extremity, is suspected, and initial imaging is needed to guide therapy¹⁰; **OR**
- Pre- and post-intervention evaluation when **ANY** of the following is **TRUE**:
 - Postoperative evaluation of the effectiveness of arterial or venous reconstruction or bypass; **OR**
 - Characterization of normal and variant vascular anatomy; **OR**
 - Determination of the patency, location, or integrity of grafts and other vascular devices (e.g., stents); **OR**
 - Planning autografts for musculoskeletal reconstruction; **OR**

- Hemodialysis access evaluation, when duplex ultrasound is inconclusive and fistulogram cannot be performed, for **ANY** of the following conditions:
 - Arteriovenous fistula (AVF) stenosis; **OR**
 - Occlusion; **OR**
 - Pseudoaneurysm; **OR**
 - Steal syndrome (cool and painful extremity)

→ **Magnetic resonance venography (MRV), upper extremity** is considered appropriate if **ALL** of the following are **TRUE**¹:

- ◆ MRA-preferred indications including venous entrapment syndrome, when ultrasound is indeterminate or for pre-treatment planning; **AND**
- ◆ Ultrasound and CT/CTV are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to IV contrast reaction, pregnancy, pediatric) with **ANY** of the following:
 - Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment-response, or prognostication); **OR**
 - Neoplastic invasion of arteries or veins; **OR**
 - Initial evaluation for known venous upper extremity ulcer, when ultrasound is indeterminate or non-diagnostic; **OR**
 - Known or suspected acute or chronic deep venous thrombosis, when results would change, or management and ultrasound have been completed¹⁶; **OR**
 - Known severe post-thrombotic changes incompletely evaluated by ultrasound; **OR**
 - Subclavian or central venous obstruction such as subclavian vein thrombosis, Paget-Schroetter syndrome, thoracic outlet syndrome, either known or suspected clinically (e.g., edema aggravated by exercise/arm position); **OR**
 - Pre and post-intervention evaluation when **ANY** of the following is **TRUE**:

- Postoperative evaluation of the effectiveness of arterial or venous reconstruction or bypass; **OR**
- Characterization of normal and variant vascular anatomy; **OR**
- Determination of the patency, location, or integrity of grafts and other vascular devices (e.g., stents); **OR**
- Planning autografts for musculoskeletal reconstruction; **OR**
- Treatment of venous entrapment syndrome

→ **Repeat imaging** (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- ◆ New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- ◆ One-time clarifying follow-up of a prior indeterminate finding; **OR**
- ◆ In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance angiography (MRA), upper extremity** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the

ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
73225	Magnetic resonance angiography (MRA), upper extremity, with or without contrast material(s)
C8934	Magnetic resonance angiography (MRA), with contrast, upper extremity
C8935	Magnetic resonance angiography (MRA), without contrast, upper extremity
C8936	Magnetic resonance angiography (MRA), without contrast followed by with contrast, upper extremity

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Nassar et al. (2022) reviewed imaging modalities for preoperative planning. CTA and MRA can generate detailed 3D images of vascular structures and surrounding anatomy, with applications in preoperative planning for breast, head, neck, and extremity reconstructions. While MRA eliminates the need for radiation exposure, it is less precise than CTA in detecting perforators smaller than 1 mm. For assessing venous anatomy, the most effective modalities include duplex ultrasound, MRV, and the outflow phase of conventional angiography. While MR scanners and software continue to advance, the general preference is for 1.5-T scanners in reconstructive applications. Lower-strength scanners allow enhanced fat suppression, contributing to clearer imaging of vascular structures.¹⁷

Ghouri et al. (2019) review the successes and failures of CTA and MRA of the upper extremities. These modalities are preferred over Doppler or digital subtraction angiography (DSA), especially in patients without contraindications to MRI. Soft tissue characterization is improved with MRA and does not expose the patient to radiation. Venous and neurological compression is also successfully evaluated with MRA. As imaging modalities, particularly CTA and MRA, continue to advance, the authors stress the importance of identifying the strengths and weaknesses of different techniques to obtain the most effective imaging test.¹⁰

The American College of Radiology, the North American Society for Cardiovascular Imaging (NASCI), and the Society for Pediatric Radiology (SPR) developed a 2020 updated practice parameter for the performance of body magnetic resonance angiography (MRA). They state that contrast-enhanced MRA is as effective as standard angiography in the evaluation of diseases related to the vascular system as well as the planning of treatment. MRA is less invasive than catheter-based angiography, reducing the risk of injury to the vascular system being examined. Noncontrast MRA is available to patients in whom contrast media is contraindicated. Specific extremity MRA evaluations include arterial occlusions, congenital anomalies, and aneurysms, as well as venous malformations, causes of peripheral edema, and varicose veins. MRA is effective in planning for dialysis access placement.⁸

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Version 1.1	05/01/2025	• Revised per CMS update for 03/27/2025 • Updated Revision Date • Updated Links and References for L34424, A56775



Cohere Medicare Advantage Policy – Magnetic Resonance Angiography (MRA), Upper Extremity

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 19, 2024

Important Notices

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Medical Necessity Criteria

Service: Magnetic Resonance Angiography (MRA), Upper Extremity

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹⁻²

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L33633\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56747\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34865\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A56805\)](#)
- [Local Coverage Determination \(LCD\). Magnetic resonance angiography \(MRA\) \(L34372\)](#)
- [Billing and Coding: Magnetic resonance angiography \(MRA\) \(A57779\)](#)

Recommended Clinical Approach

Magnetic resonance angiography (MRA) of the upper extremity is typically performed without and with gadolinium contrast. Although contrast-enhanced MRA (CE-MRA) is generally preferred, non-contrast-enhanced techniques are increasingly available. These may be a good option for patients with impaired renal function or who cannot tolerate gadolinium-based contrast agents. A broad spectrum of upper extremity vascular disorders can be assessed accurately using MRA of the upper extremity.⁸

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance angiography (MRA), upper extremity. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁸⁻⁹
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁸⁻⁹
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.
- There is a risk of increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.¹⁸

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. Ghouri et al (2019) describe the procedural benefits of MRA of the upper extremity, including increasing use for semi-urgent conditions where computed tomography was previously preferred. MRA is stated to allow better soft tissue characterization without ionizing

radiation exposure, as well as high accuracy and reproducibility, and simultaneous assessment of central vessels and soft tissues.¹⁰

- Reduction in complications and adverse effects from unnecessary procedures. According to the 2020 ACR-NASCI-SPR practice parameter for the performance of body magnetic resonance angiography (MRA), the procedure is stated to be much less invasive than standard catheter-based invasive angiography, reducing the risk of vascular injury. For patients who are unable to receive gadolinium-based contrast agents, non-contrast study techniques are available. There is no associated ionizing radiation exposure as with computed tomography studies. MRA is stated to be useful in diagnosis of vascular disease in pediatric patients, although sedation or general anesthesia may be required.⁸
- Enhanced diagnostic accuracy for complex medical conditions. Bode et al. (2012) evaluated MRA use in upper extremity vascular access planning. They stated that MRA allows examination of the entire upper extremity vascular tree compared to discrete locations from duplex ultrasound testing.¹¹
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **Magnetic resonance angiography (MRA), upper extremity** is considered appropriate if **ALL** of the following are **TRUE**⁸:
- ◆ MRA-preferred indications including **ANY** of the following:

- Arterial entrapment syndrome, when ultrasound is indeterminate or for pre-treatment planning; **OR**
- Adventitial cystic disease; **OR**
- Intimal hyperplasia evaluation within vascular devices such as stents; **AND**
- ◆ Ultrasound and CT/CTA are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to IV contrast reaction, pregnancy, pediatric) with **ANY** of the following:
 - Clinical suspicion of acute or chronic limb ischemia, when ultrasound is inconclusive or nondiagnostic, with **ANY** of the following:
 - Acute absence of radial or ulnar pulses; **OR**
 - Acute changes in motor or sensory function; **OR**
 - Symptoms with exercise attributable to vascular; **OR** etiologies such as muscle pain that resolves with rest, coolness, pallor, or fatigue; **OR**
 - Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment response, or prognostication); **OR**
 - Neoplastic invasion of arteries or veins; **OR**
 - Trauma-related conditions as indicated by **ANY** of the following¹²:
 - Expanding hematoma; **OR**
 - Major blunt trauma and the patient is hemodynamically stable¹³; **OR**
 - Neurologic deficit of upper extremity in association with trauma¹⁴; **OR**
 - Vascular trauma to an upper extremity¹⁵; **OR**
 - Vascular conditions, known or suspected, including **ANY** of the following:
 - Aneurysm, seen on ultrasound or when ultrasound is nondiagnostic; **OR**
 - Intramural hematoma; **OR**
 - Dissection; **OR**
 - Non-healing upper extremity ulcers with abnormal or inconclusive ultrasound results (e.g. arterial Doppler); **OR**

- Determination of hemorrhage source (including non-surgical, spontaneous); **OR**
- Localization and characterization of vascular malformation (e.g., assessing treatment response, treatment planning) with **ANY** of the following:
 - ◆ Duplex ultrasound indeterminate or nondiagnostic; **OR**
 - ◆ High flow lesion suspected clinically or by imaging; **OR**
 - ◆ Preoperative planning; **OR**
- Vasculitis, initial evaluation, when **ANY** of the following is **TRUE**¹⁵:
 - ◆ Biopsy proven; **OR**
 - ◆ Rheumatologic panel work-up including but not limited to erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) is suggestive of vasculitis; **OR**
 - ◆ The requesting clinician specializes in rheumatology and the outcome of the imaging is expected to change management and/or treatment plan; **OR**
- Non-inflammatory vasculopathies that are symptomatic such as Raynaud's, Buerger's disease, fibromuscular dysplasia, or scleroderma; **OR**
- Vascular steal syndrome of the upper extremity, is suspected, and initial imaging is needed to guide therapy¹⁰; **OR**
- Pre- and post-intervention evaluation when **ANY** of the following is **TRUE**:
 - Postoperative evaluation of the effectiveness of arterial or venous reconstruction or bypass; **OR**
 - Characterization of normal and variant vascular anatomy; **OR**
 - Determination of the patency, location, or integrity of grafts and other vascular devices (e.g., stents); **OR**
 - Planning autografts for musculoskeletal reconstruction; **OR**

- Hemodialysis access evaluation, when duplex ultrasound is inconclusive and fistulogram cannot be performed, for **ANY** of the following conditions:
 - Arteriovenous fistula (AVF) stenosis; **OR**
 - Occlusion; **OR**
 - Pseudoaneurysm; **OR**
 - Steal syndrome (cool and painful extremity)

→ **Magnetic resonance venography (MRV), upper extremity** is considered appropriate if **ALL** of the following are **TRUE**¹:

- ◆ MRA-preferred indications including venous entrapment syndrome, when ultrasound is indeterminate or for pre-treatment planning; **AND**
- ◆ Ultrasound and CT/CTV are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to IV contrast reaction, pregnancy, pediatric) with **ANY** of the following:
 - Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment-response, or prognostication); **OR**
 - Neoplastic invasion of arteries or veins; **OR**
 - Initial evaluation for known venous upper extremity ulcer, when ultrasound is indeterminate or non-diagnostic; **OR**
 - Known or suspected acute or chronic deep venous thrombosis, when results would change, or management and ultrasound have been completed¹⁶; **OR**
 - Known severe post-thrombotic changes incompletely evaluated by ultrasound; **OR**
 - Subclavian or central venous obstruction such as subclavian vein thrombosis, Paget-Schroetter syndrome, thoracic outlet syndrome, either known or suspected clinically (e.g., edema aggravated by exercise/arm position); **OR**
 - Pre and post-intervention evaluation when **ANY** of the following is **TRUE**:

- Postoperative evaluation of the effectiveness of arterial or venous reconstruction or bypass; **OR**
- Characterization of normal and variant vascular anatomy; **OR**
- Determination of the patency, location, or integrity of grafts and other vascular devices (e.g., stents); **OR**
- Planning autografts for musculoskeletal reconstruction; **OR**
- Treatment of venous entrapment syndrome

→ **Repeat imaging** (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- ◆ New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- ◆ One-time clarifying follow-up of a prior indeterminate finding; **OR**
- ◆ In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance angiography (MRA), upper extremity** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the

ordering provider and obstetric care provider.

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Medical Evidence

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Clinical Guideline Revision History/Information

Original Date: 09/19/2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Bone Marrow

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

Important Notices

Notices & Disclaimers:

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Bone Marrow

Date of last literature review: 10/2/2024

Document last updated: 10/2/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Bone Marrow

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)

Recommended Clinical Approach

Magnetic resonance imaging (MRI) of the bone marrow is recommended in patients with known or suspected multiple myeloma, plasmacytoma, and Gaucher Disease.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of MRI of the bone marrow. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).

- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.²
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.²
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.³
- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁴

The clinical benefits of using these criteria include:

- Expeditious and Encompassing: MRI of the bone marrow is the most sensitive method – referred to as “the gold standard” – in the detection of malignant bone marrow involvement.⁵
- Noninvasive: As an imaging modality, MRI is relatively noninvasive. It is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers.⁶
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), bone marrow** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Multiple myeloma, including **ANY** of the following⁷⁻⁸:
 - Monoclonal gammopathy of uncertain significance (MGUS) (low dose CT, whole body is preferred); **OR**
 - Solitary bone plasmacytoma⁹; **OR**
 - Systemic multiple myeloma, suspected or confirmed¹⁰; **OR**
 - Smoldering multiple myeloma, suspected or confirmed¹⁰; **OR**
- ◆ Diagnosis and assessment of treatment response of marrow involvement in storage diseases (e.g., Gaucher Disease); **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Magnetic resonance imaging (MRI), bone marrow** may not be considered appropriate if **ANY** of the following is **TRUE**:
- If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
 - The patient has metallic clips on vascular aneurysms; **OR**
 - Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
77084	Magnetic resonance imaging (MRI) (e.g., proton); bone marrow blood supply

Medical Evidence

Karampinos et al. (2018) reviewed quantitative magnetic resonance imaging (MRI) and spectroscopy of bone marrow. Due to its exceptional soft-tissue contrast capability, MRI is the preferred imaging method for tracking certain bone marrow alterations. MRI of the bone marrow is routinely utilized to diagnose and visualize marrow lesions and monitor response to treatment (e.g., plasmacytoma, multiple myeloma). Innovative quantitative MRI techniques and magnetic resonance spectroscopy (MRS) can accurately measure changes in bone marrow composition, including water-fat distribution, cellularity, and perfusion across various pathologies.¹¹

Shah et al. (2014) conducted a retrospective cohort study on the evaluation of incidental abnormal bone marrow signals on MRI. Among 49,678 MRI scans conducted, 110 patients over 18 met the inclusion criteria. Of note, 22% underwent additional evaluation, primarily consisting of complete blood counts, serum protein electrophoresis, or bone scans. Over a median follow-up period of 41 months, 6% of patients received diagnoses of malignancies, including multiple myeloma, non-Hodgkin's lymphoma, metastatic non-small cell lung cancer, and metastatic adenocarcinoma. Furthermore, one patient who had not undergone evaluation was diagnosed with breast cancer 24 months post-MRI. Abnormal or heterogeneous bone marrow signals on MRI should not be dismissed, as they often warrant further investigation.¹²

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Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Bone Marrow

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Bone Marrow

Date of last literature review: 10/2/2024

Document last updated: 10/2/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Bone Marrow

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)

Recommended Clinical Approach

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Evaluation of Clinical Benefits and Potential Harms

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The potential clinical harms of using these criteria may include:

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- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.³
- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁴

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*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
77084	Magnetic resonance imaging (MRI) (e.g., proton); bone marrow blood supply

Medical Evidence

Karampinos et al. (2018) reviewed quantitative magnetic resonance imaging (MRI) and spectroscopy of bone marrow. Due to its exceptional soft-tissue contrast capability, MRI is the preferred imaging method for tracking certain bone marrow alterations. MRI of the bone marrow is routinely utilized to diagnose and visualize marrow lesions and monitor response to treatment (e.g., plasmacytoma, multiple myeloma). Innovative quantitative MRI techniques and magnetic resonance spectroscopy (MRS) can accurately measure changes in bone marrow composition, including water-fat distribution, cellularity, and perfusion across various pathologies.¹¹

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 12. Shah GL, Rosenberg AS, Jarboe J, et al. Incidence and evaluation of incidental abnormal bone marrow signal on magnetic resonance imaging. *Scientific World Journal*. 2014;2014:380814. doi: 10.1155/2014/380814. PMID: 25374938; PMCID: PMC4211153.

Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Brain

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 17, 2024

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Brain

Date of last literature review: 10/3/2024

Document last updated: 10/16/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Brain

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹⁻⁷

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹⁻⁷

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L37373\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57204\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L35175\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\)](#)
- [Local Coverage Determination \(LCD\). Multiple Imaging in Oncology. \(L35391\)](#)
- [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Recommended Clinical Approach

Imaging analysis utilizing magnetic resonance imaging (MRI) brain can be performed alone or with magnetic resonance angiography (MRA) head based on clinical suspicion of disease presence or exclusion to direct value-based care. Contrast may or may not be necessary depending upon the clinical indication at the referring physician's request and the discretion of the supervising radiologist.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI) of the brain. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- The use of contrast agents (e.g., gadolinium-based contrast agents) cause side effects in a few patients. These may include nausea, headache, and pain at the site of injection. Rarely, patients experience hives, itchy eyes, or other allergic reactions to the contrast material.⁸
- Dynamic magnetic fields during MRI scanning create loud knocking noises which may harm hearing or cause ringing of the ears (tinnitus) if adequate ear protection is not used. They may also cause peripheral muscle or nerve stimulation that may feel like a twitching sensation.⁸
- MRI scanning could lead to heating of the body and thermal injuries, particularly during long scans, due to radiofrequency energy used in the procedure.⁸
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- MRI, a non-invasive imaging technology that provides detailed three-dimensional anatomical images, is useful in the diagnosis, treatment, and monitoring of Alzheimer's disease, Parkinson's disease, stroke, multiple sclerosis, tumors, amyotrophic lateral sclerosis (ALS), Huntington's disease, and dementia.⁹⁻¹³
- MRI of the brain offers insights into the etiology, prognosis, and treatment of intracerebral hemorrhage (ICH). Using echo-planar gradient-echo or susceptibility-weighted sequences, MRI shows sensitivity and specificity in identifying ICH and in differentiating its primary and secondary causes. Moreover, MRI can assess hemorrhage

age, secondary lesions, and progression of perihematomal edema, thereby guiding tailored therapeutic strategies.¹⁴

- Different MRI imaging biomarkers measure different aspects of the tissues in the brain. For example, T₁ tissue properties help differentiate between white and gray matter while T₂ tissue properties highlight water content of the brain. This helps in the identification of lesions, edemas, and other abnormalities. T₂* properties can detect hemorrhagic strokes.¹⁵
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), brain** is considered appropriate if **ANY** of the following is **TRUE**¹⁶⁻¹⁷:

◆ Neoplastic conditions for **ANY** of the following (with limitations as defined in the non-indications section below):

- Initial staging; **OR**
- Treatment planning; **OR**
- Response assessment; **OR**
- Surveillance, and **ANY** of the following is **TRUE**^{6-7,20-22}:
 - The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - Suspected recurrence/progression; **OR**
 - Evaluation of response to treatment when a change

in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6–8 weeks since the prior imaging evaluation); **OR**

- ◆ The patient has **ANY** of the following infections or infectious disorders²³:
 - Suspected brain abscess or brain infection with **ANY** of the following:
 - Acute altered mental status; **OR**
 - Positive lab findings (e.g., elevated WBCs or abnormal CSF analysis); **OR**
 - Follow-up assessment during or after treatment completed; **OR**
 - Endocarditis with suspected septic emboli; **OR**
 - Neurosarcoidosis with **ANY** of the following:
 - ◆ For initial evaluation with **ANY** of the following:
 - Suspected based on neurological sign(s), symptom(s), and lab work (e.g., angiotensin-converting enzyme [ACE], cerebrospinal fluid (CSF) analysis); **OR**
 - Known history of sarcoidosis with neurological signs or symptoms; **OR**
 - ◆ Follow-up of known neurosarcoidosis for **ANY** of the following reasons:
 - To assess treatment response; **OR**
 - Worsening signs or symptoms; **OR**
- ◆ The patient has a trauma-related condition, as indicated by **ANY** of the following²⁴:
 - Assessment of unexplained post-traumatic neurological deficits; **OR**
 - Post-traumatic brain injury or persistent symptoms following initial imaging (e.g., dizziness, headache); **OR**
 - Post-concussive syndrome if persistent or disabling symptoms and MRI has not been performed; **OR**
 - Subacute or chronic traumatic brain injury with new cognitive and/or neurologic deficit; **OR**
- ◆ The patient has a vascular condition including **ANY** of the following:

- Acute ischemic stroke or transient ischemic attack (TIA)²⁵; **OR**
- Known or suspected stroke with any acute, new, or fluctuating symptoms or deficits (e.g., sensory deficits, limb weakness, speech difficulties, visual loss, lack of coordination, or mental status changes); **OR**
- Suspected stroke with a personal or first-degree family history (e.g., brother, sister, parent, or child) of an aneurysm or known coagulopathy or on anticoagulation; **OR**
- Symptoms of TIA that are episodic with neurologic symptoms (e.g., sensory deficits, limb weakness, speech difficulties, visual loss, lack of coordination, or mental status changes); **OR**
- Evaluation of suspected acute subarachnoid hemorrhage (SAH); **OR**
- Follow-up for known hemorrhage, hematoma, or vascular abnormalities; **OR**
- Follow-up imaging of known cerebral cavernous malformations (CCM) should be done only to guide treatment decisions or to investigate new symptoms – includes first-degree relatives of patients with one family member with a CCM should have a screening MRI as well as genetic counseling; **OR**
- Suspected central venous thrombosis; **OR**
- Screening for silent cerebral infarcts in early school-age children and adults with HbSS sickle cell disease or HbS β 0 thalassemia; **OR**
- Suspected temporal arteritis in a patient greater than 50 years old with **ANY** of the following:
 - Temporal headache; **OR**
 - Abrupt visual changes; **OR**
 - Jaw claudication; **OR**
 - Temporal artery tenderness; **OR**
 - Constitutional symptoms; **OR**
 - Elevated erythrocyte sedimentation rate (ESR); **OR**
- Evaluation of neurological signs or symptoms in a patient with sickle cell disease; **OR**

- High stroke risk in sickle cell patients (2 to 16 years of age) with a transcranial Doppler velocity greater than 200 cm/sec²⁶; **OR**
- **ANY** of the following chronic vascular diseases²⁷:
 - Headaches with a family history of aneurysm/AVM, including **ANY** of the following²⁸⁻³¹:
 - ◆ One first-degree relative with a history of aneurysm/AVM if symptomatic or there is clinical concern for aneurysm; **OR**
 - ◆ Two or more relatives with a history of aneurysm/AVM (repeat imaging in 5 years); **OR**
 - Arterial or venous/dural venous sinus abnormalities such as **ANY** of the following:
 - ◆ Acquired thrombosis/occlusion; **OR**
 - ◆ Venous sinus stenosis; **OR**
 - Central nervous system (CNS) involvement in patients with known or suspected vasculitis or autoimmune disease with abnormal inflammatory markers or autoimmune antibodies; **OR**
 - Immunocompromised patients (e.g., transplant recipients, HIV with CD4 less than 200, primary immunodeficiency syndromes, hematologic malignancies) with focal neurologic symptoms, headaches, behavioral, cognitive or personality changes; **OR**
 - Evaluation of neurological signs or symptoms in vaso-occlusive disease (e.g., sickle cell disease, moyamoya, etc.); **OR**
- ◆ The patient has **ANY** of the following autoimmune or inflammatory conditions³²⁻³³:
 - Atypical trigeminal neuralgia, defined by **ANY** of the following symptoms³⁴:
 - Bilateral hearing loss; **OR**
 - Dizziness/vertigo; **OR**
 - Visual changes; **OR**
 - Sensory loss or numbness; **OR**
 - Pain greater than 2 minutes; **OR**
 - Pain outside trigeminal nerve distribution and

- progression; **OR**
- Refractory trigeminal neuralgia when done for surgical planning; **OR**
 - Suspected multiple sclerosis (MS), and **ANY** of the following is **TRUE**:
 - For evaluation of patients with neurologic symptoms or deficits suspicious for MS with **ANY** of the following:
 - ◆ A clinically isolated syndrome (e.g., optic neuritis, transverse myelitis, or brain stem syndrome); **OR**
 - ◆ Recurrent episodes of variable neurological signs or symptoms not attributable to another cause; **OR**
 - To demonstrate dissemination in time for diagnosis (every 6–12 months); **OR**
 - For evaluation of known multiple sclerosis (MS) and **ANY** of the following is **TRUE**:
 - ◆ To establish a new baseline and **ANY** of the following is **TRUE**:
 - No recent imaging; **OR**
 - Postpartum; **OR**
 - 3–6 months after switching disease-modifying therapy; **OR**
 - ◆ Before starting or switching disease-modifying therapy; **OR**
 - ◆ 6-month repeat scan in patients with MRI disease activity that is not associated with new clinical symptoms on a routine follow-up scan (e.g., radiographically isolated syndrome); **OR**
 - ◆ Every 1–2 years while on disease-modifying therapy to assess for subclinical disease activity, less frequently when stable for 2–3 years; **OR**
 - ◆ New signs or symptoms suggested an exacerbation or unexpected clinical worsening; **OR**
 - ◆ Progressive multifocal leukoencephalopathy (PML) surveillance for patients on natalizumab

(Tysabri) and **ANY** of the following is **TRUE**:

- 12 months after the start of treatment in all patients; **OR**
- Brain MRI every 3–4 months for up to 12 months, in high-risk patients who switch from natalizumab to other therapeutics; **OR**
- Further surveillance MRI scanning timing is based on risk, and **ANY** of the following is **TRUE**:
 - Annually, if the anti-JCV antibody is negative; **OR**
 - Every 3–4 months, if high-risk of PML occurrence and **ANY** of the following is **TRUE**:
 - ◆ Seropositive for JC virus and have been treated with natalizumab for greater than or equal to 18 months; **OR**
 - ◆ High anti-JC virus antibody index values (greater than 0.9); **OR**
 - ◆ Previously treated with immunosuppressive therapies; **OR**
- ◆ In the pediatric population, a similar scan frequency for disease and therapeutic monitoring should be used – the frequency should be increased (e.g., every 6 months) if the child has a highly active disease or when imaging will change management; **OR**
- ◆ Evaluation of **ANY** of the following miscellaneous pathologies:
 - Acute, new, or fluctuating neurologic symptoms or deficits, including **ANY** of the following:
 - Sensory deficits; **OR**
 - Limb weakness; **OR**
 - Abnormal reflexes (pathological, asymmetric, hyperreflexia); **OR**

- Speech difficulties; **OR**
 - Visual loss; **OR**
 - Lack of coordination; **OR**
 - Mental status changes; **OR**
- Brain structural abnormality identified or suspected on prior imaging; **OR**
- Chronic disequilibrium with signs of cerebellar ataxia³⁵; **OR**
- Pathology involving the cranial nerve³⁶; **OR**
- Dizziness (including vertigo) with **ANY** of the following:
 - Signs or symptoms suggestive of a CNS lesion (ataxia, visual loss, double vision, weakness, or a change in sensation); **OR**
 - Progressive unilateral hearing loss; **OR**
 - Risk factors for cerebrovascular disease with concern for stroke; **OR**
 - Acute persistent vertigo with normal neurologic examination and HINTS examination is consistent with peripheral vertigo³⁵; **OR**
 - Acute persistent vertigo with abnormal neurologic examination or HINTS examination is consistent with central vertigo³⁵; **OR**
 - Chronic recurrent vertigo that is associated with unilateral hearing loss or tinnitus³⁵; **OR**
 - Chronic recurrent vertigo that is associated with other brainstem neurologic deficits³⁵; **OR**
 - Episodic vertigo with or without associated hearing loss or aural fullness³⁷; **OR**
 - Persistent vertigo with or without neurological symptoms (central vertigo)³⁷; **OR**
- Epilepsy, known or suspected, and **ANY** of the following is **TRUE**:
 - New onset of seizures or newly identified change in seizure activity/pattern; **OR**
 - Known seizure disorder without prior imaging; **OR**
 - Medically refractory epilepsy; **OR**
- Neurodegenerative disorders (congenital or acquired), including dementia³⁸⁻³⁹; **OR**
- Movement disorders including **ANY** of the following^{38,40-42}; **OR**

- Acute onset of a movement disorder with concern for stroke or hemorrhage (brain MRI recommended over brain CT); **OR**
- For evaluation of Parkinson's disease with atypical features or other movement disorders (e.g., suspected Huntington's disease, chorea, parkinsonian syndromes, hemiballismus, atypical dystonia) to exclude an underlying structural lesion; **OR**
- Headaches as indicated by **ANY** of the following¹⁸:
 - In a pediatric patient with severe headaches who is less than 6 years old; **OR**
 - In a pediatric patient who is greater than or equal to 6 years old with severe headaches and a known underlying condition (e.g., sickle cell, cancer, immune deficiency); **OR**
 - Immediate imaging is required and the patient is considered high-risk with **ANY** of the following symptoms¹⁸:
 - ◆ Intracranial hypertension (e.g., papilledema, pulsatile tinnitus, visual symptoms worse on Valsalva); **OR**
 - ◆ Intracranial hypotension (e.g., positional, worse when upright, better when lying down); **OR**
 - ◆ **ANY** of the following "red flags":
 - Age of onset is 50 years or older; **OR**
 - Fever or neurologic deficit; **OR**
 - History of cancer or immunocompromise; **OR**
 - Increasing frequency or severity; **OR**
 - Posttraumatic onset with no prior imaging; **OR**
 - ◆ Headache with new onset or pattern during pregnancy or peripartum period; **OR**
 - ◆ Primary trigeminal autonomic cephalalgias (e.g., cluster headache); **OR**
 - Persistent headaches that have failed physician-directed conservative treatment; **OR**

- Hearing loss (e.g., acquired sensorineural, mixed conductive, sensorineural)³⁷; **OR**
- Acoustic neuroma including **ANY** of the following⁴³:
 - Initial evaluation for suspected acoustic neuroma; **OR**
 - Monitoring of a known, symptomatic acoustic neuroma when surgery is not performed; **OR**
 - Post-surgical management; **OR**
- Metabolic, nutritional, and dysmyelinating disorders⁴⁴; **OR**
- **ANY** of the following types of tinnitus⁴⁵:
 - Pulsatile tinnitus, unilateral or bilateral without retro tympanic lesion on otoscopy; **OR**
 - Nonpulsatile tinnitus, unilateral without hearing loss, neurologic deficit, or trauma; **OR**
- **ANY** of the following visual conditions⁴⁶:
 - Nontraumatic orbital asymmetry, exophthalmos, or enophthalmos; **OR**
 - Ophthalmoplegia or diplopia; **OR**
 - Suspected orbital cellulitis, uveitis, or scleritis; **OR**
 - Suspected optic neuritis; **OR**
 - Traumatic visual defect; **OR**
 - Vision loss with intraocular mass, optic nerve, or visual field defects; **OR**
 - Vision loss, nonischemic, with visual field defects; **OR**
- ◆ The patient requires **ANY** of the following preoperative, postoperative, or pre-treatment evaluations:
 - Follow-up of treatment, including iatrogenic sequelae such as radiation necrosis⁴⁷; **OR**
 - The patient has acquired conductive hearing loss (secondary to cholesteatoma or neoplasm) with suspected intracranial or inner ear extension, for **ANY** of the following purposes³⁷:
 - Surgical planning; **OR**
 - Monitoring when surgery is not performed; **OR**
 - Post-surgical management; **OR**
 - The patient has congenital hearing loss, total deafness, or is a cochlear implant candidate for **ANY** of the following³⁷:
 - Surgical planning; **OR**
 - Post-surgical management; **OR**

- ◆ The patient has a known or suspected congenital abnormality with any acute, new, or fluctuating neurologic, motor, or mental status changes, including **ANY** of the following:
 - Craniosynostosis and other head deformities; **OR**
 - Hydrocephalus (congenital or acquired)^{18,48-49}; **OR**
 - Idiopathic intracranial hypertension; **OR**
 - Intracranial hypotension; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Magnetic resonance imaging (MRI), brain** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Esophagus, oropharynx, and prostate, and non-melanoma skin cancer in the absence of symptoms of brain involvement⁴; **OR**
 - ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
 - ◆ The patient has metallic clips on vascular aneurysms; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; **OR**
 - ◆ Imaging of cortical bone and calcification; **OR**
 - ◆ Procedures involving spatial resolution of bone or calcification; **OR**
 - ◆ In the pediatric population, imaging is not indicated in simple febrile seizures or in idiopathic focal or generalized epilepsy with typical features of benign epilepsy with centro-temporal spikes (BECTS), childhood absence epilepsy (CAE), juvenile absence epilepsy (JAE), and juvenile myoclonic epilepsy (JME).

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70551	Magnetic resonance imaging (MRI) (e.g., proton), brain (including brain stem); without contrast material
70552	Magnetic resonance imaging (MRI) (e.g., proton), brain (including brain stem); with contrast material(s)
70553	Magnetic resonance imaging (MRI) (e.g., proton), brain (including brain stem); without contrast material, followed by contrast material(s) and further sequences

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Wangaryattawanich et al. (2023) review the imaging spectrum, clinical significance, and management of brain MRI. Rapid advancements have been made in imaging technology and accessibility. Consequently, radiologists discover incidental findings during brain MRI scans for unrelated reasons. These unexpected findings can range from clinically insignificant to requiring further investigation or treatment, leading to patient anxiety. Incidental findings encompass a diverse range, including asymptomatic brain infarcts, age-related white matter changes, microhemorrhages, intracranial tumors, intracranial cystic lesions, and anatomic variants.⁵⁰

Maas et al. (2022) analyze facets of managing traumatic brain injury (TBI), including imaging. An initial normal CT scan does not rule out the presence of structural traumatic abnormalities. Structural traumatic abnormalities seen on MRI (2–3 weeks post-injury) were observed in approximately 30% of patients with mild TBI who initially had a normal CT scan. Advanced MRI techniques, such as diffusion tensor imaging and volumetric analyses, can reveal further injuries that may not be discernible through visual examination of conventional clinical MR images. Emerging blood biomarkers, such as glial fibrillary acidic protein (GFAP), aid in refining decisions regarding the necessity of CT scans for patients with mild TBI or the requirement of an MRI if the initial CT scan is normal. Integrating biomarkers, quantitative CT, and MRI findings facilitates the identification of patients at-risk of persistent symptoms, enabling more tailored and frequent follow-up care.⁵¹

Tekes et al. (2018) review the use of brain MRI in pediatric patients beyond shunted hydrocephalus. In the study period, 800 patients had undergone a previous ultrafast brain MRI scan. Patients diagnosed with ventriculomegaly, macrocephaly, or intracranial cysts were included (n=101). The findings support the use of ultrafast brain MRI to assess these conditions. Given its radiation-free and sedation-free nature, ultrafast brain MRI may be appropriate as a primary screening neuroimaging modality for these indications.⁵²

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Clinical Guideline Revision History/Information

Original Date: October 17, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Brain Functional

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 17, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Brain Functional

Date of last literature review: 10/15/2024

Document last updated: 10/16/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Brain Functional

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no related National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Recommended Clinical Approach

Functional magnetic resonance imaging (fMRI) localizes areas for critical functions such as thought, speech, movement, and sensation, typically in relation to a focal brain lesion, such as a neoplasm or vascular malformation. fMRI is a non-invasive alternative to other invasive methods to identify eloquent brain areas, including the intracarotid amobarbital procedure (IAP), known as a Wada test, and electrocortical stimulation mapping (ESM). During fMRI, the patient is asked to conduct specific language, memory, or motor activities while sequential MRI images are collected. The activities cause an increase in blood flow to the areas of the brain being used, allowing for their identification and location.¹

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of functional magnetic resonance imaging (fMRI) of the brain. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.²⁻⁴
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.²⁻⁴
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for magnetic resonance imaging (MRI) in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁵
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁶

The clinical benefits of using these criteria include:

- Resting-state blood oxygen level-dependent fMRI provides a task-free method of measuring cerebrovascular reserve (the potential capacity of brain tissue to receive more blood flow when needed), which is an effective marker in evaluating ischemic risk.⁷
- A meta-analysis shows the benefit of preoperative fMRI planning for the resection of brain tumors in reducing post-surgical morbidity, particularly when used with other advanced imaging techniques like diffusion-tensor imaging (DTI), intraoperative MRI, or cortical stimulation.⁸
- In patients with medial temporal lobe, temporal, or extratemporal epilepsy, fMRI can determine lateralization of language functions instead of the intracarotid amobarbital procedure (IAP). The use of fMRI may be considered for lateralizing memory functions in place of IAP in patients with medial temporal lobe epilepsy (Level C) but is of unclear utility in other types of epilepsy types.⁹
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Functional magnetic resonance imaging (fMRI) of the brain** is considered appropriate if **ALL** of the following are **TRUE**:

- ◆ Ultrasound and computed tomography (CT)/ computed tomography angiography (CTA) are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to intravenous [IV] contrast reaction, pregnancy, pediatric); **AND**
- ◆ **ANY** of the following:
 - Evaluation of cerebral vascular reactivity when considering revascularization procedures¹; **OR**
 - Evaluation of eloquent cortex and language lateralization for epilepsy surgery¹; **OR**
 - Evaluation of preserved eloquent cortex^{1,9}; **OR**
 - Failure or poor response to 2 or more anticonvulsant medications (maximal dose) – includes refractory or drug-resistant epilepsy³; **OR**
 - Radiation treatment planning of eloquent cortex^{1,9}; **OR**
 - Radiation post-treatment evaluation of eloquent cortex^{1,9}; **OR**
 - Targeted lesions (including intracranial neoplasms, and vascular formations) for **ANY** of the following¹:
 - Presurgical planning and operative risk assessment;**OR**

- Assessment of eloquent cortex (e.g, language, sensory, motor, visual centers) in relation to a tumor or another focal lesion; **OR**
- Surgical planning (biopsy or resection); **OR**
- Therapeutic follow-up; **OR**
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Functional magnetic resonance imaging (fMRI) of the brain** may not be considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
70554	Magnetic resonance imaging, brain, functional MRI; including test selection and administration of repetitive body part movement and/or visual stimulation, not requiring physician or psychologist administration
70555	Magnetic resonance imaging, brain, functional MRI; requiring physician or psychologist administration of entire neurofunctional testing

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Kaptan et al. (2024) discuss current developments in functional MRI (fMRI) and the impact on facilitating the creation of clinically significant biomarkers for disorders impacting sensorimotor processing in the central nervous system (CNS). Research has focused on corticospinal fMRI to evaluate sensorimotor projections at various hierarchical levels of the neuraxis. This includes the cervical spinal cord, brainstem, cerebellum, subcortical structures, and cortical regions. Unlike imaging the brain or spinal cord separately, corticospinal fMRI can identify neural activity in important CNS areas related to upper limb sensorimotor processing. The authors note that the technique requires further research as it applies to neural activity from lower limb stimulations or tasks.¹¹

Luna et al. (2021) performed a meta-analysis to evaluate the comparative postoperative morbidity in patients with brain tumors undergoing surgery with preoperative fMRI guidance versus those undergoing surgery without fMRI guidance or with the use of standard (non-functional) neuronavigation. A total of 68 observational studies and existing data demonstrate a decrease in postoperative morbidity when utilizing preoperative fMRI for planning brain resections. This benefit is particularly notable when combined with other advanced imaging modalities like diffusion-tensor imaging, intraoperative MRI, or cortical stimulation.⁸

Liu et al. (2021) conducted a study to refine and assess resting-state (RS) cerebrovascular reactivity (CVR) MRI methodology and its correlation to neurosurgical intervention outcomes. Data from 170 health controls identify the optimal frequency range of temporal filtering based on spatial correlation with the reference standard CVR map obtained with CO₂ inhalation. The refined RS approach was implemented in a new cohort with 50 individuals diagnosed with Moyamoya disease. Comparative analysis of CVR values between cerebral hemispheres with and without revascularization surgery was conducted using the Mann-Whitney U test. The authors conclude that utilizing RS blood oxygen level-dependent (BOLD) fMRI, CVR mapping offered a non-task-based approach for quantifying cerebrovascular reserve. This method effectively illustrated the therapeutic impact of revascularization surgery in Moyamoya disease patients, demonstrating comparable results to the established CO₂ inhalation MRI reference standard.⁷

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Clinical Guideline Revision History/Information

Original Date: October 17, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Brain Functional

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 17, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Brain Functional

Date of last literature review: 10/15/2024

Document last updated: 10/16/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Brain Functional

Benefit Category

Not applicable.

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- Using gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.²⁻⁴
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is an uncertain risk for magnetic resonance imaging (MRI) in pregnant patients. The decision to image a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁵
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁶

The clinical benefits of using these criteria include:

- Resting-state blood oxygen level-dependent fMRI provides a task-free method of measuring cerebrovascular reserve (the potential capacity of brain tissue to receive more blood flow when needed), which is an effective marker in evaluating ischemic risk.⁷
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Indications

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- ◆ **ANY** of the following:
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*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

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Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Codes	Code Description/Definition
70554	Magnetic resonance imaging, brain, functional MRI; including test selection and administration of repetitive body part movement and/or visual stimulation, not requiring physician or psychologist administration
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Clinical Guideline Revision History/Information

Original Date: October 17, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Brain

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 17, 2024

Important Notices

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Brain

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹⁻⁷

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹⁻⁷

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L37373\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57204\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L35175\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\)](#)
- [Local Coverage Determination \(LCD\). Multiple Imaging in Oncology. \(L35391\)](#)
- [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Recommended Clinical Approach

Imaging analysis utilizing magnetic resonance imaging (MRI) brain can be performed alone or with magnetic resonance angiography (MRA) head based on clinical suspicion of disease presence or exclusion to direct value-based care. Contrast may or may not be necessary depending upon the clinical indication at the referring physician's request and the discretion of the supervising radiologist.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI) of the brain. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- The use of contrast agents (e.g., gadolinium-based contrast agents) cause side effects in a few patients. These may include nausea, headache, and pain at the site of injection. Rarely, patients experience hives, itchy eyes, or other allergic reactions to the contrast material.⁸
- Dynamic magnetic fields during MRI scanning create loud knocking noises which may harm hearing or cause ringing of the ears (tinnitus) if adequate ear protection is not used. They may also cause peripheral muscle or nerve stimulation that may feel like a twitching sensation.⁸
- MRI scanning could lead to heating of the body and thermal injuries, particularly during long scans, due to radiofrequency energy used in the procedure.⁸
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- MRI, a non-invasive imaging technology that provides detailed three-dimensional anatomical images, is useful in the diagnosis, treatment, and monitoring of Alzheimer's disease, Parkinson's disease, stroke, multiple sclerosis, tumors, amyotrophic lateral sclerosis (ALS), Huntington's disease, and dementia.⁹⁻¹³
- MRI of the brain offers insights into the etiology, prognosis, and treatment of intracerebral hemorrhage (ICH). Using echo-planar gradient-echo or susceptibility-weighted sequences, MRI shows sensitivity and specificity in identifying ICH and in differentiating its primary and secondary causes. Moreover, MRI can assess hemorrhage

age, secondary lesions, and progression of perihematomal edema, thereby guiding tailored therapeutic strategies.¹⁴

- Different MRI imaging biomarkers measure different aspects of the tissues in the brain. For example, T₁ tissue properties help differentiate between white and gray matter while T₂ tissue properties highlight water content of the brain. This helps in the identification of lesions, edemas, and other abnormalities. T₂* properties can detect hemorrhagic strokes.¹⁵
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), brain** is considered appropriate if **ANY** of the following is **TRUE**¹⁶⁻¹⁷:

◆ Neoplastic conditions for **ANY** of the following (with limitations as defined in the non-indications section below):

- Initial staging; **OR**
- Treatment planning; **OR**
- Response assessment; **OR**
- Surveillance, and **ANY** of the following is **TRUE**^{6-7,20-22}:
 - The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - Suspected recurrence/progression; **OR**
 - Evaluation of response to treatment when a change

in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6–8 weeks since the prior imaging evaluation); **OR**

- ◆ The patient has **ANY** of the following infections or infectious disorders²³:
 - Suspected brain abscess or brain infection with **ANY** of the following:
 - Acute altered mental status; **OR**
 - Positive lab findings (e.g., elevated WBCs or abnormal CSF analysis); **OR**
 - Follow-up assessment during or after treatment completed; **OR**
 - Endocarditis with suspected septic emboli; **OR**
 - Neurosarcoidosis with **ANY** of the following:
 - ◆ For initial evaluation with **ANY** of the following:
 - Suspected based on neurological sign(s), symptom(s), and lab work (e.g., angiotensin-converting enzyme [ACE], cerebrospinal fluid (CSF) analysis); **OR**
 - Known history of sarcoidosis with neurological signs or symptoms; **OR**
 - ◆ Follow-up of known neurosarcoidosis for **ANY** of the following reasons:
 - To assess treatment response; **OR**
 - Worsening signs or symptoms; **OR**
- ◆ The patient has a trauma-related condition, as indicated by **ANY** of the following²⁴:
 - Assessment of unexplained post-traumatic neurological deficits; **OR**
 - Post-traumatic brain injury or persistent symptoms following initial imaging (e.g., dizziness, headache); **OR**
 - Post-concussive syndrome if persistent or disabling symptoms and MRI has not been performed; **OR**
 - Subacute or chronic traumatic brain injury with new cognitive and/or neurologic deficit; **OR**
- ◆ The patient has a vascular condition including **ANY** of the following:

- Acute ischemic stroke or transient ischemic attack (TIA)²⁵; **OR**
- Known or suspected stroke with any acute, new, or fluctuating symptoms or deficits (e.g., sensory deficits, limb weakness, speech difficulties, visual loss, lack of coordination, or mental status changes); **OR**
- Suspected stroke with a personal or first-degree family history (e.g., brother, sister, parent, or child) of an aneurysm or known coagulopathy or on anticoagulation; **OR**
- Symptoms of TIA that are episodic with neurologic symptoms (e.g., sensory deficits, limb weakness, speech difficulties, visual loss, lack of coordination, or mental status changes); **OR**
- Evaluation of suspected acute subarachnoid hemorrhage (SAH); **OR**
- Follow-up for known hemorrhage, hematoma, or vascular abnormalities; **OR**
- Follow-up imaging of known cerebral cavernous malformations (CCM) should be done only to guide treatment decisions or to investigate new symptoms – includes first-degree relatives of patients with one family member with a CCM should have a screening MRI as well as genetic counseling; **OR**
- Suspected central venous thrombosis; **OR**
- Screening for silent cerebral infarcts in early school-age children and adults with HbSS sickle cell disease or HbS β 0 thalassemia; **OR**
- Suspected temporal arteritis in a patient greater than 50 years old with **ANY** of the following:
 - Temporal headache; **OR**
 - Abrupt visual changes; **OR**
 - Jaw claudication; **OR**
 - Temporal artery tenderness; **OR**
 - Constitutional symptoms; **OR**
 - Elevated erythrocyte sedimentation rate (ESR); **OR**
- Evaluation of neurological signs or symptoms in a patient with sickle cell disease; **OR**

- High stroke risk in sickle cell patients (2 to 16 years of age) with a transcranial Doppler velocity greater than 200 cm/sec²⁶; **OR**
- **ANY** of the following chronic vascular diseases²⁷:
 - Headaches with a family history of aneurysm/AVM, including **ANY** of the following²⁸⁻³¹:
 - ◆ One first-degree relative with a history of aneurysm/AVM if symptomatic or there is clinical concern for aneurysm; **OR**
 - ◆ Two or more relatives with a history of aneurysm/AVM (repeat imaging in 5 years); **OR**
 - Arterial or venous/dural venous sinus abnormalities such as **ANY** of the following:
 - ◆ Acquired thrombosis/occlusion; **OR**
 - ◆ Venous sinus stenosis; **OR**
 - Central nervous system (CNS) involvement in patients with known or suspected vasculitis or autoimmune disease with abnormal inflammatory markers or autoimmune antibodies; **OR**
 - Immunocompromised patients (e.g., transplant recipients, HIV with CD4 less than 200, primary immunodeficiency syndromes, hematologic malignancies) with focal neurologic symptoms, headaches, behavioral, cognitive or personality changes; **OR**
 - Evaluation of neurological signs or symptoms in vaso-occlusive disease (e.g., sickle cell disease, moyamoya, etc.); **OR**
- ◆ The patient has **ANY** of the following autoimmune or inflammatory conditions³²⁻³³:
 - Atypical trigeminal neuralgia, defined by **ANY** of the following symptoms³⁴:
 - Bilateral hearing loss; **OR**
 - Dizziness/vertigo; **OR**
 - Visual changes; **OR**
 - Sensory loss or numbness; **OR**
 - Pain greater than 2 minutes; **OR**
 - Pain outside trigeminal nerve distribution and

- progression; **OR**
- Refractory trigeminal neuralgia when done for surgical planning; **OR**
 - Suspected multiple sclerosis (MS), and **ANY** of the following is **TRUE**:
 - For evaluation of patients with neurologic symptoms or deficits suspicious for MS with **ANY** of the following:
 - ◆ A clinically isolated syndrome (e.g., optic neuritis, transverse myelitis, or brain stem syndrome); **OR**
 - ◆ Recurrent episodes of variable neurological signs or symptoms not attributable to another cause; **OR**
 - To demonstrate dissemination in time for diagnosis (every 6–12 months); **OR**
 - For evaluation of known multiple sclerosis (MS) and **ANY** of the following is **TRUE**:
 - ◆ To establish a new baseline and **ANY** of the following is **TRUE**:
 - No recent imaging; **OR**
 - Postpartum; **OR**
 - 3–6 months after switching disease-modifying therapy; **OR**
 - ◆ Before starting or switching disease-modifying therapy; **OR**
 - ◆ 6-month repeat scan in patients with MRI disease activity that is not associated with new clinical symptoms on a routine follow-up scan (e.g., radiographically isolated syndrome); **OR**
 - ◆ Every 1–2 years while on disease-modifying therapy to assess for subclinical disease activity, less frequently when stable for 2–3 years; **OR**
 - ◆ New signs or symptoms suggested an exacerbation or unexpected clinical worsening; **OR**
 - ◆ Progressive multifocal leukoencephalopathy (PML) surveillance for patients on natalizumab

(Tysabri) and **ANY** of the following is **TRUE**:

- 12 months after the start of treatment in all patients; **OR**
- Brain MRI every 3–4 months for up to 12 months, in high-risk patients who switch from natalizumab to other therapeutics; **OR**
- Further surveillance MRI scanning timing is based on risk, and **ANY** of the following is **TRUE**:
 - Annually, if the anti-JCV antibody is negative; **OR**
 - Every 3–4 months, if high-risk of PML occurrence and **ANY** of the following is **TRUE**:
 - ◆ Seropositive for JC virus and have been treated with natalizumab for greater than or equal to 18 months; **OR**
 - ◆ High anti-JC virus antibody index values (greater than 0.9); **OR**
 - ◆ Previously treated with immunosuppressive therapies; **OR**
- ◆ In the pediatric population, a similar scan frequency for disease and therapeutic monitoring should be used – the frequency should be increased (e.g., every 6 months) if the child has a highly active disease or when imaging will change management; **OR**
- ◆ Evaluation of **ANY** of the following miscellaneous pathologies:
 - Acute, new, or fluctuating neurologic symptoms or deficits, including **ANY** of the following:
 - Sensory deficits; **OR**
 - Limb weakness; **OR**
 - Abnormal reflexes (pathological, asymmetric, hyperreflexia); **OR**

- Speech difficulties; **OR**
 - Visual loss; **OR**
 - Lack of coordination; **OR**
 - Mental status changes; **OR**
- Brain structural abnormality identified or suspected on prior imaging; **OR**
- Chronic disequilibrium with signs of cerebellar ataxia³⁵; **OR**
- Pathology involving the cranial nerve³⁶; **OR**
- Dizziness (including vertigo) with **ANY** of the following:
 - Signs or symptoms suggestive of a CNS lesion (ataxia, visual loss, double vision, weakness, or a change in sensation); **OR**
 - Progressive unilateral hearing loss; **OR**
 - Risk factors for cerebrovascular disease with concern for stroke; **OR**
 - Acute persistent vertigo with normal neurologic examination and HINTS examination is consistent with peripheral vertigo³⁵; **OR**
 - Acute persistent vertigo with abnormal neurologic examination or HINTS examination is consistent with central vertigo³⁵; **OR**
 - Chronic recurrent vertigo that is associated with unilateral hearing loss or tinnitus³⁵; **OR**
 - Chronic recurrent vertigo that is associated with other brainstem neurologic deficits³⁵; **OR**
 - Episodic vertigo with or without associated hearing loss or aural fullness³⁷; **OR**
 - Persistent vertigo with or without neurological symptoms (central vertigo)³⁷; **OR**
- Epilepsy, known or suspected, and **ANY** of the following is **TRUE**:
 - New onset of seizures or newly identified change in seizure activity/pattern; **OR**
 - Known seizure disorder without prior imaging; **OR**
 - Medically refractory epilepsy; **OR**
- Neurodegenerative disorders (congenital or acquired), including dementia³⁸⁻³⁹; **OR**
- Movement disorders including **ANY** of the following^{38,40-42}; **OR**

- Acute onset of a movement disorder with concern for stroke or hemorrhage (brain MRI recommended over brain CT); **OR**
- For evaluation of Parkinson's disease with atypical features or other movement disorders (e.g., suspected Huntington's disease, chorea, parkinsonian syndromes, hemiballismus, atypical dystonia) to exclude an underlying structural lesion; **OR**
- Headaches as indicated by **ANY** of the following¹⁸:
 - In a pediatric patient with severe headaches who is less than 6 years old; **OR**
 - In a pediatric patient who is greater than or equal to 6 years old with severe headaches and a known underlying condition (e.g., sickle cell, cancer, immune deficiency); **OR**
 - Immediate imaging is required and the patient is considered high-risk with **ANY** of the following symptoms¹⁸:
 - ◆ Intracranial hypertension (e.g., papilledema, pulsatile tinnitus, visual symptoms worse on Valsalva); **OR**
 - ◆ Intracranial hypotension (e.g., positional, worse when upright, better when lying down); **OR**
 - ◆ **ANY** of the following "red flags":
 - Age of onset is 50 years or older; **OR**
 - Fever or neurologic deficit; **OR**
 - History of cancer or immunocompromise; **OR**
 - Increasing frequency or severity; **OR**
 - Posttraumatic onset with no prior imaging; **OR**
 - ◆ Headache with new onset or pattern during pregnancy or peripartum period; **OR**
 - ◆ Primary trigeminal autonomic cephalalgias (e.g., cluster headache); **OR**
 - Persistent headaches that have failed physician-directed conservative treatment; **OR**

- Hearing loss (e.g., acquired sensorineural, mixed conductive, sensorineural)³⁷; **OR**
- Acoustic neuroma including **ANY** of the following⁴³:
 - Initial evaluation for suspected acoustic neuroma; **OR**
 - Monitoring of a known, symptomatic acoustic neuroma when surgery is not performed; **OR**
 - Post-surgical management; **OR**
- Metabolic, nutritional, and dysmyelinating disorders⁴⁴; **OR**
- **ANY** of the following types of tinnitus⁴⁵:
 - Pulsatile tinnitus, unilateral or bilateral without retro tympanic lesion on otoscopy; **OR**
 - Nonpulsatile tinnitus, unilateral without hearing loss, neurologic deficit, or trauma; **OR**
- **ANY** of the following visual conditions⁴⁶:
 - Nontraumatic orbital asymmetry, exophthalmos, or enophthalmos; **OR**
 - Ophthalmoplegia or diplopia; **OR**
 - Suspected orbital cellulitis, uveitis, or scleritis; **OR**
 - Suspected optic neuritis; **OR**
 - Traumatic visual defect; **OR**
 - Vision loss with intraocular mass, optic nerve, or visual field defects; **OR**
 - Vision loss, nonischemic, with visual field defects; **OR**
- ◆ The patient requires **ANY** of the following preoperative, postoperative, or pre-treatment evaluations:
 - Follow-up of treatment, including iatrogenic sequelae such as radiation necrosis⁴⁷; **OR**
 - The patient has acquired conductive hearing loss (secondary to cholesteatoma or neoplasm) with suspected intracranial or inner ear extension, for **ANY** of the following purposes³⁷:
 - Surgical planning; **OR**
 - Monitoring when surgery is not performed; **OR**
 - Post-surgical management; **OR**
 - The patient has congenital hearing loss, total deafness, or is a cochlear implant candidate for **ANY** of the following³⁷:
 - Surgical planning; **OR**
 - Post-surgical management; **OR**

- ◆ The patient has a known or suspected congenital abnormality with any acute, new, or fluctuating neurologic, motor, or mental status changes, including **ANY** of the following:
 - Craniosynostosis and other head deformities; **OR**
 - Hydrocephalus (congenital or acquired)^{18,48-49}; **OR**
 - Idiopathic intracranial hypertension; **OR**
 - Intracranial hypotension; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Magnetic resonance imaging (MRI), brain** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Esophagus, oropharynx, and prostate, and non-melanoma skin cancer in the absence of symptoms of brain involvement⁴; **OR**
 - ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
 - ◆ The patient has metallic clips on vascular aneurysms; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; **OR**
 - ◆ Imaging of cortical bone and calcification; **OR**
 - ◆ Procedures involving spatial resolution of bone or calcification; **OR**
 - ◆ In the pediatric population, imaging is not indicated in simple febrile seizures or in idiopathic focal or generalized epilepsy with typical features of benign epilepsy with centro-temporal spikes (BECTS), childhood absence epilepsy (CAE), juvenile absence epilepsy (JAE), and juvenile myoclonic epilepsy (JME).

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70551	Magnetic resonance imaging (MRI) (e.g., proton), brain (including brain stem); without contrast material
70552	Magnetic resonance imaging (MRI) (e.g., proton), brain (including brain stem); with contrast material(s)
70553	Magnetic resonance imaging (MRI) (e.g., proton), brain (including brain stem); without contrast material, followed by contrast material(s) and further sequences

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Wangaryattawanich et al. (2023) review the imaging spectrum, clinical significance, and management of brain MRI. Rapid advancements have been made in imaging technology and accessibility. Consequently, radiologists discover incidental findings during brain MRI scans for unrelated reasons. These unexpected findings can range from clinically insignificant to requiring further investigation or treatment, leading to patient anxiety. Incidental findings encompass a diverse range, including asymptomatic brain infarcts, age-related white matter changes, microhemorrhages, intracranial tumors, intracranial cystic lesions, and anatomic variants.⁵⁰

Maas et al. (2022) analyze facets of managing traumatic brain injury (TBI), including imaging. An initial normal CT scan does not rule out the presence of structural traumatic abnormalities. Structural traumatic abnormalities seen on MRI (2–3 weeks post-injury) were observed in approximately 30% of patients with mild TBI who initially had a normal CT scan. Advanced MRI techniques, such as diffusion tensor imaging and volumetric analyses, can reveal further injuries that may not be discernible through visual examination of conventional clinical MR images. Emerging blood biomarkers, such as glial fibrillary acidic protein (GFAP), aid in refining decisions regarding the necessity of CT scans for patients with mild TBI or the requirement of an MRI if the initial CT scan is normal. Integrating biomarkers, quantitative CT, and MRI findings facilitates the identification of patients at-risk of persistent symptoms, enabling more tailored and frequent follow-up care.⁵¹

Tekes et al. (2018) review the use of brain MRI in pediatric patients beyond shunted hydrocephalus. In the study period, 800 patients had undergone a previous ultrafast brain MRI scan. Patients diagnosed with ventriculomegaly, macrocephaly, or intracranial cysts were included (n=101). The findings support the use of ultrafast brain MRI to assess these conditions. Given its radiation-free and sedation-free nature, ultrafast brain MRI may be appropriate as a primary screening neuroimaging modality for these indications.⁵²

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Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Breast

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Important Notices

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Magnetic Resonance Imaging (MRI), Breast

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Breast

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁴

- [Local Coverage Determination \(LCD\). Breast imaging: Breast echography \(sonography\)/breast MRI/ductography \(L33585\)](#)
 - [Billing and Coding: Breast imaging: Breast echography \(sonography\)/breast MRI/ductography \(A52849\)](#)
- [Local Coverage Determination \(LCD\). Breast imaging mammography/breast echography \(sonography\)/breast MRI/ductography \(L33950\)](#)
 - [Billing and Coding: Breast imaging mammography/breast echography \(sonography\)/breast MRI/ductography \(A56448\)](#)

Description

Findings from magnetic resonance imaging (MRI) of the breast should be correlated with the patient's clinical history, physical examination findings, and results from previous imaging (e.g., mammography, ultrasound). MRI may yield findings that are not evident clinically or on mammography or ultrasound; the additional abnormalities detected on MRI may result in a follow-up examination or recommendation for biopsy.⁵

Medical Necessity Criteria

Indications

Magnetic resonance imaging (MRI), breast is considered appropriate if **ANY** of the following is **TRUE**:

- **MRI, breast with or without IV contrast**, may be used as a supplement to mammogram or ultrasound for screening for **ANY** of the following^{6,7}:
 - Personal history of **ANY** of the following:
 - Chest radiation treatment between age 10 and 30 years; **OR**
 - Breast cancer diagnosed before age 50; **OR**
 - Breast cancer diagnosed after age 50 AND dense breasts (heterogeneously dense or extremely dense)⁸; **OR**
 - Atypical ductal hyperplasia, atypical lobular hyperplasia, or lobular carcinoma in situ AND dense breasts (heterogeneously dense or extremely dense)⁸; **OR**
 - BRCA1 gene, BRCA2 gene, or TP53 gene mutation (Li-Fraumeni syndrome) AND at least 25 years of age; **OR**
 - PTEN gene mutation (Cowden and Bannayan-Riley-Ruvalcaba syndromes), STK11/LKB1 gene mutation (Puetz-Jaeger syndrome), PALB2 gene mutation, CDH1 gene mutation, or NF1 gene mutation AND at least 30 years of age; **OR**
 - ATM gene mutation, CHEK2 gene mutation, NBN gene, BARD1 gene, RAD51C gene, or RAD51D gene mutation AND at least 40 years of age; **OR**
 - First-degree family relative (parent, sibling, child) with BRCA1 or BRCA2 mutation; **OR**
 - Lifetime breast cancer risk of greater than or equal to 20% using standard risk assessment models; **OR**
 - Family history of first-degree male relative (father, brother) with breast cancer; **OR**
 - To detect silicone implant rupture in asymptomatic patients, beginning 3 years after implant, then every 2 years^{6,9,10}; **OR**
 - To detect suspected breast implant-associated anaplastic large cell lymphoma; **OR**
- **MRI, breast with or without IV contrast**, for **ANY** of the following diagnostic indications^{1,3}:
 - When diagnosis is inconclusive following a standard work-up (BI-RADS

- 3 lesions seen on mammography are not indeterminate); **OR**
- Evaluation of the post-operative patient when scar tissue cannot be differentiated from tumors; **OR**
- Patients with positive axillary nodes but no known primary; **OR**
- Patients with known or suspected leak or rupture of a breast implant; **OR**
- Recently diagnosed breast cancer to evaluate tumor extent; **OR**
- Recently diagnosed breast cancer before and after neoadjuvant chemotherapy¹¹; **OR**
- Recently diagnosed Paget's disease of the breast; **OR**
- Recently diagnosed Phyllodes tumor of the breast; **OR**
- To detect suspected cancer recurrence in patients with a history of mastectomy¹²; **OR**
- To detect suspected cancer recurrence in patients with a history of breast conservation therapy or lumpectomy¹²; **OR**
- To guide biopsy of suspicious MRI findings¹³; **OR**
- To guide presurgical localization of MRI findings¹³; **OR**
- To further evaluate suspicious breast symptoms such as bloody or clear nipple discharge, nipple retraction, or palpable breast mass following a benign or inconclusive mammogram or ultrasound¹⁴; **OR**
- To follow-up a probably benign finding (BI-RADS 3) seen on prior MRI, every 6 months for up to 2 years total; **OR**
- To further evaluate positive or close surgical margins following breast surgery¹²; **OR**
- To evaluate the extent of disease of newly diagnosed high-risk benign findings, including lobular carcinoma in situ, atypical lobular hyperplasia, atypical ductal hyperplasia, papillary neoplasm, radial scar, or complex sclerosing lesion; **OR**
- One-time follow-up after a benign MRI-guided biopsy in 6 months; **OR**
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary with **ANY** of the following:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

* NOTE: Inappropriate uses of MRI of the breast: MRI should not supplant careful problem-solving mammographic views or ultrasound in the diagnostic setting. MRI should not be used in lieu of a biopsy of a suspicious finding identifiable by mammography, ultrasound, or clinical examination.⁵

**NOTE: Ultrasound is generally the primary imaging modality used in young patients, aiding in the initial diagnosis, assisting in imaging-guided biopsy when indicated, and offering a safe method of follow-up. In the pediatric patient, MRI of the breast is rarely used, though in select cases, it may be useful for surgical planning or assessing the extent of disease.¹⁵

Non-Indications

Magnetic resonance imaging (MRI), breast is not considered appropriate if **ANY** of the following is **TRUE**:

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms.¹⁶

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
77046	Magnetic resonance imaging, breast, without contrast material; unilateral
77047	Magnetic resonance imaging, breast, without contrast material; bilateral
77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization, and pharmacokinetic analysis), when performed; unilateral
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral
C8903	Magnetic resonance imaging with contrast, breast; unilateral
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
C8906	Magnetic resonance imaging with contrast, breast; bilateral
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for breast MRI may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.¹⁵
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.^{5,17}
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.¹⁸

The clinical benefits of using these criteria for breast MRI include:

- Improved patient outcomes through timely and appropriate access to the procedure. Cancer detection rates are improved in high-risk patients compared to use of mammography alone.¹⁹

- Reduction in complications and adverse effects from unnecessary procedures. Breast MRI is particularly effective in evaluating complications of breast augmentation.¹⁹
- Enhanced diagnostic accuracy for complex medical conditions. MRI is stated to be the most sensitive examination for detecting breast cancer, particularly in high-risk screening.²⁰
- Enhanced overall patient satisfaction and healthcare experience.

Medical Evidence

Lobig et al. (2023) conducted a systematic review to evaluate the evidence surrounding supplemental screening methods among asymptomatic women with dense breasts, stratified by their breast cancer risk. Research comparing functional imaging methods like MRI and contrast-enhanced mammography (CEM) to conventional ultrasound for supplemental breast cancer screening in women with dense breasts remains limited. The sole randomized controlled trial (RCT) on MRI indicated its superior screening efficacy compared to other modalities in dense breast populations with an average risk of breast cancer. However, evidence regarding the effectiveness of MRI in women with intermediate breast cancer risk is minimal. A single study examined CEM as an alternative to MRI due to its high cancer detection and low interval cancer rates. Regardless of the screening modality, all women with dense breasts may derive benefits from supplemental screening following mammography or digital breast tomosynthesis (DBT). Additional research on women with average breast cancer risk and dense breasts is needed.²¹

Yeh et al. (2020) conducted a comparative modeling study on the clinical benefits and harms of breast cancer screening for survivors of childhood cancer treated with chest radiation. The study, funded by the American Cancer Society and National Institutes of Health, utilized data from the Childhood Cancer Survivor Study and existing published literature. The target population was females at least 20 years of age with a history of chest radiotherapy. Implementing annual MRI screenings, with or without mammography (commencing at ages 25, 30, or 35 years), shows the potential to reduce breast cancer mortality by 50% or more among survivors of childhood cancer.²²

Kaneda and colleagues (2013) reviewed the literature regarding pediatric breast masses and stated that most are benign lesions, often secondary to normal developmental changes. Obtaining family history is important in treating these patients. MRI is less frequently used than ultrasound in pediatric patients; however, it may be found to be useful in surgical planning or assessing extent of disease. MRI screening is recommended in women who

have received radiation to the chest, as this patient group is at increased risk for development of breast cancer.¹⁵

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Policy Revision History/Information

Original Date: October 3, 2024		
Review History		
Version 1.1	03/18/2025	Updated policy per CMS revisions for 12/05/2024; updated effective date. Updated links and bookmarks.
Version 2	10/02/2025	Annual review. No changes to medical necessity criteria or procedure codes. Removed relative contraindications (contrast allergy, metallic clips, incompatible implantable devices, metallic foreign body) Reordered references to reflect order of first appearance.
Version 2.1	02/16/2026	Revision. Per CMS update, links and references for L33950 and A56448.



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Breast

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Magnetic Resonance Imaging (MRI), Breast

Date of last literature review: 10/2/2024

Document last updated: 10/3/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Breast

Benefit Category

Not Applicable

Recommended Clinical Approach

Findings from magnetic resonance imaging (MRI) of the breast should be correlated with the patient's clinical history, physical examination findings, and results from previous imaging (e.g., mammography, ultrasound). MRI may yield findings that are not evident clinically or on mammography or ultrasound; the additional abnormalities detected on MRI may result in a follow-up examination or recommendation for biopsy.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.²⁻⁵

- [Breast Imaging: Breast Echography \(Sonography\)/Breast MRI/Ductography \(L33585\)](#)
- [Billing and Coding: Breast Imaging: Breast Echography \(Sonography\)/Breast MRI/Ductography \(A52849\)](#)
- [Breast Imaging Mammography/Breast Echography \(Sonography\)/Breast MRI/Ductography \(L33950\)](#)
- [Billing and Coding: Breast Imaging Mammography/Breast Echography \(Sonography\)/Breast MRI/Ductography \(A56448\)](#)

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI), breast. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.¹⁻³
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.^{1,6}
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁷

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. Cancer detection rates are improved in high-risk patients compared to use of mammography alone.⁸
- Reduction in complications and adverse effects from unnecessary procedures. Breast MRI is particularly effective in evaluating complications of breast augmentation.⁹
- Enhanced diagnostic accuracy for complex medical conditions. MRI is stated to be the most sensitive examination for detecting breast cancer, particularly in high-risk screening.¹⁰
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), breast** is considered appropriate if **ANY** of the following is **TRUE**:

◆ **MRI, breast with or without IV contrast**, may be used as a supplement to mammogram or ultrasound for **screening** for **ANY** of the following¹¹⁻¹²:

- Personal history of chest radiation treatment between age 10 and 30 years; **OR**
- Personal history of breast cancer diagnosed before age 50; **OR**
- Personal history of breast cancer diagnosed after age 50 **AND** dense breasts (heterogeneously dense or extremely dense)¹³; **OR**
- Personal history of atypical ductal hyperplasia, atypical lobular hyperplasia, or lobular carcinoma in situ **AND** dense breasts (heterogeneously dense or extremely dense)¹³; **OR**
- Personal history of BRCA1 gene, BRCA2 gene, or TP53 gene mutation (Li-Fraumeni syndrome) **AND** at least 25 years of age; **OR**
- Personal history of PTEN gene mutation (Cowden and Bannayan-Riley-Ruvalcaba syndromes), STK11/LKB1 gene mutation (Puetz-Jaeger syndrome), PALB2 gene mutation, CDH1 gene mutation, or NF1 gene mutation **AND** at least 30 years of age; **OR**
- Personal history of ATM gene mutation, CHEK2 gene mutation, NBN gene, BARD1 gene, RAD51C gene, or RAD51D gene mutation **AND** at least 40 years of age; **OR**
- First-degree family relative (parent, sibling, child) with BRCA 1 or BRCA2 mutation; **OR**
- Lifetime breast cancer risk of greater than or equal to 20% using standard risk assessment models; **OR**
- To detect silicone implant rupture in asymptomatic patients, beginning 3 years after implant, then every 2

- years^{9,11,15}; **OR**
- To detect suspected breast implant-associated anaplastic large cell lymphoma; **OR**
- ◆ **MRI, breast with or without IV contrast**, may be used for **ANY** of the following **diagnostic** indications^{2,4}:
 - When diagnosis is inconclusive, even after standard work-up; **OR**
 - Evaluation of the post-operative patient when scar tissue cannot be differentiated from tumors; **OR**
 - Patients with positive axillary nodes but no known primary; **OR**
 - Patients with known or suspected leak or rupture of a breast implant; **OR**
 - Recently diagnosed breast cancer to evaluate tumor extent, including possible chest wall invasion; **OR**
 - Recently diagnosed breast cancer before and after neoadjuvant chemotherapy¹⁶; **OR**
 - Recently diagnosed Paget's disease of the breast; **OR**
 - Recently diagnosed Phyllodes tumor of the breast; **OR**
 - To detect suspected cancer recurrence in patients with a history of mastectomy¹⁷; **OR**
 - To detect suspected cancer recurrence in patients with a history of breast conservation therapy or lumpectomy¹⁷; **OR**
 - To guide biopsy of suspicious MRI findings¹⁸; **OR**
 - To guide presurgical localization of MRI findings¹⁸; **OR**
 - To further evaluate suspicious breast symptoms such as bloody or clear nipple discharge, nipple retraction, or palpable breast mass following a benign or inconclusive mammogram or ultrasound¹⁹; **OR**
 - To follow-up a probably benign finding (BI-RADS 3) seen on prior MRI, every 6 months for up to 2 years total; **OR**
 - To further evaluate positive or close surgical margins following breast surgery¹⁷; **OR**
 - To evaluate the extent of disease of newly diagnosed high-risk benign findings, including lobular carcinoma in situ, atypical lobular hyperplasia, atypical ductal hyperplasia, papillary neoplasm, radial scar, or complex sclerosing lesion; **OR**

- One-time follow-up after a benign MRI-guided biopsy in 6 months; **OR**
- Family history of first-degree male relative (father, brother) with breast cancer; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

* NOTE: Inappropriate uses of MRI of the breast: MRI should not supplant careful problem-solving mammographic views or ultrasound in the diagnostic setting. MRI should not be used in lieu of a biopsy of a suspicious finding identifiable by mammography, ultrasound, or clinical examination.¹

**NOTE: Ultrasound is generally the primary imaging modality used in young patients, aiding in the initial diagnosis, assisting in imaging-guided biopsy when indicated, and offering a safe method of follow-up. In the pediatric patient, MRI of the breast is rarely used, though in select cases, it may be useful for surgical planning or assessing the extent of disease.²⁰

Non-Indications

- **Magnetic resonance imaging (MRI), breast** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
 - ◆ The patient has metallic clips on vascular aneurysms; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
77046	Magnetic resonance imaging, breast, without contrast material; unilateral
77047	Magnetic resonance imaging, breast, without contrast material; bilateral
77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization, and pharmacokinetic analysis), when performed; unilateral
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral
C8903	Magnetic resonance imaging with contrast, breast; unilateral
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
C8906	Magnetic resonance imaging with contrast, breast; bilateral
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral

Medical Evidence

Lobig et al. (2023) conducted a systematic review to evaluate the evidence surrounding supplemental screening methods among asymptomatic women with dense breasts, stratified by their breast cancer risk. Research comparing functional imaging methods like MRI and contrast-enhanced mammography (CEM) to conventional ultrasound for supplemental breast cancer screening in women with dense breasts remains limited. The sole randomized controlled trial (RCT) on MRI indicated its superior screening efficacy compared to other modalities in dense breast populations with an average risk of breast cancer. However, evidence regarding the effectiveness of MRI in women with intermediate breast cancer risk is minimal. A single study examined CEM as an alternative to MRI due to its high cancer detection and low interval cancer rates. Regardless of the screening modality, all women with dense breasts may derive benefits from supplemental screening following mammography or digital breast tomosynthesis (DBT). Additional research on women with average breast cancer risk and dense breasts is needed.²¹

Yeh et al. (2020) conducted a comparative modeling study on the clinical benefits and harms of breast cancer screening for survivors of childhood cancer treated with chest radiation. The study, funded by the American Cancer Society and National Institutes of Health, utilized data from the Childhood Cancer Survivor Study and existing published literature. The target population was females at least 20 years of age with a history of chest radiotherapy. Implementing annual MRI screenings, with or without mammography (commencing at ages 25, 30, or 35 years), shows the potential to reduce breast cancer mortality by 50% or more among survivors of childhood cancer.²²

Kaneda and colleagues (2013) reviewed the literature regarding pediatric breast masses and stated that most are benign lesions, often secondary to normal developmental changes. Obtaining family history is important in treating these patients. MRI is less frequently used than ultrasound in pediatric patients; however, it may be found to be useful in surgical planning or assessing extent of disease. MRI screening is recommended in women who have received radiation to the chest, as this patient group is at increased risk for development of breast cancer.²⁰

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Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Cardiac

Clinical Policy for Medical Necessity Review

Version: 2

Cohere Health UMC Approval Date: October 2, 2025

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Next Annual Review: October 2, 2026

Important Notices

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Cardiac

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Cardiac

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁵

- [National Coverage Determination \(NCD\) 220.2. Magnetic Resonance Imaging \(MRI\)](#)
- [Local Coverage Determination \(LCD\). Cardiology non-emergent outpatient stress testing \(L35083\)](#)
 - [Billing and Coding: Cardiology non-emergent outpatient stress testing \(A56423\)](#)
- [Local Coverage Determination \(LCD\). Cardiology non-emergent outpatient stress testing \(L38396\)](#)
 - [Billing and Coding: Cardiology non-emergent outpatient stress testing \(A56952\)](#)

Description

Cardiac magnetic resonance imaging (MRI) offers exquisite anatomic detail of the heart and can also provide valuable functional information through various sequences. While not a first-line imaging modality, it proves highly useful when structural abnormalities (congenital or acquired) or functional deficiencies require further investigation of the heart and pericardial structures.

Medical Necessity Criteria

Indications

Cardiac magnetic resonance imaging (MRI) without stress testing is considered appropriate if **ALL** of the following are **TRUE**:

- First-line cardiac imaging modality, such as transthoracic echocardiogram (TTE), is inconclusive/non-diagnostic, and further imaging is indicated for diagnostic and therapeutic purposes⁶; **AND**
- **ANY** of the following⁶:
 - Documented or suspected neoplastic conditions of the heart (including cardiac masses or mass-like conditions such as cardiac or para-cardiac mass); **OR**
 - Infection or an infectious disorder, including infective endocarditis, myocarditis, or complications not diagnosable by other imaging modalities; **OR**
 - Known or suspected pericardial disease, including **ANY** of the following⁶:
 - Pericardial effusion; **OR**
 - Structural pericardial anomalies; **OR**
 - Pericardial thickening; **OR**
 - Tamponade; **OR**
 - Pericarditis; **OR**
 - Evaluation of cancer-related cardiotoxicity and radiation-induced heart disease⁶; **OR**
 - Post-cardiac transplant assessment of acute or chronic rejection⁶; **OR**
 - Cardiac trauma-related conditions, including iatrogenic injury⁷; **OR**
 - Cardiovascular conditions, known or suspected, including **ANY** of the following:
 - Suspected intracardiac thrombus, mass, aneurysm, or pseudoaneurysm when echocardiogram is indeterminate⁸; **OR**
 - Cardiomyopathies, including **ANY** of the following:
 - Hypertrophic cardiomyopathy⁹; **OR**
 - Suspected arrhythmogenic cardiomyopathy of ventricular origin;**OR**
 - Preoperative or pre-treatment evaluation, including **ANY** of the following:
 - Atrial septal defect/patent foramen ovale (ASD/PFO) closure if transesophageal echocardiogram (TEE) is indeterminate; **OR**

- Aortic root replacement; **OR**
- Pacemaker placement planning, including the evaluation of the coronary vein before biventricular pacing; **OR**
- Pulmonary vein ablation therapy for cardiac dysrhythmia; **OR**
- Surgical valve replacement; **OR**
- Surgical myectomy or septal ablation for hypertrophic cardiomyopathy; **OR**
- Transcatheter left atrial appendage occlusion; **OR**
- Planning for aortic endovascular valve replacement; **OR**
- Post-procedure follow-up or complication to evaluate complications of valve repair or replacement (open or endovascular) including **ANY** of the following:
 - Leaflet thrombosis; **OR**
 - Pannus formation; **OR**
 - Paravalvular leak; **OR**
 - Pseudoaneurysms; **OR**
 - Root abscess; **OR**
- Ventricular assist device placement; **OR**
- Pre-procedural planning for atrial fibrillation-related procedures¹⁰, including **ANY** of the following:
 - Left atrial ablation (pulmonary vein isolation); **OR**
 - Electrical cardioversion or pharmacologic cardioversion when an indicated TEE has a contraindication or is unable to be completed; **OR**
- Planned transcatheter treatment and the patient has valvular heart disease with **ANY** of the following:
 - Mitral replacement or repair; **OR**
 - Pulmonary replacement or repair; **OR**
 - Transcatheter aortic; **OR**
 - Tricuspid replacement or repair; **OR**
- Congenital anomalies and variants (e.g., cardiac, vascular), including **ANY** of the following as indicated in cited references^{6,11,12}:
 - **ANY** of the following:
 - Aortic and pulmonary anomalies; **OR**
 - Atrial and ventricular septal defects; **OR**
 - Coronary artery anomalies; **OR**
 - Left-sided cardiac obstructive disorders; **OR**
 - Right-sided cardiac obstructive disorders; **OR**

- Systemic and pulmonary venous anomalies; **OR**
- Other complex structural disorders of the cardiac chambers, morphology, and valves (e.g., heterotaxy); **OR**
- Follow-up of corrected or palliated congenital heart disease and assessment of postoperative complications (e.g., shunt or conduit stenosis, thrombosis, pseudoaneurysms) in children and adults; **OR**
- Postoperative evaluation of corrected or palliated congenital heart disease, including **ANY** of the following:
 - Pseudoaneurysms; **OR**
 - Stenosis (shunt/conduit); **OR**
 - Thrombosis; **OR**
- Repeat imaging (defined as a repeat request following recent imaging of the same anatomic region with the same or similar modality) will be considered reasonable and necessary if **ALL** of the following are **TRUE**:
 - There are no established guidelines; **AND**
 - **ANY** of the following:
 - There are new or worsening symptoms not addressed in the guidelines, such that repeat imaging would influence treatment; **OR**
 - There is need for a one-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Cardiac magnetic resonance imaging (MRI) with stress testing is considered appropriate with **ANY** of the following^{2,4}:

- Patients experiencing new, recurrent, or worsening cardiac symptoms, including otherwise unexplained anginal equivalent^A symptoms, and **ANY** of the following:
 - Physical inability to perform a maximum exercise workload; **OR**
 - New or previously unrecognized or uninterpretable electrocardiogram (ECG), as qualified by **ANY** of the following:
 - Complete left bundle branch block (and right bundle branch does not render ECG uninterpretable for ischemia); **OR**
 - Ventricular paced rhythm; **OR**
 - Pre-excitation patterns (such as Wolff-Parkinson-White); **OR**
 - Greater than 1 mm ST segment depression; **OR**

- Left ventricular hypertrophy (LVH) with repolarization abnormalities, also called LVH with strain; **OR**
- Patient on digoxin therapy; **OR**
- A history of coronary artery disease (CAD) based on a prior anatomic evaluation of the coronary arteries; **OR**
- A history of coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI); **OR**
- Syncope for patients with an intermediate or high coronary heart disease (CHD) risk (ATP III risk criteria) and where cardiac etiology is suspected based on an initial evaluation, including history, physical examination, or ECG and the patient is unable to exercise; **OR**
- Evidence or high suspicion of ventricular arrhythmias; **OR**
- Worsening or continuing symptoms after normal or submaximal exercise stress test with suspicion of a false negative result; **OR**
- Patients with recent equivocal or borderline testing where ischemia remains a concern; **OR**
- Patients on beta blocker, calcium channel blocker, and/or antiarrhythmic medication where an adequate workload may not be attainable for a fully diagnostic exercise study; **OR**
- History of false positive exercise stress test (e.g., one that is abnormal, but the abnormality does not appear to be due to macrovascular CAD); **OR**
- Evaluation of chest pain syndrome after revascularization, or in patients with intermediate to high pre-test probability for CAD regardless of ECG interpretability or ability to exercise; **OR**
- High pre-test probability for CAD regardless of ECG interpretability or the ability to exercise, and a decision to perform cardiac catheterization or other angiography has not already been made; **OR**
- Patients with hypertrophic cardiomyopathy (HCM); **OR**
- New-onset atrial fibrillation (with no prior cardiac evaluation); **OR**
- Patients with disease conditions associated with CAD with no stress imaging evaluation performed within the preceding 2 years and are unable to exercise; **OR**
- Patients without clear cardiac symptoms in the presence of an elevated cardiac troponin; **OR**
- Patients without cardiac symptoms who have not undergone an evaluation for CAD within the past 2 years (stress echocardiogram, SPECT MPI, PET MPI, CMR, coronary computed tomography angiography [CCTA],

cardiac catheterization), and are unable to exercise, who underwent **ANY** of the following procedures:

- PCI (with stent) more than 2 years prior to evaluation for CAD; **OR**
- CABG procedure more than 5 years prior to evaluation for CAD; **OR**
- Patients with established CAD who experienced an ACS event (ST-segment elevation myocardial infarction [STEMI], non-ST elevation myocardial infarction [NSTEMI], or unstable angina) within the past 90 days, provided they did not undergo coronary angiography at the time of the acute event and are currently clinically stable; **OR**
- Evaluating new, recurrent, or worsening left ventricular dysfunction/congestive heart failure; **OR**
- Assessing myocardial viability in patients with significant ischemic ventricular dysfunction (suspected hibernating myocardium) and persistent symptoms or heart failure such that revascularization would be considered; **OR**
- Preoperative cardiac evaluation in patients not able to exercise and who will be undergoing noncardiac surgery with **ANY** of the following:
 - Intermediate risk for surgery (cardiac risk 1–5%), poor (less than 4 metabolic equivalents [METs]) or unknown functional capacity, inability to exercise adequately, or ECG uninterpretable for ischemia; **OR**
 - High-risk for surgery (greater than 5% cardiac risk), poor (less than 4 METs) or unknown functional capacity, inability to exercise adequately, or ECG uninterpretable for ischemia; **OR**
- Asymptomatic patients with a coronary calcium Agatston score greater than 400; **OR**
- Planned cardiac or other solid-organ transplant when no cardiac evaluation has been performed within the past year; **OR**
- Patients who will be treated with interleukin-2 products for various malignant disorders; **OR**
- Patients with HCM, when echocardiography is inconclusive or there are poor echocardiographic imaging windows; **OR**
- Patients with HCM, when echocardiography is inconclusive, or there are poor echocardiographic imaging windows; **OR**
- Evaluation of transplant coronary artery disease (TCAD) or cardiac allograft vasculopathy (CAV) in patients with a history of organ transplantation; **OR**

- Patients with recently demonstrated coronary stenosis of uncertain functional significance in a major coronary branch on an anatomic imaging study (coronary angiogram or CCTA); **OR**
- Repeat imaging (defined as a repeat request following recent imaging of the same anatomic region with the same or similar modality) will be considered reasonable and necessary if **ALL** of the following are **TRUE**:
 - There are no established guidelines; **AND**
 - **ANY** of the following:
 - There are new or worsening symptoms not addressed in the guidelines, such that repeat imaging would influence treatment; **OR**
 - There is need for a one-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

Cardiac magnetic resonance imaging (MRI) without stress testing is not considered appropriate if **ANY** of the following is **TRUE**:

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms¹³; **OR**
- The request is for a low-field MRI, which is considered experimental and investigational imaging.^{14,15}

Cardiac magnetic resonance imaging (MRI) with stress testing is not considered appropriate if **ANY** of the following is **TRUE**:

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms¹³; **OR**
- Routine screening for CAD in asymptomatic patients with diabetes mellitus²⁴; **OR**
- Routine stress testing in asymptomatic patients with abnormal prior stress imaging²⁴; **OR**
- Routine stress testing in asymptomatic patients with obstructive or nonobstructive CAD without a revascularization procedure²⁴; **OR**

- Exercise testing or radiologic imaging within the first 2 years following PCI without specific symptoms (e.g., chest pain, ECG changes, etc.)^{2,4}; **OR**
- Exercise stress testing performed in patients with **ANY** of the following^{2,4}:
 - Acute myocardial infarction within 2 to 4 days; **OR**
 - High-risk unstable angina; **OR**
 - Uncontrolled cardiac arrhythmias causing symptoms or hemodynamic compromise; **OR**
 - Symptomatic severe aortic stenosis; **OR**
 - Decompensated or uncontrolled congestive heart failure; **OR**
 - The patient has a systolic blood pressure (BP) at rest greater than 200 mmHg or a diastolic BP at rest greater than 110 mmHg; **OR**
 - Acute pulmonary embolus or pulmonary infarction; **OR**
 - Acute myocarditis or pericarditis; **OR**
 - Acute aortic dissection; **OR**
 - Severe pulmonary hypertension; **OR**
 - Acute symptomatic medical illness; **OR**
- The request is for a low-field MRI, which is considered experimental and investigational imaging.^{14,15}

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider

Definitions

^A**Angina equivalent:** Any constellation of clinical findings that the physician believes is consistent with CAD manifestations. Examples of such findings include, but are not limited to: pain, pressure, tightness, or discomfort in the chest, shoulders, arms, neck, back, upper abdomen, or jaw, new ECG abnormalities, or other symptoms/findings suggestive of CAD. Clinical presentations in the absence of chest pain (e.g., dyspnea with exertion, fatigue, or reduced/worsening effort tolerance) consistent with a high risk of CAD may be considered an ischemic equivalent.¹⁶

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
75557	Cardiac magnetic resonance imaging (MRI) without contrast material, for evaluation of morphology and function
75559	Cardiac magnetic resonance imaging (MRI) with stress imaging, without contrast material, for evaluation of morphology and function
75561	Cardiac magnetic resonance imaging (MRI) without contrast material, followed by contrast material and further sequences, for evaluation of morphology and function
75563	Cardiac magnetic resonance imaging (MRI) with stress imaging, without contrast material, followed by contrast material and further sequences, for evaluation of morphology and function
75565	Cardiac magnetic resonance imaging (MRI) for velocity flow mapping (List separately in addition to code for primary procedure)
C9762	Cardiac magnetic resonance imaging (MRI) for morphology and function, quantification of segmental dysfunction; with strain imaging
C9763	Cardiac magnetic resonance imaging (MRI) for morphology and function, quantification of segmental dysfunction; with stress imaging
S8042	Magnetic resonance imaging (MRI), low-field

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established," Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

Clinical coverage criteria for magnetic resonance imaging (MRI), cardiac with stress testing were fully defined and established by NCDs and/or LCDs. Cohere Health did not supplement this policy with any additional criteria or interpretations.

The potential clinical harms of using these criteria for MRI, cardiac without stress testing may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁶
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.¹⁷
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is an uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.¹⁸
- Adverse effects from delayed or denied treatment, such as increased risk of cardiac events or worsening cardiac diseases (e.g., coronary artery disease, heart disease).¹⁹
- Increased healthcare costs and complications from the inappropriate use of additional interventions.²⁰

The clinical benefits of using these criteria for MRI, cardiac without stress testing include:

- Maintenance of rigorous patient safety standards aligned to best available evidence.
- Improved therapeutic yield for MRI, cardiac, resulting in better long-term outcomes. Among patients who are referred for invasive angiography, those who are evaluated by cardiac MRI experience higher rates of revascularization and therefore improved treatment efficacy as compared to patients who are not imaged with cardiac MRI.^{[21](#)}
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels. Noninvasive cardiac procedures are less costly, associated with fewer complications, and preferred by both patients and providers.^{[22,23](#)}

Medical Evidence

Miller et al. (2023) CMR-IMPACT (Cardiac Magnetic Resonance Imaging Strategy for the Management of Patients with Acute Chest Pain and Detectable to Elevated Troponin) trial conducted from September 2013 to July 2018 at four U.S. tertiary care hospitals. The trial involved the management of patients with acute chest pain and detectable elevated troponin levels. The 312 participants were randomized into two care pathways: invasive-based (156 participants) and CMR-based (156 participants), with adjustments permitted based on the patient's condition. The primary outcome measured was a composite of death, myocardial infarction, and cardiac-related hospital readmissions or emergency visits. The study followed 312 participants (mean age 60.6 years, 59.9% women) over a median of 2.6 years. The authors conclude no significant difference between clinical and safety outcomes. Benefits include reducing the long-term utilization of invasive angiography, positive discharge outcomes, and enhanced therapeutic yield of angiography. (Clinicaltrials.gov Identifier NCT01931852).²¹

Alabed et al. (2020) performed a meta-analysis concerning patient mortality due to pulmonary arterial hypertension (PAH). A total of 1938 patients in 22 studies were included. Research indicates that CMR-derived metrics for right ventricular (RV) volume and function, rather than left ventricular (LV) measurements, predict clinical deterioration. This insight is pertinent for regulatory authorities seeking clinically relevant trial endpoints. Further, this meta-analysis reaffirms the prognostic significance of CMR metrics across a large patient cohort, enabling assessment of how changes in these metrics relate to clinical outcomes such as worsening health and mortality. The authors reaffirm CMR as a useful prognostic marker in PAH among a large cohort. The study confirms that RV function, RV, and left ventricular volumes predict mortality and clinical deterioration in PAH. The study underscores the rationale for using CMR as a meaningful clinical endpoint in trials testing PAH therapies.²⁴

Kwong et al. (2019) conducted a retrospective study to evaluate the diagnostic and prognostic value. The study enrolled 2349 patients with chest pain syndrome at 13 centers in 11 states. The median follow-up was 5.4 years. A stress CMR showing no ischemia or LGE was linked to a very low incidence of adverse cardiac events in patients with stable intermediate-risk chest pain syndromes. Subsequent cardiac testing was also reduced. (Clinicaltrials.gov Identifier NCT03192891).²⁵

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Policy Revision History/Information

Original Date: October 3, 2024		
Review History		
Version 2	10/02/2025	Annual review. Updated repeat imaging indications. Updated “with stress testing” section to ensure alignment with L35083 & L38396, including non-indications. Split non-indications into “without stress testing” and “with stress testing” sections. Revised Harms and Benefits section.



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Chest

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 25, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Magnetic Resonance Imaging (MRI), Chest

Date of last literature review: 9/25/2024

Document last updated: 9/25/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Chest

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻³

- [National Coverage Determination \(NCD\) 220.2. Magnetic Resonance Imaging](#)
- [Local Coverage Determination \(LCD\) L35391. Multiple Imaging in Oncology](#)
- [Local Coverage Determination \(LCD\) Reference Article: Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Recommended Clinical Approach

Imaging analysis utilizing magnetic resonance imaging (MRI) of the chest can be performed based on clinical suspicion of disease presence or exclusion to direct value-based care. Contrast may or may not be necessary depending upon the clinical indication at the referring physician's request and the discretion of the supervising radiologist. Staging, presurgical planning, and screening are recommendations for a clinical approach.⁴

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of MRI of the chest. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks

associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁴⁻⁵
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁴⁻⁵
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁶
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁷

The clinical benefits of using these criteria include:

- Diagnosis of a wide range of conditions: MRI is useful for multiple conditions and tumor staging.
- Soft tissue resolution: MRI can identify a mass across tissue planes, including the chest wall, diaphragm, and neurovascular structures. MRI may also be performed when characterizing mediastinal lesions.⁸⁻⁹
- Treatment response: MRI of the chest may be performed to predict treatment response, especially for early-stage lung cancer.¹⁰
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous

clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), chest** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ MR-preferred indications, including **ANY** of the following:
 - Brachial plexus pathology, suspected, due to anatomic (e.g. cervical rib) or clinical symptoms (e.g., positive EMG results, symptoms related to scalene muscles, symptoms that worsen with arms overhead) – this includes but is not limited to, trauma, neurogenic thoracic outlet syndrome, neuropathies affecting brachial plexus (e.g, chronic inflammatory demyelinating polyneuropathy [CIDP]), or suspected or known mass; **OR**
 - Evaluation of non-bony musculoskeletal abnormalities, congenital or acquired (e.g., muscle tear, tendon or cartilage injury)⁵; **OR**
 - Inflammatory myopathies (e.g., polymyositis); **OR**
 - Fetal lung or chest wall anomaly is needed to determine further management; **OR**
- ◆ CT is contraindicated or inconclusive, chest radiographs were inadequate for diagnosis or determination of management, and **ANY** of the following is **TRUE**:
 - Chest wall abnormalities, including **ANY** of the following:
 - Anatomic abnormalities, congenital or acquired (e.g., pectus excavatum or rib abnormalities); **OR**
 - Palpable chest wall mass with non-diagnostic or indeterminate radiograph or ultrasound; **OR**
 - Chest wall mass identified on prior imaging when further information is needed to determine the need for biopsy or surgery; **OR**

- Suspected or known chest wall abscess and further evaluation is needed; **OR**
- Congenital pulmonary malformations (e.g., pulmonary sequestration) when MRA/CTA is contraindicated or cannot be done; **OR**
- Persistent lymphadenopathy for initial evaluation; **OR**
- Neoplastic conditions for **ANY** of the following:
 - Initial staging; **OR**
 - Treatment planning; **OR**
 - Response assessment; **OR**
 - Surveillance, and **ANY** of the following is **TRUE**^{2-3,11-13}:
 - ◆ The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - ◆ Suspected recurrence/progression; **OR**
 - ◆ Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6-8 weeks since the prior imaging evaluation); **OR**
- Screening for thymoma in myasthenia gravis; **OR**
- Herniation into thorax of abdominal contents, including diaphragmatic hernias, and hiatal hernias; **OR**
- Hoarseness, dysphonia, and vocal cord weakness/paralysis after laryngoscopy completed with **ANY** of the following:
 - Findings suggest recurrent laryngeal nerve dysfunction; **OR**
 - Suspicious lesion identified and needs further evaluation; **OR**
 - Symptoms persisting longer than 1 month which are unexplained by laryngoscopy; **OR**
- Preoperative, postoperative, and pre-treatment evaluation for procedure, surgery, radiation, or chemotherapy; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance imaging (MRI), chest** may not be considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
71550	Magnetic resonance imaging (MRI) (e.g., proton), chest; without contrast material(s)
71551	Magnetic resonance imaging (MRI) (e.g., proton), chest; with contrast material(s)
71552	Magnetic resonance imaging (MRI) (e.g., proton), chest (e.g., for evaluation of hilar and mediastinal lymphadenopathy); with contrast material(s),

	followed by contrast material(s) and further sequences
C9791	Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent

Medical Evidence

Archer et al. (2023) reviewed the utilization of cross-sectional imaging techniques such as computed tomography (CT) or magnetic resonance imaging (MRI) is essential for assessing mediastinal pathologies. Precisely localizing lesions within specific compartments and analyzing their morphology, density/intensity, enhancement patterns, and any mass effect on adjacent structures can significantly aid in narrowing down diagnostic possibilities. While CT is readily available and fast, MRI does not use radiation and can delineate soft tissue contrasts. Precise imaging allows for identifying masses across tissue planes (e.g., chest wall, diaphragm) and the involvement of neurovascular structures. MRI also provides dynamic sequences that enable the assessment of mass motion relative to neighboring structures during free-breathing or cinematic cardiac gating. Finally, MRI can distinguish between cystic and solid lesions and detect fat, which aids in differentiating thymic hyperplasia from thymic malignancy.⁸

Cavanna et al. (2022) conducted a literature review on thoracic outlet syndrome (TOS). Plain chest and cervical region radiographs often exclude anatomical anomalies and structural irregularities (e.g., cervical ribs, clavicular fracture malunion, elongated transverse processes, or thoracic cavity tumors). Conditions such as compressive effects on the brachial plexus need imaging beyond ultrasound, which may overlook regional pathologies (e.g., Pancoast tumor, cervical spondylopathy). Non-contrast MRI may help diagnose neurogenic TOS (nTOS). However, MR or CT angiography is preferred for confirming venous or arterial TOS.¹⁴

Bueno et al. (2018) reviewed MR imaging of primary chest wall neoplasms, representing a rare and diverse array of lesions. MR imaging allows detailed insights into tissue composition, disease extent, and the integrity of surrounding structures. Utilization of this modality has increased due to its superior contrast resolution vs CT scans, which are free of radiation. MR imaging allows clinicians to distinguish tumors, identify infectious and inflammatory conditions, and visualize internal components (e.g., fat, fluid, soft tissue, vascularity post-intravenous contrast administration).¹⁵

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Clinical Guideline Revision History/Information

Original Date: September 25, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Chest

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 25, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Magnetic Resonance Imaging (MRI), Chest

Date of last literature review: 9/25/2024

Document last updated: 9/25/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Chest

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻³

- [National Coverage Determination \(NCD\) 220.2. Magnetic Resonance Imaging](#)
- [Local Coverage Determination \(LCD\) L35391. Multiple Imaging in Oncology](#)
- [Local Coverage Determination \(LCD\) Reference Article: Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Recommended Clinical Approach

Imaging analysis utilizing magnetic resonance imaging (MRI) of the chest can be performed based on clinical suspicion of disease presence or exclusion to direct value-based care. Contrast may or may not be necessary depending upon the clinical indication at the referring physician's request and the discretion of the supervising radiologist. Staging, presurgical planning, and screening are recommendations for a clinical approach.⁴

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of MRI of the chest. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks

associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁴⁻⁵
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁴⁻⁵
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁶
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁷

The clinical benefits of using these criteria include:

- Diagnosis of a wide range of conditions: MRI is useful for multiple conditions and tumor staging.
- Soft tissue resolution: MRI can identify a mass across tissue planes, including the chest wall, diaphragm, and neurovascular structures. MRI may also be performed when characterizing mediastinal lesions.⁸⁻⁹
- Treatment response: MRI of the chest may be performed to predict treatment response, especially for early-stage lung cancer.¹⁰
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous

clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), chest** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ MR-preferred indications, including **ANY** of the following:
 - Brachial plexus pathology, suspected, due to anatomic (e.g. cervical rib) or clinical symptoms (e.g., positive EMG results, symptoms related to scalene muscles, symptoms that worsen with arms overhead) – this includes but is not limited to, trauma, neurogenic thoracic outlet syndrome, neuropathies affecting brachial plexus (e.g, chronic inflammatory demyelinating polyneuropathy [CIDP]), or suspected or known mass; **OR**
 - Evaluation of non-bony musculoskeletal abnormalities, congenital or acquired (e.g., muscle tear, tendon or cartilage injury)⁵; **OR**
 - Inflammatory myopathies (e.g., polymyositis); **OR**
 - Fetal lung or chest wall anomaly is needed to determine further management; **OR**
- ◆ CT is contraindicated or inconclusive, chest radiographs were inadequate for diagnosis or determination of management, and **ANY** of the following is **TRUE**:
 - Chest wall abnormalities, including **ANY** of the following:
 - Anatomic abnormalities, congenital or acquired (e.g., pectus excavatum or rib abnormalities); **OR**
 - Palpable chest wall mass with non-diagnostic or indeterminate radiograph or ultrasound; **OR**
 - Chest wall mass identified on prior imaging when further information is needed to determine the need for biopsy or surgery; **OR**

- Suspected or known chest wall abscess and further evaluation is needed; **OR**
- Congenital pulmonary malformations (e.g., pulmonary sequestration) when MRA/CTA is contraindicated or cannot be done; **OR**
- Persistent lymphadenopathy for initial evaluation; **OR**
- Neoplastic conditions for **ANY** of the following:
 - Initial staging; **OR**
 - Treatment planning; **OR**
 - Response assessment; **OR**
 - Surveillance, and **ANY** of the following is **TRUE**^{2-3,11-13}:
 - ◆ The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - ◆ Suspected recurrence/progression; **OR**
 - ◆ Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6-8 weeks since the prior imaging evaluation); **OR**
- Screening for thymoma in myasthenia gravis; **OR**
- Herniation into thorax of abdominal contents, including diaphragmatic hernias, and hiatal hernias; **OR**
- Hoarseness, dysphonia, and vocal cord weakness/paralysis after laryngoscopy completed with **ANY** of the following:
 - Findings suggest recurrent laryngeal nerve dysfunction; **OR**
 - Suspicious lesion identified and needs further evaluation; **OR**
 - Symptoms persisting longer than 1 month which are unexplained by laryngoscopy; **OR**
- Preoperative, postoperative, and pre-treatment evaluation for procedure, surgery, radiation, or chemotherapy; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance imaging (MRI), chest** may not be considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
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CPT/HCPCS Code	Code Description
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Clinical Guideline Revision History/Information

Original Date: September 25, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Fetal/Placental

Clinical Policy for Medical Necessity Review

Version: 2

Cohere Health UMC Approval Date: November 13, 2025

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Important Notices

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Fetal/Placental

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Fetal/Placental

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)

Description

Magnetic resonance imaging (MRI) of a fetus/placenta is a diagnostic tool used to provide a detailed view of suspected or known fetal anomalies, congenital in origin, while the fetus is still in utero. Anomalies of interest include neural tube defects (such as spina bifida), cardiovascular abnormalities, pulmonary differences, and certain complications associated with high-risk multiple-gestation pregnancies, including twin-to-twin transfusion syndrome. Fetal MRI is of additional use in the advanced planning of technically difficult deliveries, such as fetuses with compromised airways who may require complex, assisted delivery methods to maintain oxygen and blood flow. Fetal MRI also provides a view of the placenta, critical for diagnosing and planning the treatment of placenta accreta spectrum disorders (PAS).¹⁻⁴

Medical Necessity Criteria

Indications

Fetal/placental MRI is considered appropriate if **ALL** of the following are **TRUE**²⁻²⁸:

- Ultrasonography has been performed and is indeterminate, technically inadequate, nondiagnostic, or provides an incomplete clinical evaluation;
AND
- **ANY** of the following:
 - Evaluation of known or suspected fetal anomaly, including but not limited to **ANY** of the following³:
 - Anatomical anomaly (e.g., brain, spine, facial, neck, oropharyngeal, thoracoabdominal, cardiac, vascular, pulmonary, gastrointestinal, genitourinary, musculoskeletal); **OR**
 - Diaphragmatic hernia; **OR**
 - Tumor or mass; **OR**
 - Anatomical obstruction (e.g., gastrointestinal, genitourinary); **OR**
 - Assessment of the fetal airway²; **OR**
 - Evaluation of known or suspected fetal infection³; **OR**
 - Evaluation of fetus in the setting of abnormal amniotic fluid, including **ANY** of the following^{4,5}:
 - Polyhydramnios; **OR**
 - Oligohydramnios; **OR**
 - Anhydramnios; **OR**
 - Planning or evaluation of candidacy for fetal surgery or other in-utero intervention²; **OR**
 - Planning or evaluation of candidacy for complex assisted delivery (e.g., ex utero intrapartum treatment [EXIT] procedure)^{2,29}; **OR**
 - Planning or evaluation of candidacy for post-delivery neonatal surgery²; **OR**
 - Complications related to a multiple-gestation pregnancy²; **OR**
 - Assessment of fetal morbidity of remaining fetus following in-utero death of a co-twin or co-multiple²; **OR**
 - Maternal placental complication as indicated by **ANY** of the following^{6,7}:
 - For planning of cesarean section delivery or peripartum hysterectomy among patients with **ANY** of the following:

- Known or suspected placenta accreta spectrum disorder (PAS) (e.g., placenta increta, placenta percreta, placenta accreta); **OR**
- High risk of PAS, including **ANY** of the following:
 - History of cesarean section; **OR**
 - Prior uterine surgery or curettage; **OR**
 - Prior or current placenta previa; **OR**
 - Prior placenta accreta spectrum disorder; **OR**
 - Known adenomyosis; **OR**
 - Pregnancy was conceived with assisted reproductive technology (e.g., in vitro fertilization [IVF], frozen embryo transfer, Intracytoplasmic sperm injection [ICSI]); **OR**
 - Advanced maternal age (greater than or equal to 35 years of age); **OR**
 - Asherman's syndrome; **OR**
 - Prior curettage; **OR**
 - Multiparity; **OR**
- Known or suspected placental abruption⁷; **OR**
- Known or suspected gestational trophoblastic disease; **OR**
- Evaluation, during pregnancy, of known maternal leiomyoma at high-risk of degeneration or rupture, including **ANY** of the following¹⁴:
 - Submucosal leiomyoma; **OR**
 - Retroplacental leiomyoma; **OR**
 - Leiomyoma that enlarges in the first trimester; **OR**
- Screening with **ANY** of the following²:
 - Family risk for inheritable brain abnormalities (e.g., tuberous sclerosis, corpus callosal dysgenesis, lissencephaly); **OR**
 - Volumetric assessment of fetal lung parenchyma among fetuses at risk for pulmonary hypoplasia; **OR**
- Repeat imaging with fetal/placental MRI is indicated with **ANY** of the following²:
 - In-utero fetal surgery or in-utero intervention has been performed and necessitates follow-up imaging; **OR**
 - Serial antepartum imaging is necessary for ongoing planning, management, or evaluation of the fetal or placental condition; **OR**
 - The initial study was limited, incomplete, or of poor quality due to **ANY** of the following:
 - Insufficient gestational age; **OR**
 - Small fetal size; **OR**

- Atypical fetal position; **OR**
- Fetal movement degraded the image of the region of interest.

Non-Indications

Fetal/placental MRI is not considered appropriate if **ANY** of the following is **TRUE**²⁻²⁸:

- When complete diagnostic information can be obtained by ultrasonography; **OR**
- When used solely to evaluate preterm premature rupture of membranes (PPROM) in the absence of any other indication.

*NOTE: Gadolinium-based contrast is considered to hold unknown risk and potential harm to a fetus and is not recommended for routine administration with fetal/placental MRIs. The decision to use gadolinium in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.^{2,13}

**NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
74712	Magnetic resonance (e.g., proton) imaging, fetal, including placental and maternal pelvic imaging when performed; single or first gestation
74713	Magnetic resonance (e.g., proton) imaging, fetal, including placental and maternal pelvic imaging when performed; each additional gestation (List separately in addition to code for primary procedure)

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for fetal/placental MRI may include:

- A risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.[30-32](#)
- The use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.[30-32](#)
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of oversedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for magnetic resonance imaging (MRI) in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.[33](#)
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.[34](#)

The clinical benefits of using these criteria for fetal/placental MRI include:

- MRI demonstrates superior visibility and detail of conditions not sufficiently imaged on other conventional imaging, such as congenital anomalies.

- Because MRI does not use ionizing radiation, it is a safer peripartum alternative to computed tomography (CT) when ultrasonography, the traditional first-line imaging modality of pregnancy, is not adequate.
- MRI, as an adjunct to ultrasonography, can help to counsel patients, guide physicians in selecting the appropriate course of management, and plan for delivery.
- MRI is a noninvasive method of diagnosing a fetus with congenital anomalies or placental abnormality, which may impact the course of – and management of – a pregnancy.
- Enhanced overall patient satisfaction and healthcare experience.

Medical Evidence

Bank et al. (2023) reviewed 58 cases of patients with polyhydramnios who underwent fetal MRI. The authors compared prenatal diagnoses made by ultrasound and fetal MRI to postnatal diagnoses. Of the 58 cases reviewed, 26.6% had new diagnoses detected on fetal MRI that were not detected on ultrasound. Of these new diagnoses, 25% were neurological and another 25% were genitourinary in nature. Fetal MRI confirmed 76.2% of the ultrasound diagnoses. The authors concluded that fetal MRI should be considered when evaluating pregnancies complicated by polyhydramnios to help improve diagnosis and management.⁵

Recio Rodríguez et al. (2020) conducted a retrospective study to determine the diagnostic accuracy of fetal MRI for the prenatal diagnosis of both central nervous system (CNS) pathology and non-CNS pathology. 623 pregnant patients referred to radiology for fetal MRI due to a detection of anomaly on ultrasound, high-risk pregnancy, or inconclusive fetal ultrasound were included in the study. The diagnostic accuracy of fetal MRI was 97%, compared to 90.4% for ultrasound. The concordance between fetal ultrasound and fetal MRI was 92.1%. In 45 cases (7.2%), fetal MRI alone provided accurate diagnostic information. The authors concluded that fetal MRI offers superior diagnostic accuracy, especially for CNS pathology.¹⁵

Griffiths et al. (2017) conducted a cohort study to evaluate the diagnostic accuracy of in-utero MRI (iuMRI) for the prenatal diagnosis of fetal brain abnormalities. 570 pregnant patients carrying a fetus 18 weeks of age or older with a suspected brain anomaly on ultrasound had a follow-up iuMRI within 14 days of the ultrasound. The authors then evaluated any changes in diagnosis, prognosis, or clinical management resulting from the iuMRI. Overall, diagnostic accuracy was 68% for ultrasound and 93% for iuMRI. IuMRI resulted in expanded diagnostic detail, adjusted prognosis, and changes in clinical management in 49%, 20%, and 35% of cases, respectively. The authors conclude that iuMRI provides an opportunity to obtain additional clarity regarding fetal neuropathology to guide clinical decision-making.²⁰

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Policy Revision History/Information

Original Date: November 21, 2024		
Review History		
Version 2	11/13/2025	Annual review Updated description and medical evidence sections Minor language updates Removed the following indication: “Per the treating physician, the benefits are felt to outweigh the theoretical risks “ Removed relative contraindications (contrast allergy, metallic clips, incompatible implantable devices, metallic foreign body) Reordered references to reflect order of first appearance in policy



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Lower Extremity

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Lower Extremity

Date of last literature review: 10/2/2024

Document last updated: 10/3/2024

Type: ☒ Adult (18+ yo) | ☐ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Lower Extremity

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)

Recommended Clinical Approach

Magnetic resonance imaging (MRI) is segmented into joint and non-joint distribution and may be performed without or with contrast (intravenous or intra-articular). Metal hardware in the bone can limit certain exams and is generally inappropriate for imaging by 3 Tesla scanners. Based on the clinician and supervising radiologist's discussion, alternate modalities may sometimes be more clinically appropriate.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI) of the lower extremities. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.²⁻³
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.²⁻³
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁴
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁵

The clinical benefits of using these criteria include:

- Analyzing soft tissue: MRI is the "gold standard" for imaging of lower extremity soft tissue and detection of abnormal tissue.⁶
- Ability to quantify changes: MRI can detect changes in the musculoskeletal system following a spinal cord injury.⁶
- Diagnosis of low back pain: MRI aids in the diagnosis of radiculopathy that does not respond to conservative management, neurogenic claudication, myelopathy, or when "red flag" symptoms are present.⁷
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), lower extremity** is considered appropriate if **ANY** of the following is **TRUE**:

◆ Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment response, or prognostication), including **ANY** of the following:

- Malignant or aggressive primary musculoskeletal tumor⁸; **OR**
- Malignant or aggressive primary soft tissue tumor⁷; **OR**
- Malignant or aggressive bone tumor⁸; **OR**
- Nonsuperficial (deep) soft tissue mass⁹; **OR**
- Soft tissue mass⁹; **OR**
- A primary bone tumor is suspected with **ANY** of the following¹⁰:
 - Lesion is suspected on plain radiograph; **OR**
 - “Incidental” osseous lesion on MRI or CT of another region and not fully evaluated by other imaging; **OR**
- Presence of a mass with **ANY** of the following⁹:
 - Absence of trauma; **OR**
 - Rapid growth; **OR**
 - Recurrence after prior surgery; **OR**
 - Non-diagnostic ultrasound or other inconclusive imaging; **OR**
- Follow-up exam to further characterize a bone or soft tissue lesion diagnosed on initial imaging study⁹⁻¹⁰; **OR**
- Known malignancy with localized lower extremity pain or swelling and **ANY** of the following are required:
 - Monitor response to treatment; **OR**
 - Surveillance after treatment or surgery; **OR**
- Persistent palpable abnormality with a non-diagnostic radiograph or ultrasound; **OR**
- Routine surveillance of known malignancy; **OR**

- ◆ Acute traumatic lower extremity injury (e.g., fracture, dislocation) that requires additional detail than is available with plain radiographs and **ANY** of the following is **TRUE**:
 - Bony injury and **ANY** of the following is **TRUE**:
 - Acute injury with occult fracture suspected; **OR**
 - Joint dislocation or instability; **OR**
 - Internal derangement; **OR**
 - Stress/insufficiency fracture (known) and follow-up imaging needed; **OR**
 - Stress/insufficiency fracture (suspected) with negative radiographs; **OR**
 - Suspected soft tissue injury (e.g., peroneal tendon injury, meniscal tear); **OR**
- ◆ Chronic injury with ongoing symptoms for greater than or equal to 6 weeks and **ALL** of the following is **TRUE**:
 - The patient has failed conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 6 weeks; **AND**
 - Radiographs are negative for osseous injury, and an alignment injury is suspected based on physical exam, including **ANY** of the following:
 - Dislocation; **OR**
 - Syndesmotic injury; **OR**
 - Other ligamentous or soft tissue injury; **OR**
- ◆ Infection or an infectious disorder, including **ANY** of the following:
 - Septic arthritis is suspected with initial radiographs that are normal or with findings suggestive of joint effusion or soft tissue swelling¹¹⁻¹²; **OR**
 - Osteomyelitis, suspected^{11,13}; **OR**
 - Soft tissue infection suspected with **ANY** of the following¹¹:
 - Normal initial radiographs or with findings suggestive of joint effusion or soft tissue swelling; **OR**
 - History of puncture wound with possible retained foreign body; **OR**
 - High clinical suspicion of necrotizing fasciitis; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:

- Osteonecrosis, known or suspected, with negative radiographs¹⁴; **OR**
- Vascular malformation (with or without pain) and **ANY** of the following findings of physical deformity are suspected¹⁵:
 - Diffuse or focal enlargement; **OR**
 - Discoloration; **OR**
 - Soft-tissue mass; **OR**
 - Ulceration; **OR**
 - Vascular bruit or thrill; **OR**
- Neuropathy, nerve entrapment, or nerve lesion with **ANY** of the following¹⁶:
 - Clinically suspected nerve entrapment and **ALL** of the following are **TRUE**:
 - ◆ Abnormal EMG; **AND**
 - ◆ MRI is to assist in diagnosis and treatment options; **OR**
 - Known peripheral nerve sheath tumor or syndrome and **ANY** of the following:
 - ◆ Enlarging mass; **OR**
 - ◆ New or worsening localized pain; **OR**
 - ◆ Recurrence after prior resection; **OR**
 - Persistent symptoms following conservative treatment and localized EMG abnormality; **OR**
 - Trauma/ injury with suspected nerve injury or laceration based on site of injury and associated neurological deficits; **OR**
- ◆ Pre and post-intervention evaluation (including the diagnosis of postoperative complications) when **ANY** of the following is **TRUE**:
 - Imaging after hip arthroplasty and **ANY** of the following is **TRUE**¹⁷:
 - Hardware fracture; **OR**
 - Infection; **OR**
 - Pain with **ANY** of the following (infection excluded):
 - ◆ Aseptic loosening; **OR**
 - ◆ Instability; **OR**
 - ◆ Osteolysis; **OR**
 - ◆ Periprosthetic fracture; **OR**
 - History of acute injury; **OR**

- Metal-on-metal prosthesis with an adverse reaction to metal debris; **OR**
 - Trunnionosis (corrosion or metallosis), suspected; **OR**
- Imaging after knee arthroplasty and **ANY** of the following are suspected (with or without pain)¹³:
 - Hardware fracture; **OR**
 - Infection; **OR**
 - Periprosthetic fracture; **OR**
 - Pain with **ANY** of the following (infection excluded):
 - ◆ Aseptic loosening; **OR**
 - ◆ Instability; **OR**
 - ◆ Osteolysis; **OR**
 - ◆ Acute injury with suspected extensor mechanism involvement; **OR**
- ◆ Evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when applicable¹⁸:
 - Marrow abnormalities¹⁴; **OR**
 - Pain or weakness of a lower extremity as indicated by **ALL** of the following:
 - Joint-specific orthopedic evaluation and maneuvers suggesting **ANY** of the following:
 - ◆ Tear; **OR**
 - ◆ Tendonitis; **OR**
 - ◆ Other abnormality; **OR**
 - ◆ Other injury; **AND**
 - Radiographs and/or ultrasound are nondiagnostic or indeterminate; **AND**
 - Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 6 weeks; **AND**
 - Concern for rupture or high-grade tear based on **ALL** of the following:
 - ◆ Clinical history; **AND**
 - ◆ Physical exam; **OR**
 - Screening, surveillance, or follow-up of autoimmune, collagen vascular diseases, or inflammatory conditions (e.g., inflammatory arthritis)¹²; **OR**

- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Magnetic resonance imaging (MRI), lower extremity** may not be considered appropriate if **ANY** of the following is **TRUE**:
- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
 - ◆ The patient has metallic clips on vascular aneurysms¹; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; **OR**
 - ◆ Imaging of cortical bone and calcifications¹; **OR**
 - ◆ Procedures involving spatial resolution of bone and calcifications.¹

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.¹

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
73718	Magnetic resonance imaging (MRI) (e.g., proton), lower extremity other than joint; without contrast

	material(s)
73719	Magnetic resonance imaging (MRI) (e.g., proton), of lower extremity (other than joint); with contrast material(s)
73720	Magnetic resonance imaging (MRI) (e.g., proton), lower extremity other than joint; without contrast material(s), followed by contrast material(s) and further sequences
73721	Magnetic resonance imaging (MRI) (e.g., proton), any joint of lower extremity; without contrast material
73722	Magnetic resonance imaging (MRI) (e.g., proton), any joint of lower extremity; with contrast material(s)
73723	Magnetic resonance imaging (MRI) (e.g., proton), any joint of lower extremity; without contrast material(s) followed by contrast material(s) and further sequences

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Drake et al. (2022) conducted a systematic review and meta-analysis of observational studies comparing medical imaging (specifically magnetic resonance imaging [MRI]) of adults with plantar heel pain. A total of 42 studies were included. Patients with PHP had higher rates of thickened plantar fascia (greater than 4 mm) as well as abnormal plantar fascia tissue, a thicker loaded plantar heel fat pad on ultrasound, and a plantar calcaneal spur on plain film x-ray. Continued research is needed on high-quality imaging to increase the accuracy of MRI.¹⁹

Lansdown and Ma (2020) review the clinical utility of advanced imaging of the knee. MRI excels in sensitivity and specificity for diagnosing injuries such as ligament, meniscus, and full-thickness cartilage defects in the knee. High-resolution qualitative assessment ensures accurate detection and characterization of these conditions. Utilizing compositional MRI sequences enables an assessment of the biochemical characteristics of cartilage, meniscus, and ligaments, providing additional insights into pathology beyond traditional imaging. Progress in image processing, shape modeling, and dynamic studies is an innovative approach to assess conditions of the lower extremities and to track post-treatment outcomes.²⁰

Warner et al. (2019) conducted a study to compare the diagnostic efficacy of injury (non-stress) and stress radiographs vs MRI to identify deep deltoid ligament ruptures among patients with operative supination-external rotation (SER) ankle fractures. The medial clear space (MCS) was considered to be positive if measurements exceeded 5 mm on either injury or stress mortise radiographs. Compared to intra-operative visualization, MCS measurements and MRI exhibited differential diagnostic capabilities for identifying deep deltoid ruptures. When MCS measured less than 5 mm on injury radiographs with subsequent stress testing, MCS assessments proved less accurate than MRI in predicting deltoid ruptures (46% vs 79%, respectively), with a notably high false positive rate (80%). An MCS exceeding 5 mm on injury radiographs strongly correlated with deep deltoid rupture diagnosis (accuracy of 95%). In contrast, to direct intra-operative visualization of the deltoid ligament, these findings advocate for surgical intervention when MCS measures greater than 5 mm on injury radiographs without necessitating additional stress tests or advanced imaging. However, MRI analysis is recommended when MCS measures less than 5 mm because of its heightened accuracy and reduced false positive rates. Enhanced diagnostic capabilities promise more effective management of patients with SER ankle fractures.²¹

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Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Lower Extremity

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Type: ☒ Adult (18+ yo) | ☐ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Lower Extremity

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)

Recommended Clinical Approach

Magnetic resonance imaging (MRI) is segmented into joint and non-joint distribution and may be performed without or with contrast (intravenous or intra-articular). Metal hardware in the bone can limit certain exams and is generally inappropriate for imaging by 3 Tesla scanners. Based on the clinician and supervising radiologist's discussion, alternate modalities may sometimes be more clinically appropriate.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI) of the lower extremities. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.²⁻³
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.²⁻³
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁴
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁵

The clinical benefits of using these criteria include:

- Analyzing soft tissue: MRI is the "gold standard" for imaging of lower extremity soft tissue and detection of abnormal tissue.⁶
- Ability to quantify changes: MRI can detect changes in the musculoskeletal system following a spinal cord injury.⁶
- Diagnosis of low back pain: MRI aids in the diagnosis of radiculopathy that does not respond to conservative management, neurogenic claudication, myelopathy, or when "red flag" symptoms are present.⁷
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), lower extremity** is considered appropriate if **ANY** of the following is **TRUE**:

◆ Neoplastic conditions (including masses or mass-like conditions) when the arterial blood supply needs to be evaluated (e.g., for treatment planning, treatment response, or prognostication), including **ANY** of the following:

- Malignant or aggressive primary musculoskeletal tumor⁸; **OR**
- Malignant or aggressive primary soft tissue tumor⁷; **OR**
- Malignant or aggressive bone tumor⁸; **OR**
- Nonsuperficial (deep) soft tissue mass⁹; **OR**
- Soft tissue mass⁹; **OR**
- A primary bone tumor is suspected with **ANY** of the following¹⁰:
 - Lesion is suspected on plain radiograph; **OR**
 - “Incidental” osseous lesion on MRI or CT of another region and not fully evaluated by other imaging; **OR**
- Presence of a mass with **ANY** of the following⁹:
 - Absence of trauma; **OR**
 - Rapid growth; **OR**
 - Recurrence after prior surgery; **OR**
 - Non-diagnostic ultrasound or other inconclusive imaging; **OR**
- Follow-up exam to further characterize a bone or soft tissue lesion diagnosed on initial imaging study⁹⁻¹⁰; **OR**
- Known malignancy with localized lower extremity pain or swelling and **ANY** of the following are required:
 - Monitor response to treatment; **OR**
 - Surveillance after treatment or surgery; **OR**
- Persistent palpable abnormality with a non-diagnostic radiograph or ultrasound; **OR**
- Routine surveillance of known malignancy; **OR**

- ◆ Acute traumatic lower extremity injury (e.g., fracture, dislocation) that requires additional detail than is available with plain radiographs and **ANY** of the following is **TRUE**:
 - Bony injury and **ANY** of the following is **TRUE**:
 - Acute injury with occult fracture suspected; **OR**
 - Joint dislocation or instability; **OR**
 - Internal derangement; **OR**
 - Stress/insufficiency fracture (known) and follow-up imaging needed; **OR**
 - Stress/insufficiency fracture (suspected) with negative radiographs; **OR**
 - Suspected soft tissue injury (e.g., peroneal tendon injury, meniscal tear); **OR**
- ◆ Chronic injury with ongoing symptoms for greater than or equal to 6 weeks and **ALL** of the following is **TRUE**:
 - The patient has failed conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 6 weeks; **AND**
 - Radiographs are negative for osseous injury, and an alignment injury is suspected based on physical exam, including **ANY** of the following:
 - Dislocation; **OR**
 - Syndesmotic injury; **OR**
 - Other ligamentous or soft tissue injury; **OR**
- ◆ Infection or an infectious disorder, including **ANY** of the following:
 - Septic arthritis is suspected with initial radiographs that are normal or with findings suggestive of joint effusion or soft tissue swelling¹¹⁻¹²; **OR**
 - Osteomyelitis, suspected^{11,13}; **OR**
 - Soft tissue infection suspected with **ANY** of the following¹¹:
 - Normal initial radiographs or with findings suggestive of joint effusion or soft tissue swelling; **OR**
 - History of puncture wound with possible retained foreign body; **OR**
 - High clinical suspicion of necrotizing fasciitis; **OR**
- ◆ Vascular conditions, known or suspected, including **ANY** of the following:

- Osteonecrosis, known or suspected, with negative radiographs¹⁴; **OR**
- Vascular malformation (with or without pain) and **ANY** of the following findings of physical deformity are suspected¹⁵:
 - Diffuse or focal enlargement; **OR**
 - Discoloration; **OR**
 - Soft-tissue mass; **OR**
 - Ulceration; **OR**
 - Vascular bruit or thrill; **OR**
- Neuropathy, nerve entrapment, or nerve lesion with **ANY** of the following¹⁶:
 - Clinically suspected nerve entrapment and **ALL** of the following are **TRUE**:
 - ◆ Abnormal EMG; **AND**
 - ◆ MRI is to assist in diagnosis and treatment options; **OR**
 - Known peripheral nerve sheath tumor or syndrome and **ANY** of the following:
 - ◆ Enlarging mass; **OR**
 - ◆ New or worsening localized pain; **OR**
 - ◆ Recurrence after prior resection; **OR**
 - Persistent symptoms following conservative treatment and localized EMG abnormality; **OR**
 - Trauma/ injury with suspected nerve injury or laceration based on site of injury and associated neurological deficits; **OR**
- ◆ Pre and post-intervention evaluation (including the diagnosis of postoperative complications) when **ANY** of the following is **TRUE**:
 - Imaging after hip arthroplasty and **ANY** of the following is **TRUE**¹⁷:
 - Hardware fracture; **OR**
 - Infection; **OR**
 - Pain with **ANY** of the following (infection excluded):
 - ◆ Aseptic loosening; **OR**
 - ◆ Instability; **OR**
 - ◆ Osteolysis; **OR**
 - ◆ Periprosthetic fracture; **OR**
 - History of acute injury; **OR**

- Metal-on-metal prosthesis with an adverse reaction to metal debris; **OR**
 - Trunnionosis (corrosion or metallosis), suspected; **OR**
- Imaging after knee arthroplasty and **ANY** of the following are suspected (with or without pain)¹³:
 - Hardware fracture; **OR**
 - Infection; **OR**
 - Periprosthetic fracture; **OR**
 - Pain with **ANY** of the following (infection excluded):
 - ◆ Aseptic loosening; **OR**
 - ◆ Instability; **OR**
 - ◆ Osteolysis; **OR**
 - ◆ Acute injury with suspected extensor mechanism involvement; **OR**
- ◆ Evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when applicable¹⁸:
 - Marrow abnormalities¹⁴; **OR**
 - Pain or weakness of a lower extremity as indicated by **ALL** of the following:
 - Joint-specific orthopedic evaluation and maneuvers suggesting **ANY** of the following:
 - ◆ Tear; **OR**
 - ◆ Tendonitis; **OR**
 - ◆ Other abnormality; **OR**
 - ◆ Other injury; **AND**
 - Radiographs and/or ultrasound are nondiagnostic or indeterminate; **AND**
 - Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 6 weeks; **AND**
 - Concern for rupture or high-grade tear based on **ALL** of the following:
 - ◆ Clinical history; **AND**
 - ◆ Physical exam; **OR**
 - Screening, surveillance, or follow-up of autoimmune, collagen vascular diseases, or inflammatory conditions (e.g., inflammatory arthritis)¹²; **OR**

- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Magnetic resonance imaging (MRI), lower extremity** may not be considered appropriate if **ANY** of the following is **TRUE**:
- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
 - ◆ The patient has metallic clips on vascular aneurysms¹; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; **OR**
 - ◆ Imaging of cortical bone and calcifications¹; **OR**
 - ◆ Procedures involving spatial resolution of bone and calcifications.¹

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.¹

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
73718	Magnetic resonance imaging (MRI) (e.g., proton), lower extremity other than joint; without contrast

	material(s)
73719	Magnetic resonance imaging (MRI) (e.g., proton), of lower extremity (other than joint); with contrast material(s)
73720	Magnetic resonance imaging (MRI) (e.g., proton), lower extremity other than joint; without contrast material(s), followed by contrast material(s) and further sequences
73721	Magnetic resonance imaging (MRI) (e.g., proton), any joint of lower extremity; without contrast material
73722	Magnetic resonance imaging (MRI) (e.g., proton), any joint of lower extremity; with contrast material(s)
73723	Magnetic resonance imaging (MRI) (e.g., proton), any joint of lower extremity; without contrast material(s) followed by contrast material(s) and further sequences

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Drake et al. (2022) conducted a systematic review and meta-analysis of observational studies comparing medical imaging (specifically magnetic resonance imaging [MRI]) of adults with plantar heel pain. A total of 42 studies were included. Patients with PHP had higher rates of thickened plantar fascia (greater than 4 mm) as well as abnormal plantar fascia tissue, a thicker loaded plantar heel fat pad on ultrasound, and a plantar calcaneal spur on plain film x-ray. Continued research is needed on high-quality imaging to increase the accuracy of MRI.¹⁹

Lansdown and Ma (2020) review the clinical utility of advanced imaging of the knee. MRI excels in sensitivity and specificity for diagnosing injuries such as ligament, meniscus, and full-thickness cartilage defects in the knee. High-resolution qualitative assessment ensures accurate detection and characterization of these conditions. Utilizing compositional MRI sequences enables an assessment of the biochemical characteristics of cartilage, meniscus, and ligaments, providing additional insights into pathology beyond traditional imaging. Progress in image processing, shape modeling, and dynamic studies is an innovative approach to assess conditions of the lower extremities and to track post-treatment outcomes.²⁰

Warner et al. (2019) conducted a study to compare the diagnostic efficacy of injury (non-stress) and stress radiographs vs MRI to identify deep deltoid ligament ruptures among patients with operative supination-external rotation (SER) ankle fractures. The medial clear space (MCS) was considered to be positive if measurements exceeded 5 mm on either injury or stress mortise radiographs. Compared to intra-operative visualization, MCS measurements and MRI exhibited differential diagnostic capabilities for identifying deep deltoid ruptures. When MCS measured less than 5 mm on injury radiographs with subsequent stress testing, MCS assessments proved less accurate than MRI in predicting deltoid ruptures (46% vs 79%, respectively), with a notably high false positive rate (80%). An MCS exceeding 5 mm on injury radiographs strongly correlated with deep deltoid rupture diagnosis (accuracy of 95%). In contrast, to direct intra-operative visualization of the deltoid ligament, these findings advocate for surgical intervention when MCS measures greater than 5 mm on injury radiographs without necessitating additional stress tests or advanced imaging. However, MRI analysis is recommended when MCS measures less than 5 mm because of its heightened accuracy and reduced false positive rates. Enhanced diagnostic capabilities promise more effective management of patients with SER ankle fractures.²¹

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Important Notices

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Lumbar Spine

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Lumbar Spine

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁵

- [National Coverage Determination \(NCD\) Magnetic Resonance Imaging \(MRI\) \(220.2\)](#)
- [Local Coverage Determination \(LCD\) Lumbar MRI \(L34220\)](#)
 - [Billing and Coding: Lumbar MRI \(A57206\)](#)
- [Local Coverage Determination \(LCD\) Lumbar MRI \(L37281\)](#)
 - [Billing and Coding: Lumbar MRI \(A57207\)](#)

Description

Magnetic resonance imaging (MRI) is a versatile imaging technique that operates on the interaction between radiofrequency electromagnetic fields and specific atomic nuclei in the body, typically hydrogen nuclei, following exposure to a powerful magnetic field. This method allows for the discrimination between normal and abnormal tissues, offering a highly sensitive diagnostic tool for detecting diseases. The effectiveness of MRI stems from the notable contrast inherent in various tissues, both healthy and diseased, owing to differences in their magnetic relaxation properties. MRI of the spine is the preferred imaging modality for pain, radiculopathy, or neurological symptoms. This includes clinical suspicion of cancer, infection, autoimmune disease, persistent symptoms following six weeks of conservative management, or new or worsening symptoms with a history of spine surgery.⁶

Contrast should be used at the discretion of the ordering clinician, with guidance from the radiologist as needed. Common indications for administering contrast for an MRI of the spine include infection, prior spine surgery, demyelinating diseases, or tumor. A detailed patient history and indication will ensure the appropriate region is covered when ordering an MRI

of the spine. For many patients with neck or back pain, symptoms resolve after a trial of conservative treatment without performing imaging, especially patients with low back pain.⁷

Medical Necessity Criteria

Indications

Magnetic resonance imaging (MRI), lumbar spine is considered appropriate if **ANY** of the following is **TRUE**^{2,3}:

- Patient history and physical examination reveal the existence of **ANY** of the following “red flag” conditions:
 - Suspected tumor; **OR**
 - Infection; **OR**
 - Herniated intervertebral disc with nerve compression; **OR**
 - Major neurological problem; **OR**
 - Major trauma; **OR**
 - Minor trauma in patient with potential osteoporosis; **OR**
 - History of cancer; **OR**
 - Fever; **OR**
 - Chills; **OR**
 - Unexplained weight loss; **OR**
 - Recent bacterial infection; **OR**
 - Intravenous drug abuse; **OR**
 - History of immune suppression; **OR**
 - Pain that worsens when supine at night; **OR**
 - Saddle anesthesia; **OR**
 - Recent onset of bladder dysfunction; **OR**
 - Clinically significant or progressive neurologic deficit in the lower extremity; **OR**
 - Unexpected laxity of the anal sphincter; **OR**
 - Perianal or perineal sensory loss; **OR**
 - Clinically significant motor weakness; **OR**
 - Other nerve root compromise; **OR**
- Evaluation of a known “red flag” condition to determine need for surgery or other aggressive therapy; **OR**
- **ALL** of the following:
 - Symptoms are not suggestive of a “red flag” condition; **AND**

- Symptoms persist despite at least 4 weeks of conservative management; **OR**
- To clarify inconclusive findings on a computed tomography (CT) scan; **OR**
- Repeat imaging (defined as a repeat request following recent imaging of the same anatomic region with the same or similar modality) will be considered reasonable and necessary if **ALL** of the following are **TRUE**:
 - There are no established guidelines; **AND**
 - **ANY** of the following:
 - There are new or worsening symptoms not addressed in the guidelines, such that repeat imaging would influence treatment; **OR**
 - There is need for a one-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

Magnetic resonance imaging (MRI), lumbar spine is not considered appropriate if **ANY** of the following is **TRUE**^{2,3}:

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms⁸; **OR**
- **ALL** of the following^{2,3}:
 - **ANY** of the following:
 - Uncomplicated degenerative disc disease; **OR**
 - Herniated nucleus pulposus; **AND**
 - Surgery or other aggressive intervention (e.g. intervertebral joint injection) are not under consideration; **OR**
- For measurement of blood flow^{2,3}; **OR**
- For purposes of spectroscopy^{2,3}; **OR**
- Cortical bone and calcification is being imaged^{2,3}; **OR**
- Spatial resolution of bone or calcification is required for a procedure^{2,3}.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72148	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, lumbar; without contrast material
72149	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, lumbar; with contrast material(s)
72158	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; lumbar

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for magnetic resonance imaging of the lumbar spine may include¹²:

- The use of contrast agents (e.g., gadolinium-based contrast agents) may have adverse effects including nausea, headache, and pain at the site of injection. Rarely, patients experience hives, itchy eyes, or other allergic reactions to the contrast material.
- Dynamic magnetic fields during MRI scanning create loud knocking noises which may harm hearing if adequate ear protection is not used. They may also cause peripheral muscle or nerve stimulation that may feel like a twitching sensation.
- MRI scanning could lead to heating of the body, particularly during long MRA scans, due to radiofrequency energy used in the procedure.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria for magnetic resonance imaging of the lumbar spine may include:

- MRI of the spinal canal allows for the non-invasive visualization of the spinal cord.²
- Compared to computed tomography (CT) and radiography, MRI provides improved evaluation of soft tissue pathology. MRI of the soft tissues in the cervical spine is typically indicated when there is neurologic deficit or clinical suspicion of a vascular abnormality following trauma. Pulse sequence, a short-tau inversion-recovery sequence in MRI, can highlight undetected fractures, bone bruising, and tumors using fat suppression.¹³

- MRI without and with contrast of the affected spine segment is the initial diagnostic test of choice when spinal infection is clinically suspected. The sensitivity, specificity, and accuracy of MRI in spine infection are 96%, 94%, and 92%, respectively.¹⁴
- MRI allows timely diagnosis and treatment for spine emergencies. Traumatic spine injury classification systems provide an algorithm for clinical decision-making. Diagnostic considerations for atraumatic spine emergencies are broad, and MRI is the first line imaging modality for detecting compressive pathology.⁹
- Enhanced overall patient satisfaction and healthcare experience.

Medical Evidence

Mathieu and Talbott (2022) assessed the use of magnetic resonance imaging (MRI) in spinal emergencies. As an adjunct to CT, MRI has proven to be most valuable when additional imaging is necessary to assess spinal stability or compromise of neural elements. Vessel wall imaging techniques and MRA may also be utilized in cases of blunt traumatic cerebrovascular injury, mainly when findings from CTA are inconclusive. The American College of Radiology (ACR) has established guidelines outlining the appropriateness of MRI usage in various clinical scenarios related to spinal injuries and emergencies. MRI is considered 'usually appropriate' for patients with confirmed or suspected spinal cord or nerve root injuries.⁹

Suri et al. (2021) reported on a randomized control trial (RCT) that investigated the impact of inserting epidemiological benchmarks into lumbar spine imaging reports as part of the Lumbar Imaging with Reporting of Epidemiology (LIRE) trial. The trial analyzed secondary outcomes, focusing on subsequent nonsurgical and surgical procedures involving the thoracolumbosacral spine and sacroiliac joints. The study included 238,886 adult patients who underwent lumbar diagnostic imaging between 2013 and 2016. Results indicated that including epidemiological benchmarks (the 'LIRE intervention') did not significantly affect the utilization of non-surgical procedures (e.g., lumbosacral epidural steroid injections, facet joint injections, or facet joint radiofrequency ablation). In addition, the intervention did not impact surgical procedures such as decompression surgery, spinal fusion, or other spine surgeries involving the lumbar, sacral, or thoracic spine. The intervention also did not significantly affect any specific spine procedure.¹⁰

Ghaffari-Rafi et al. (2021) performed a systematic review and meta-analysis on the role of MRI in clinical decision-making in acute spinal cord injury. Obtaining MRI scans significantly influences the clinical management of patients experiencing acute spinal cord injury (SCI) across all presentations. Guidelines support MRI scans in adult patients with acute SCI before surgical intervention, when feasible, to enhance clinical decision-making. Additional research is needed to establish the utility and efficacy of MRI in various types of SCI further.¹¹

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Policy Revision History/Information

Original Date: October 2, 2025		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Neck/Orbit/Face

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 24, 2024

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Neck/Orbit/Face

Date of last literature review: 10/01/2024

Document last updated: 10/23/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Neck/Orbit/Face

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁷

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\)\(220.2\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L37373\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57204\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L35175\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\)](#)

Recommended Clinical Approach

Magnetic resonance imaging (MRI) is a versatile imaging technique that operates on the interaction between radiofrequency electromagnetic fields and specific nuclei in the body, typically hydrogen nuclei, following exposure to a powerful magnetic field. This method allows for the discrimination between normal and abnormal tissues, offering a highly sensitive diagnostic tool for detecting diseases. The effectiveness of MRI stems from the notable contrast inherent in various healthy and diseased tissues, owing to differences in their magnetic relaxation properties.⁸ Because of the complex anatomy of the neck, orbit, and face, and the many available imaging

choices, clear communication of the patient's symptoms and physical exam findings by the referring clinician to the interpreting radiologists is most critical in choosing the best imaging exam to address the patient's problem.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI), neck/orbit/face. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁸⁻¹⁰
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁸⁻¹⁰
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for magnetic resonance imaging (MRI) in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.¹¹
- There is a risk of increased healthcare costs and complications from the inappropriate use of emergency services and additional interventions.¹²

The clinical benefits of using these criteria include:

- MRI of the orbits can reveal abnormal thickening of medial and inferior recti muscles associated with orbital inflammatory syndrome when serologic laboratory data is unrevealing.¹³
- MRI is the most widely studied modality in patients with suspected olfactory dysfunction, along with detailed medical history and orthonasal smell tests. Anosmia and hyposmia have many etiologies, including trauma, chronic sinusitis, neoplasms, and respiratory viral infections. Criteria for the timing and sequence of imaging modalities vary in patients with olfactory dysfunction.¹⁴⁻¹⁵
- MRI and computed tomography (CT) are the primary imaging modalities used to evaluate patients with visual loss and are often complementary in evaluating these patients.¹⁶
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), neck/orbit/face** is considered appropriate if **ANY** of the following is **TRUE**:

◆ **ANY** of the following orbital indications:

- Trauma-related conditions, including traumatic visual defect with suspected orbital injury¹⁶; **OR**
- Trauma that is not related to the cervical spine; **OR**
- **ANY** of the following conditions, known or suspected:
 - Congenital conditions (e.g. capillary hemangioma, optic nerve hypoplasia); **OR**

- Neoplastic conditions, benign or malignant, detection, and follow-up (e.g., dermoid, lymphoma, metastases)¹⁶⁻¹⁷; **OR**
- Orbital pseudotumor or orbital inflammatory disease; **OR**
- Osseous lesions (e.g., fibrodysplasia, Paget's), when computed tomography (CT) is completed or contraindicated and further evaluation is needed; **OR**
- Foreign body, suspected clinically or seen on prior imaging when CT is completed or contraindicated and further evaluation is needed; **OR**
- Orbital infectious process, suspected or known, and **ANY** of the following is **TRUE**:
 - ◆ Medical management has failed (e.g., orbital cellulitis not responding appropriately to antibiotics); **OR**
 - ◆ The patient is pediatric; **OR**
 - ◆ The patient is immunocompromised; **OR**
- Optic nerve inflammation is suspected, including optic neuritis; **OR**
- Scleritis confirmed clinically with failure of medical management or with complication suspected¹⁸; **OR**
- Uveitis, confirmed clinically with complication suspected; **OR**
- Thyroid orbitopathy¹⁹; **OR**
- Venous conditions, such as orbital varices; **OR**
- Additional evaluation is needed when etiology remains unclear following a complete eye examination that includes funduscopy, including **ANY** of the following:
 - Diplopia; **OR**
 - Enophthalmos; **OR**
 - Exophthalmos; **OR**
 - Eye pain, with history or other signs or symptoms indicating non-ischemic pathology; **OR**
 - Orbital asymmetry; **OR**
 - Preseptal or postseptal orbital mass, otherwise unexplained; **OR**
 - Ophthalmoplegia; **OR**

- Eye movement abnormality in a child (e.g., strabismus or nystagmus in a child 6 months or older); **OR**
- Proptosis; **OR**
- Unilateral papilledema; **OR**
- Orbital hemorrhage, when the underlying lesion is suspected, and CT has been completed; **OR**
- Vision loss or visual field deficit with history or other signs/symptoms indicating non-ischemic intra-orbital pathology; **OR**
- Preoperative, postoperative, or pre-treatment evaluation for surgery, radiation, or chemotherapy; **OR**
- ◆ Temporal bone and inner ear indications including **ANY** of the following:
 - MRI-preferred indications, including **ANY** of the following:
 - Cholesteatoma, initial, and 9 to 12-month postoperative follow-up; **OR**
 - Sensorineural hearing loss, acquired or congenital; **OR**
 - Bell's palsy or other facial nerve abnormalities requiring evaluation of the extracranial portion of the nerve; **OR**
 - Tinnitus, unexplained by history or physical examination, and is worsening or affects daily function; **OR**
 - CT is contraindicated or already performed, and further evaluation is needed, including **ANY** of the following:
 - **ANY** of the following conditions, known or suspected²⁰:
 - ◆ Neoplastic conditions, detection, and follow-up (including tumors of the internal or external auditory canal, inner ear, and mastoid); **OR**
 - ◆ Otitis media, recurrent with at least 3 episodes in the past 12 months, with complications suspected (e.g., hearing loss, intracranial extension, mastoiditis); **OR**
 - ◆ Malignant otitis externa, unresponsive to antibiotics; **OR**
 - ◆ Mastoiditis; **OR**

- ◆ Other infectious processes involving the middle or inner ear, where imaging is needed to direct appropriate management; **OR**
- Symptoms/signs, evaluated by complete auditory examination including **ANY** of the following²⁰:
 - ◆ Conductive, mixed-conductive, or congenital hearing loss; **OR**
 - ◆ Total deafness, otherwise unexplained; **OR**
 - ◆ Vertigo, unexplained by history or physical examination with **ANY** of the following:
 - Worsening symptoms; **OR**
 - Affects daily function; **OR**
 - Associated hearing loss or other neurological deficits; **OR**
 - History of prior infection, such as otitis or meningitis; **OR**
 - History of prior trauma; **OR**
- Trauma-related conditions related to the ear, further evaluation after CT completed²¹⁻²³; **OR**
- Vascular conditions, known or suspected, related to the ear or temporal bone including evaluation of pulsatile tinnitus²⁴; **OR**
- Preoperative, postoperative, or pre-treatment evaluation for surgery, radiation, or chemotherapy (including evaluation for cochlear implant); **OR**
- ◆ Face/paranasal sinus indications, including **ANY** of the following:
 - **ANY** of the following MR-preferred indications:
 - Bell's palsy or other facial nerve abnormalities requiring evaluation of the extracranial portion of the nerve; **OR**
 - Trigeminal neuralgia with **ANY** of the following²⁵:
 - ◆ Atypical trigeminal neuralgia, defined by **ANY** of the following symptoms:
 - Bilateral hearing loss; **OR**
 - Dizziness/vertigo; **OR**
 - Visual changes; **OR**
 - Sensory loss or numbness; **OR**
 - Pain greater than 2 minutes; **OR**

- Pain outside trigeminal nerve distribution and progression; **OR**
 - ◆ Refractory trigeminal neuralgia when done for surgical planning; **OR**
- Conditions (known or suspected), with CT either contraindicated or already performed, and further evaluation is needed for **ANY** of the following²⁰:
 - Anatomic abnormalities (e.g. deviated septum), suspected as a cause of patient symptoms and surgical management is being considered; **OR**
 - Congenital conditions and craniofacial abnormalities⁸; **OR**
 - Sinusitis and **ANY** of the following is **TRUE**^{8,26-28}:
 - ◆ Four or more acute episodes per year and surgery/biologic therapy are contemplated; **OR**
 - ◆ Not resolving despite 2 courses of antibiotics; **OR**
 - ◆ A complication is suspected (e.g., abscess formation, involvement of adjacent structures, such as orbits, cavernous sinus, or intracranial); **OR**
 - ◆ The patient is immunocompromised, and invasive fungal sinusitis is suspected; **OR**
 - ◆ Allergic fungal sinusitis (AFS) suspected, with failed medical treatment or surgery is contemplated; **OR**
 - ◆ Chronic rhinosinusitis, symptomatic (discharge, congestion, anosmia, pain), severity staging or restaging when management change is contemplated; **OR**
 - Osteomyelitis; **OR**
 - Odontogenic infections with suspected complications (e.g., abscess formation, facial swelling, nerve, sinus involvement); **OR**
 - Unexplained facial swelling (e.g., over the mandible); **OR**
 - Foreign body (suspected), clinically or seen on prior imaging; **OR**

- Neoplastic conditions for initial staging, treatment planning, response assessment, and surveillance; **OR**
- Lymphadenopathy with failure of conservative management (e.g., rest, antibiotics, anti-inflammatory, analgesics) that is documented for a period of greater than two weeks for reactive adenopathy; **OR**
- Sinonasal polyposis detected on nasal endoscopy with **ALL** of the following^{26,29}:
 - ◆ The patient is symptomatic; **AND**
 - ◆ No relief with appropriate medical therapy, such as systemic corticosteroids, antihistamines, and antibiotics; **AND**
 - ◆ Surgical intervention or biologic therapy is being contemplated; **OR**
- Known sinonasal polyposis with complications suspected, such as involvement of the orbits; **OR**
- Non-infectious inflammatory involvement of the sinus is suspected based on clinical history and symptoms, such as a history of granulomatosis with polyangiitis¹; **OR**
- Salivary gland disorder (e.g. chronic unexplained xerostoma, autoimmune involvement, palpable mass, or salivary duct evaluation via MR sialography); **OR**
- Vascular malformations, such as arteriovenous malformations^{8,24}; **OR**
- For evaluation of **ANY** of the following symptoms when applicable:
 - Anosmia with **ANY** of the following³⁰:
 - ◆ Persistent anosmia with nondiagnostic endoscopy; **OR**
 - ◆ Abnormal endoscopy with further evaluation needed; **OR**
 - ◆ Known or suspected neoplasm; **OR**
 - ◆ History of head or facial trauma; **OR**
 - Cerebrospinal fluid (CSF) leak (MR cisternography), confirmed on testing or strong clinical history, such as prior trauma or CSF leak that increases after Valsalva

maneuvers, further evaluation after CT is completed²⁶; **OR**

- Epistaxis with failure of conservative management (e.g., nasal packing/tampon, cautery, etc) **OR**
- Epistaxis with detection of mass, polyp, or other pathology on examination that requires further evaluation⁸; **OR**

◆ Neck indications, including **ANY** of the following:

- Initial staging, treatment assessment, and surveillance of known malignant conditions in the neck not otherwise listed (e.g., nasopharynx, oropharynx, hypopharynx, larynx, salivary glands, jaw, oral cavity); **OR**
- Thyroid masses or goiter when ultrasound is non-diagnostic or requires further work-up; **OR**
- Lymphadenopathy or palpable mass, when **ANY** of the following is **TRUE**³¹:
 - Unlikely to be due to infection (non-mobile, firm, greater than 1.5 cm, or history of cancer); **OR**
 - Ultrasound was suspicious for malignancy; **OR**
 - Not resolving despite at least 2 weeks of conservative management (watchful waiting, antibiotics, etc.); **OR**
 - Overlying skin changes present, such as ulceration **OR**
 - Lymphadenopathy in a patient older than 50 years; **OR**
 - Mass or lesion detected on laryngoscopy; **OR**
- Assessment of signs and symptoms, including **ANY** of the following:
 - Odynophagia; **OR**
 - Globus sensation or dysphagia when clinical examination, including endoscopy and fluoroscopy, are negative or require further evaluation; **OR**
 - Vocal cord paralysis; **OR**
 - Neck pain that is not related to cervical spine or dissection and has not resolved with conservative treatment (e.g., rest and analgesics) that is documented for a period of greater than 4 weeks; **OR**
 - Cranial neuropathy of cranial nerves (CN) 9–11; **OR**

- Brachial plexus pathology, suspected due to anatomic (e.g. cervical rib) or clinical symptoms (e.g., positive electromyography [EMG]) results, symptoms related to scalene muscles, symptoms that worsen with arm overhead), includes but not limited to trauma, neurogenic thoracic outlet syndrome, neuropathies affecting brachial plexus (e.g, chronic inflammatory demyelinating polyneuropathy [CIDP], or suspected or known mass); **OR**
- Infectious conditions (e.g., tonsillitis, epiglottitis, cellulitis, etc.) when **ANY** of the following is **TRUE**:
 - Suspected compromise of the airway; **OR**
 - Surgery is planned; **OR**
 - Not improving with appropriate therapy; **OR**
 - Retropharyngeal abscess suspected; **OR**
 - Ludwig's angina, suspected; **OR**
- Localization of parathyroid adenoma when lab tests indicate primary hyperparathyroidism and neck ultrasound and Sestamibi scan (nuclear medicine scan) are normal or nondiagnostic³²; **OR**
- Presurgical evaluation, planning, or guidance, including radiation planning; **OR**
- Foreign body when initial radiographs and CT are non-diagnostic, unavailable, or contraindicated; **OR**
- Suspected extracapsular spread of a tumor into the surrounding neck structures; **OR**
- Suspected recurrent thyroid cancer or rising thyroglobulin, with negative ultrasound and physical exams to detect occult neck nodes¹⁹; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**

- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance imaging (MRI), neck/orbit/face** may not be considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; **OR**
- ◆ Cortical bone imaging and calcification; **OR**
- ◆ Procedures involving spatial resolution of bone or calcification

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70540	Magnetic resonance imaging (MRI) (e.g., proton); orbit, face and/or neck; without contrast material(s)
70542	Magnetic resonance imaging (MRI) (e.g., proton); orbit, face and/or neck; with contrast material(s)
70543	Magnetic resonance imaging (MRI) (e.g., proton); orbit, face and/or neck; without contrast material(s) and further sequences

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Saltagi et al. (2021) reviewed spontaneous intracranial hypotension (SIH). The condition manifests as decreased cerebrospinal fluid (CSF) volume due to leakage through a dural defect, occurring without a discernible underlying cause. Magnetic resonance imaging (MRI) is a preferred initial, non-invasive diagnostic tool (with and without gadolinium contrast enhancement). Spinal MRI or CT myelography is useful for extradural fluid collection to identify a 'fast' leak; a dynamic CT myelogram or digital subtraction myelogram can locate the precise leak. Spine MRI may reveal secondary findings indicative of SIH, such as dural thickening, enhancement, or engorgement of the epidural venous plexus.¹⁴

Bond et al. (2020) present a review of the diagnostic evaluation of anosmia and hyposmia, including etiology (e.g., trauma, chronic sinusitis, neoplasms, respiratory viral infections). Smell tests primarily diagnose the conditions; however, MRI is often widely used. Functional MRI can diagnose suspected post-traumatic abnormalities.¹⁵

Nael et al. (2015) conducted a study to identify distinctive MR perfusion patterns (PTAs) to allow differentiation from neighboring thyroid tissue and cervical lymph nodes, which may exhibit similar imaging characteristics. Utilizing dynamic 4D contrast-enhanced MR imaging enables the exploitation of the hypervascular features of PTAs. Multiparametric MR perfusion analysis demonstrates a diagnostic accuracy of 96% in distinguishing PTAs from adjacent thyroid tissue or lymph nodes.³³

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Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Neck/Orbit/Face

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 24, 2024

Important Notices

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Neck/Orbit/Face

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁷

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\)\(220.2\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L37373\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57204\)](#)
- [Local Coverage Determination \(LCD\). MRI and CT Scans of the Head and Neck \(L35175\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\)](#)

Recommended Clinical Approach

Magnetic resonance imaging (MRI) is a versatile imaging technique that operates on the interaction between radiofrequency electromagnetic fields and specific nuclei in the body, typically hydrogen nuclei, following exposure to a powerful magnetic field. This method allows for the discrimination between normal and abnormal tissues, offering a highly sensitive diagnostic tool for detecting diseases. The effectiveness of MRI stems from the notable contrast inherent in various healthy and diseased tissues, owing to differences in their magnetic relaxation properties.⁸ Because of the complex anatomy of the neck, orbit, and face, and the many available imaging

choices, clear communication of the patient's symptoms and physical exam findings by the referring clinician to the interpreting radiologists is most critical in choosing the best imaging exam to address the patient's problem.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI), neck/orbit/face. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁸⁻¹⁰
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁸⁻¹⁰
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for magnetic resonance imaging (MRI) in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.¹¹
- There is a risk of increased healthcare costs and complications from the inappropriate use of emergency services and additional interventions.¹²

The clinical benefits of using these criteria include:

- MRI of the orbits can reveal abnormal thickening of medial and inferior recti muscles associated with orbital inflammatory syndrome when serologic laboratory data is unrevealing.¹³
- MRI is the most widely studied modality in patients with suspected olfactory dysfunction, along with detailed medical history and orthonasal smell tests. Anosmia and hyposmia have many etiologies, including trauma, chronic sinusitis, neoplasms, and respiratory viral infections. Criteria for the timing and sequence of imaging modalities vary in patients with olfactory dysfunction.¹⁴⁻¹⁵
- MRI and computed tomography (CT) are the primary imaging modalities used to evaluate patients with visual loss and are often complementary in evaluating these patients.¹⁶
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), neck/orbit/face** is considered appropriate if **ANY** of the following is **TRUE**:

◆ **ANY** of the following orbital indications:

- Trauma-related conditions, including traumatic visual defect with suspected orbital injury¹⁶; **OR**
- Trauma that is not related to the cervical spine; **OR**
- **ANY** of the following conditions, known or suspected:
 - Congenital conditions (e.g. capillary hemangioma, optic nerve hypoplasia); **OR**

- Neoplastic conditions, benign or malignant, detection, and follow-up (e.g., dermoid, lymphoma, metastases)¹⁶⁻¹⁷; **OR**
- Orbital pseudotumor or orbital inflammatory disease; **OR**
- Osseous lesions (e.g., fibrodysplasia, Paget's), when computed tomography (CT) is completed or contraindicated and further evaluation is needed; **OR**
- Foreign body, suspected clinically or seen on prior imaging when CT is completed or contraindicated and further evaluation is needed; **OR**
- Orbital infectious process, suspected or known, and **ANY** of the following is **TRUE**:
 - ◆ Medical management has failed (e.g., orbital cellulitis not responding appropriately to antibiotics); **OR**
 - ◆ The patient is pediatric; **OR**
 - ◆ The patient is immunocompromised; **OR**
- Optic nerve inflammation is suspected, including optic neuritis; **OR**
- Scleritis confirmed clinically with failure of medical management or with complication suspected¹⁸; **OR**
- Uveitis, confirmed clinically with complication suspected; **OR**
- Thyroid orbitopathy¹⁹; **OR**
- Venous conditions, such as orbital varices; **OR**
- Additional evaluation is needed when etiology remains unclear following a complete eye examination that includes funduscopy, including **ANY** of the following:
 - Diplopia; **OR**
 - Enophthalmos; **OR**
 - Exophthalmos; **OR**
 - Eye pain, with history or other signs or symptoms indicating non-ischemic pathology; **OR**
 - Orbital asymmetry; **OR**
 - Preseptal or postseptal orbital mass, otherwise unexplained; **OR**
 - Ophthalmoplegia; **OR**

- Eye movement abnormality in a child (e.g., strabismus or nystagmus in a child 6 months or older); **OR**
- Proptosis; **OR**
- Unilateral papilledema; **OR**
- Orbital hemorrhage, when the underlying lesion is suspected, and CT has been completed; **OR**
- Vision loss or visual field deficit with history or other signs/symptoms indicating non-ischemic intra-orbital pathology; **OR**
- Preoperative, postoperative, or pre-treatment evaluation for surgery, radiation, or chemotherapy; **OR**
- ◆ Temporal bone and inner ear indications including **ANY** of the following:
 - MRI-preferred indications, including **ANY** of the following:
 - Cholesteatoma, initial, and 9 to 12-month postoperative follow-up; **OR**
 - Sensorineural hearing loss, acquired or congenital; **OR**
 - Bell's palsy or other facial nerve abnormalities requiring evaluation of the extracranial portion of the nerve; **OR**
 - Tinnitus, unexplained by history or physical examination, and is worsening or affects daily function; **OR**
 - CT is contraindicated or already performed, and further evaluation is needed, including **ANY** of the following:
 - **ANY** of the following conditions, known or suspected²⁰:
 - ◆ Neoplastic conditions, detection, and follow-up (including tumors of the internal or external auditory canal, inner ear, and mastoid); **OR**
 - ◆ Otitis media, recurrent with at least 3 episodes in the past 12 months, with complications suspected (e.g., hearing loss, intracranial extension, mastoiditis); **OR**
 - ◆ Malignant otitis externa, unresponsive to antibiotics; **OR**
 - ◆ Mastoiditis; **OR**

- ◆ Other infectious processes involving the middle or inner ear, where imaging is needed to direct appropriate management; **OR**
- Symptoms/signs, evaluated by complete auditory examination including **ANY** of the following²⁰:
 - ◆ Conductive, mixed-conductive, or congenital hearing loss; **OR**
 - ◆ Total deafness, otherwise unexplained; **OR**
 - ◆ Vertigo, unexplained by history or physical examination with **ANY** of the following:
 - Worsening symptoms; **OR**
 - Affects daily function; **OR**
 - Associated hearing loss or other neurological deficits; **OR**
 - History of prior infection, such as otitis or meningitis; **OR**
 - History of prior trauma; **OR**
- Trauma-related conditions related to the ear, further evaluation after CT completed²¹⁻²³; **OR**
- Vascular conditions, known or suspected, related to the ear or temporal bone including evaluation of pulsatile tinnitus²⁴; **OR**
- Preoperative, postoperative, or pre-treatment evaluation for surgery, radiation, or chemotherapy (including evaluation for cochlear implant); **OR**
- ◆ Face/paranasal sinus indications, including **ANY** of the following:
 - **ANY** of the following MR-preferred indications:
 - Bell's palsy or other facial nerve abnormalities requiring evaluation of the extracranial portion of the nerve; **OR**
 - Trigeminal neuralgia with **ANY** of the following²⁵:
 - ◆ Atypical trigeminal neuralgia, defined by **ANY** of the following symptoms:
 - Bilateral hearing loss; **OR**
 - Dizziness/vertigo; **OR**
 - Visual changes; **OR**
 - Sensory loss or numbness; **OR**
 - Pain greater than 2 minutes; **OR**

- Pain outside trigeminal nerve distribution and progression; **OR**
 - ◆ Refractory trigeminal neuralgia when done for surgical planning; **OR**
- Conditions (known or suspected), with CT either contraindicated or already performed, and further evaluation is needed for **ANY** of the following²⁰:
 - Anatomic abnormalities (e.g. deviated septum), suspected as a cause of patient symptoms and surgical management is being considered; **OR**
 - Congenital conditions and craniofacial abnormalities⁸; **OR**
 - Sinusitis and **ANY** of the following is **TRUE**^{8,26-28}:
 - ◆ Four or more acute episodes per year and surgery/biologic therapy are contemplated; **OR**
 - ◆ Not resolving despite 2 courses of antibiotics; **OR**
 - ◆ A complication is suspected (e.g., abscess formation, involvement of adjacent structures, such as orbits, cavernous sinus, or intracranial); **OR**
 - ◆ The patient is immunocompromised, and invasive fungal sinusitis is suspected; **OR**
 - ◆ Allergic fungal sinusitis (AFS) suspected, with failed medical treatment or surgery is contemplated; **OR**
 - ◆ Chronic rhinosinusitis, symptomatic (discharge, congestion, anosmia, pain), severity staging or restaging when management change is contemplated; **OR**
 - Osteomyelitis; **OR**
 - Odontogenic infections with suspected complications (e.g., abscess formation, facial swelling, nerve, sinus involvement); **OR**
 - Unexplained facial swelling (e.g., over the mandible); **OR**
 - Foreign body (suspected), clinically or seen on prior imaging; **OR**

- Neoplastic conditions for initial staging, treatment planning, response assessment, and surveillance; **OR**
- Lymphadenopathy with failure of conservative management (e.g., rest, antibiotics, anti-inflammatory, analgesics) that is documented for a period of greater than two weeks for reactive adenopathy; **OR**
- Sinonasal polyposis detected on nasal endoscopy with **ALL** of the following^{26,29}:
 - ◆ The patient is symptomatic; **AND**
 - ◆ No relief with appropriate medical therapy, such as systemic corticosteroids, antihistamines, and antibiotics; **AND**
 - ◆ Surgical intervention or biologic therapy is being contemplated; **OR**
- Known sinonasal polyposis with complications suspected, such as involvement of the orbits; **OR**
- Non-infectious inflammatory involvement of the sinus is suspected based on clinical history and symptoms, such as a history of granulomatosis with polyangiitis¹; **OR**
- Salivary gland disorder (e.g. chronic unexplained xerostoma, autoimmune involvement, palpable mass, or salivary duct evaluation via MR sialography); **OR**
- Vascular malformations, such as arteriovenous malformations^{8,24}; **OR**
- For evaluation of **ANY** of the following symptoms when applicable:
 - Anosmia with **ANY** of the following³⁰:
 - ◆ Persistent anosmia with nondiagnostic endoscopy; **OR**
 - ◆ Abnormal endoscopy with further evaluation needed; **OR**
 - ◆ Known or suspected neoplasm; **OR**
 - ◆ History of head or facial trauma; **OR**
 - Cerebrospinal fluid (CSF) leak (MR cisternography), confirmed on testing or strong clinical history, such as prior trauma or CSF leak that increases after Valsalva

maneuvers, further evaluation after CT is completed²⁶; **OR**

- Epistaxis with failure of conservative management (e.g., nasal packing/tampon, cautery, etc) **OR**
- Epistaxis with detection of mass, polyp, or other pathology on examination that requires further evaluation⁸; **OR**

◆ Neck indications, including **ANY** of the following:

- Initial staging, treatment assessment, and surveillance of known malignant conditions in the neck not otherwise listed (e.g., nasopharynx, oropharynx, hypopharynx, larynx, salivary glands, jaw, oral cavity); **OR**
- Thyroid masses or goiter when ultrasound is non-diagnostic or requires further work-up; **OR**
- Lymphadenopathy or palpable mass, when **ANY** of the following is **TRUE**³¹:
 - Unlikely to be due to infection (non-mobile, firm, greater than 1.5 cm, or history of cancer); **OR**
 - Ultrasound was suspicious for malignancy; **OR**
 - Not resolving despite at least 2 weeks of conservative management (watchful waiting, antibiotics, etc.); **OR**
 - Overlying skin changes present, such as ulceration **OR**
 - Lymphadenopathy in a patient older than 50 years; **OR**
 - Mass or lesion detected on laryngoscopy; **OR**
- Assessment of signs and symptoms, including **ANY** of the following:
 - Odynophagia; **OR**
 - Globus sensation or dysphagia when clinical examination, including endoscopy and fluoroscopy, are negative or require further evaluation; **OR**
 - Vocal cord paralysis; **OR**
 - Neck pain that is not related to cervical spine or dissection and has not resolved with conservative treatment (e.g., rest and analgesics) that is documented for a period of greater than 4 weeks; **OR**
 - Cranial neuropathy of cranial nerves (CN) 9–11; **OR**

- Brachial plexus pathology, suspected due to anatomic (e.g. cervical rib) or clinical symptoms (e.g., positive electromyography [EMG]) results, symptoms related to scalene muscles, symptoms that worsen with arm overhead), includes but not limited to trauma, neurogenic thoracic outlet syndrome, neuropathies affecting brachial plexus (e.g, chronic inflammatory demyelinating polyneuropathy [CIDP], or suspected or known mass); **OR**
- Infectious conditions (e.g., tonsillitis, epiglottitis, cellulitis, etc.) when **ANY** of the following is **TRUE**:
 - Suspected compromise of the airway; **OR**
 - Surgery is planned; **OR**
 - Not improving with appropriate therapy; **OR**
 - Retropharyngeal abscess suspected; **OR**
 - Ludwig's angina, suspected; **OR**
- Localization of parathyroid adenoma when lab tests indicate primary hyperparathyroidism and neck ultrasound and Sestamibi scan (nuclear medicine scan) are normal or nondiagnostic³²; **OR**
- Presurgical evaluation, planning, or guidance, including radiation planning; **OR**
- Foreign body when initial radiographs and CT are non-diagnostic, unavailable, or contraindicated; **OR**
- Suspected extracapsular spread of a tumor into the surrounding neck structures; **OR**
- Suspected recurrent thyroid cancer or rising thyroglobulin, with negative ultrasound and physical exams to detect occult neck nodes¹⁹; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**

- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance imaging (MRI), neck/orbit/face** may not be considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; **OR**
- ◆ Cortical bone imaging and calcification; **OR**
- ◆ Procedures involving spatial resolution of bone or calcification

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70540	Magnetic resonance imaging (MRI) (e.g., proton); orbit, face and/or neck; without contrast material(s)
70542	Magnetic resonance imaging (MRI) (e.g., proton); orbit, face and/or neck; with contrast material(s)
70543	Magnetic resonance imaging (MRI) (e.g., proton); orbit, face and/or neck; without contrast material(s) and further sequences

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Saltagi et al. (2021) reviewed spontaneous intracranial hypotension (SIH). The condition manifests as decreased cerebrospinal fluid (CSF) volume due to leakage through a dural defect, occurring without a discernible underlying cause. Magnetic resonance imaging (MRI) is a preferred initial, non-invasive diagnostic tool (with and without gadolinium contrast enhancement). Spinal MRI or CT myelography is useful for extradural fluid collection to identify a 'fast' leak; a dynamic CT myelogram or digital subtraction myelogram can locate the precise leak. Spine MRI may reveal secondary findings indicative of SIH, such as dural thickening, enhancement, or engorgement of the epidural venous plexus.¹⁴

Bond et al. (2020) present a review of the diagnostic evaluation of anosmia and hyposmia, including etiology (e.g., trauma, chronic sinusitis, neoplasms, respiratory viral infections). Smell tests primarily diagnose the conditions; however, MRI is often widely used. Functional MRI can diagnose suspected post-traumatic abnormalities.¹⁵

Nael et al. (2015) conducted a study to identify distinctive MR perfusion patterns (PTAs) to allow differentiation from neighboring thyroid tissue and cervical lymph nodes, which may exhibit similar imaging characteristics. Utilizing dynamic 4D contrast-enhanced MR imaging enables the exploitation of the hypervascular features of PTAs. Multiparametric MR perfusion analysis demonstrates a diagnostic accuracy of 96% in distinguishing PTAs from adjacent thyroid tissue or lymph nodes.³³

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Clinical Guideline Revision History/Information

Original Date: October 24, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Pelvis

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 17, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Pelvis

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻³

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)
- [Local Coverage Determination \(LCD\) Multiple Imaging in Oncology \(L35391\)](#)
- [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Recommended Clinical Approach

The use of contrast and the type of magnetic resonance (MR) contrast (e.g., extracellular or hepatobiliary-specific) should be at the request of the ordering provider with guidance from the radiologist. The MR field of view should be limited to the area of interest and, in some cases, may not be the preferred imaging study.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI) of the pelvis. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary

procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁴⁻⁶
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁴⁻⁶
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for magnetic resonance imaging (MRI) in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁷
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁸

The clinical benefits of using these criteria include:

- MRI demonstrates superior sensitivity and diagnostic accuracy in identifying acute pelvic fractures when compared to computed tomography (CT). MRI is also effective in detecting occult pelvic fractures and soft tissue anomalies.⁹
- MRI demonstrates high sensitivity and specificity in detecting various types of pelvic endometriosis. MRI allows the localization of lesions with highly fibrotic components that may not be recognizable with other imaging methods or visible during video laparoscopy.¹⁰
- Quantitative diffusion MRI of the abdomen and pelvis allows the ability to gauge tissue microstructure sensitivity. In contrast to qualitative diffusion-weighted MRI, the quantitative approach enhances the standardization of tissue characterization, which is crucial for disease detection, staging, and treatment monitoring.¹¹
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), pelvis** is considered appropriate if **ANY** of the following are **TRUE**¹²⁻¹³:

- ◆ For evaluation of the prostate with **ANY** of the following:
 - Prostatitis when symptoms worsen despite treatment¹⁴⁻¹⁶;
OR
 - For detection and surveillance of prostate cancer and **ANY** of the following:
 - Initial imaging including **ANY** of the following:
 - ◆ Biopsy is planned, and digital rectal examination (DRE) has been performed; **OR**
 - ◆ Suspicious nodule on DRE, with or without prior biopsy; **OR**
 - ◆ The patient meets intermediate or high-risk criteria, including **ANY** of the following:
 - Clinical stage T2b or higher–T2c³⁷; **OR**
 - Prostate specific antigen (PSA) greater than 10 mg/mL; **OR**
 - Gleason score greater than or equal to 7 on prior biopsy; **OR**
 - Indeterminate, intermediate-risk lesion(s) (PIRADS-3) characterized on prior MRI with prostate cancer, surveillance (up to annual)¹⁷; **OR**

- Indeterminate, low-risk lesion(s) (PIRADS-1 or PIRADS-2)
- Known prostate cancer, low-risk, annual active surveillance as defined by **ANY** of the following:
 - ◆ PSA less than 10 mg/mL **OR**
 - ◆ Low clinical tumor grade (cT1-cT2a); **OR**
 - ◆ Grade Group 1 (Gleason score less than or equal to 6)¹⁷; **OR**
- Prostate cancer, post-treatment follow-up for **ANY** of the following indications:
 - ◆ Detectable and rising PSA; **OR**
 - ◆ Prior radical prostatectomy (surgical removal of the whole of the prostate) with detectable PSA; **OR**
- Prostate cancer, metastatic with concern for progression; **OR**
- ◆ For the evaluation of the uterus, ovaries, or cervix, including **ALL** of the following:
 - Ultrasound has been performed; **AND**
 - **ANY** of the following:
 - Intrauterine pregnancy with the presence of **ANY** of the following on pelvic ultrasound:
 - ◆ Fetal anomalies¹⁸; **OR**
 - ◆ Placental attachment disorders (e.g., placenta accreta, placenta increta)¹⁹; **OR**
 - Follow-up to initial imaging study for further evaluation to characterize a uterine abnormality or lesion if pelvic ultrasound results are inconclusive^{13,21}; **OR**
 - Further evaluation of dysfunctional uterine bleeding when ultrasound was indeterminate; **OR**
 - Known or suspected malignancies, including **ANY** of the following:
 - ◆ Uterine, ovarian, or cervical cancer, including borderline tumors such as Brenner tumor and moles (gestational trophoblastic tumors); **OR**
 - ◆ Endometrial cancer, biopsy-proven, staging, and follow-up; **OR**

- ◆ Pelvic abnormalities as indicated by **ALL** of the following^{4,15}:
 - **ANY** of the following is **TRUE**:
 - Ultrasound has been performed and is indeterminate; **OR**
 - Ultrasound has been performed, and the patient requires further evaluation or surgical planning; **AND**
 - **ANY** of the following:
 - Abscess of the pelvis^{23,24}; **OR**
 - Endometriosis with involvement beyond the ovary²¹; **OR**
 - Pelvic organ prolapse²⁵; **OR**
 - Uterine leiomyoma (fibroid) when an intervention is planned²⁶; **OR**
 - Urethral stricture or mass; **OR**
 - Pelvic neoplasms; **OR**
 - Uterine or cervical abnormalities; **OR**
- ◆ Musculoskeletal imaging of the pelvis when plain radiograph is inconclusive, including **ANY** of the following:
 - Sacroiliac joint, including inflammatory arthropathies such as psoriatic arthritis or ankylosing spondylitis²⁷; **OR**
 - Lumbosacral plexopathy²⁸; **OR**
 - Potential bony infection (osteomyelitis)²⁹; **OR**
 - Septic arthritis²⁹; **OR**
 - Characterization, staging, or follow-up of a bony lesion for suspected or known malignancy or metastatic disease³⁰; **OR**
 - Ulcer or wound with clinical concern for soft tissue infection or osteomyelitis²⁹; **OR**
 - Persistent athletic pubalgia (sports hernia) or osteitis pubis after 3 months of conservative treatment³⁰; **OR**
 - Trauma-related conditions including suspected traumatic or stress fracture with indeterminate CT³¹⁻³³; **OR**
 - Avascular necrosis (AVN) or osteonecrosis; **OR**
- ◆ Other evaluation of the pelvis when ultrasound is not appropriate or non-diagnostic, computed tomography (CT) is contraindicated or inconclusive, and **ANY** of the following is **TRUE**:
 - Extension of an indicated abdominal MRI for complete evaluation of organs and structures such as ureters or

bowel (e.g., MR enterography, MR urography) or for neoplastic staging; **OR**

- Pouchitis¹⁴; **OR**
- Fistula; **OR**
- Lymphadenopathy; **OR**
- Neoplastic conditions for **ANY** of the following:
 - Initial staging; **OR**
 - Treatment planning; **OR**
 - Response assessment; **OR**
 - Surveillance, and **ANY** of the following is **TRUE**^{2-3,34-36}:
 - ◆ The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - ◆ Suspected recurrence/progression; **OR**
 - ◆ Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6-8 weeks since the prior imaging evaluation); **OR**
- Follow-up to initial imaging study for further evaluation to characterize an abnormality/lesion related to an infection; **OR**
- For evaluation of **ANY** of the following miscellaneous pathologies when prior testing has failed:
 - Further work-up or characterization of initial abnormal findings on physical or clinical exam including **ANY** of the following:
 - ◆ Lumbosacral plexopathy²⁸; **OR**
 - ◆ Potential bony infection (osteomyelitis)²⁹; **OR**
 - ◆ Septic arthritis²⁹; **OR**
 - ◆ Ulcer or wound with clinical concern for infection²⁹; **OR**
 - Peri-anal fissures; **OR**
 - Pre-treatment for treatment planning, including staging (e.g., interventional radiology procedures, before biopsy, radiation, surgery); **OR**
- Follow-up to initial imaging study for further evaluation to

characterize an abnormality/lesion related to congenital anomalies; **OR**

- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality) in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following are true:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance imaging (MRI), pelvis** may not be considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72195	Magnetic resonance imaging (MRI) (e.g., proton), pelvis; without contrast material(s)
72196	Magnetic resonance imaging (MRI) (e.g., proton), pelvis;

	with contrast material(s)
72197	Magnetic resonance imaging (MRI) (e.g., proton), pelvis; without contrast material(s) followed by contrast material(s) and further sections

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Almansouri et al. (2024) performed a systematic review to analyze the role of magnetic resonance imaging (MRI) and computed tomography (CT) for pelvic fractures. Twelve studies were analyzed involving 1,798 patients (52% female). Two of the studies were prospective, and the remaining ten were retrospective. Diagnosing and managing pelvic fractures necessitates a personalized approach considering patient characteristics, injury mechanisms, and hemodynamic status. The authors note that MRI demonstrates superior sensitivity and diagnostic accuracy in identifying acute pelvic fractures, mainly concealed sacral fractures. MRI is also effective in detecting occult pelvic fractures and soft tissue anomalies. However, despite its diagnostic benefits, MRI is unlikely to replace CT as the initial gold standard due to factors such as shorter emergency department time and contraindications for MRI, especially in elderly patients. CT scanning remains preferred for initial diagnosis, aiding in the determination of emergent angiographic embolization needs and facilitating surgical planning in cases of pelvic fractures.⁹

Manti et al. (2022) conducted a prospective study that included 72 patients with symptoms indicative of endometriosis who underwent evaluation to plan surgical treatment. The mean age of the patients was 35.5 years (range: 20-46 years). Pelvic endometriosis was pathologically confirmed in 56 (77.7%) of the 72 patients. Among them, 22 patients (39.3%) underwent video laparoscopy (VLS), and 16 (72.2%) of those underwent surgery. MRI demonstrated high sensitivity and specificity for detecting various types of pelvic endometriosis. MRI allows the localization of lesions with highly fibrotic components that may not be recognizable with other imaging methods or visible during video laparoscopy.¹⁰

Hernando et al. (2022) reviewed quantitative diffusion MRI of the abdomen and pelvis, which involves employing multiple diffusion encodings and mapping diffusion parameters. Diffusion MRI allows the ability to gauge tissue microstructure sensitivity. In contrast to qualitative diffusion-weighted MRI, the quantitative approach enhances the standardization of tissue characterization, which is crucial for disease detection, staging, and treatment monitoring. Challenges include acquisition artifacts, limitations in signal modeling, and biological variability. Technical performance concerns include addressing physiologic motion (respiratory, peristaltic, and pulsatile), handling image distortions, and managing a low signal-to-noise ratio. Currently, multi-center studies focus on validation through systematic assessments to assess reproducibility.¹¹

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Clinical Guideline Revision History/Information

Original Date: October 17, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Pelvis

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 17, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Pelvis

Date of last literature review: 10/15/2024

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Pelvis

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻³

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)
- [Local Coverage Determination \(LCD\) Multiple Imaging in Oncology \(L35391\)](#)
- [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Recommended Clinical Approach

The use of contrast and the type of magnetic resonance (MR) contrast (e.g., extracellular or hepatobiliary-specific) should be at the request of the ordering provider with guidance from the radiologist. The MR field of view should be limited to the area of interest and, in some cases, may not be the preferred imaging study.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI) of the pelvis. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary

procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁴⁻⁶
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁴⁻⁶
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for magnetic resonance imaging (MRI) in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁷
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁸

The clinical benefits of using these criteria include:

- MRI demonstrates superior sensitivity and diagnostic accuracy in identifying acute pelvic fractures when compared to computed tomography (CT). MRI is also effective in detecting occult pelvic fractures and soft tissue anomalies.⁹
- MRI demonstrates high sensitivity and specificity in detecting various types of pelvic endometriosis. MRI allows the localization of lesions with highly fibrotic components that may not be recognizable with other imaging methods or visible during video laparoscopy.¹⁰
- Quantitative diffusion MRI of the abdomen and pelvis allows the ability to gauge tissue microstructure sensitivity. In contrast to qualitative diffusion-weighted MRI, the quantitative approach enhances the standardization of tissue characterization, which is crucial for disease detection, staging, and treatment monitoring.¹¹
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), pelvis** is considered appropriate if **ANY** of the following are **TRUE**¹²⁻¹³:

- ◆ For evaluation of the prostate with **ANY** of the following:
 - Prostatitis when symptoms worsen despite treatment¹⁴⁻¹⁶;
OR
 - For detection and surveillance of prostate cancer and **ANY** of the following:
 - Initial imaging including **ANY** of the following:
 - ◆ Biopsy is planned, and digital rectal examination (DRE) has been performed; **OR**
 - ◆ Suspicious nodule on DRE, with or without prior biopsy; **OR**
 - ◆ The patient meets intermediate or high-risk criteria, including **ANY** of the following:
 - Clinical stage T2b or higher–T2c³⁷; **OR**
 - Prostate specific antigen (PSA) greater than 10 mg/mL; **OR**
 - Gleason score greater than or equal to 7 on prior biopsy; **OR**
 - Indeterminate, intermediate-risk lesion(s) (PIRADS-3) characterized on prior MRI with prostate cancer, surveillance (up to annual)¹⁷; **OR**

- Indeterminate, low-risk lesion(s) (PIRADS-1 or PIRADS-2)
- Known prostate cancer, low-risk, annual active surveillance as defined by **ANY** of the following:
 - ◆ PSA less than 10 mg/mL **OR**
 - ◆ Low clinical tumor grade (cT1-cT2a); **OR**
 - ◆ Grade Group 1 (Gleason score less than or equal to 6)¹⁷; **OR**
- Prostate cancer, post-treatment follow-up for **ANY** of the following indications:
 - ◆ Detectable and rising PSA; **OR**
 - ◆ Prior radical prostatectomy (surgical removal of the whole of the prostate) with detectable PSA; **OR**
- Prostate cancer, metastatic with concern for progression; **OR**
- ◆ For the evaluation of the uterus, ovaries, or cervix, including **ALL** of the following:
 - Ultrasound has been performed; **AND**
 - **ANY** of the following:
 - Intrauterine pregnancy with the presence of **ANY** of the following on pelvic ultrasound:
 - ◆ Fetal anomalies¹⁸; **OR**
 - ◆ Placental attachment disorders (e.g., placenta accreta, placenta increta)¹⁹; **OR**
 - Follow-up to initial imaging study for further evaluation to characterize a uterine abnormality or lesion if pelvic ultrasound results are inconclusive^{13,21}; **OR**
 - Further evaluation of dysfunctional uterine bleeding when ultrasound was indeterminate; **OR**
 - Known or suspected malignancies, including **ANY** of the following:
 - ◆ Uterine, ovarian, or cervical cancer, including borderline tumors such as Brenner tumor and moles (gestational trophoblastic tumors); **OR**
 - ◆ Endometrial cancer, biopsy-proven, staging, and follow-up; **OR**

- ◆ Pelvic abnormalities as indicated by **ALL** of the following^{4,15}:
 - **ANY** of the following is **TRUE**:
 - Ultrasound has been performed and is indeterminate; **OR**
 - Ultrasound has been performed, and the patient requires further evaluation or surgical planning; **AND**
 - **ANY** of the following:
 - Abscess of the pelvis^{23,24}; **OR**
 - Endometriosis with involvement beyond the ovary²¹; **OR**
 - Pelvic organ prolapse²⁵; **OR**
 - Uterine leiomyoma (fibroid) when an intervention is planned²⁶; **OR**
 - Urethral stricture or mass; **OR**
 - Pelvic neoplasms; **OR**
 - Uterine or cervical abnormalities; **OR**
- ◆ Musculoskeletal imaging of the pelvis when plain radiograph is inconclusive, including **ANY** of the following:
 - Sacroiliac joint, including inflammatory arthropathies such as psoriatic arthritis or ankylosing spondylitis²⁷; **OR**
 - Lumbosacral plexopathy²⁸; **OR**
 - Potential bony infection (osteomyelitis)²⁹; **OR**
 - Septic arthritis²⁹; **OR**
 - Characterization, staging, or follow-up of a bony lesion for suspected or known malignancy or metastatic disease³⁰; **OR**
 - Ulcer or wound with clinical concern for soft tissue infection or osteomyelitis²⁹; **OR**
 - Persistent athletic pubalgia (sports hernia) or osteitis pubis after 3 months of conservative treatment³⁰; **OR**
 - Trauma-related conditions including suspected traumatic or stress fracture with indeterminate CT³¹⁻³³; **OR**
 - Avascular necrosis (AVN) or osteonecrosis; **OR**
- ◆ Other evaluation of the pelvis when ultrasound is not appropriate or non-diagnostic, computed tomography (CT) is contraindicated or inconclusive, and **ANY** of the following is **TRUE**:
 - Extension of an indicated abdominal MRI for complete evaluation of organs and structures such as ureters or

bowel (e.g., MR enterography, MR urography) or for neoplastic staging; **OR**

- Pouchitis¹⁴; **OR**
- Fistula; **OR**
- Lymphadenopathy; **OR**
- Neoplastic conditions for **ANY** of the following:
 - Initial staging; **OR**
 - Treatment planning; **OR**
 - Response assessment; **OR**
 - Surveillance, and **ANY** of the following is **TRUE**^{2-3,34-36}:
 - ◆ The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - ◆ Suspected recurrence/progression; **OR**
 - ◆ Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6-8 weeks since the prior imaging evaluation); **OR**
- Follow-up to initial imaging study for further evaluation to characterize an abnormality/lesion related to an infection; **OR**
- For evaluation of **ANY** of the following miscellaneous pathologies when prior testing has failed:
 - Further work-up or characterization of initial abnormal findings on physical or clinical exam including **ANY** of the following:
 - ◆ Lumbosacral plexopathy²⁸; **OR**
 - ◆ Potential bony infection (osteomyelitis)²⁹; **OR**
 - ◆ Septic arthritis²⁹; **OR**
 - ◆ Ulcer or wound with clinical concern for infection²⁹; **OR**
 - Peri-anal fissures; **OR**
 - Pre-treatment for treatment planning, including staging (e.g., interventional radiology procedures, before biopsy, radiation, surgery); **OR**
- Follow-up to initial imaging study for further evaluation to

characterize an abnormality/lesion related to congenital anomalies; **OR**

- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality) in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following are true:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance imaging (MRI), pelvis** may not be considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72195	Magnetic resonance imaging (MRI) (e.g., proton), pelvis; without contrast material(s)
72196	Magnetic resonance imaging (MRI) (e.g., proton), pelvis;

	with contrast material(s)
72197	Magnetic resonance imaging (MRI) (e.g., proton), pelvis; without contrast material(s) followed by contrast material(s) and further sections

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Medical Evidence

Almansouri et al. (2024) performed a systematic review to analyze the role of magnetic resonance imaging (MRI) and computed tomography (CT) for pelvic fractures. Twelve studies were analyzed involving 1,798 patients (52% female). Two of the studies were prospective, and the remaining ten were retrospective. Diagnosing and managing pelvic fractures necessitates a personalized approach considering patient characteristics, injury mechanisms, and hemodynamic status. The authors note that MRI demonstrates superior sensitivity and diagnostic accuracy in identifying acute pelvic fractures, mainly concealed sacral fractures. MRI is also effective in detecting occult pelvic fractures and soft tissue anomalies. However, despite its diagnostic benefits, MRI is unlikely to replace CT as the initial gold standard due to factors such as shorter emergency department time and contraindications for MRI, especially in elderly patients. CT scanning remains preferred for initial diagnosis, aiding in the determination of emergent angiographic embolization needs and facilitating surgical planning in cases of pelvic fractures.⁹

Manti et al. (2022) conducted a prospective study that included 72 patients with symptoms indicative of endometriosis who underwent evaluation to plan surgical treatment. The mean age of the patients was 35.5 years (range: 20-46 years). Pelvic endometriosis was pathologically confirmed in 56 (77.7%) of the 72 patients. Among them, 22 patients (39.3%) underwent video laparoscopy (VLS), and 16 (72.2%) of those underwent surgery. MRI demonstrated high sensitivity and specificity for detecting various types of pelvic endometriosis. MRI allows the localization of lesions with highly fibrotic components that may not be recognizable with other imaging methods or visible during video laparoscopy.¹⁰

Hernando et al. (2022) reviewed quantitative diffusion MRI of the abdomen and pelvis, which involves employing multiple diffusion encodings and mapping diffusion parameters. Diffusion MRI allows the ability to gauge tissue microstructure sensitivity. In contrast to qualitative diffusion-weighted MRI, the quantitative approach enhances the standardization of tissue characterization, which is crucial for disease detection, staging, and treatment monitoring. Challenges include acquisition artifacts, limitations in signal modeling, and biological variability. Technical performance concerns include addressing physiologic motion (respiratory, peristaltic, and pulsatile), handling image distortions, and managing a low signal-to-noise ratio. Currently, multi-center studies focus on validation through systematic assessments to assess reproducibility.¹¹

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Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Spine (Cervical and Thoracic)

Clinical Policy for Medical Necessity Review

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Procedure Codes (CPT/HCPCS)

Service: Magnetic Resonance Imaging (MRI), Spine (Cervical and Thoracic)

Code	Description
72141	Magnetic resonance (eg, proton) imaging, spinal canal and contents, cervical; without contrast material
72142	Magnetic resonance (eg, proton) imaging, spinal canal and contents, cervical; with contrast material(s)
72146	Magnetic resonance (eg, proton) imaging, spinal canal and contents, thoracic; without contrast material
72147	Magnetic resonance (eg, proton) imaging, spinal canal and contents, thoracic; with contrast material(s)
72156	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; cervical
72157	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; thoracic

Service: Repeat Imaging

Code	Description
72141	Magnetic resonance (eg, proton) imaging, spinal canal and contents, cervical; without contrast material
72142	Magnetic resonance (eg, proton) imaging, spinal canal and contents, cervical; with contrast material(s)
72146	Magnetic resonance (eg, proton) imaging, spinal canal and contents, thoracic; without contrast material
72147	Magnetic resonance (eg, proton) imaging, spinal canal and contents, thoracic; with contrast material(s)
72156	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; cervical
72157	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; thoracic

Important Notices

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Service: Magnetic Resonance Imaging (MRI), Spine (Cervical and Thoracic) - Description

Magnetic resonance imaging (MRI) is a versatile imaging technique that operates on the interaction between radiofrequency electromagnetic fields and specific atomic nuclei in the body, typically hydrogen nuclei, following exposure to a powerful magnetic field. This method allows for the discrimination between normal and abnormal tissues, offering a highly sensitive diagnostic tool for detecting diseases. The effectiveness of MRI stems from the notable contrast inherent in various tissues, both healthy and diseased, owing to differences in their magnetic relaxation properties. MRI of the spine is the preferred imaging modality for pain, radiculopathy, or neurological symptoms. This includes clinical suspicion of cancer, infection, autoimmune disease, persistent symptoms following six weeks of conservative management, or new or worsening symptoms with a history of spine surgery.⁶

Contrast should be used at the discretion of the ordering clinician, with guidance from the radiologist as needed. Common indications for administering contrast for an MRI of the spine include infection, prior spine surgery, demyelinating diseases, or tumor. A detailed patient history and indication will ensure the appropriate region is covered when ordering an MRI of the spine. For many patients with neck or back pain, symptoms resolve after a trial of conservative treatment without performing imaging, especially patients with low back pain.⁷

Service: Magnetic Resonance Imaging (MRI), Spine (Cervical and Thoracic) - Medical Necessity Criteria

Indications

- **Magnetic resonance imaging (MRI), spine (cervical/thoracic)** is considered appropriate if **ANY** of the following is **TRUE**:
 - New onset pain or radiculopathy without trauma or significant mechanism of injury with **ALL** of the following:
 - Documented failure of at least 6 weeks of conservative treatment within the past 6 months, including **ALL** of the following^{8,9}:
 - Anti-inflammatory medications, non-opioid analgesics, or prescription medications (e.g., oral steroids, neuropathic pain medications) if not contraindicated; **AND**
 - Physical therapy, chiropractic care, or a provider-directed home exercise program (HEP)^A; **OR**
 - New-onset symptoms without trauma or significant mechanism of injury and **ANY** of the following^{6,12}:
 - Myelopathic symptoms; **OR**
 - Bladder dysfunction; **OR**
 - Bowel dysfunction; **OR**
 - Dermatomal sensory loss not related to peripheral neuropathy; **OR**
 - Objective muscle weakness not related to peripheral neuropathy; **OR**
 - Saddle anesthesia; **OR**
 - Sexual dysfunction; **OR**
 - Suspected amyloid deposition in the spine⁶; **OR**
 - Cerebrospinal fluid (CSF) leak (may include spontaneous intracranial hypotension)⁶; **OR**
 - Suspected gout⁶; **OR**
 - Suspected atlantoaxial instability in a patient with rheumatoid arthritis (RA) with abnormal or inconclusive radiographs of the cervical spine; **OR**
 - Known or suspected axial spondyloarthritis (axSpA) (e.g., ankylosing spondylitis [AS], reactive arthritis, psoriatic spondyloarthritis, enteropathic spondyloarthritis, juvenile spondyloarthritis, undifferentiated spondyloarthritis) and **ALL** of the following^{12,13}:
 - Initial imaging with radiographs; **AND**
 - axSpA of unclear disease activity while on biologic medication to assess disease activity; **OR**
 - Neoplastic conditions for **ANY** of the following⁴:
 - Initial staging; **OR**
 - Treatment planning; **OR**
 - Response assessment; **OR**
 - Surveillance, and **ANY** of the following¹⁴⁻¹⁶:
 - The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - Suspected recurrence/progression; **OR**
 - Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6-8 weeks since the prior imaging evaluation); **OR**

- Suspected or known infection involving the spine, with **ANY** of the following¹⁷:
 - **ALL** of the following:
 - Signs or symptoms (e.g., new/worsening back or neck pain with or without fever); **AND**
 - **ANY** of the following:
 - ▲ Abnormal laboratory evaluation (i.e., abnormal white blood cell count, ESR, or CRP); **OR**
 - ▲ "Red flag" risk factor (diabetes mellitus, current or prior IV drug use, cancer, HIV, or dialysis); **OR**
 - ▲ Wound overlying the spine; **OR**
 - Prior imaging findings concerning for infection; **OR**
 - History of surgical or interventional procedure to the spine with clinical suspicion for infection; **OR**
 - Follow-up imaging of infection with worsening symptoms/laboratory values (i.e., white blood cell count, ESR/CRP) or radiographic findings; **OR**
- Trauma-related conditions, including **ANY** of the following¹⁸⁻²⁰:
 - Follow-up to initial imaging (e.g., CT) with positive findings; **OR**
 - Follow-up to inconclusive imaging, with high suspicion for **ANY** of the following injury types:
 - Fracture; **OR**
 - Ligamentous; **OR**
 - New-onset post-traumatic radiculopathy with **ANY** of the following:
 - Back pain with or without radiculopathy and **ANY** of the following risk factors¹²:
 - ▲ Low-velocity trauma; **OR**
 - ▲ Osteoporosis; **OR**
 - ▲ Elderly age; **OR**
 - ▲ Chronic steroid use; **OR**
 - Follow-up of acute cervical spine blunt trauma without unstable injury on initial imaging; **OR**
 - Acute cervical or thoracic spine blunt trauma with suspected or confirmed ligamentous, spinal cord, or nerve root injury on CT imaging; **OR**
 - Any suspected thoracic spine trauma in a child¹⁹; **OR**
 - New onset post-traumatic neurological deficit (myelopathy) following significant trauma^C with **ANY** of the following^{12,21}:
 - Bladder dysfunction; **OR**
 - Bowel dysfunction; **OR**
 - Fecal incontinence; **OR**
 - Loss of anal sphincter tone; **OR**
 - Objective muscle weakness; **OR**
 - Saddle anesthesia; **OR**
 - Objective dermatomal sensory loss; **OR**
 - Urinary retention or overflow incontinence; **OR**
 - Objective weakness (bilateral or progressive) in the lower extremities that is not related to peripheral neuropathy; **OR**
 - Persistent or worsening post-traumatic pain without acute findings on initial imaging among patients who are high-risk (including patients who are elderly, osteoporotic, or have chronic steroid use); **OR**
- Vascular conditions, known or suspected, including **ANY** of the following⁶:
 - Extrapinal vascular malformations; **OR**
 - Spinal cord infarction; **OR**
 - Spinal vascular malformations and/or the cause of occult subarachnoid hemorrhage; **OR**

- Myelopathic symptoms, and **ANY** of the following⁶:
 - Connective tissue disorders (e.g., systemic lupus erythematosus)^{22,23}; **OR**
 - Muscular dystrophies and myopathies; **OR**
 - **ANY** of the following demyelinating diseases:
 - Transverse myelitis; **OR**
 - Acute disseminated encephalomyelitis; **OR**
 - Acute inflammatory demyelinating polyradiculopathy (Guillain-Barré syndrome); **OR**
 - Chronic inflammatory demyelinating polyradiculopathy (including relapsing polyneuropathy); **OR**
 - Myelin oligodendrocyte glycoprotein antibody-associated disease; **OR**
 - Neuromyelitis optica spectrum disorder; **OR**
- Multiple sclerosis (MS) and its suspected variants, and **ANY** of the following²⁴:
 - Diagnosis of MS with **ANY** of the following:
 - Clinically isolated syndrome (CIS)^D with **ANY** of the following:
 - ▲ Establishing a diagnosis according to the 2017 McDonald criteria, including **ANY** of the following clinical scenarios²⁵:
 - △ Evidence of MS on recent baseline brain MRI; **OR**
 - △ Suspected or known MS with new or changing symptoms compatible with spinal cord disease; **OR**
 - △ Evaluation of CIS in patients without an established MS diagnosis; **OR**
 - △ Recent brain MRI has not established another cause and is not sufficient to fulfill the McDonald criteria for diagnosis of MS; **OR**
 - ▲ Differential diagnosis in the case of inconclusive brain MRI findings; **OR**
 - Establishing the diagnosis of primary progressive multiple sclerosis; **OR**
 - Follow-up of MS with **ANY** of the following:
 - To evaluate new or recurrent signs or symptoms of myelopathy; **OR**
 - To aid in treatment switch decision-making for inconclusive clinical presentation or findings on brain MRI; **OR**
 - To determine a new baseline prior to starting or changing therapy; **OR**
 - Serial follow-up (6-12 months post-diagnosis) for CIS that is consistent with demyelination; **OR**
 - In the absence of other criteria, regular imaging (e.g., every 2-3 years) for known progressive MS; **OR**
- Preoperative, postoperative, or pretreatment evaluation for **ANY** of the following:
 - Postradiation changes (e.g., myelopathy); **OR**
 - Epidural and subdural fluid collection⁶; **OR**
 - Pre-procedure assessment for vertebroplasty and kyphoplasty, when imaging will impact management^{26,27}; **OR**
 - Postoperative fluid collections and soft-tissue changes (extradural and intradural)²; **OR**
 - Postoperative with new or worsening neurological symptoms^{12,13}; **OR**
- **ANY** of the following congenital conditions^{6,28}:
 - Back and neck pain in a child under 16 years of age with red flags (e.g., fevers, chills, malaise, weight loss, decreased appetite, unrelenting pain, night pain that awakens one from sleep, focal neurological signs, loss of bowel or bladder control, neck stiffness, rash, photophobia, confusion)²⁹; **OR**
 - Toe walking in a child under 5.5 years of age³⁰⁻³²; **OR**
 - Known high-risk disorders affecting the atlantoaxial articulation (e.g., Down syndrome, Marfan syndrome) with abnormal or inconclusive radiographs of the cervical spine; **OR**
 - Chiari malformation with **ANY** of the following³³:

- ☐ There is concern for clinically relevant pathology, such as hydrocephalus or spine syrinx; **OR**
- ☐ To aid treatment planning prior to surgical decompression; **OR**
- Scoliosis with **ANY** of the following³⁴:
 - ☐ Neurological symptoms; **OR**
 - ☐ Requiring preoperative assessment; **OR**
 - ☐ Worsening pain not previously imaged; **OR**
- Syringohydromyelia (syrinx).

Non-Indications

- **Magnetic resonance imaging (MRI), spine (cervical/thoracic)** is not considered appropriate if **ANY** of the following is **TRUE**:
 - The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms³⁵; **OR**
 - Stable axial spondyloarthropathy (axSpA) (i.e., ankylosing spondylitis [AS], reactive arthritis, psoriatic spondyloarthritis, enteropathic spondyloarthritis, juvenile spondyloarthritis, undifferentiated spondyloarthritis) with the intent of seeking subclinical inflammation or confirming disease inactivity.¹³

Definitions and Notes

^A **Provider-directed home exercise programs (HEP)** should include³⁶:

- Patient education of prescribed exercises with written instructions,
- Documentation of patient compliance with the HEP.

^B **Myelopathic symptoms**: Reduction or loss of fine motor skills, gait abnormality, increased muscular reflexes, pathological reflexes, paresthesia of limb, loss of hand dexterity.³⁷

^C **Trauma**: Blunt trauma, unintentional falls, fall from greater than or equal to 3 ft (0.9 m) or at least 5 stairs, axial load injury, vehicular trauma, high speed MVC/rollover/ejection, bicycle collision, motorized recreational vehicle accident, firearms injury, or sports-related injury.^{38,39}

^D **Clinically isolated syndrome (CIS)**: A single episode of inflammation that attacks the brain or spinal cord, developing suddenly or over a short period of time and lasting at least 24 hours, with or without recovery, and in the absence of fever or infection. This attack is similar to a typical multiple sclerosis relapse (attack and exacerbation), but it occurs in a patient not known to have multiple sclerosis. Symptoms may include vision loss in one eye, problems with eye movement, problems with balance or coordination, or weakness or numbness in part of the body. Less common symptoms may include vision loss in both eyes, total loss of movement in eyes, confusion, headache, neck stiffness, fatigue, or complete paralysis.²⁵

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Service: Repeat Imaging - Medical Necessity Criteria

Indications

- Repeat imaging (defined as a repeat request following recent imaging of the same anatomic region with the same or similar modality) will be considered reasonable and necessary if **ALL** of the following are **TRUE**:
 - There are no established guidelines; **AND**
 - **ANY** of the following:
 - There are new or worsening symptoms not addressed in the guidelines, such that repeat imaging would influence treatment; **OR**
 - There is need for a one-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Magnetic resonance imaging (MRI), spine (cervical/thoracic)** is not considered appropriate if **ANY** of the following is **TRUE**:
 - The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms³⁵; **OR**
 - Stable axial spondyloarthropathy (axSpA) (i.e., ankylosing spondylitis [AS], reactive arthritis, psoriatic spondyloarthritis, enteropathic spondyloarthritis, juvenile spondyloarthritis, undifferentiated spondyloarthritis) with the intent of seeking subclinical inflammation or confirming disease inactivity.¹³

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria may include:

- The use of contrast agents (e.g., gadolinium-based contrast agents) cause side effects in a few patients. These may include nausea, headache, and pain at the site of injection. Rarely, patients experience hives, itchy eyes, or other allergic reactions to the contrast material.⁴⁰
- Dynamic magnetic fields during MRI scanning create loud knocking noises which may harm hearing if adequate ear protection is not used. They may also cause peripheral muscle or nerve stimulation that may feel like a twitching sensation.⁴⁰
- MRI scanning could lead to heating of the body, particularly during long MRA scans, due to radiofrequency energy used in the procedure.⁴⁰
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- MRI of the spinal canal allows for the non-invasive visualization of the spinal cord.¹
- Compared to computed tomography (CT) and radiography, MRI provides for the best evaluation of soft tissue pathology. MRI of the soft tissues in the cervical spine is typically indicated when there is neurologic deficit or clinical suspicion of a vascular abnormality following trauma. Pulse sequence, a short-tau inversion-recovery sequence in MRI, can highlight undetected fractures, bone bruising, and tumors using fat suppression.⁴¹
- MRI without and with contrast of the affected spine segment is the initial diagnostic test of choice when spinal infection is clinically suspected. The sensitivity, specificity, and accuracy of MRI in spine infection are 96%, 94%, and 92%, respectively.¹⁷
- MRI allows timely diagnosis and treatment for spine emergencies. Traumatic spine injury classification systems provide an algorithm for clinical decision-making. Diagnostic considerations for atraumatic spine emergencies are broad, and MRI is the first line imaging modality for detecting compressive pathology.²⁰
- Enhanced overall patient satisfaction and healthcare experience.

Medical Evidence

Mathieu and Talbotts (2022) assessed the use of magnetic resonance imaging (MRI) in spinal emergencies. As an adjunct to CT, MRI has proven to be most valuable when additional imaging is necessary to assess spinal stability or compromise of neural elements. Vessel wall imaging techniques and MRA may also be utilized in cases of blunt traumatic cerebrovascular injury, mainly when findings from CTA are inconclusive. The American College of Radiology (ACR) has established guidelines outlining the appropriateness of MRI usage in various clinical scenarios related to spinal injuries and emergencies. MRI is considered 'usually appropriate' for patients with confirmed or suspected spinal cord or nerve root injuries.²⁰

Ghaffari-Rafi et al. (2021) performed a systematic review and meta-analysis on the role of MRI in clinical decision-making in acute spinal cord injury. Obtaining MRI scans significantly influences the clinical management of patients experiencing acute spinal cord injury (SCI) across all presentations. Guidelines support MRI scans in adult patients with acute SCI before surgical intervention, when feasible, to enhance clinical decision-making. Additional research is needed to establish the utility and efficacy of MRI in various types of SCI further.⁴²

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Policy Revision History/Information

Clinical Policy Version	Date	Review History
Version 1	10/03/2024	Original Date.
Version 2	10/02/2025	Annual review. Further refined conservative care indications. Added new indications for spondylosis/spondylolisthesis; axial spondyloarthropathy; toe walking in a child; back/neck pain with red flag symptoms in a child; atlantoaxial instability. Expanded indications for spinal infection, multiple sclerosis, and Chiari malformation. Added non-indication for axial spondyloarthropathy when the disease is stable. Updated indications for neoplastic conditions. Added definitions. Removed relative contraindications (contrast allergy, metallic clips, incompatible implantable devices, metallic foreign body).
Version 2.1	03/10/2026	Revision. Added L37373 and A57204 per CMS update.



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Spine (Cervical, Thoracic, and Lumbar)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Spine (Cervical, Thoracic, and Lumbar)

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Spine (Cervical, Thoracic, and Lumbar)

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.^{1-4,23-25}

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.^{1-4,23-25}

- [National Coverage Determination \(NCD\) Magnetic Resonance Imaging \(MRI\) \(220.2\)](#)
- [Local Coverage Determination \(LCD\) Lumbar MRI \(L34220\)](#)
- [Billing and Coding: Lumbar MRI \(A57206\)](#)
- [Local Coverage Determination \(LCD\) Lumbar MRI \(L37281\)](#)
- [Billing and Coding: Lumbar MRI \(A57207\)](#)
- [Local Coverage Determination \(LCD\) Multiple Imaging in Oncology \(L35391\)](#)
- [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Recommended Clinical Approach

Magnetic resonance imaging (MRI) is a versatile imaging technique that operates on the interaction between radiofrequency electromagnetic fields and specific atomic nuclei in the body, typically hydrogen nuclei, following exposure to a powerful magnetic field. This method allows for the discrimination between normal and abnormal tissues, offering a highly sensitive diagnostic tool for detecting diseases. The effectiveness of MRI stems from the notable contrast inherent in various tissues, both healthy and diseased, owing to differences in their magnetic relaxation properties. MRI of

the spine is the preferred imaging modality for pain, radiculopathy, or neurological symptoms. This includes clinical suspicion of cancer, infection, autoimmune disease, persistent symptoms following six weeks of conservative management, or new or worsening symptoms with a history of spine surgery.⁵

Contrast should be used at the discretion of the ordering clinician, with guidance from the radiologist as needed. Common indications for administering contrast for an MRI of the spine include infection, prior spine surgery, demyelinating diseases, or tumor. A detailed patient history and indication will ensure the appropriate region is covered when ordering an MRI of the spine. For many patients with neck or back pain, symptoms resolve after a trial of conservative treatment without performing imaging, especially patients with low back pain.⁶

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI) of the spine (cervical, thoracic, and lumbar). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- The use of contrast agents (e.g., gadolinium-based contrast agents) cause side effects in a few patients. These may include nausea, headache, and pain at the site of injection. Rarely, patients experience hives, itchy eyes, or other allergic reactions to the contrast material.⁷
- Dynamic magnetic fields during MRI scanning create loud knocking noises which may harm hearing if adequate ear protection is not used. They may also cause peripheral muscle or nerve stimulation that may feel like a twitching sensation.⁷
- MRI scanning could lead to heating of the body, particularly during long MRA scans, due to radiofrequency energy used in the procedure.⁷
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- MRI of the spinal canal allows for the non-invasive visualization of the spinal cord.²
- Compared to computed tomography (CT) and radiography, MRI provides for the best evaluation of soft tissue pathology. MRI of the soft tissues in the cervical spine is typically indicated when there is neurologic deficit or clinical suspicion of a vascular abnormality following trauma. Pulse sequence, a short-tau inversion-recovery sequence in MRI, can highlight undetected fractures, bone bruising, and tumors using fat suppression.⁸
- MRI without and with contrast of the affected spine segment is the initial diagnostic test of choice when spinal infection is clinically suspected. The sensitivity, specificity, and accuracy of MRI in spine infection are 96%, 94%, and 92%, respectively.⁹
- MRI allows timely diagnosis and treatment for spine emergencies. Traumatic spine injury classification systems provide an algorithm for clinical decision-making. Diagnostic considerations for atraumatic spine emergencies are broad, and MRI is the first line imaging modality for detecting compressive pathology.¹⁰
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), spine (cervical/thoracic/lumbar)** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Neoplastic conditions (including masses or mass-like conditions) including **ANY** of the following^{5,11,12}:
 - Bone tumors; **OR**
 - Intradural-extramedullary masses, including leptomeningeal disease; **OR**
 - Intramedullary masses; **OR**
 - Other extradural soft-tissue neoplasms of **ANY** of the following:
 - Connective tissues; **OR**
 - Muscles; **OR**
 - Regional nerves; **OR**
 - Initial diagnosis of suspected tumor or malignancy as indicated by **ANY** of the following:
 - Abnormal laboratory values; **OR**
 - Inconclusive or abnormal prior imaging; **OR**
 - Primary or metastatic lesion to the spinal cord (including the spinal canal or vertebral bodies) for **ANY** of the following scenarios:
 - Known tumor or malignancy with worsening symptoms or pain; **OR**
 - To monitor response to treatment; **OR**
 - Neoplastic conditions for **ANY** of the following:
 - Initial staging; **OR**
 - Treatment planning; **OR**
 - Response assessment; **OR**
 - Surveillance, and **ANY** of the following is **TRUE**^{4,13-15,25}:
 - ◆ The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - ◆ Suspected recurrence/progression; **OR**
 - ◆ Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6-8 weeks since the prior imaging evaluation); **OR**
- ◆ Concern for infection or an infectious disorder in the spine, with **ANY** of the following^{11,12,16,17}:

- **ANY** of the following⁵:
 - Discitis; **OR**
 - Epidural abscess; **OR**
 - Postoperative infections; **OR**
 - Surrounding soft-tissue infection; **OR**
 - Vertebral osteomyelitis; **OR**
- Spinal cord infection and inflammation, including abscess⁵; **OR**
- Pain (including back and neck) with elevated laboratory markers suspicious of infection; **OR**
- Follow-up to abnormal initial imaging with suspected infection; **OR**
- Trauma-related conditions, and **ANY** of the following^{5,10,12,17}:
 - Follow-up to initial imaging (e.g., radiograph, CT) with positive findings; **OR**
 - High suspicion for **ANY** of the following injury types:
 - ◆ Fracture; **OR**
 - ◆ Ligamentous; **OR**
 - ◆ Nerve; **OR**
 - ◆ Spine; **OR**
 - Neurological deficit (myelopathy) or radiculopathy, following traumatic event including accident, surgery, or intervention or with **ANY** of the following^{12,18}:
 - Bladder dysfunction; **OR**
 - Bowel dysfunction; **OR**
 - Fecal incontinence; **OR**
 - Loss of anal sphincter tone; **OR**
 - Physical exam finding of major muscle weakness; **OR**
 - Saddle anesthesia; **OR**
 - Severe sciatic/dermatomal sensory loss; **OR**
 - Urinary retention or overflow incontinence; **OR**
 - Weakness (bilateral or progressive) in the lower extremities; **OR**
- Persistent or worsening pain without acute findings on initial imaging (including patients who are elderly, osteoporotic, or have chronic steroid use); **OR**

- ◆ Vascular conditions, known or suspected, including **ANY** of the following⁵:
 - Extraspinal vascular malformations; **OR**
 - Spinal cord infarction; **OR**
 - Spinal vascular malformations and/or the cause of occult subarachnoid hemorrhage; **OR**
- ◆ Autoimmune, collagen vascular diseases, or inflammatory conditions including **ANY** of the following⁵:
 - Connective tissue disorders (systemic lupus erythematosus); **OR**
 - Muscular dystrophies and myopathies; **OR**
 - **ANY** of the following demyelinating diseases:
 - Acute disseminated encephalomyelitis; **OR**
 - Acute inflammatory demyelinating polyradiculopathy (Guillain-Barre syndrome); **OR**
 - Chronic inflammatory demyelinating polyradiculopathy (including relapsing polyneuropathy); **OR**
 - Multiple sclerosis (MS) and its variants (cervical or thoracic); **OR**
 - Myelin oligodendrocyte glycoprotein antibody-associated disease; **OR**
 - Neuromyelitis optica spectrum disorder; **OR**
- ◆ For evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when applicable:
 - Pain or radiculopathy without trauma or known malignancy with **ANY** of the following^{5,12}:
 - Discordant pain or radiculopathy to radiograph findings; **OR**
 - Neurological deficit (myelopathy) or severe radiculopathy not previously imaged with **ANY** of the following:
 - ◆ Abnormal electromyography (EMG); **OR**
 - ◆ New or worsening symptoms; **OR**
 - ◆ Not previously imaged; **OR**
 - Degenerative conditions including **ANY** of the following⁵:

- Degenerative disc disease and its sequelae in the lumbar, thoracic, and cervical spine (including myelopathy); **OR**
 - Symptomatic radiculopathy; **OR**
- Compression (suspected) in **ANY** of the following¹⁸:
 - Spinal cord; **OR**
 - Cauda equina; **OR**
 - Myelopathy (acute or progressive); **OR**
 - Nerve root; **OR**
- **ANY** of the following⁵:
 - Amyloid deposition in the spine; **OR**
 - Cerebrospinal fluid (CSF) leak (may include spontaneous intracranial hypotension); **OR**
 - Gout; **OR**
 - Spinal cord herniation¹⁹; **OR**
- ◆ Preoperative, postoperative, or pre-treatment evaluation for **ANY** of the following:
 - Planning for treatment fields for radiation therapy; **OR**
 - Postradiation changes (e.g., myelopathy); **OR**
 - Epidural and subdural fluid collection⁵; **OR**
 - Follow-up of incidental or concerning findings seen on other imaging examinations⁵; **OR**
 - Pre-procedure assessment for vertebroplasty and kyphoplasty²⁰; **OR**
 - Postoperative fluid collections and soft-tissue changes (extradural and intradural)¹; **OR**
 - Postoperative with new or worsening neurological symptoms^{11,12}; **OR**
- ◆ **ANY** of the following congenital conditions^{5,21}:
 - Chiari malformation; **OR**
 - Scoliosis with **ANY** of the following²²:
 - Neurological symptoms; **OR**
 - Requiring preoperative assessment; **OR**
 - Worsening pain not previously imaged; **OR**
 - Syringohydromyelia (syrinx); **OR**
 - Congenital spinal dysraphism (failure of fusion of parts along the dorsal midline of the spinal cord)²; **OR**
- ◆ Repeat imaging (defined as repeat request following recent

imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance imaging (MRI), spine (cervical/thoracic/lumbar)** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; **OR**
- ◆ Cortical bone and calcification is being imaged²; **OR**
- ◆ Spatial resolution of bone or calcification is required for a procedure.²

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72141	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, cervical; without contrast material

72142	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents; with contrast material(s)
72146	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, thoracic; without contrast material
72147	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, thoracic; with contrast material(s)
72148	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, lumbar; without contrast material
72149	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, lumbar; with contrast material(s)
72156	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; cervical
72157	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; thoracic
72158	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; lumbar

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Mathieu and Talbotts (2022) review using magnetic resonance imaging (MRI) to assess spinal emergencies. As an adjunct to CT, MRI proves to be most valuable in situations where additional imaging is necessary to assess spinal stability or compromise of neural elements. Vessel wall imaging techniques and MRA may also be utilized in cases of blunt traumatic cerebrovascular injury, mainly when findings from CTA are inconclusive. The American College of Radiology (ACR) has established guidelines outlining the appropriateness of MRI usage in various clinical scenarios related to spinal injuries and emergencies. MRI is considered 'usually appropriate' for patients with confirmed or suspected spinal cord or nerve root injuries.¹⁰

Suri et al. (2021) report on a randomized control trial (RCT) that investigated the impact of inserting epidemiological benchmarks into lumbar spine imaging reports as part of the Lumbar Imaging with Reporting of Epidemiology (LIRE) trial. The trial analyzed secondary outcomes, focusing on subsequent nonsurgical and surgical procedures involving the thoracolumbosacral spine and sacroiliac joints. The study included 238,886 adult patients from primary care clinics across four integrated healthcare systems in the United States. All participants underwent lumbar diagnostic imaging between 2013 and 2016. Results indicate that including epidemiological benchmarks (the 'LIRE intervention') did not significantly affect the utilization of non-surgical procedures (e.g., lumbosacral epidural steroid injections, facet joint injections, or facet joint radiofrequency ablation). In addition, the intervention did not impact surgical procedures such as decompression surgery, spinal fusion, or other spine surgeries involving the lumbar, sacral, or thoracic spine. The intervention also did not significantly affect any specific spine procedure.²⁰

Ghaffari-Rafi et al. (2021) performed a systematic review and meta-analysis on the role of MRI in clinical decision-making in acute spinal cord injury. Obtaining MRI scans significantly influences the clinical management of patients experiencing acute spinal cord injury (SCI) across all presentations. Guidelines support MRI scans in adult patients with acute SCI before surgical intervention, when feasible, to enhance clinical decision-making. Additional research is needed to establish the utility and efficacy of MRI in various types of SCI further.¹⁹

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Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Spine (Cervical, Thoracic, and Lumbar)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

Important Notices

Notices & Disclaimers:

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Spine (Cervical, Thoracic, and Lumbar)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Spine (Cervical, Thoracic, and Lumbar)

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.^{1-4,23-25}

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.^{1-4,23-25}

- [National Coverage Determination \(NCD\) Magnetic Resonance Imaging \(MRI\) \(220.2\)](#)
- [Local Coverage Determination \(LCD\) Lumbar MRI \(L34220\)](#)
- [Billing and Coding: Lumbar MRI \(A57206\)](#)
- [Local Coverage Determination \(LCD\) Lumbar MRI \(L37281\)](#)
- [Billing and Coding: Lumbar MRI \(A57207\)](#)
- [Local Coverage Determination \(LCD\) Multiple Imaging in Oncology \(L35391\)](#)
- [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)

Recommended Clinical Approach

Magnetic resonance imaging (MRI) is a versatile imaging technique that operates on the interaction between radiofrequency electromagnetic fields and specific atomic nuclei in the body, typically hydrogen nuclei, following exposure to a powerful magnetic field. This method allows for the discrimination between normal and abnormal tissues, offering a highly sensitive diagnostic tool for detecting diseases. The effectiveness of MRI stems from the notable contrast inherent in various tissues, both healthy and diseased, owing to differences in their magnetic relaxation properties. MRI of

the spine is the preferred imaging modality for pain, radiculopathy, or neurological symptoms. This includes clinical suspicion of cancer, infection, autoimmune disease, persistent symptoms following six weeks of conservative management, or new or worsening symptoms with a history of spine surgery.⁵

Contrast should be used at the discretion of the ordering clinician, with guidance from the radiologist as needed. Common indications for administering contrast for an MRI of the spine include infection, prior spine surgery, demyelinating diseases, or tumor. A detailed patient history and indication will ensure the appropriate region is covered when ordering an MRI of the spine. For many patients with neck or back pain, symptoms resolve after a trial of conservative treatment without performing imaging, especially patients with low back pain.⁶

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI) of the spine (cervical, thoracic, and lumbar). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- The use of contrast agents (e.g., gadolinium-based contrast agents) cause side effects in a few patients. These may include nausea, headache, and pain at the site of injection. Rarely, patients experience hives, itchy eyes, or other allergic reactions to the contrast material.⁷
- Dynamic magnetic fields during MRI scanning create loud knocking noises which may harm hearing if adequate ear protection is not used. They may also cause peripheral muscle or nerve stimulation that may feel like a twitching sensation.⁷
- MRI scanning could lead to heating of the body, particularly during long MRA scans, due to radiofrequency energy used in the procedure.⁷
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- MRI of the spinal canal allows for the non-invasive visualization of the spinal cord.²
- Compared to computed tomography (CT) and radiography, MRI provides for the best evaluation of soft tissue pathology. MRI of the soft tissues in the cervical spine is typically indicated when there is neurologic deficit or clinical suspicion of a vascular abnormality following trauma. Pulse sequence, a short-tau inversion-recovery sequence in MRI, can highlight undetected fractures, bone bruising, and tumors using fat suppression.⁸
- MRI without and with contrast of the affected spine segment is the initial diagnostic test of choice when spinal infection is clinically suspected. The sensitivity, specificity, and accuracy of MRI in spine infection are 96%, 94%, and 92%, respectively.⁹
- MRI allows timely diagnosis and treatment for spine emergencies. Traumatic spine injury classification systems provide an algorithm for clinical decision-making. Diagnostic considerations for atraumatic spine emergencies are broad, and MRI is the first line imaging modality for detecting compressive pathology.¹⁰
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), spine (cervical/thoracic/lumbar)** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Neoplastic conditions (including masses or mass-like conditions) including **ANY** of the following^{5,11,12}:
 - Bone tumors; **OR**
 - Intradural-extramedullary masses, including leptomeningeal disease; **OR**
 - Intramedullary masses; **OR**
 - Other extradural soft-tissue neoplasms of **ANY** of the following:
 - Connective tissues; **OR**
 - Muscles; **OR**
 - Regional nerves; **OR**
 - Initial diagnosis of suspected tumor or malignancy as indicated by **ANY** of the following:
 - Abnormal laboratory values; **OR**
 - Inconclusive or abnormal prior imaging; **OR**
 - Primary or metastatic lesion to the spinal cord (including the spinal canal or vertebral bodies) for **ANY** of the following scenarios:
 - Known tumor or malignancy with worsening symptoms or pain; **OR**
 - To monitor response to treatment; **OR**
 - Neoplastic conditions for **ANY** of the following:
 - Initial staging; **OR**
 - Treatment planning; **OR**
 - Response assessment; **OR**
 - Surveillance, and **ANY** of the following is **TRUE**^{4,13-15,25}:
 - ◆ The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - ◆ Suspected recurrence/progression; **OR**
 - ◆ Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6-8 weeks since the prior imaging evaluation); **OR**
- ◆ Concern for infection or an infectious disorder in the spine, with **ANY** of the following^{11,12,16,17}:

- **ANY** of the following⁵:
 - Discitis; **OR**
 - Epidural abscess; **OR**
 - Postoperative infections; **OR**
 - Surrounding soft-tissue infection; **OR**
 - Vertebral osteomyelitis; **OR**
- Spinal cord infection and inflammation, including abscess⁵; **OR**
- Pain (including back and neck) with elevated laboratory markers suspicious of infection; **OR**
- Follow-up to abnormal initial imaging with suspected infection; **OR**
- Trauma-related conditions, and **ANY** of the following^{5,10,12,17}:
 - Follow-up to initial imaging (e.g., radiograph, CT) with positive findings; **OR**
 - High suspicion for **ANY** of the following injury types:
 - ◆ Fracture; **OR**
 - ◆ Ligamentous; **OR**
 - ◆ Nerve; **OR**
 - ◆ Spine; **OR**
 - Neurological deficit (myelopathy) or radiculopathy, following traumatic event including accident, surgery, or intervention or with **ANY** of the following^{12,18}:
 - Bladder dysfunction; **OR**
 - Bowel dysfunction; **OR**
 - Fecal incontinence; **OR**
 - Loss of anal sphincter tone; **OR**
 - Physical exam finding of major muscle weakness; **OR**
 - Saddle anesthesia; **OR**
 - Severe sciatic/dermatomal sensory loss; **OR**
 - Urinary retention or overflow incontinence; **OR**
 - Weakness (bilateral or progressive) in the lower extremities; **OR**
- Persistent or worsening pain without acute findings on initial imaging (including patients who are elderly, osteoporotic, or have chronic steroid use); **OR**

- ◆ Vascular conditions, known or suspected, including **ANY** of the following⁵:
 - Extraspinal vascular malformations; **OR**
 - Spinal cord infarction; **OR**
 - Spinal vascular malformations and/or the cause of occult subarachnoid hemorrhage; **OR**
- ◆ Autoimmune, collagen vascular diseases, or inflammatory conditions including **ANY** of the following⁵:
 - Connective tissue disorders (systemic lupus erythematosus); **OR**
 - Muscular dystrophies and myopathies; **OR**
 - **ANY** of the following demyelinating diseases:
 - Acute disseminated encephalomyelitis; **OR**
 - Acute inflammatory demyelinating polyradiculopathy (Guillain-Barre syndrome); **OR**
 - Chronic inflammatory demyelinating polyradiculopathy (including relapsing polyneuropathy); **OR**
 - Multiple sclerosis (MS) and its variants (cervical or thoracic); **OR**
 - Myelin oligodendrocyte glycoprotein antibody-associated disease; **OR**
 - Neuromyelitis optica spectrum disorder; **OR**
- ◆ For evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when applicable:
 - Pain or radiculopathy without trauma or known malignancy with **ANY** of the following^{5,12}:
 - Discordant pain or radiculopathy to radiograph findings; **OR**
 - Neurological deficit (myelopathy) or severe radiculopathy not previously imaged with **ANY** of the following:
 - ◆ Abnormal electromyography (EMG); **OR**
 - ◆ New or worsening symptoms; **OR**
 - ◆ Not previously imaged; **OR**
 - Degenerative conditions including **ANY** of the following⁵:

- Degenerative disc disease and its sequelae in the lumbar, thoracic, and cervical spine (including myelopathy); **OR**
 - Symptomatic radiculopathy; **OR**
- Compression (suspected) in **ANY** of the following¹⁸:
 - Spinal cord; **OR**
 - Cauda equina; **OR**
 - Myelopathy (acute or progressive); **OR**
 - Nerve root; **OR**
- **ANY** of the following⁵:
 - Amyloid deposition in the spine; **OR**
 - Cerebrospinal fluid (CSF) leak (may include spontaneous intracranial hypotension); **OR**
 - Gout; **OR**
 - Spinal cord herniation¹⁹; **OR**
- ◆ Preoperative, postoperative, or pre-treatment evaluation for **ANY** of the following:
 - Planning for treatment fields for radiation therapy; **OR**
 - Postradiation changes (e.g., myelopathy); **OR**
 - Epidural and subdural fluid collection⁵; **OR**
 - Follow-up of incidental or concerning findings seen on other imaging examinations⁵; **OR**
 - Pre-procedure assessment for vertebroplasty and kyphoplasty²⁰; **OR**
 - Postoperative fluid collections and soft-tissue changes (extradural and intradural)¹; **OR**
 - Postoperative with new or worsening neurological symptoms^{11,12}; **OR**
- ◆ **ANY** of the following congenital conditions^{5,21}:
 - Chiari malformation; **OR**
 - Scoliosis with **ANY** of the following²²:
 - Neurological symptoms; **OR**
 - Requiring preoperative assessment; **OR**
 - Worsening pain not previously imaged; **OR**
 - Syringohydromyelia (syrinx); **OR**
 - Congenital spinal dysraphism (failure of fusion of parts along the dorsal midline of the spinal cord)²; **OR**
- ◆ Repeat imaging (defined as repeat request following recent

imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance imaging (MRI), spine (cervical/thoracic/lumbar)** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; **OR**
- ◆ Cortical bone and calcification is being imaged²; **OR**
- ◆ Spatial resolution of bone or calcification is required for a procedure.²

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
72141	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, cervical; without contrast material

72142	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents; with contrast material(s)
72146	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, thoracic; without contrast material
72147	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, thoracic; with contrast material(s)
72148	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, lumbar; without contrast material
72149	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, lumbar; with contrast material(s)
72156	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; cervical
72157	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; thoracic
72158	Magnetic resonance imaging (MRI) (e.g., proton), spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; lumbar

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Mathieu and Talbotts (2022) review using magnetic resonance imaging (MRI) to assess spinal emergencies. As an adjunct to CT, MRI proves to be most valuable in situations where additional imaging is necessary to assess spinal stability or compromise of neural elements. Vessel wall imaging techniques and MRA may also be utilized in cases of blunt traumatic cerebrovascular injury, mainly when findings from CTA are inconclusive. The American College of Radiology (ACR) has established guidelines outlining the appropriateness of MRI usage in various clinical scenarios related to spinal injuries and emergencies. MRI is considered 'usually appropriate' for patients with confirmed or suspected spinal cord or nerve root injuries.¹⁰

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Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Temporomandibular Joint (TMJ)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 17, 2024

Important Notices

Notices & Disclaimers:

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Temporomandibular Joint (TMJ)

Date of last literature review: 10/15/2024

Document last updated: 10/16/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Temporomandibular Joint (TMJ)

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹⁻³

- [National Coverage Determination \(NCD\) 220.12. Magnetic resonance imaging \(MRI\)](#)
- [Local Coverage Determination \(LCD\) L37373. MRI and CT Scans of the Head and Neck](#)
- [Local Coverage Determination \(LCD\) L35175. MRI and CT Scans of the Head and Neck](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57204\)](#)
- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\)](#)

Recommended Clinical Approach

Magnetic resonance imaging (MRI) of the temporomandibular joint (TMJ) is a non-invasive diagnostic tool that provides detailed images of the soft tissues and hard structures within the joint. It is highly effective in diagnosing internal derangements, such as disc displacement, inflammation, and degenerative changes. MRI can assess the position and condition of the articular disc, joint effusion, bone marrow edema, and other soft tissue abnormalities. Its superior contrast resolution makes it the gold standard for evaluating TMJ disorders,

guiding treatment decisions, and monitoring the efficacy of interventions, particularly in complex cases requiring precise anatomical details.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Magnetic Resonance Imaging (MRI), Temporomandibular Joint (TMJ). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁴⁻⁶
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁴⁻⁶
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁷
- Compared to other imaging modalities, MR imaging can be more resource intensive.⁸
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁹

The clinical benefits of using these criteria include:

- Magnetic resonance imaging (MRI) is commonly considered the best modality for evaluating articular disc morphology and diagnosing temporomandibular disorders, due to the excellent soft tissue contrast and high spatial resolution the imaging technique provides.^{10,11}
- MRI is a non-invasive imaging modality that employs a short radio-frequency pulse rather than the ionizing radiation used in other imaging procedures. As an alternative to imaging techniques that employ radiation, MRI represents a lower risk to individuals sensitive to radiation, including children and pregnant women.^{10,11,12}
- As MRI is the gold standard for imaging and evaluating the temporomandibular joint (TMJ), if clinical symptoms do not match radiographic findings, a false-positive or false-negative imaging diagnosis is suspected.¹²
- Enhanced overall patient satisfaction and healthcare experience.⁹

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **Magnetic resonance imaging (MRI), temporomandibular joint (TMJ)** is considered appropriate if **ANY** of the following is **TRUE**^{9,11}:
 - ◆ Suspected TMJ disorder and **ALL** of the following is **TRUE**:
 - Failure of conservative management (e.g., rest, analgesics, soft diet, oral appliances) must be documented for a period of greater than 6 weeks; **AND**
 - The patient has **ANY** of the following from the clinical presentation and typical physical exam findings lists¹³:

- Clicking sounds in the jaw joint when opening or closing the mouth; **OR**
- Difficulty chewing; **OR**
- Ear pain in front of or below the ear without any signs of infection; **OR**
- Headaches exacerbated by jaw movement; **OR**
- Irregular jaw movement with difficulty opening or closing the mouth; **OR**
- Jaw pain or toothache when waking up after sleep; **OR**
- Pain localized to the ear when speaking, chewing, or opening the mouth widely; **OR**
- Pain in the jaw, tooth, neck, and shoulders when speaking, chewing, or opening the mouth widely; **OR**
- Sensation of teeth not aligning properly; **OR**
- ◆ Assessment of known TMJ disorder after treatment; **OR**
- ◆ Assessment of known TMJ disorder with new, worsening, or persistent symptoms; **OR**
- ◆ Imaging needed before TMJ surgery; **OR**
- ◆ Inflammatory arthropathy and **ALL** of the following is **TRUE**¹⁴:
 - Failure of conservative management (e.g., rest, analgesics, soft diet, oral appliances) must be documented for a period of greater than 6 weeks; **AND**
 - **ANY** of the following:
 - Ankylosing spondylitis; **OR**
 - Psoriatic arthritis; **OR**
 - Rheumatoid arthritis¹⁴; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**

- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance imaging (MRI), temporomandibular joint (TMJ)**

is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70336	Magnetic resonance imaging (MRI) (e.g., proton); temporomandibular joint (TMJ)

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Kopp et al. (2024) conducted a prospective study to compare the image quality between 0.55 Tesla magnetic resonance imaging (MRI) and the standard 1.5 Tesla MRI for the assessment of temporomandibular disorders (TMDs). The disorders are often associated with enduring functional impairments and discomfort. The study included 17 patients (34 temporomandibular joints [TMJs]) with suspected intra-articular TMDs. Patients underwent 0.55 Tesla and 1.5 Tesla MRI scans on the same day. MRI is the standard imaging modality for assessing TMDs and provides detailed visualization of disc pathologies and structural changes within the joint. While advancements in MRI technology have focused on enhancing magnetic field strength to achieve higher spatial resolution, these high-field MRI systems necessitate extensive cooling systems, consume substantial energy, and incur significant maintenance expenses, limiting their accessibility in rural areas worldwide. Modern low-field MRI systems are a promising alternative due to their reduced energy requirements and lower maintenance costs. Additional research is needed concerning the suitability of contemporary low-field MRI for TMD evaluation.¹⁰

Gharavi et al. (2022) reviewed imaging techniques of the TMJ. Chronic TMJ pain affects 5–31% of individuals, with approximately 4% experiencing new onset pain annually. Disorders of the TMJ encompass a range of conditions affecting the TMJ and surrounding structures, ranking as the second most prevalent musculoskeletal ailment, following back pain. While internal derangement stands as the most prevalent TMJ pathology, other less common conditions include conditions such as inflammatory arthritis, infections, trauma, and neoplasms. MRI is the primary modality to assess intra-articular conditions due to the exceptional contrast resolution in soft tissues. Contrast-enhanced MRI and CT scans are used in the assessment of arthritis that affects the TMJ as it offers comprehensive visualization of both acute inflammatory changes and subsequent degenerative arthritis.¹¹

Hegab et al. (2021) performed a prospective clinical study on a new classification system for TMJ internal derangement based on MRI and clinical findings to aid nonsurgical treatment. The study involved 435 patients and

747 joints and measured outcomes like maximum mouth opening, pain (via visual analog scale), and joint sound. Results showed significant improvements in mouth opening, pain reduction, and reduced joint sounds over 12 months. The new classification system is comprehensive, and the nonsurgical treatment protocol is practical and tailored to joint pathology.¹²

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Clinical Guideline Revision History/Information

Original Date: October 17, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Temporomandibular Joint (TMJ)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 17, 2024

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Temporomandibular Joint (TMJ)

Date of last literature review: 10/15/2024

Document last updated: 10/16/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Temporomandibular Joint (TMJ)

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

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- [Billing and Coding: MRI and CT Scans of the Head and Neck \(A57215\)](#)

Recommended Clinical Approach

Magnetic resonance imaging (MRI) of the temporomandibular joint (TMJ) is a non-invasive diagnostic tool that provides detailed images of the soft tissues and hard structures within the joint. It is highly effective in diagnosing internal derangements, such as disc displacement, inflammation, and degenerative changes. MRI can assess the position and condition of the articular disc, joint effusion, bone marrow edema, and other soft tissue abnormalities. Its superior contrast resolution makes it the gold standard for evaluating TMJ disorders,

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- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁴⁻⁶
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁴⁻⁶
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- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁷
- Compared to other imaging modalities, MR imaging can be more resource intensive.⁸
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁹

The clinical benefits of using these criteria include:

- Magnetic resonance imaging (MRI) is commonly considered the best modality for evaluating articular disc morphology and diagnosing temporomandibular disorders, due to the excellent soft tissue contrast and high spatial resolution the imaging technique provides.^{10,11}
- MRI is a non-invasive imaging modality that employs a short radio-frequency pulse rather than the ionizing radiation used in other imaging procedures. As an alternative to imaging techniques that employ radiation, MRI represents a lower risk to individuals sensitive to radiation, including children and pregnant women.^{10,11,12}
- As MRI is the gold standard for imaging and evaluating the temporomandibular joint (TMJ), if clinical symptoms do not match radiographic findings, a false-positive or false-negative imaging diagnosis is suspected.¹²
- Enhanced overall patient satisfaction and healthcare experience.⁹

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **Magnetic resonance imaging (MRI), temporomandibular joint (TMJ)** is considered appropriate if **ANY** of the following is **TRUE**^{9,11}:
 - ◆ Suspected TMJ disorder and **ALL** of the following is **TRUE**:
 - Failure of conservative management (e.g., rest, analgesics, soft diet, oral appliances) must be documented for a period of greater than 6 weeks; **AND**
 - The patient has **ANY** of the following from the clinical presentation and typical physical exam findings lists¹³:

- Clicking sounds in the jaw joint when opening or closing the mouth; **OR**
- Difficulty chewing; **OR**
- Ear pain in front of or below the ear without any signs of infection; **OR**
- Headaches exacerbated by jaw movement; **OR**
- Irregular jaw movement with difficulty opening or closing the mouth; **OR**
- Jaw pain or toothache when waking up after sleep; **OR**
- Pain localized to the ear when speaking, chewing, or opening the mouth widely; **OR**
- Pain in the jaw, tooth, neck, and shoulders when speaking, chewing, or opening the mouth widely; **OR**
- Sensation of teeth not aligning properly; **OR**
- ◆ Assessment of known TMJ disorder after treatment; **OR**
- ◆ Assessment of known TMJ disorder with new, worsening, or persistent symptoms; **OR**
- ◆ Imaging needed before TMJ surgery; **OR**
- ◆ Inflammatory arthropathy and **ALL** of the following is **TRUE**¹⁴:
 - Failure of conservative management (e.g., rest, analgesics, soft diet, oral appliances) must be documented for a period of greater than 6 weeks; **AND**
 - **ANY** of the following:
 - Ankylosing spondylitis; **OR**
 - Psoriatic arthritis; **OR**
 - Rheumatoid arthritis¹⁴; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**

- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance imaging (MRI), temporomandibular joint (TMJ)**

is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70336	Magnetic resonance imaging (MRI) (e.g., proton); temporomandibular joint (TMJ)

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Kopp et al. (2024) conducted a prospective study to compare the image quality between 0.55 Tesla magnetic resonance imaging (MRI) and the standard 1.5 Tesla MRI for the assessment of temporomandibular disorders (TMDs). The disorders are often associated with enduring functional impairments and discomfort. The study included 17 patients (34 temporomandibular joints [TMJs]) with suspected intra-articular TMDs. Patients underwent 0.55 Tesla and 1.5 Tesla MRI scans on the same day. MRI is the standard imaging modality for assessing TMDs and provides detailed visualization of disc pathologies and structural changes within the joint. While advancements in MRI technology have focused on enhancing magnetic field strength to achieve higher spatial resolution, these high-field MRI systems necessitate extensive cooling systems, consume substantial energy, and incur significant maintenance expenses, limiting their accessibility in rural areas worldwide. Modern low-field MRI systems are a promising alternative due to their reduced energy requirements and lower maintenance costs. Additional research is needed concerning the suitability of contemporary low-field MRI for TMD evaluation.¹⁰

Gharavi et al. (2022) reviewed imaging techniques of the TMJ. Chronic TMJ pain affects 5–31% of individuals, with approximately 4% experiencing new onset pain annually. Disorders of the TMJ encompass a range of conditions affecting the TMJ and surrounding structures, ranking as the second most prevalent musculoskeletal ailment, following back pain. While internal derangement stands as the most prevalent TMJ pathology, other less common conditions include conditions such as inflammatory arthritis, infections, trauma, and neoplasms. MRI is the primary modality to assess intra-articular conditions due to the exceptional contrast resolution in soft tissues. Contrast-enhanced MRI and CT scans are used in the assessment of arthritis that affects the TMJ as it offers comprehensive visualization of both acute inflammatory changes and subsequent degenerative arthritis.¹¹

Hegab et al. (2021) performed a prospective clinical study on a new classification system for TMJ internal derangement based on MRI and clinical findings to aid nonsurgical treatment. The study involved 435 patients and

747 joints and measured outcomes like maximum mouth opening, pain (via visual analog scale), and joint sound. Results showed significant improvements in mouth opening, pain reduction, and reduced joint sounds over 12 months. The new classification system is comprehensive, and the nonsurgical treatment protocol is practical and tailored to joint pathology.¹²

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Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Upper Extremity

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

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Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Upper Extremity

Date of last literature review: 10/2/2024

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Type: ☒ Adult (18+ yo) | ☐ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Upper Extremity

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)

Recommended Clinical Approach

Magnetic resonance imaging (MRI) is an advanced imaging modality used when further anatomic detail is required for diagnosis or treatment. It is segmented into joint and non-joint examinations and may be performed without or with contrast (IV or intra-articular). Metal hardware can limit certain exams and is generally inappropriate for imaging by 3 Tesla scanners. Alternate modalities may sometimes be more clinically appropriate based on clinician and supervising radiologist discussion.²⁻³

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI) of the upper extremities. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁴⁻⁵
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁴⁻⁵
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁶
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁷
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Detailed soft tissue visualization: MRI is valuable for assessing conditions related to the shoulder joint and for surgical planning.⁸⁻⁹
- Multiplanar imaging: Allows for a multiplanar approach to visualize the shoulder joint to improve diagnostic accuracy and identify abnormalities that are unlikely to be visible in a single-plane image.⁹
- Detection of conditions: Contrast agents allow for the identification of labral tears, various shoulder pathologies, tumors, lesions, and abnormalities.⁸ MRI is also beneficial for locating the origination of cervical spine pain (e.g., inflammatory arthritis).⁹
- Evaluation of thoracic outlet anatomy.¹⁰
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive

medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), upper extremity** is considered appropriate if **ALL** of the following is **TRUE**:

◆ **ANY** of the following:

- Plain radiographs are contraindicated or inconclusive; **OR**
- Ultrasound and CT/CTA are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to IV contrast reaction, pregnancy, pediatric); **AND**

◆ **ANY** of the following is **TRUE**:

- Trauma-related conditions as indicated by **ANY** of the following¹¹⁻¹²:
 - Fracture (traumatic or stress), and **ANY** of the following is **TRUE**¹³:
 - ◆ Joint dislocation or instability; **OR**
 - ◆ Stress/insufficiency fracture (known) and follow-up imaging needed; **OR**
 - ◆ Stress/insufficiency fracture (suspected) with negative radiographs; **OR**
 - Soft tissue injury or tear (e.g., tendon, ligament, muscle)¹¹⁻¹⁵; **OR**
- Detection, screening, and surveillance of neoplasms, masses, and cysts of an upper extremity and **ANY** of the following is **TRUE**⁵:
 - Malignant or aggressive primary tumor¹⁶; **OR**
 - Evaluation of metastatic lesions of the upper extremity; **OR**
 - Bone tumor is suspected with **ANY** of the following¹⁷:

- ◆ Initial radiographs are negative or do not explain symptoms; **OR**
- ◆ Osteoid osteoma is suspected; **OR**
- ◆ Lesion present on plain radiographs; **OR**
- ◆ Indeterminate or aggressive appearance concerning malignancy; **OR**
- ◆ “Incidental” osseous lesion on other imaging for unrelated indication; **OR**
- Presence of a mass with **ANY** of the following³:
 - ◆ Absence of trauma; **OR**
 - ◆ Rapid growth; **OR**
 - ◆ Recurrence after prior surgery; **OR**
 - ◆ Non-diagnostic ultrasound or other inconclusive imaging; **OR**
- Known malignancy and **ANY** of the following is required:
 - ◆ Monitor response to treatment; **OR**
 - ◆ Surveillance after treatment or surgery; **OR**
 - ◆ Non-diagnostic ultrasound or other inconclusive imaging; **OR**
- Palpable abnormality with a non-diagnostic radiograph or ultrasound; **OR**
- Infectious disorder including **ANY** of the following:
 - Osteomyelitis, suspected¹⁸; **OR**
 - Suspected septic arthritis or soft tissue infection is with **ANY** of the following initial radiographs¹⁸⁻¹⁹:
 - ◆ Normal; **OR**
 - ◆ Suggestive of joint effusion; **OR**
 - ◆ Suggestive of soft tissue swelling; **OR**
 - History of puncture wound with possible retained foreign body; **OR**
 - High clinical suspicion of necrotizing fasciitis; **OR**
- Vascular conditions, known or suspected, including **ANY** of the following:
 - Osteonecrosis or avascular necrosis, known or suspected, (e.g., suspected Kienböck's disease) with negative radiographs²⁰; **OR**
 - Vascular compromise, suspected¹⁵; **OR**

- Vascular malformation (with or without pain) and **ANY** of the following findings of physical deformity are suspected²¹:
 - ◆ Diffuse or focal enlargement; **OR**
 - ◆ Discoloration; **OR**
 - ◆ Soft-tissue mass; **OR**
 - ◆ Ulceration; **OR**
- Vascular bruit or thrill; **OR**
- For evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when applicable:
 - Marrow abnormalities^{5,20}; **OR**
 - Pain or weakness of an upper extremity, and **ALL** of the following are **TRUE**^{15,22}:
 - ◆ Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 3 months; **AND**
 - ◆ Concern for acute rupture or high-grade tear of tendon, ligament, or soft tissue injury based on **ALL** of the following:
 - Clinical history; **AND**
 - Physical exam; **AND**
 - Prior radiographs excluding chronic pain or suspicion of a chronic or low-grade injury; **OR**
 - Neurological symptoms or deficits with **ANY** of the following:
 - ◆ Peripheral nerve sheath tumor suspected with **ANY** of the following:
 - Enlarging mass; **OR**
 - New or worsening localized pain; **OR**
 - Recurrence after prior resection; **OR**
 - ◆ Localized EMG abnormality; **OR**
 - ◆ Persistent symptoms or suspected nerve entrapment as confirmed by abnormal EMG; **OR**
 - ◆ Trauma or injury with suspected nerve injury or laceration; **OR**

- Initial diagnosis or follow-up of autoimmune, collagen vascular diseases, or inflammatory conditions (e.g., inflammatory arthritis)¹⁹; **OR**
- Synovial-related disorders (e.g., synovitis, bursitis, metaplasia, and neoplasia)²³; **OR**
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance imaging (MRI), upper extremity** may not be considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; **OR**
- ◆ Incompatible implanted devices (e.g., pacemakers, defibrillators, cardiac valves, spinal cord stimulators); **OR**
- ◆ Imaging of cortical bone and calcifications¹; **OR**
- ◆ Procedures involving spatial resolution of bone and calcifications.¹

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
73218	Magnetic resonance imaging (MRI) (e.g., proton), upper extremity, other than joint; without contrast material(s)
73219	Magnetic resonance imaging (MRI) (e.g., proton), upper extremity, other than joint; with contrast material(s)
73220	Magnetic resonance imaging (MRI) (e.g., proton), upper extremity, other than joint; without contrast material(s), followed by contrast material(s) and further sequences
73221	Magnetic resonance imaging (MRI) (e.g., proton), any joint of upper extremity; without contrast material(s)
73222	Magnetic resonance imaging (MRI) (e.g., proton), any joint of upper extremity; with contrast material(s)
73223	Magnetic resonance imaging (MRI) (e.g., proton), any joint of upper extremity; without contrast material(s), followed by contrast material(s) and further sequences.

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

DeFrance et al. (2021) performed a study using magnetic resonance imaging (MRI) for diagnosing upper extremity conditions and assessed how MRI findings influenced patient management. Findings from 187 patients who had an MRI were analyzed on the usefulness of imaging and how they influenced treatment decisions. Imaging was ordered to assess for suspected occult scaphoid fractures, ulnar wrist pain, collateral ligament injuries of the metacarpophalangeal joint, and masses. Surgeons concurred with radiologists' interpretations in 88% of cases. Overall, surgeons noted MRI findings as helpful in 92% of cases.²⁴

Cortes et al. (2019) conducted a small prospective study on patients with suspected cuff tendinopathy. Fifty-one patients were included and underwent magnetic resonance imaging (MRI). Ninety percent (n=46) did not require surgical intervention; individuals who underwent surgery (10%) within an average of 68.3 days post-imaging. A significant proportion (over 90%) underwent premature MRI, which illustrates early MRI utilization in patients with atraumatic shoulder pain whose condition may have improved with conservative treatment first.²⁵

Rubin (2019) analyzed MRI and ultrasound findings of patients with rheumatoid arthritis in the hands and wrists. Advanced imaging modalities allow for visualization of synovitis and active soft-tissue inflammation, which are early indicators of potential structural damage. MRI can also identify osteitis, a crucial prognostic marker for disease aggressiveness. Findings include the distinct definitions (specifically synovitis, osteitis, and erosions) that enhance clinical assessment and imaging interpretation.²⁶

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Upper Extremity

Date of last literature review: 10/2/2024

Document last updated: 10/3/2024

Type: ☒ Adult (18+ yo) | ☐ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Upper Extremity

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\). Magnetic resonance imaging \(MRI\) \(220.2\)](#)

Recommended Clinical Approach

Magnetic resonance imaging (MRI) is an advanced imaging modality used when further anatomic detail is required for diagnosis or treatment. It is segmented into joint and non-joint examinations and may be performed without or with contrast (IV or intra-articular). Metal hardware can limit certain exams and is generally inappropriate for imaging by 3 Tesla scanners. Alternate modalities may sometimes be more clinically appropriate based on clinician and supervising radiologist discussion.²⁻³

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI) of the upper extremities. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁴⁻⁵
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁴⁻⁵
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁶
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁷
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Detailed soft tissue visualization: MRI is valuable for assessing conditions related to the shoulder joint and for surgical planning.⁸⁻⁹
- Multiplanar imaging: Allows for a multiplanar approach to visualize the shoulder joint to improve diagnostic accuracy and identify abnormalities that are unlikely to be visible in a single-plane image.⁹
- Detection of conditions: Contrast agents allow for the identification of labral tears, various shoulder pathologies, tumors, lesions, and abnormalities.⁸ MRI is also beneficial for locating the origination of cervical spine pain (e.g., inflammatory arthritis).⁹
- Evaluation of thoracic outlet anatomy.¹⁰
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive

medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), upper extremity** is considered appropriate if **ALL** of the following is **TRUE**:

◆ **ANY** of the following:

- Plain radiographs are contraindicated or inconclusive; **OR**
- Ultrasound and CT/CTA are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to IV contrast reaction, pregnancy, pediatric); **AND**

◆ **ANY** of the following is **TRUE**:

- Trauma-related conditions as indicated by **ANY** of the following¹¹⁻¹²:
 - Fracture (traumatic or stress), and **ANY** of the following is **TRUE**¹³:
 - ◆ Joint dislocation or instability; **OR**
 - ◆ Stress/insufficiency fracture (known) and follow-up imaging needed; **OR**
 - ◆ Stress/insufficiency fracture (suspected) with negative radiographs; **OR**
 - Soft tissue injury or tear (e.g., tendon, ligament, muscle)¹¹⁻¹⁵; **OR**
- Detection, screening, and surveillance of neoplasms, masses, and cysts of an upper extremity and **ANY** of the following is **TRUE**⁵:
 - Malignant or aggressive primary tumor¹⁶; **OR**
 - Evaluation of metastatic lesions of the upper extremity; **OR**
 - Bone tumor is suspected with **ANY** of the following¹⁷:

- ◆ Initial radiographs are negative or do not explain symptoms; **OR**
- ◆ Osteoid osteoma is suspected; **OR**
- ◆ Lesion present on plain radiographs; **OR**
- ◆ Indeterminate or aggressive appearance concerning malignancy; **OR**
- ◆ “Incidental” osseous lesion on other imaging for unrelated indication; **OR**
- Presence of a mass with **ANY** of the following³:
 - ◆ Absence of trauma; **OR**
 - ◆ Rapid growth; **OR**
 - ◆ Recurrence after prior surgery; **OR**
 - ◆ Non-diagnostic ultrasound or other inconclusive imaging; **OR**
- Known malignancy and **ANY** of the following is required:
 - ◆ Monitor response to treatment; **OR**
 - ◆ Surveillance after treatment or surgery; **OR**
 - ◆ Non-diagnostic ultrasound or other inconclusive imaging; **OR**
- Palpable abnormality with a non-diagnostic radiograph or ultrasound; **OR**
- Infectious disorder including **ANY** of the following:
 - Osteomyelitis, suspected¹⁸; **OR**
 - Suspected septic arthritis or soft tissue infection is with **ANY** of the following initial radiographs¹⁸⁻¹⁹:
 - ◆ Normal; **OR**
 - ◆ Suggestive of joint effusion; **OR**
 - ◆ Suggestive of soft tissue swelling; **OR**
 - History of puncture wound with possible retained foreign body; **OR**
 - High clinical suspicion of necrotizing fasciitis; **OR**
- Vascular conditions, known or suspected, including **ANY** of the following:
 - Osteonecrosis or avascular necrosis, known or suspected, (e.g., suspected Kienböck's disease) with negative radiographs²⁰; **OR**
 - Vascular compromise, suspected¹⁵; **OR**

- Vascular malformation (with or without pain) and **ANY** of the following findings of physical deformity are suspected²¹:
 - ◆ Diffuse or focal enlargement; **OR**
 - ◆ Discoloration; **OR**
 - ◆ Soft-tissue mass; **OR**
 - ◆ Ulceration; **OR**
- Vascular bruit or thrill; **OR**
- For evaluation of **ANY** of the following uncategorized/miscellaneous symptoms when applicable:
 - Marrow abnormalities^{5,20}; **OR**
 - Pain or weakness of an upper extremity, and **ALL** of the following are **TRUE**^{15,22}:
 - ◆ Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 3 months; **AND**
 - ◆ Concern for acute rupture or high-grade tear of tendon, ligament, or soft tissue injury based on **ALL** of the following:
 - Clinical history; **AND**
 - Physical exam; **AND**
 - Prior radiographs excluding chronic pain or suspicion of a chronic or low-grade injury; **OR**
 - Neurological symptoms or deficits with **ANY** of the following:
 - ◆ Peripheral nerve sheath tumor suspected with **ANY** of the following:
 - Enlarging mass; **OR**
 - New or worsening localized pain; **OR**
 - Recurrence after prior resection; **OR**
 - ◆ Localized EMG abnormality; **OR**
 - ◆ Persistent symptoms or suspected nerve entrapment as confirmed by abnormal EMG; **OR**
 - ◆ Trauma or injury with suspected nerve injury or laceration; **OR**

- Initial diagnosis or follow-up of autoimmune, collagen vascular diseases, or inflammatory conditions (e.g., inflammatory arthritis)¹⁹; **OR**
- Synovial-related disorders (e.g., synovitis, bursitis, metaplasia, and neoplasia)²³; **OR**
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance imaging (MRI), upper extremity** may not be considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern; **OR**
- ◆ Incompatible implanted devices (e.g., pacemakers, defibrillators, cardiac valves, spinal cord stimulators); **OR**
- ◆ Imaging of cortical bone and calcifications¹; **OR**
- ◆ Procedures involving spatial resolution of bone and calcifications.¹

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
73218	Magnetic resonance imaging (MRI) (e.g., proton), upper extremity, other than joint; without contrast material(s)
73219	Magnetic resonance imaging (MRI) (e.g., proton), upper extremity, other than joint; with contrast material(s)
73220	Magnetic resonance imaging (MRI) (e.g., proton), upper extremity, other than joint; without contrast material(s), followed by contrast material(s) and further sequences
73221	Magnetic resonance imaging (MRI) (e.g., proton), any joint of upper extremity; without contrast material(s)
73222	Magnetic resonance imaging (MRI) (e.g., proton), any joint of upper extremity; with contrast material(s)
73223	Magnetic resonance imaging (MRI) (e.g., proton), any joint of upper extremity; without contrast material(s), followed by contrast material(s) and further sequences.

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

DeFrance et al. (2021) performed a study using magnetic resonance imaging (MRI) for diagnosing upper extremity conditions and assessed how MRI findings influenced patient management. Findings from 187 patients who had an MRI were analyzed on the usefulness of imaging and how they influenced treatment decisions. Imaging was ordered to assess for suspected occult scaphoid fractures, ulnar wrist pain, collateral ligament injuries of the metacarpophalangeal joint, and masses. Surgeons concurred with radiologists' interpretations in 88% of cases. Overall, surgeons noted MRI findings as helpful in 92% of cases.²⁴

Cortes et al. (2019) conducted a small prospective study on patients with suspected cuff tendinopathy. Fifty-one patients were included and underwent magnetic resonance imaging (MRI). Ninety percent (n=46) did not require surgical intervention; individuals who underwent surgery (10%) within an average of 68.3 days post-imaging. A significant proportion (over 90%) underwent premature MRI, which illustrates early MRI utilization in patients with atraumatic shoulder pain whose condition may have improved with conservative treatment first.²⁵

Rubin (2019) analyzed MRI and ultrasound findings of patients with rheumatoid arthritis in the hands and wrists. Advanced imaging modalities allow for visualization of synovitis and active soft-tissue inflammation, which are early indicators of potential structural damage. MRI can also identify osteitis, a crucial prognostic marker for disease aggressiveness. Findings include the distinct definitions (specifically synovitis, osteitis, and erosions) that enhance clinical assessment and imaging interpretation.²⁶

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Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		



Cohere Medicare Advantage Policy – MR Spectroscopy

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 25, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - MR Spectroscopy

Date of last literature review: 9/20/2024

Document last updated: 9/25/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: MR Spectroscopy

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for MR Spectroscopy.

Recommended Clinical Approach

Magnetic resonance spectroscopy (MRS) is a non-invasive diagnostic test that measures biochemical changes in the brain, muscles, and other organs. It primarily evaluates metabolic disorders, tumors, and other lesions. MRS provides additional information to conventional MRI by measuring the concentration of specific metabolites, such as N-acetylaspartate (NAA), choline (Cho), creatine (Cr), and myoinositol (mI).¹⁻²

MRS is particularly valuable in grading and assessing types of brain tumors and in assessing metabolic changes associated with tumor progression or response to therapy. For example, high choline levels can indicate increased cell membrane turnover associated with tumor growth, while reduced NAA levels may suggest neuronal loss or dysfunction.² Additionally, MRS can help differentiate between tumor recurrence, abscess, and radiation necrosis, aiding in treatment planning and monitoring.²

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of MR spectroscopy. This process helps to prevent both incorrect denials and inappropriate approvals of medically

necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.¹¹
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹²

The clinical benefits of using these criteria include:

- Specificity: MRS is uniquely able to differentiate between primary brain tumors and clinical mimics; it can also predict the clinical course of a brain tumor by diagnosing high-grade versus low-grade tumors.² In addition, MRS plays a unique role following treatment by serving as one of the few imaging modalities that can delineate radiation necrosis from tumor tissue, thereby allaying a common diagnostic challenge.²
- Noninvasive: As an imaging modality, MR spectroscopy is noninvasive; it is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers. It also utilizes no injected contrast agent and no ionizing radiation, conferring an inherent safety benefit.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

→ **Magnetic resonance spectroscopy (MRS)** is considered appropriate when **ALL** of the following are **TRUE**:

- ◆ Conventional imaging by magnetic resonance imaging (MRI) or computed tomography (CT) is inconclusive; **AND**
- ◆ **ANY** of the following is **TRUE**:
 - Neoplastic conditions (including masses or mass-like conditions) and **ANY** of the following is **TRUE**:
 - Grading of primary glial neoplasm, particularly high-grade versus low-grade glioma²; **OR**
 - Evaluation of brain tumors, including differentiation between tumor recurrence and radiation necrosis²⁻⁴; **OR**
 - Vascular conditions, known or suspected, including **ANY** of the following:
 - Neonatal hypoxic ischemic encephalopathy⁵; **OR**
 - Congenital condition as indicated by **ANY** of the following:
 - Diagnosis and evaluation of metabolic disorders such as mitochondrial diseases and inborn errors of metabolism⁶; **OR**
 - Inherited metabolic disorders (e.g., Canavan disease, mitochondrial encephalopathies, and other leukodystrophies)⁷; **OR**
 - Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Magnetic resonance spectroscopy (MRS)** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Presence of metallic implants or devices such as pacemakers that are not MRI-compatible; **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
76390	Magnetic resonance spectroscopy

Medical Evidence

Weinberg et al. (2021) conducted a systematic review of the literature regarding the clinical applications of magnetic resonance spectroscopy (MRS) in brain tumors. The writers state that MRS is utilized in clinical practice as well as research applications. The diagnostic clinical relevance of MRS includes its use as a type of virtual biopsy, as well as distinguishing gliomas from other types of diagnoses such as edema, necrosis, infection, or lymphoma. It is recommended by the group to use MRS in conjunction with conventional MRI due to occasional overlap in the appearance of different conditions. In tumor grading, the distinction between high and low-grade gliomas can be achieved with MRS. Limitations of MRS use in brain tumor imaging include similarities in the appearance of different diseases despite the differentiation of tissue types. Image quality may be affected by equipment variability and artifacts.²

In a 2022 systematic review of the literature, Germano et al. updated the 2014 Congress of Neurological Surgeons evidence-based guidelines on the management of progressive glioblastoma (pGBM) in adults. The literature search range was between 2012 to 2019, with 237 full-text articles extracted from 8786 total abstracts. The group made two new level II recommendations based on this review, with an additional 21 level III recommendations. The level II recommendations included the use of diffusion-weighted images included with magnetic resonance images with and without contrast in the diagnosis of patients with GBM as well as for surveillance. The other new level II recommendation is related to surgical procedures.⁴

Feldmann and colleagues (2022) examined MR-spectroscopy in metachromatic leukodystrophy (MLD) in a controlled cohort study consisting of 29 patients (10 infants, 19 juveniles) and 12 controls in 53 MRS datasets. MLD spectra were found to differ from the control group. White matter revealed the greatest differences compared to gray matter. Infant patients were found to have more severe changes when compared to later-onset patients in *N*-acetylaspartate (NAA), aspartate, glutamine, and choline intervals. It was concluded that NAA seemed to be the most clinically meaningful biomarker correlating with urine measurements obtained during the study.⁷

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Clinical Guideline Revision History/Information

Original Date: September 25, 2024		
Review History		



Cohere Medicare Advantage Policy – MR Spectroscopy

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 25, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - MR Spectroscopy

Date of last literature review: 9/20/2024

Document last updated: 9/25/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: MR Spectroscopy

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for MR Spectroscopy.

Recommended Clinical Approach

Magnetic resonance spectroscopy (MRS) is a non-invasive diagnostic test that measures biochemical changes in the brain, muscles, and other organs. It primarily evaluates metabolic disorders, tumors, and other lesions. MRS provides additional information to conventional MRI by measuring the concentration of specific metabolites, such as N-acetylaspartate (NAA), choline (Cho), creatine (Cr), and myoinositol (mI).¹⁻²

MRS is particularly valuable in grading and assessing types of brain tumors and in assessing metabolic changes associated with tumor progression or response to therapy. For example, high choline levels can indicate increased cell membrane turnover associated with tumor growth, while reduced NAA levels may suggest neuronal loss or dysfunction.² Additionally, MRS can help differentiate between tumor recurrence, abscess, and radiation necrosis, aiding in treatment planning and monitoring.²

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of MR spectroscopy. This process helps to prevent both incorrect denials and inappropriate approvals of medically

necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.¹¹
- Increased healthcare costs and complications from the inappropriate use of additional interventions.¹²

The clinical benefits of using these criteria include:

- Specificity: MRS is uniquely able to differentiate between primary brain tumors and clinical mimics; it can also predict the clinical course of a brain tumor by diagnosing high-grade versus low-grade tumors.² In addition, MRS plays a unique role following treatment by serving as one of the few imaging modalities that can delineate radiation necrosis from tumor tissue, thereby allaying a common diagnostic challenge.²
- Noninvasive: As an imaging modality, MR spectroscopy is noninvasive; it is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers. It also utilizes no injected contrast agent and no ionizing radiation, conferring an inherent safety benefit.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

→ **Magnetic resonance spectroscopy (MRS)** is considered appropriate when **ALL** of the following are **TRUE**:

- ◆ Conventional imaging by magnetic resonance imaging (MRI) or computed tomography (CT) is inconclusive; **AND**
- ◆ **ANY** of the following is **TRUE**:
 - Neoplastic conditions (including masses or mass-like conditions) and **ANY** of the following is **TRUE**:
 - Grading of primary glial neoplasm, particularly high-grade versus low-grade glioma²; **OR**
 - Evaluation of brain tumors, including differentiation between tumor recurrence and radiation necrosis²⁻⁴; **OR**
 - Vascular conditions, known or suspected, including **ANY** of the following:
 - Neonatal hypoxic ischemic encephalopathy⁵; **OR**
 - Congenital condition as indicated by **ANY** of the following:
 - Diagnosis and evaluation of metabolic disorders such as mitochondrial diseases and inborn errors of metabolism⁶; **OR**
 - Inherited metabolic disorders (e.g., Canavan disease, mitochondrial encephalopathies, and other leukodystrophies)⁷; **OR**
 - Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- **Magnetic resonance spectroscopy (MRS)** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Presence of metallic implants or devices such as pacemakers that are not MRI-compatible; **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
76390	Magnetic resonance spectroscopy

Medical Evidence

Weinberg et al. (2021) conducted a systematic review of the literature regarding the clinical applications of magnetic resonance spectroscopy (MRS) in brain tumors. The writers state that MRS is utilized in clinical practice as well as research applications. The diagnostic clinical relevance of MRS includes its use as a type of virtual biopsy, as well as distinguishing gliomas from other types of diagnoses such as edema, necrosis, infection, or lymphoma. It is recommended by the group to use MRS in conjunction with conventional MRI due to occasional overlap in the appearance of different conditions. In tumor grading, the distinction between high and low-grade gliomas can be achieved with MRS. Limitations of MRS use in brain tumor imaging include similarities in the appearance of different diseases despite the differentiation of tissue types. Image quality may be affected by equipment variability and artifacts.²

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Clinical Guideline Revision History/Information

Original Date: September 25, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Abdomen and Magnetic Resonance Cholangiopancreatography (MRCP)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 26, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Magnetic Resonance Imaging (MRI), Abdomen and Magnetic Resonance Cholangiopancreatography (MRCP)

Date of last literature review: 9/20/2024

Document last updated: 9/26/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Abdomen and Magnetic Resonance Cholangiopancreatography (MRCP)

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.⁴¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- [National Coverage Determination \(NCD\). Magnetic Resonance Imaging \(MRI\)\(220.2\).](#)

Recommended Clinical Approach

The use of contrast and the type of magnetic resonance (MR) contrast (e.g., extracellular or hepatobiliary-specific) should be at the request of the ordering provider with guidance from the radiologist. The MR field of view should be limited to the area of interest and, in some cases, may not be the preferred imaging study.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI), abdomen and magnetic resonance cholangiopancreatography (MRCP). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g.,

- implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.^{1,42-44}
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.^{1,42-44}
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁴⁴

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. MRI is useful in obtaining images of any part of the body in any direction, as well as providing better soft tissue contrast compared to computed tomography.⁴⁵
- Reduction in complications and adverse effects from unnecessary procedures. The absence of exposure of ionizing radiation compared to computed tomography use, and imaging quality when contrast is not used are several benefits of MRI use in abdominal evaluations.⁴⁶
- Enhanced diagnostic accuracy for complex medical conditions. Per the American College of Radiology practice parameters for MRI of the abdomen and MRI of the liver, MRI imaging is useful for detection, characterization, and/or staging of abdominal neoplasms such as those in the pancreas, spleen, kidneys, and liver. Additionally, patients with traumatic abdominal injury, abdominal wall abnormalities, or vascular malformations may benefit from MRI.⁴⁷
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive

medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), abdomen** is considered appropriate if **ALL** of the following are **TRUE**¹:

◆ Ultrasound and CT/CTA are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to IV contrast reaction, pregnancy, pediatric); **AND**

◆ **ANY** of the following is **TRUE**:

- Suspected appendicitis in pregnant people; **OR**
- Suspected appendicitis in a pediatric patient; **OR**
- Unexplained abdominal pain in a pregnant person or pediatric patient with non-diagnostic ultrasound; **OR**
- Suspected abdominal abscess, diverticulitis, complicated UTI in a pregnant person or pediatric patient; **OR**
- Detection, screening, surveillance, and follow-up of malignancies or metastatic involvement in the abdomen for **ANY** of the following²⁻⁴:
 - To further characterize a lesion previously identified on a CT scan when the CT result is inconclusive; **OR**
 - Metastases, known or suspected, including preoperative mapping for liver resection; **OR**
 - Known or suspected primary malignancies with an assessment of vascular and biliary invasion, including but not limited to **ANY** of the following⁵:
 - ◆ Rising alpha-fetoprotein (AFP) in a high-risk patient or patient with known hepatocellular carcinoma (HCC); **OR**
 - ◆ CA 19-9; **OR**
 - ◆ Painless jaundice; **OR**

- ◆ Persistent hematuria; **OR**
- ◆ Other biomarker/sign/symptom suggestive of underlying malignancy; **OR**
- Neoplastic conditions for **ANY** of the following:
 - ◆ Initial staging; **OR**
 - ◆ Treatment planning; **OR**
 - ◆ Response assessment; **OR**
 - ◆ Surveillance, and **ANY** of the following is **TRUE**^{2,9-11}:
 - The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - Suspected recurrence/progression; **OR**
 - Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6-8 weeks since the prior imaging evaluation); **OR**
- Annual screening of a patient with an increased risk of cancer due to **ANY** of the following:
 - ◆ Cirrhosis or chronic viral hepatitis where ultrasound or CT is nondiagnostic; **OR**
 - ◆ Primary sclerosing cholangitis after age 20⁷; **OR**
 - ◆ Known mutation that increases susceptibility (e.g., Von Hippel Lindai, Tuberous Sclerosis, BRCA-1/2); **OR**
 - ◆ The patient has two or more first-degree or second-degree relatives with the same or related cancer from the same side of the family; **OR**
- For evaluation of known benign or indeterminate adrenal masses with **ANY** of the following⁸⁻⁹:
 - Indeterminate adrenal mass found on initial imaging, and **ANY** of the following:
 - ◆ 1-4 cm with follow-up at 6-12 months¹⁰; **OR**
 - ◆ Potential metastatic involvement and less than 4 cm; **OR**

- Adrenal adenoma, known or suspected based on clinical **AND** laboratory findings; **OR**
- Abdominal wall abnormalities, including hernias¹¹; **OR**
- Peritoneal or mesenteric abnormalities such as carcinomatosis, internal hernias, or infarct; **OR**
- Characterization, and follow-up of intra-abdominal fluid collections; **OR**
- Gastrointestinal tract evaluation, as indicated by **ANY** of the following¹²:
 - Celiac disease with recurring symptoms despite maintaining a gluten-free diet for 12 months or more¹³; **OR**
 - Crohn's disease, known or suspected¹⁴; **OR**
 - Other autoimmune enteritis with small bowel involvement; **OR**
 - Volvulus, internal hernias, incarceration; **OR**
- Hepatobiliary system (liver, bile ducts, gallbladder, and associated structures) as indicated by **ANY** of the following⁶:
 - To further characterize a lesion previously identified on a CT scan when the CT result is inconclusive; **OR**
 - Infection/inflammation (e.g. cholangitis)⁶; **OR**
 - Pre-operative or post-operative evaluation (e.g., liver resection, donor or transplant, hepatic shunt placement); **OR**
 - Non-invasive quantification of iron, fat, and fibrosis in chronic liver disease (e.g., hemochromatosis, hemosiderosis, nonalcoholic steatohepatitis [NASH] hepatitis), includes hepatic elastography; **OR**
 - Gallbladder disease, including evaluation of indeterminate polyps/nodules detected with other imaging modalities¹⁵; **OR**
- Kidney and urinary system disease as indicated by **ANY** of the following¹⁶⁻¹⁹:
 - Renal cysts with classification of Bosniak IIF or above (up to annually); **OR**
 - Solid indeterminate renal masses (up to annually); **OR**

- Renal angiomyolipomas more than 3 cm (up to annually); **OR**
- Characterization of other indeterminate lesions detected with other imaging modalities; **OR**
- Diagnostic evaluation of concerning signs/symptoms (e.g., pain, concern for rupture, infection, hemorrhage) in a patient with known polycystic kidney disease²⁰; **OR**
- Infectious or inflammatory disease (e.g., complicated pyelonephritis); **OR**
- Anatomic abnormalities, congenital or acquired (e.g., horseshoe kidney, retroperitoneal fibrosis); **OR**
- Evaluation of the ureters/collecting system (e.g., stones, tumors, or stricture); **OR**
- Pancreatic abnormalities as indicated by **ANY** of the following²¹:
 - Duct anomaly²²; **OR**
 - Duct obstruction (e.g., calculi, stricture, or mass)²²; **OR**
 - Fluid collections; **OR**
 - Pancreatic pseudocysts; **OR**
 - Indeterminate lesions; **OR**
 - Pancreatitis (acute or chronic) with **ANY** of the following²³⁻²⁴:
 - ◆ Concern for complications such as necrosis or abscess; **OR**
 - ◆ Lack of response to conservative treatment and management; **OR**
 - ◆ Ultrasound did not show clear etiology such as a stone; **OR**
 - Indeterminate cyst in an asymptomatic patient that requires follow-up, and **ANY** of the following is **TRUE**^{22,25}:
 - ◆ One-year follow-up imaging when interval growth is present on the previous follow-up; **OR**
 - ◆ The cyst is less than 1.5 cm without interval growth, and **ANY** of the following is **TRUE**:
 - For patients less than 65 years of age, annually up to five years; **OR**

- For patients from 65 to 79 years of age, every two years up to ten years; **OR**
- For patients more than 80 years of age, every two years up to four years; **OR**
- ◆ Cyst is greater than 1.5 cm without interval growth, and **ANY** of the following is **TRUE** :
 - The patient is less than 80 years old, and **ANY** of the following frequency limitations is **TRUE**:
 - Up to every 6 months for 2 years from diagnosis; **OR**
 - Up to annually for up to ten years from diagnosis; **OR**
 - The patient is greater or equal to 80 years old with a frequency limitation of every 2 years for 4 years; **OR**
- Splenic abnormalities as indicated by **ANY** of the following:
 - ◆ Characterization of indeterminate lesions detected with other imaging modalities; **OR**
 - ◆ Detection and characterization of suspected diffuse abnormalities of the spleen; **OR**
- Post-traumatic organ injury; **OR**
- Fever of unknown origin greater than 101°F for at least 3 weeks where laboratory and clinical workup has been performed and have not revealed a diagnosis²⁶⁻²⁷; **OR**
- Preoperative, postoperative, or pre-treatment evaluation for **ANY** of the following:
 - Post-surgical complications involving the hepatobiliary system (bile ducts, gallbladder, and associated structures)⁶; **OR**
 - Post-treatment follow-up for **ANY** of the following:
 - ◆ Complications of pancreatitis; **OR**
 - ◆ Fluid collections; **OR**
 - ◆ Pancreatic duct anomalies; **OR**
- Characterization of complex congenital anomalies (e.g., genitourinary and pelvic organs)¹⁶⁻¹⁹; **OR**
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be

considered reasonable and necessary if **ANY** of the following is **TRUE**:

- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Magnetic resonance cholangiopancreatography (MRCP)** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The patient has **ANY** of the following:
 - Evidence of biliary obstruction or involvement, including **ANY** of the following²⁸⁻³⁰:
 - Biliary duct dilation requiring further work-up; **OR**
 - Jaundice³¹; **OR**
 - Laboratory or biochemical markers, including increased alkaline phosphatase, gamma-glutamyl transpeptidase, or conjugated (direct) bilirubinemia; **OR**
 - Clinical suspicion of primary sclerosing cholangitis; **OR**
 - Known or suspected abnormalities of the pancreatic and biliary ducts, including **ANY** of the following^{28-29,32-33}:
 - Acute pancreatitis³⁴; **OR**
 - Chronic pancreatitis³⁴; **OR**
 - Cystic lesions in the pancreas²²; **OR**
 - Ductal stones; **OR**
 - Evaluation of bile duct dilation or stricture; **OR**
 - Unexplained right upper quadrant pain when ultrasound or CT are inconclusive^{15,28-29}; **OR**
- ◆ Assessment of post-liver transplant biliary complications; **OR**
- ◆ When ERCP is unsuccessful or contraindicated, or therapeutic ERCP is unlikely to be needed^{11,28-29,35}; **OR**
- ◆ Delineation of ductal anatomy before liver transplantation; **OR**
- ◆ Detection and anatomic delineation of bile leaks; **OR**
- ◆ Detection, staging, and post-treatment follow-up of bile duct and gallbladder cancer; **OR**

- ◆ Evaluation of suspected congenital abnormalities of the gallbladder or bile ducts; **OR**
- ◆ Follow-up after surgery or intervention; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance imaging (MRI), abdomen or magnetic resonance cholangiopancreatography (MRCP)** are is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ MRCP ordered with procedure code S8037; **OR**
- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description

74181	Magnetic resonance imaging (MRI) (e.g., proton), abdomen; without contrast material(s)
74182	Magnetic resonance imaging (MRI) (e.g., proton), abdomen; with contrast material(s)
74183	Magnetic resonance imaging (MRI) (e.g., proton), abdomen, without contrast material(s), followed by contrast material(s) and further sequences
S8037	Magnetic resonance cholangiopancreatography (MRCP)(Not covered per CMS guidelines)

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Hernando et al. (2022) reviewed quantitative diffusion MRI of the abdomen and pelvis, which involves employing multiple diffusion encodings and mapping diffusion parameters. Diffusion MRI allows the ability to gauge tissue microstructure sensitivity. In contrast to qualitative diffusion-weighted MRI, the quantitative approach enhances the standardization of tissue characterization, which is crucial for disease detection, staging, and treatment monitoring. Challenges include acquisition artifacts, limitations in signal modeling, and biological variability. Technical performance concerns include addressing physiologic motion (respiratory, peristaltic, and pulsatile), handling image distortions, and managing a low signal-to-noise ratio.³⁷

The American Urological Association (AUA) published guidelines on renal mass and localized renal cancer. Based on recommendations from the American College of Radiology (ACR), cross-sectional nervous system imaging is the preferred diagnostic method for identifying or ruling out metastases in the brain and spine. While MRI may exhibit greater sensitivity in detecting small central nervous system (CNS) neoplasms, CT can be beneficial for promptly assessing acute neurological signs or symptoms. MRI benefits patients who cannot receive IV iodinated contrast before and after administering gadolinium. Cross-sectional MRI with diffusion-weighted imaging benefits for patients who cannot tolerate conventional contrast. If there is suspicion of a mass, contrast-enhanced ultrasound can be employed to assess for enhancement.¹⁸⁻¹⁹

Staubli et al. (2022) performed a randomized control trial (RCT) comparing intraoperative cholangiography (IOC) and magnetic resonance cholangiopancreatography (MRCP) in patients suspected of having common bile duct stones (CBDS). It was a multicenter randomized controlled trial conducted across five hospitals. Patients were randomly assigned to receive either IOC followed by laparoscopic cholecystectomy (LC) with potential endoscopic retrograde cholangiopancreatography (ERCP) or MRCP followed by ERCP and LC if deemed necessary. The primary focus was on the LOS, with secondary measures encompassing cost, stone detection, and complication rates. The findings indicated that IOC was more effective in diagnosing CBDS than MRCP. Although the median LOS was slightly shorter in the IOC group, this variance did not reach statistical significance. No significant cost difference was observed between the two approaches. However, CBDS were more frequently detected in the IOC group. Complication rates did not exhibit disparity between the two methods. The study concluded that while IOC and MRCP are viable options, IOC stands out for its notably higher diagnostic yield in detecting CBDS. (Clinicaltrials.gov Identifier: NCT02351492).³⁸

Suzuki et al. conducted an RCT to evaluate the diagnostic precision of endoscopic ultrasound (EUS) and MRCP in detecting choledocholithiasis cases initially overlooked on CT scans. Patients suspected of having CBDS were divided into two groups: one receiving EUS and the other MRCP. Initially, those diagnosed with CBDS or sludge underwent ERCP, while CBDS-negative patients underwent a second diagnostic procedure, either MRCP or EUS, different from the initial one. The main focus was on the accuracy of diagnosis, with secondary interests in diagnostic capabilities, CBDS detection rates and characteristics during the second examination, and adverse event occurrence. Overall, EUS may provide higher diagnostic ability than MRCP; however, the authors did not note significant differences in recommending one procedure over the other.³⁹

Timmerhuis et al. (2021) performed a systematic review of available guidelines for diagnosing a disrupted pancreatic duct in patients with acute pancreatitis. Eight studies with five distinct diagnostic modalities in 142 severe acute pancreatitis patients were included. Endoscopic ultrasound and ERCP reported a sensitivity of 100%. A sensitivity of 83% was reported with MRCP, with or without secretin. A combined cohort of secretin-enhanced MRCP and standard MRCP showed a sensitivity of 92%. Amylase measurements in drain fluid exhibited a sensitivity of 100% and specificity of 50% compared to ERCP. The authors concluded that various diagnostic modalities effectively diagnose disrupted pancreatic ducts in acute pancreatitis patients. Considering the invasiveness of alternative modalities, secretin-enhanced MRCP is recommended as the initial diagnostic approach.⁴⁰

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Clinical Guideline Revision History/Information

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Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI), Abdomen and Magnetic Resonance Cholangiopancreatography (MRCP)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: September 26, 2024

Important Notices

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Guideline Information:

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Abdomen and Magnetic Resonance Cholangiopancreatography (MRCP)

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.⁴¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- [National Coverage Determination \(NCD\). Magnetic Resonance Imaging \(MRI\)\(220.2\).](#)

Recommended Clinical Approach

The use of contrast and the type of magnetic resonance (MR) contrast (e.g., extracellular or hepatobiliary-specific) should be at the request of the ordering provider with guidance from the radiologist. The MR field of view should be limited to the area of interest and, in some cases, may not be the preferred imaging study.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI), abdomen and magnetic resonance cholangiopancreatography (MRCP). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g.,

- implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.^{1,42-44}
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.^{1,42-44}
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.⁴⁴

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. MRI is useful in obtaining images of any part of the body in any direction, as well as providing better soft tissue contrast compared to computed tomography.⁴⁵
- Reduction in complications and adverse effects from unnecessary procedures. The absence of exposure of ionizing radiation compared to computed tomography use, and imaging quality when contrast is not used are several benefits of MRI use in abdominal evaluations.⁴⁶
- Enhanced diagnostic accuracy for complex medical conditions. Per the American College of Radiology practice parameters for MRI of the abdomen and MRI of the liver, MRI imaging is useful for detection, characterization, and/or staging of abdominal neoplasms such as those in the pancreas, spleen, kidneys, and liver. Additionally, patients with traumatic abdominal injury, abdominal wall abnormalities, or vascular malformations may benefit from MRI.⁴⁷
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive

medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Magnetic resonance imaging (MRI), abdomen** is considered appropriate if **ALL** of the following are **TRUE**¹:

◆ Ultrasound and CT/CTA are contraindicated or inconclusive (e.g., body habitus for ultrasound, anaphylactic reaction due to IV contrast reaction, pregnancy, pediatric); **AND**

◆ **ANY** of the following is **TRUE**:

- Suspected appendicitis in pregnant people; **OR**
- Suspected appendicitis in a pediatric patient; **OR**
- Unexplained abdominal pain in a pregnant person or pediatric patient with non-diagnostic ultrasound; **OR**
- Suspected abdominal abscess, diverticulitis, complicated UTI in a pregnant person or pediatric patient; **OR**
- Detection, screening, surveillance, and follow-up of malignancies or metastatic involvement in the abdomen for **ANY** of the following²⁻⁴:
 - To further characterize a lesion previously identified on a CT scan when the CT result is inconclusive; **OR**
 - Metastases, known or suspected, including preoperative mapping for liver resection; **OR**
 - Known or suspected primary malignancies with an assessment of vascular and biliary invasion, including but not limited to **ANY** of the following⁵:
 - ◆ Rising alpha-fetoprotein (AFP) in a high-risk patient or patient with known hepatocellular carcinoma (HCC); **OR**
 - ◆ CA 19-9; **OR**
 - ◆ Painless jaundice; **OR**

- ◆ Persistent hematuria; **OR**
- ◆ Other biomarker/sign/symptom suggestive of underlying malignancy; **OR**
- Neoplastic conditions for **ANY** of the following:
 - ◆ Initial staging; **OR**
 - ◆ Treatment planning; **OR**
 - ◆ Response assessment; **OR**
 - ◆ Surveillance, and **ANY** of the following is **TRUE**^{2,9-11}:
 - The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - Suspected recurrence/progression; **OR**
 - Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6-8 weeks since the prior imaging evaluation); **OR**
- Annual screening of a patient with an increased risk of cancer due to **ANY** of the following:
 - ◆ Cirrhosis or chronic viral hepatitis where ultrasound or CT is nondiagnostic; **OR**
 - ◆ Primary sclerosing cholangitis after age 20⁷; **OR**
 - ◆ Known mutation that increases susceptibility (e.g., Von Hippel Lindai, Tuberous Sclerosis, BRCA-1/2); **OR**
 - ◆ The patient has two or more first-degree or second-degree relatives with the same or related cancer from the same side of the family; **OR**
- For evaluation of known benign or indeterminate adrenal masses with **ANY** of the following⁸⁻⁹:
 - Indeterminate adrenal mass found on initial imaging, and **ANY** of the following:
 - ◆ 1-4 cm with follow-up at 6-12 months¹⁰; **OR**
 - ◆ Potential metastatic involvement and less than 4 cm; **OR**

- Adrenal adenoma, known or suspected based on clinical **AND** laboratory findings; **OR**
- Abdominal wall abnormalities, including hernias¹¹; **OR**
- Peritoneal or mesenteric abnormalities such as carcinomatosis, internal hernias, or infarct; **OR**
- Characterization, and follow-up of intra-abdominal fluid collections; **OR**
- Gastrointestinal tract evaluation, as indicated by **ANY** of the following¹²:
 - Celiac disease with recurring symptoms despite maintaining a gluten-free diet for 12 months or more¹³; **OR**
 - Crohn's disease, known or suspected¹⁴; **OR**
 - Other autoimmune enteritis with small bowel involvement; **OR**
 - Volvulus, internal hernias, incarceration; **OR**
- Hepatobiliary system (liver, bile ducts, gallbladder, and associated structures) as indicated by **ANY** of the following⁶:
 - To further characterize a lesion previously identified on a CT scan when the CT result is inconclusive; **OR**
 - Infection/inflammation (e.g. cholangitis)⁶; **OR**
 - Pre-operative or post-operative evaluation (e.g., liver resection, donor or transplant, hepatic shunt placement); **OR**
 - Non-invasive quantification of iron, fat, and fibrosis in chronic liver disease (e.g., hemochromatosis, hemosiderosis, nonalcoholic steatohepatitis [NASH] hepatitis), includes hepatic elastography; **OR**
 - Gallbladder disease, including evaluation of indeterminate polyps/nodules detected with other imaging modalities¹⁵; **OR**
- Kidney and urinary system disease as indicated by **ANY** of the following¹⁶⁻¹⁹:
 - Renal cysts with classification of Bosniak IIF or above (up to annually); **OR**
 - Solid indeterminate renal masses (up to annually); **OR**

- Renal angiomyolipomas more than 3 cm (up to annually); **OR**
- Characterization of other indeterminate lesions detected with other imaging modalities; **OR**
- Diagnostic evaluation of concerning signs/symptoms (e.g., pain, concern for rupture, infection, hemorrhage) in a patient with known polycystic kidney disease²⁰; **OR**
- Infectious or inflammatory disease (e.g., complicated pyelonephritis); **OR**
- Anatomic abnormalities, congenital or acquired (e.g., horseshoe kidney, retroperitoneal fibrosis); **OR**
- Evaluation of the ureters/collecting system (e.g., stones, tumors, or stricture); **OR**
- Pancreatic abnormalities as indicated by **ANY** of the following²¹:
 - Duct anomaly²²; **OR**
 - Duct obstruction (e.g., calculi, stricture, or mass)²²; **OR**
 - Fluid collections; **OR**
 - Pancreatic pseudocysts; **OR**
 - Indeterminate lesions; **OR**
 - Pancreatitis (acute or chronic) with **ANY** of the following²³⁻²⁴:
 - ◆ Concern for complications such as necrosis or abscess; **OR**
 - ◆ Lack of response to conservative treatment and management; **OR**
 - ◆ Ultrasound did not show clear etiology such as a stone; **OR**
 - Indeterminate cyst in an asymptomatic patient that requires follow-up, and **ANY** of the following is **TRUE**^{22,25}:
 - ◆ One-year follow-up imaging when interval growth is present on the previous follow-up; **OR**
 - ◆ The cyst is less than 1.5 cm without interval growth, and **ANY** of the following is **TRUE**:
 - For patients less than 65 years of age, annually up to five years; **OR**

- For patients from 65 to 79 years of age, every two years up to ten years; **OR**
- For patients more than 80 years of age, every two years up to four years; **OR**
- ◆ Cyst is greater than 1.5 cm without interval growth, and **ANY** of the following is **TRUE** :
 - The patient is less than 80 years old, and **ANY** of the following frequency limitations is **TRUE**:
 - Up to every 6 months for 2 years from diagnosis; **OR**
 - Up to annually for up to ten years from diagnosis; **OR**
 - The patient is greater or equal to 80 years old with a frequency limitation of every 2 years for 4 years; **OR**
- Splenic abnormalities as indicated by **ANY** of the following:
 - ◆ Characterization of indeterminate lesions detected with other imaging modalities; **OR**
 - ◆ Detection and characterization of suspected diffuse abnormalities of the spleen; **OR**
- Post-traumatic organ injury; **OR**
- Fever of unknown origin greater than 101°F for at least 3 weeks where laboratory and clinical workup has been performed and have not revealed a diagnosis²⁶⁻²⁷; **OR**
- Preoperative, postoperative, or pre-treatment evaluation for **ANY** of the following:
 - Post-surgical complications involving the hepatobiliary system (bile ducts, gallbladder, and associated structures)⁸; **OR**
 - Post-treatment follow-up for **ANY** of the following:
 - ◆ Complications of pancreatitis; **OR**
 - ◆ Fluid collections; **OR**
 - ◆ Pancreatic duct anomalies; **OR**
- Characterization of complex congenital anomalies (e.g., genitourinary and pelvic organs)¹⁶⁻¹⁹; **OR**
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be

considered reasonable and necessary if **ANY** of the following is **TRUE**:

- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Magnetic resonance cholangiopancreatography (MRCP)** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The patient has **ANY** of the following:
 - Evidence of biliary obstruction or involvement, including **ANY** of the following²⁸⁻³⁰:
 - Biliary duct dilation requiring further work-up; **OR**
 - Jaundice³¹; **OR**
 - Laboratory or biochemical markers, including increased alkaline phosphatase, gamma-glutamyl transpeptidase, or conjugated (direct) bilirubinemia; **OR**
 - Clinical suspicion of primary sclerosing cholangitis; **OR**
 - Known or suspected abnormalities of the pancreatic and biliary ducts, including **ANY** of the following^{28-29,32-33}:
 - Acute pancreatitis³⁴; **OR**
 - Chronic pancreatitis³⁴; **OR**
 - Cystic lesions in the pancreas²²; **OR**
 - Ductal stones; **OR**
 - Evaluation of bile duct dilation or stricture; **OR**
 - Unexplained right upper quadrant pain when ultrasound or CT are inconclusive^{15,28-29}; **OR**
- ◆ Assessment of post-liver transplant biliary complications; **OR**
- ◆ When ERCP is unsuccessful or contraindicated, or therapeutic ERCP is unlikely to be needed^{11,28-29,35}; **OR**
- ◆ Delineation of ductal anatomy before liver transplantation; **OR**
- ◆ Detection and anatomic delineation of bile leaks; **OR**
- ◆ Detection, staging, and post-treatment follow-up of bile duct and gallbladder cancer; **OR**

- ◆ Evaluation of suspected congenital abnormalities of the gallbladder or bile ducts; **OR**
- ◆ Follow-up after surgery or intervention; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Magnetic resonance imaging (MRI), abdomen or magnetic resonance cholangiopancreatography (MRCP)** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ MRCP ordered with procedure code S8037; **OR**
- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description

74181	Magnetic resonance imaging (MRI) (e.g., proton), abdomen; without contrast material(s)
74182	Magnetic resonance imaging (MRI) (e.g., proton), abdomen; with contrast material(s)
74183	Magnetic resonance imaging (MRI) (e.g., proton), abdomen, without contrast material(s), followed by contrast material(s) and further sequences
S8037	Magnetic resonance cholangiopancreatography (MRCP)(Not covered per CMS guidelines)

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Hernando et al. (2022) reviewed quantitative diffusion MRI of the abdomen and pelvis, which involves employing multiple diffusion encodings and mapping diffusion parameters. Diffusion MRI allows the ability to gauge tissue microstructure sensitivity. In contrast to qualitative diffusion-weighted MRI, the quantitative approach enhances the standardization of tissue characterization, which is crucial for disease detection, staging, and treatment monitoring. Challenges include acquisition artifacts, limitations in signal modeling, and biological variability. Technical performance concerns include addressing physiologic motion (respiratory, peristaltic, and pulsatile), handling image distortions, and managing a low signal-to-noise ratio.³⁷

The American Urological Association (AUA) published guidelines on renal mass and localized renal cancer. Based on recommendations from the American College of Radiology (ACR), cross-sectional nervous system imaging is the preferred diagnostic method for identifying or ruling out metastases in the brain and spine. While MRI may exhibit greater sensitivity in detecting small central nervous system (CNS) neoplasms, CT can be beneficial for promptly assessing acute neurological signs or symptoms. MRI benefits patients who cannot receive IV iodinated contrast before and after administering gadolinium. Cross-sectional MRI with diffusion-weighted imaging benefits for patients who cannot tolerate conventional contrast. If there is suspicion of a mass, contrast-enhanced ultrasound can be employed to assess for enhancement.¹⁸⁻¹⁹

Staubli et al. (2022) performed a randomized control trial (RCT) comparing intraoperative cholangiography (IOC) and magnetic resonance cholangiopancreatography (MRCP) in patients suspected of having common bile duct stones (CBDS). It was a multicenter randomized controlled trial conducted across five hospitals. Patients were randomly assigned to receive either IOC followed by laparoscopic cholecystectomy (LC) with potential endoscopic retrograde cholangiopancreatography (ERCP) or MRCP followed by ERCP and LC if deemed necessary. The primary focus was on the LOS, with secondary measures encompassing cost, stone detection, and complication rates. The findings indicated that IOC was more effective in diagnosing CBDS than MRCP. Although the median LOS was slightly shorter in the IOC group, this variance did not reach statistical significance. No significant cost difference was observed between the two approaches. However, CBDS were more frequently detected in the IOC group. Complication rates did not exhibit disparity between the two methods. The study concluded that while IOC and MRCP are viable options, IOC stands out for its notably higher diagnostic yield in detecting CBDS. (Clinicaltrials.gov Identifier: NCT02351492).³⁸

Suzuki et al. conducted an RCT to evaluate the diagnostic precision of endoscopic ultrasound (EUS) and MRCP in detecting choledocholithiasis cases initially overlooked on CT scans. Patients suspected of having CBDS were divided into two groups: one receiving EUS and the other MRCP. Initially, those diagnosed with CBDS or sludge underwent ERCP, while CBDS-negative patients underwent a second diagnostic procedure, either MRCP or EUS, different from the initial one. The main focus was on the accuracy of diagnosis, with secondary interests in diagnostic capabilities, CBDS detection rates and characteristics during the second examination, and adverse event occurrence. Overall, EUS may provide higher diagnostic ability than MRCP; however, the authors did not note significant differences in recommending one procedure over the other.³⁹

Timmerhuis et al. (2021) performed a systematic review of available guidelines for diagnosing a disrupted pancreatic duct in patients with acute pancreatitis. Eight studies with five distinct diagnostic modalities in 142 severe acute pancreatitis patients were included. Endoscopic ultrasound and ERCP reported a sensitivity of 100%. A sensitivity of 83% was reported with MRCP, with or without secretin. A combined cohort of secretin-enhanced MRCP and standard MRCP showed a sensitivity of 92%. Amylase measurements in drain fluid exhibited a sensitivity of 100% and specificity of 50% compared to ERCP. The authors concluded that various diagnostic modalities effectively diagnose disrupted pancreatic ducts in acute pancreatitis patients. Considering the invasiveness of alternative modalities, secretin-enhanced MRCP is recommended as the initial diagnostic approach.⁴⁰

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Important Notices

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Cardiac

Benefit Category

Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁵

- [National Coverage Determination \(NCD\) 220.2. Magnetic Resonance Imaging](#)
- [Local Coverage Determination \(LCD\) L38396. Cardiology Non-Emergent Outpatient Stress Testing](#)
- [Local Coverage Determination \(LCD\) L35083. Cardiology Non-Emergent Outpatient Stress Testing](#)
- [Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing \(A56423\)](#)
- [Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing \(A56952\)](#)

Recommended Clinical Approach

Cardiac magnetic resonance imaging (MRI) offers exquisite anatomic detail and can also provide valuable functional information through various sequences. While not a first-line imaging modality, it proves highly useful when structural abnormalities (congenital or acquired) or functional deficiencies require further investigation of the heart and pericardial structures.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of cardiac MRI. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁶
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁶
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁷
- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁸

The clinical benefits of using these criteria include:

- Noninvasive: As a cardiac imaging modality, cardiac MRI is noninvasive; it is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers.⁹⁻¹⁰
- Reduced need for invasive angiography: When triaging patients with undifferentiated chest pain, patients evaluated with cardiac MRI are more likely to be discharged without the need for invasive angiography, thereby avoiding the additional risks and costs associated with an invasive procedure.¹¹
- Improved therapeutic yield: Among patients who are referred for invasive angiography, those who are evaluated by cardiac MRI

experience higher rates of revascularization and therefore improved treatment efficacy as compared to patients who are not imaged with cardiac MRI.¹¹

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Cardiac magnetic resonance imaging (MRI)** is considered appropriate if **ALL** of the following are **TRUE**:

- ◆ First-line cardiac imaging modality such as transthoracic echo is inconclusive/non-diagnostic, and further imaging is indicated for diagnostic and therapeutic purposes; **AND**
- ◆ **ANY** of the following is **TRUE**:
 - Documented or suspected neoplastic conditions of the heart (including cardiac masses or mass-like conditions); **OR**
 - Infection or an infectious disorder, including infective endocarditis, myocarditis, or complications not diagnosable by other imaging modalities; **OR**
 - Known or suspected pericardial disease, including **ANY** of the following¹²:
 - Pericardial effusion; **OR**
 - Structural pericardial anomalies; **OR**
 - Pericardial thickening; **OR**
 - Tamponade; **OR**
 - Pericarditis; **OR**

- Evaluation of cancer-related cardiotoxicity and radiation-induced heart disease¹²; **OR**
- Post-cardiac transplant assessment of acute or chronic rejection¹²; **OR**
- Cardiac trauma-related conditions, including iatrogenic injury¹³; **OR**
- Cardiovascular conditions, known or suspected, including **ANY** of the following:
 - Suspected intracardiac thrombus, mass, aneurysm, or pseudoaneurysm when ECHO is indeterminant¹⁴; **OR**
 - Cardiomyopathies including **ANY** of the following:
 - ◆ Hypertrophic cardiomyopathy¹⁵; **OR**
 - ◆ Suspected arrhythmogenic cardiomyopathy of ventricular origin; **OR**
- Preoperative or pre-treatment evaluation including **ANY** of the following:
 - Atrial septal defect/patent foramen ovale (ASD/PFO) closure if TEE is indeterminate; **OR**
 - Aortic root replacement; **OR**
 - Pacemaker placement planning including the evaluation of coronary vein before biventricular pacing; **OR**
 - Pulmonary vein ablation therapy for cardiac dysrhythmia; **OR**
 - Surgical valve replacement; **OR**
 - Surgical myectomy or septal ablation hypertrophic cardiomyopathy; **OR**
 - Transcatheter left atrial appendage occlusion; **OR**
 - Planning for aortic endovascular valve replacement; **OR**
 - Post-procedure follow-up or complication to evaluate complications of valve repair or replacement (open or endovascular) including **ANY** of the following:
 - ◆ Leaflet thrombosis; **OR**
 - ◆ Pannus formation; **OR**
 - ◆ Paravalvular leak; **OR**

- ◆ Pseudoaneurysms; **OR**
 - ◆ Root abscess; **OR**
- Ventricular assist devices; **OR**
- Pre-procedural planning for atrial fibrillation-related procedures¹⁶, including **ANY** of the following:
 - ◆ Left atrial ablation (pulmonary vein isolation); **OR**
 - ◆ Left atrial appendage endovascular occlusion; **OR**
 - ◆ Electrical cardioversion or pharmacologic cardioversion when an indicated TEE has a contraindication or is unable to be completed; **OR**
- Planned transcatheter treatment and the patient has valvular heart disease with **ANY** of the following:
 - ◆ Mitral replacement or repair; **OR**
 - ◆ Pulmonary replacement or repair; **OR**
 - ◆ Transcatheter aortic; **OR**
 - ◆ Tricuspid replacement or repair; **OR**
- Congenital anomalies and variants (e.g., cardiac, vascular) including **ANY** of the following as indicated in cited references^{12,17-18}:
 - **ANY** of the following:
 - ◆ Aortic and pulmonary anomalies; **OR**
 - ◆ Atrial and ventricular septal defects; **OR**
 - ◆ Coronary artery anomalies; **OR**
 - ◆ Left-sided cardiac obstructive disorders; **OR**
 - ◆ Right-sided cardiac obstructive disorders; **OR**
 - ◆ Systemic and pulmonary venous anomalies; **OR**
 - ◆ Other complex structural disorders of the cardiac chambers, morphology, and valves (e.g., heterotaxy); **OR**
 - Follow-up of corrected or palliated congenital heart disease and assessment of postoperative complications (e.g., shunt or conduit stenosis, thrombosis, pseudoaneurysms) in children and adults; **OR**

- Postoperative evaluation of corrected or palliated congenital heart disease including **ANY** of the following:
 - ◆ Pseudoaneurysms; **OR**
 - ◆ Stenosis (shunt/conduit); **OR**
 - ◆ Thrombosis; **OR**
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Cardiac magnetic resonance imaging (MRI)** with stress testing is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Patients experiencing new, recurrent, or worsening cardiac symptoms, including otherwise unexplained angina equivalent symptoms, **AND** any of the following:
 - Physical inability to perform a maximum exercise workload; **OR**
 - New or previously unrecognized uninterpretable ECG, as qualified by **ANY** of the following:
 - Complete left bundle branch block; **OR**
 - Ventricular paced rhythm; **OR**
 - Pre-excitation patterns such as Wolff-Parkinson-White; **OR**
 - A greater than 1 mm ST segment depression; **OR**
 - Left ventricular hypertrophy (LVH) with repolarization abnormalities, also called LVH with strain; **OR**
 - Patient on digoxin therapy; **OR**
 - A history of CAD based on a prior anatomic evaluation of the coronary arteries OR a history of CABG or PCI; **OR**

- Syncope for patients with an intermediate or high CHD risk (ATP III risk criteria) and where cardiac etiology is suspected based on an initial evaluation, including history, physical examination, or ECG and the patient is unable to exercise; **OR**
- Evidence or high suspicion of ventricular arrhythmias; **OR**
- Worsening or continuing symptoms after normal or submaximal exercise stress test with suspicion of a false negative result; **OR**
- Patients with recent equivocal or borderline testing where ischemia remains a concern; **OR**
- Patients on beta blocker, calcium channel blocker, and/or antiarrhythmic medication where an adequate workload may not be attainable for a diagnostic exercise study; **OR**
- History of false positive exercise stress test; **OR**
- Evaluation of chest pain syndrome after revascularization, or in patients with intermediate to high pre-test probability for CAD regardless of ECG interpretability or ability to exercise; **OR**
- High pre-test probability for CAD regardless of ECG interpretability or the ability to exercise, and a decision to perform cardiac catheterization or other angiography has not already been made; **OR**
- Patients with HCM; **OR**
- New-onset atrial fibrillation (with no prior cardiac evaluation); **OR**
- Patients with disease conditions associated with CAD with no stress imaging evaluation performed within the preceding 2 years and are unable to exercise; **OR**
- Patients without clear cardiac symptoms in the presence of an elevated cardiac troponin; **OR**
- Patients without cardiac symptoms who underwent a PCI (with stent) procedure more than 2 years prior or a CABG more than 5 years prior and have not undergone an evaluation for CAD within the past 2 years (stress echocardiogram, SPECT MPI, PET MPI, CMR, coronary computed tomography angiography [CCTA], cardiac catheterization) and are unable to exercise; **OR**

- Patients with established CAD who experienced an ACS event (STEMI, NSTEMI, or unstable angina) within the past 90 days provided that they did not undergo coronary angiography at the time of the acute event and are currently clinically stable; **OR**
- Evaluating new, recurrent, or worsening left ventricular dysfunction/congestive heart failure; **OR**
- Assessing myocardial viability in patients with significant ischemic ventricular dysfunction (suspected hibernating myocardium) and persistent symptoms or heart failure such that revascularization would be considered; **OR**
- Preoperative cardiac evaluation in patients not able to exercise and who will be undergoing noncardiac surgery with **ONE** of the following:
 - Intermediate risk for surgery (cardiac risk 1–5%), poor (less than 4 metabolic equivalents [METs]) or unknown functional capacity, inability to exercise adequately, or ECG uninterpretable for ischemia; **OR**
 - High risk for surgery (greater than 5% cardiac risk), poor (less than 4 METs) or unknown functional capacity, inability to exercise adequately or ECG uninterpretable for ischemia; **OR**
- Asymptomatic patients with a coronary calcium Agatston score greater than 400; **OR**
- Planned cardiac or other solid-organ transplant when no cardiac evaluation has been performed within the past year; **OR**
- Patients who will be treated with interleukin 2 products for various malignant disorders; **OR**
- Patients with HCM when echocardiography is inconclusive, or there are poor echocardiograph imaging windows; **OR**
- Evaluation of transplant coronary artery disease (TCAD) or cardiac allograft vasculopathy (CAV) in patients with a history of organ transplantation; **OR**
- Patients with recently demonstrated coronary stenosis of uncertain functional significance in a major coronary branch on an anatomic imaging study (coronary angiogram or CCTA).

Non-Indications

- **Cardiac magnetic resonance imaging (MRI)** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
 - ◆ The patient has metallic clips on vascular aneurysms; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
75557	Cardiac magnetic resonance imaging (MRI) without contrast material, for evaluation of morphology and function
75559	Cardiac magnetic resonance imaging (MRI) with stress imaging, without contrast material, for evaluation of morphology and function
75561	Cardiac magnetic resonance imaging (MRI) without contrast material, followed by contrast material and further sequences, for evaluation of morphology and function

75563	Cardiac magnetic resonance imaging (MRI) with stress imaging, without contrast material, followed by contrast material and further sequences, for evaluation of morphology and function
75565	Cardiac magnetic resonance imaging (MRI) for velocity flow mapping (List separately in addition to code for primary procedure)
C9762	Cardiac magnetic resonance imaging (MRI) for morphology and function, quantification of segmental dysfunction; with strain imaging
C9763	Cardiac magnetic resonance imaging (MRI) for morphology and function, quantification of segmental dysfunction; with stress imaging
S8042	Magnetic resonance imaging (MRI), low-field

Disclaimer: S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Miller et al. (2023) CMR-IMPACT (Cardiac Magnetic Resonance Imaging Strategy for the Management of Patients with Acute Chest Pain and Detectable to Elevated Troponin) trial conducted from September 2013 to July 2018 at four U.S. tertiary care hospitals. The trial involved the management of patients with acute chest pain and detectable elevated troponin levels. The 312 participants were randomized into two care pathways: invasive-based (156 participants) and CMR-based (156 participants), with adjustments permitted based on the patient's condition. The primary outcome measured was a composite of death, myocardial infarction, and cardiac-related hospital readmissions or emergency visits. The study followed 312 participants (mean age 60.6 years, 59.9% women) over a median of 2.6 years. The authors conclude no significant difference between clinical and safety outcomes. Benefits include reducing the long-term utilization of invasive angiography, positive discharge outcomes, and enhanced therapeutic yield of angiography. (Clinicaltrials.gov Identifier NCT01931852).¹¹

Alabed et al. (2020) performed a meta-analysis concerning patient mortality due to pulmonary arterial hypertension (PAH). A total of 1938 patients in 22 studies were included. Research indicates that CMR-derived metrics for right ventricular (RV) volume and function, rather than left ventricular (LV) measurements, predict clinical deterioration. This insight is pertinent for regulatory authorities seeking clinically relevant trial endpoints. Further, this meta-analysis reaffirms the prognostic significance of CMR metrics across a large patient cohort, enabling assessment of how changes in these metrics relate to clinical outcomes such as worsening health and mortality. The authors reaffirm CMR as a useful prognostic marker in PAH among a large cohort. The study confirms that RV function, RV, and left ventricular volumes predict mortality and clinical deterioration in PAH. The study underscores the rationale for using CMR as a meaningful clinical endpoint in trials testing PAH therapies.¹⁹

Kwong et al. (2019) conducted a retrospective study to evaluate the diagnostic and prognostic value. The study enrolled 2349 patients with chest pain syndrome at 13 centers in 11 states. The median follow-up was 5.4 years.

A stress CMR showing no ischemia or LGE were linked to a very low incidence of adverse cardiac events in patients with stable intermediate-risk chest pain syndromes. Subsequent cardiac testing also reduced. (Clinicaltrials.gov Identifier NCT03192891).²⁰

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Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		



Cohere Medicare Advantage Policy – Magnetic Resonance Imaging (MRI) Cardiac

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI) Cardiac

Date of last literature review: 10/2/2024

Document last updated: 10/3/2024

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)

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Recommended Clinical Approach

Cardiac magnetic resonance imaging (MRI) offers exquisite anatomic detail and can also provide valuable functional information through various sequences. While not a first-line imaging modality, it proves highly useful when structural abnormalities (congenital or acquired) or functional deficiencies require further investigation of the heart and pericardial structures.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of cardiac MRI. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.⁶
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.⁶
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.⁷
- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁸

The clinical benefits of using these criteria include:

- Noninvasive: As a cardiac imaging modality, cardiac MRI is noninvasive; it is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers.⁹⁻¹⁰
- Reduced need for invasive angiography: When triaging patients with undifferentiated chest pain, patients evaluated with cardiac MRI are more likely to be discharged without the need for invasive angiography, thereby avoiding the additional risks and costs associated with an invasive procedure.¹¹
- Improved therapeutic yield: Among patients who are referred for invasive angiography, those who are evaluated by cardiac MRI

experience higher rates of revascularization and therefore improved treatment efficacy as compared to patients who are not imaged with cardiac MRI.¹¹

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Cardiac magnetic resonance imaging (MRI)** is considered appropriate if **ALL** of the following are **TRUE**:

- ◆ First-line cardiac imaging modality such as transthoracic echo is inconclusive/non-diagnostic, and further imaging is indicated for diagnostic and therapeutic purposes; **AND**
- ◆ **ANY** of the following is **TRUE**:
 - Documented or suspected neoplastic conditions of the heart (including cardiac masses or mass-like conditions); **OR**
 - Infection or an infectious disorder, including infective endocarditis, myocarditis, or complications not diagnosable by other imaging modalities; **OR**
 - Known or suspected pericardial disease, including **ANY** of the following¹²:
 - Pericardial effusion; **OR**
 - Structural pericardial anomalies; **OR**
 - Pericardial thickening; **OR**
 - Tamponade; **OR**
 - Pericarditis; **OR**

- Evaluation of cancer-related cardiotoxicity and radiation-induced heart disease¹²; **OR**
- Post-cardiac transplant assessment of acute or chronic rejection¹²; **OR**
- Cardiac trauma-related conditions, including iatrogenic injury¹³; **OR**
- Cardiovascular conditions, known or suspected, including **ANY** of the following:
 - Suspected intracardiac thrombus, mass, aneurysm, or pseudoaneurysm when ECHO is indeterminant¹⁴; **OR**
 - Cardiomyopathies including **ANY** of the following:
 - ◆ Hypertrophic cardiomyopathy¹⁵; **OR**
 - ◆ Suspected arrhythmogenic cardiomyopathy of ventricular origin; **OR**
- Preoperative or pre-treatment evaluation including **ANY** of the following:
 - Atrial septal defect/patent foramen ovale (ASD/PFO) closure if TEE is indeterminate; **OR**
 - Aortic root replacement; **OR**
 - Pacemaker placement planning including the evaluation of coronary vein before biventricular pacing; **OR**
 - Pulmonary vein ablation therapy for cardiac dysrhythmia; **OR**
 - Surgical valve replacement; **OR**
 - Surgical myectomy or septal ablation hypertrophic cardiomyopathy; **OR**
 - Transcatheter left atrial appendage occlusion; **OR**
 - Planning for aortic endovascular valve replacement; **OR**
 - Post-procedure follow-up or complication to evaluate complications of valve repair or replacement (open or endovascular) including **ANY** of the following:
 - ◆ Leaflet thrombosis; **OR**
 - ◆ Pannus formation; **OR**
 - ◆ Paravalvular leak; **OR**

- ◆ Pseudoaneurysms; **OR**
 - ◆ Root abscess; **OR**
- Ventricular assist devices; **OR**
- Pre-procedural planning for atrial fibrillation-related procedures¹⁶, including **ANY** of the following:
 - ◆ Left atrial ablation (pulmonary vein isolation); **OR**
 - ◆ Left atrial appendage endovascular occlusion; **OR**
 - ◆ Electrical cardioversion or pharmacologic cardioversion when an indicated TEE has a contraindication or is unable to be completed; **OR**
- Planned transcatheter treatment and the patient has valvular heart disease with **ANY** of the following:
 - ◆ Mitral replacement or repair; **OR**
 - ◆ Pulmonary replacement or repair; **OR**
 - ◆ Transcatheter aortic; **OR**
 - ◆ Tricuspid replacement or repair; **OR**
- Congenital anomalies and variants (e.g., cardiac, vascular) including **ANY** of the following as indicated in cited references^{12,17-18}:
 - **ANY** of the following:
 - ◆ Aortic and pulmonary anomalies; **OR**
 - ◆ Atrial and ventricular septal defects; **OR**
 - ◆ Coronary artery anomalies; **OR**
 - ◆ Left-sided cardiac obstructive disorders; **OR**
 - ◆ Right-sided cardiac obstructive disorders; **OR**
 - ◆ Systemic and pulmonary venous anomalies; **OR**
 - ◆ Other complex structural disorders of the cardiac chambers, morphology, and valves (e.g., heterotaxy); **OR**
 - Follow-up of corrected or palliated congenital heart disease and assessment of postoperative complications (e.g., shunt or conduit stenosis, thrombosis, pseudoaneurysms) in children and adults; **OR**

- Postoperative evaluation of corrected or palliated congenital heart disease including **ANY** of the following:
 - ◆ Pseudoaneurysms; **OR**
 - ◆ Stenosis (shunt/conduit); **OR**
 - ◆ Thrombosis; **OR**
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

→ **Cardiac magnetic resonance imaging (MRI)** with stress testing is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Patients experiencing new, recurrent, or worsening cardiac symptoms, including otherwise unexplained angina equivalent symptoms, **AND** any of the following:
 - Physical inability to perform a maximum exercise workload; **OR**
 - New or previously unrecognized uninterpretable ECG, as qualified by **ANY** of the following:
 - Complete left bundle branch block; **OR**
 - Ventricular paced rhythm; **OR**
 - Pre-excitation patterns such as Wolff-Parkinson-White; **OR**
 - A greater than 1 mm ST segment depression; **OR**
 - Left ventricular hypertrophy (LVH) with repolarization abnormalities, also called LVH with strain; **OR**
 - Patient on digoxin therapy; **OR**
 - A history of CAD based on a prior anatomic evaluation of the coronary arteries OR a history of CABG or PCI; **OR**

- Syncope for patients with an intermediate or high CHD risk (ATP III risk criteria) and where cardiac etiology is suspected based on an initial evaluation, including history, physical examination, or ECG and the patient is unable to exercise; **OR**
- Evidence or high suspicion of ventricular arrhythmias; **OR**
- Worsening or continuing symptoms after normal or submaximal exercise stress test with suspicion of a false negative result; **OR**
- Patients with recent equivocal or borderline testing where ischemia remains a concern; **OR**
- Patients on beta blocker, calcium channel blocker, and/or antiarrhythmic medication where an adequate workload may not be attainable for a diagnostic exercise study; **OR**
- History of false positive exercise stress test; **OR**
- Evaluation of chest pain syndrome after revascularization, or in patients with intermediate to high pre-test probability for CAD regardless of ECG interpretability or ability to exercise; **OR**
- High pre-test probability for CAD regardless of ECG interpretability or the ability to exercise, and a decision to perform cardiac catheterization or other angiography has not already been made; **OR**
- Patients with HCM; **OR**
- New-onset atrial fibrillation (with no prior cardiac evaluation); **OR**
- Patients with disease conditions associated with CAD with no stress imaging evaluation performed within the preceding 2 years and are unable to exercise; **OR**
- Patients without clear cardiac symptoms in the presence of an elevated cardiac troponin; **OR**
- Patients without cardiac symptoms who underwent a PCI (with stent) procedure more than 2 years prior or a CABG more than 5 years prior and have not undergone an evaluation for CAD within the past 2 years (stress echocardiogram, SPECT MPI, PET MPI, CMR, coronary computed tomography angiography [CCTA], cardiac catheterization) and are unable to exercise; **OR**

- Patients with established CAD who experienced an ACS event (STEMI, NSTEMI, or unstable angina) within the past 90 days provided that they did not undergo coronary angiography at the time of the acute event and are currently clinically stable; **OR**
- Evaluating new, recurrent, or worsening left ventricular dysfunction/congestive heart failure; **OR**
- Assessing myocardial viability in patients with significant ischemic ventricular dysfunction (suspected hibernating myocardium) and persistent symptoms or heart failure such that revascularization would be considered; **OR**
- Preoperative cardiac evaluation in patients not able to exercise and who will be undergoing noncardiac surgery with **ONE** of the following:
 - Intermediate risk for surgery (cardiac risk 1–5%), poor (less than 4 metabolic equivalents [METs]) or unknown functional capacity, inability to exercise adequately, or ECG uninterpretable for ischemia; **OR**
 - High risk for surgery (greater than 5% cardiac risk), poor (less than 4 METs) or unknown functional capacity, inability to exercise adequately or ECG uninterpretable for ischemia; **OR**
- Asymptomatic patients with a coronary calcium Agatston score greater than 400; **OR**
- Planned cardiac or other solid-organ transplant when no cardiac evaluation has been performed within the past year; **OR**
- Patients who will be treated with interleukin 2 products for various malignant disorders; **OR**
- Patients with HCM when echocardiography is inconclusive, or there are poor echocardiograph imaging windows; **OR**
- Evaluation of transplant coronary artery disease (TCAD) or cardiac allograft vasculopathy (CAV) in patients with a history of organ transplantation; **OR**
- Patients with recently demonstrated coronary stenosis of uncertain functional significance in a major coronary branch on an anatomic imaging study (coronary angiogram or CCTA).

Non-Indications

- **Cardiac magnetic resonance imaging (MRI)** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
 - ◆ The patient has metallic clips on vascular aneurysms; **OR**
 - ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
75557	Cardiac magnetic resonance imaging (MRI) without contrast material, for evaluation of morphology and function
75559	Cardiac magnetic resonance imaging (MRI) with stress imaging, without contrast material, for evaluation of morphology and function
75561	Cardiac magnetic resonance imaging (MRI) without contrast material, followed by contrast material and further sequences, for evaluation of morphology and function

75563	Cardiac magnetic resonance imaging (MRI) with stress imaging, without contrast material, followed by contrast material and further sequences, for evaluation of morphology and function
75565	Cardiac magnetic resonance imaging (MRI) for velocity flow mapping (List separately in addition to code for primary procedure)
C9762	Cardiac magnetic resonance imaging (MRI) for morphology and function, quantification of segmental dysfunction; with strain imaging
C9763	Cardiac magnetic resonance imaging (MRI) for morphology and function, quantification of segmental dysfunction; with stress imaging
S8042	Magnetic resonance imaging (MRI), low-field

Disclaimer: S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Miller et al. (2023) CMR-IMPACT (Cardiac Magnetic Resonance Imaging Strategy for the Management of Patients with Acute Chest Pain and Detectable to Elevated Troponin) trial conducted from September 2013 to July 2018 at four U.S. tertiary care hospitals. The trial involved the management of patients with acute chest pain and detectable elevated troponin levels. The 312 participants were randomized into two care pathways: invasive-based (156 participants) and CMR-based (156 participants), with adjustments permitted based on the patient's condition. The primary outcome measured was a composite of death, myocardial infarction, and cardiac-related hospital readmissions or emergency visits. The study followed 312 participants (mean age 60.6 years, 59.9% women) over a median of 2.6 years. The authors conclude no significant difference between clinical and safety outcomes. Benefits include reducing the long-term utilization of invasive angiography, positive discharge outcomes, and enhanced therapeutic yield of angiography. (Clinicaltrials.gov Identifier NCT01931852).¹¹

Alabed et al. (2020) performed a meta-analysis concerning patient mortality due to pulmonary arterial hypertension (PAH). A total of 1938 patients in 22 studies were included. Research indicates that CMR-derived metrics for right ventricular (RV) volume and function, rather than left ventricular (LV) measurements, predict clinical deterioration. This insight is pertinent for regulatory authorities seeking clinically relevant trial endpoints. Further, this meta-analysis reaffirms the prognostic significance of CMR metrics across a large patient cohort, enabling assessment of how changes in these metrics relate to clinical outcomes such as worsening health and mortality. The authors reaffirm CMR as a useful prognostic marker in PAH among a large cohort. The study confirms that RV function, RV, and left ventricular volumes predict mortality and clinical deterioration in PAH. The study underscores the rationale for using CMR as a meaningful clinical endpoint in trials testing PAH therapies.¹⁹

Kwong et al. (2019) conducted a retrospective study to evaluate the diagnostic and prognostic value. The study enrolled 2349 patients with chest pain syndrome at 13 centers in 11 states. The median follow-up was 5.4 years.

A stress CMR showing no ischemia or LGE were linked to a very low incidence of adverse cardiac events in patients with stable intermediate-risk chest pain syndromes. Subsequent cardiac testing also reduced. (Clinicaltrials.gov Identifier NCT03192891).²⁰

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Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		



Cohere Medicare Advantage Policy – Positron Emission Tomography (PET), Cardiac

Clinical Policy for Medical Necessity Review

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Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Positron Emission Tomography (PET), Cardiac

Policy Number: CHP-231-2.1

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Positron Emission Tomography (PET), Cardiac

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻¹³

- [National Coverage Determination \(NCD\). FDG PET for Myocardial Viability \(220.6.8\)](#)
- [National Coverage Determination \(NCD\). PET for Perfusion of the Heart \(220.6.1\)](#)
- [National Coverage Determination \(NCD\). Positron Emission Tomography \(FDG\) for Oncologic Conditions \(220.6.17\)](#)
- [Local Coverage Determination \(LCD\). Multiple Imaging in Oncology \(L35391\)](#)
 - [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)
- [Local Coverage Determination \(LCD\). Positron Emission Tomography \(PET\) Scan for Inflammation and Infection \(L39521\)](#)
 - [Billing and Coding: Positron Emission Tomography \(PET\) Scan for Inflammation and Infection \(A59318\)](#)
- [Local Coverage Determination \(LCD\). Cardiac Radionuclide Imaging \(L33457\)](#)
 - [Billing and Coding: Cardiac Radionuclide Imaging \(A56476\)](#)
- [Local Coverage Determination \(LCD\). Cardiology Non-Emergency Outpatient Stress Testing \(L35083\)](#)
 - [Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing \(A56423\)](#)
- [Local Coverage Determination \(LCD\). Cardiology Non-Emergent Outpatient Stress Testing \(L38396\)](#)
 - [Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing \(A56952\)](#)

Description

Cardiac PET is considered advanced imaging, and it is best utilized per institutional internal medicine and cardiology protocols. Radiologic and cardiology guidelines from the American Society of Nuclear Cardiology (ASNC), American College of Radiology (ACR), American College of Cardiology (ACC), Society of Nuclear Medicine and Molecular Imaging (SNMMI), and European Association of Nuclear Medicine (EANM) may be consulted prior to ordering.

Cardiac PET is specifically optimized for the evaluation of myocardial perfusion and viability. It may also be utilized to evaluate infection and inflammation. Myocardial perfusion in the setting of suspected or known coronary artery disease (CAD) can be evaluated with cyclotron-produced (^{13}N -ammonia) or generator-produced (^{82}Rb) PET agents.^{[14-29](#)}

Medical Necessity Criteria

Indications

Positron emission tomography (PET) cardiac perfusion stress testing with or without computed tomography (CT) (CPT codes 78430, 78431, 78491, 78492) is considered appropriate if **ANY** of the following is **TRUE**:

- Evaluation of post-transplant cardiac allograft vasculopathy (CAV); **OR**
- **ALL** of the following¹⁵:
 - **ANY** of the following:
 - The patient has morbid obesity (i.e., greater than or equal to 35m²/kg); **OR**
 - The patient has macromastia (i.e., large breasts or very dense breasts); **OR**
 - Equivocal results of myocardial perfusion imaging single-photon emission computed tomography (MPI-SPECT); **AND**
 - Criteria for MPI-SPECT are met, including **ANY** of the following:
 - The patient has angina (or an anginal equivalent^A) with **ANY** of the following³⁰:
 - No known coronary artery disease (CAD) with an intermediate or high pre-test probability (PTP) (as indicated by the [CAD Consortium Calculator](#) or coronary calcium score greater than or equal to 100 Agatston); **OR**
 - No known CAD with **ANY** of the following:
 - ECG abnormalities that interfere with the ECG diagnosis of ischemia and **ANY** of the following³¹:
 - An inability to achieve the target heart rate with a standard exercise treadmill test (greater than or equal to 85% of age-predicted maximal heart rate); **OR**
 - Ventricular pre-excitation (Wolff-Parkinson-White pattern); **OR**
 - Ventricular-paced rhythm; **OR**
 - Left bundle branch block (LBBB); **OR**
 - LBBB or pacemaker; **OR**
 - Greater than 1 mm ST depression at rest; **OR**
 - Left ventricular hypertrophy with ST-T abnormalities; **OR**
 - The patient takes digoxin; **OR**
 - Prior stress testing with **ANY** of the following:

- Plain exercise treadmill test that was equivocal (heart rate that did not reach 85% of age-predicted maximum heart rate, significant chest pain or anginal equivalent during the study, less than or equal to 3 METS); **OR**
 - Previous stress echocardiography had poor echocardiographic windows; **OR**
- No known CAD with prior testing and **ALL** of the following²⁸:
 - Symptoms of angina (or an anginal equivalent^A); **AND**
 - **ANY** of the following:
 - Inconclusive routine stress ECG; **OR**
 - Abnormal routine stress ECG; **OR**
 - Coronary computed tomographic angiography (CCTA) with moderate stenosis 50 to 69%; **OR**
 - Inconclusive CCTA; **OR**
 - Invasive coronary angiography with intermediate severity (maximal coronary diameter stenosis is 40% to 69%) or invasive physiological testing not done; **OR**
- Newly diagnosed heart failure with preserved ejection fraction (HFpEF), heart failure with reduced ejection fraction (HFrEF), or asymptomatic low EF less than 45%, and **ALL** of the following³²:
 - No previous evaluation for CAD; **AND**
 - No planned cardiac catheterization; **OR**
- Screening for transplant vasculopathy without a prior MPI in the previous year; **OR**
- Evaluation of new ventricular arrhythmias without prior cardiac evaluation for ischemia as indicated by **ANY** of the following:
 - Frequent premature ventricular contractions (PVCs) greater than 30 per hour; **OR**
 - Non-sustained ventricular tachycardia (greater than or equal to 3 consecutive beats at greater than 100 beats per minute)³³; **OR**
 - Exercise-induced ventricular tachycardia; **OR**
 - Sustained ventricular tachycardia; **OR**
 - Ventricular fibrillation; **OR**
- Before initiation of antiarrhythmic therapy (such as flecainide), and the patient has intermediate or high PTP of CAD (as indicated by the [CAD Consortium Calculator](#)); **OR**
- Syncope without an ischemic equivalent^A and the initial evaluation suggests a CV abnormality (e.g., abnormal EKG or echo); **OR**

- Known coronary heart disease (CHD) with a history of prior myocardial infarction (MI) or coronary revascularization and **ANY** of the following²⁸:
 - Surveillance testing and **ANY** of the following:
 - Percutaneous coronary intervention (PCI) performed at least 2 years ago and no testing within the last 2 years; **OR**
 - Coronary artery bypass graft (CABG) performed at least 5 years ago and no testing within the last 5 years; **OR**
 - The patient has prior myocardial infarction or documented incomplete revascularization and is at high-risk for silent ischemia or has a history of silent ischemia as indicated by **ANY** of the following:
 - Diabetes mellitus with known accelerated progression of CAD; **OR**
 - Chronic kidney disease (CKD Stage 3 or above – estimated glomerular filtration rate [eGFR] 15–59 mL/min/1.73 m² with or without albuminuria that is not treated with dialysis or kidney transplantation); **OR**
 - Symptoms of ischemia with a change in clinical or functional status on guideline-directed medical therapy (GDMT) (or documented intolerance to GDMT); **OR**
- Preoperative testing before intermediate- or high-risk surgery (Table 1) and **ANY** of the following³⁴:
 - Planned solid organ transplant (renal, pancreas, combined renal pancreas, liver, lung, or intestinal); **OR**
 - No known or suspected CHD^B and **ALL** of the following³⁴:
 - No recent (3–8 months) testing; **AND**
 - New or worsening possible cardiac symptoms; **AND**
 - Functional status less than 4 METS and **ANY** of the following:
 - High-risk vascular surgery (Table 1); **OR**
 - High-risk nonvascular surgery (Table 1); **OR**
 - Intermediate risk vascular surgery (Table 1); **OR**
 - Intermediate risk non-vascular surgery (Table 1) with at least an intermediate (16% or greater) pre-test probability of obstructive CAD by the [CAD Consortium Calculator](#); **OR**
 - Known or suspected CHD^C and **ANY** of the following³⁴:
 - No recent (3–8 months) stress testing and **ANY** of the following:

- High-risk vascular surgery (Table 1) **OR**
- High-risk nonvascular surgery (Table 1) **OR**
- Intermediate risk vascular surgery and **ANY** of the following:
 - Greater than 4 METS and **ALL** of the following:
 - Without new or worsening possible cardiac symptoms; **AND**
 - Revised Cardiac Risk Index of 3 or greater (intermediate or high-risk); **OR**
 - Less than 4 METS with or without new or worsening possible cardiac symptoms; **OR**
 - Greater than 4 METS with new or worsening possible cardiac symptoms **OR**
- Intermediate nonvascular surgery (Table 1) and **ANY** of the following:
 - Less than 4 METS with or without possible cardiac symptoms; **OR**
 - Greater than 4 METS with new or worsening possible cardiac symptoms; **OR**
- Low-risk vascular or nonvascular surgery (Table 1) planned and **ANY** of the following:
 - New or worsening possible cardiovascular symptoms; **OR**
 - Revised Cardiac Risk Index of 3 or greater (intermediate or high-risk).

F-Fluorodeoxyglucose (FDG) PET/CT with or without resting perfusion imaging (CPT codes 78429, 78432, 78433, 78459) is considered appropriate if **ANY** of the following is **TRUE**²⁵:

- Evaluation of cardiac sources of infection or inflammation, as indicated by **ALL** of the following⁵:
 - Documented suspicion on clinical exam and laboratory evaluation; **AND**
 - Non-specific or inconclusive imaging from echocardiography and/or CT; **AND**
 - The patient is being evaluated for **ANY** of the following conditions:
 - Infective endocarditis with a prosthetic valve; **OR**
 - Suspected cardiac device infection (pacemaker, defibrillators, LVAD, metallic implants); **OR**

- CTA or MRA are inconclusive or nondiagnostic for **ANY** of the following:
 - Aortitis; **OR**
 - Systemic vasculitis; **OR**
 - Vascular graft infection; **OR**
- Cardiac sarcoidosis with **ANY** of the following:
 - Risk factors (such as systemic sarcoidosis with cardiac findings); **OR**
 - Patient less than 60 years old with unexplained, new onset conduction system disease; **OR**
 - Patient less than 60 years old with unexplained heart failure; **OR**
 - Idiopathic sustained ventricular tachycardia unexplained by other causes; **OR**
 - For guiding subsequent treatment of cardiac sarcoidosis if PET scan is the primary test used to follow the patient for the cardiac aspect of sarcoidosis/inflammatory cardiomyopathies (additional studies, such cardiac MRI, CT or other nuclear imaging studies for the same purpose are non-covered); **OR**
- Indeterminate intracardiac mass with **ANY** of the following:
 - Nondiagnostic transthoracic echocardiogram (TTE) or transesophageal echocardiogram (TEE); **OR**
 - Cardiac MRI is non-diagnostic³⁴; **OR**
- Myocardial viability assessment and **ALL** of the following:
 - Determination of the appropriateness of invasive revascularization management; **AND**
 - EF less than or equal to 45%.

Repeat imaging (defined as a repeat request following recent imaging of the same anatomic region with the same or similar modality) will be considered reasonable and necessary if **ALL** of the following are **TRUE**:

- There are no established guidelines; **AND**
- **ANY** of the following:
 - There are new or worsening symptoms not addressed in the guidelines, such that repeat imaging would influence treatment; **OR**
 - There is need for a one-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

Positron emission tomography (PET), cardiac is not considered appropriate if **ANY** of the following is **TRUE**:

- The imaging request is for **myocardial perfusion PET** and patient has chest trauma^{18,37}; **OR**
- The imaging request is for **FDG PET/CT** with **ANY** of the following:
 - If used as first-line diagnostic test; **OR**
 - If **ANY** of the following tests have already been performed or are planned as part of diagnostic evaluation without documented medical necessity:
 - Labeled white blood cell (WBC) scan; **OR**
 - 67Ga single-photon emission computed tomography (SPECT)/CT; **OR**
 - Cardiac magnetic resonance imaging (MRI); **OR**
 - Endocarditis in a native valve; **OR**
 - If used for monitoring response to treatment with the exception of cardiac sarcoidosis; **OR**
 - Acute chest pain with suspected aortic dissection; **OR**
 - Chest trauma³⁷; **OR**
 - Congenital or acquired heart disease³⁸; **OR**
 - Nonischemic myocardial disease (excluding sarcoidosis)^{17,18}; **OR**
- The use of PET scan for inflammation and infection of other conditions not specifically addressed in the indications will be considered investigational.

*NOTE: PET in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

**NOTE: PET scans should be scheduled at least 4–6 weeks after radiation therapy or surgery to avoid false positives due to inflammation from recent treatments.

Definitions

^A Anginal equivalent: Any constellation of clinical findings that the physician believes is consistent with CAD manifestations. Examples of such findings include, but are not limited to: pain, pressure, tightness, or discomfort in the chest, shoulders, arms, neck, back, upper abdomen, or jaw, new ECG abnormalities, or other symptoms/findings suggestive of CAD. Clinical presentations in the absence of chest pain (e.g., dyspnea with exertion, fatigue, or reduced/worsening effort tolerance) consistent with a high risk of CAD may be considered an ischemic equivalent.³⁹

^B No known or suspected heart disease by history, exam, or electrocardiogram³⁴: Heart disease is not suspected based on the history of no prior cardiac event, lack of cardiac risk factors, or prior cardiac testing indicating no ischemic heart disease, VHD, or HF. The exam does not suggest underlying heart disease by lack of murmurs, other than functional, and no signs of cardiac decompensation (e.g., rales, edema not explained by other causes, or S3 gallop). ECG does not show prior myocardial infarction, left ventricular hypertrophy, LBBB, or atrial fibrillation. B-type natriuretic peptide (BNP) or proBNP, if measured, is normal.

^C Known or suspected heart disease by history, exam, or electrocardiogram³⁴: PCI, coronary artery bypass graft (CABG), prior infarct, cardiac risk factors (HTN, HLD, DM, tobacco use, FHx premature CAD), disease conditions associated with atherosclerosis (PAD, carotid disease, abdominal aneurysm, stroke due to atherosclerosis), prior cardiac testing showing CAD, heart failure, moderate or severe valvular disease, rales, old infarct on EKG, LVH with repolarization changes, LBBB, or atrial fibrillation. There may be prior evidence of biomarker elevation (troponin, proBNP) in the absence of other explanatory findings. B-type natriuretic peptide (BNP) or proBNP, if measured, is more than 3 times the upper limit of normal.

Tables

Table 1. Definitions of Low, Intermediate, and High-Risk Surgery²⁴

Specialty	Surgical Risk Level		
	Low	Intermediate	High
Vascular	1. Carotid stenting (monitored anesthesia care) 2. Renal artery stenosis angioplasty or stent 3. Vein stripping	1. Infra-inguinal peripheral angioplasty/stent 2. Carotid stenting (carotid approach, general anesthesia) 3. Open carotid endarterectomy 4. Above or below-knee amputation	1. Abdominal aortic aneurysm repair 2. Aorto-femoral bypass graft 3. Thoracic aortic aneurysm repair 4. Infra-inguinal open peripheral revascularization
General	1. Laparoscopic appendectomy 2. Hemorrhoidectomy	1. Open appendectomy 2. Ostomy procedures 3. Inguinal/umbilical hernia repair 4. Laparoscopic lysis of adhesions/obstruction 5. Laparoscopic cholecystectomy 6. Laparoscopic colon resection, segmental, for tumor	1. Laparoscopic bariatric surgery 2. Open cholecystectomy 3. Hepatic radiofrequency ablation tumor ablation 4. Splenectomy 5. Open colonic segmental resection tumor 6. Laparoscopic colonic abdominal perineal resection 7. Open lysis of adhesions/bowel obstruction 8. Esophageal Heller myotomy 9. Nissen fundoplication 10. Cancer resection (gastric pull-through) 11. Open bariatric surgery

			12. Pancreatic/Whipple resection 13. Gastric resection (tumor/ulcer) 14. Hepatic segmental resection 15. Colonic open abdominal perineal resection
Endocrine	1. Thyroidectomy 2. Parathyroidectomy	1. Adrenalectomy 2. Pheochromocytoma resection	-
Ortho.	1. Shoulder arthroscopy 2. Knee arthroscopy 3. Ankle arthroscopy 4. Closed joint reduction	1. Shoulder arthroplasty 2. Hip fracture pinning	1. Hip/ankle/knee arthroplasty
Thoracic	-	1. Pleural procedures (decortication, pleurodesis) 2. VATS lung biopsy 3. VATS wedge/lobe resection 4. Thymectomy	1. Open wedge/lobe resection 2. Tracheal surgery 3. Lung reduction 4. Pneumonectomy
Neuro-functional	1. Deep brain stimulator placement 2. Seizure mapping procedures	-	-
Neuro-intracranial	-	1. Hydrocephalus shunt/repair 2. Subdural drainage 3. Transsphenoidal resection	1. Intracranial tumor resection 2. Open intracranial aneurysm resection 3. Acoustic neuroma/cranial nerve tumor resection
Neuro/Ortho. Spine	-	1. Laminectomy	1. Spinal fusion 2. Extreme lateral interbody fusion

			procedures (abdominal)
Genito-urinary	1. Transurethral prostate resection 2. Transurethral bladder tumor resection 3. Ureteral stents 4. Nephrostomy 5. Extracorporeal shock wave lithotripsy	1. Bladder repair	1. Radical retropubic prostatectomy 2. Nephrectomy 3. Cystectomy
Gyn.	1. Vaginal hysterectomy 2. Diagnostic gynecologic procedures (laparoscopy)	1. Total abdominal hysterectomy 2. Bilateral salpingo-oophorectomy	-
Breast	1. Diagnostic breast surgery (lumpectomy, node dissection) 2. Simple mastectomy	1. Complex breast surgery	-
Plastic Surgery	1. Hand 2. Cosmetic procedures	1. Reconstructive flaps 2. Post-bariatric repair abdominoplasty	-
Ear, Nose, Throat	1. Diagnostic laryngoscopy 2. Diagnostic esophagoscopy	1. Nasal septal procedures 2. Functional endoscopic sinus surgery	1. Head/neck cancer dissection (with/without laryngectomy)
Oral & Maxillofacial Surgery	1. Jaw reduction	1. Temporomandibular procedures/osteotomy	-
Podiatry	1. Arthroplasty 2. Toe amputation 3. Bunion procedure	-	-
Eye	1. Cataract repair 2. Retinal surgery 3. Eye muscle surgery		
Organ Transplant	-	-	1. Renal Transplant 2. Pancreas Transplant

			3. Kidney-Pancreas Combined Transplant 4. Liver 5. Lung 6. Intestinal

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure. [40,41](#)

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography. [40,41](#)

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation. [40,41](#)

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images. [40,41](#)

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
78429	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study; with concurrently acquired computed tomography transmission scan
78430	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography (CT) transmission scan
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability)
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed

	tomography (CT) transmission scan
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study
78491	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic)
78492	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic)
78811	Positron emission tomography (PET) imaging; limited area (e.g., of chest, head/neck)

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for cardiac PET may include:

- Inherent risk of procedure: There are inherent risks of PET imaging, including cumulative radiation exposure, allergy, and harm to breast milk.^{[42](#)}
- Potential danger to pregnancy: PET imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.^{[43](#)} Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.^{[43](#)}
- Increased healthcare costs and complications from the inappropriate use of additional interventions.^{[44](#)}

The clinical benefits of using these criteria for cardiac PET include:

- Noninvasive: As an imaging modality, cardiac PET is noninvasive; it is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers. It also utilizes no injected contrast agent, conferring an inherent safety benefit.
- Enhanced overall patient satisfaction and healthcare experience.

Medical Evidence

Patel et al. (2020) assessed the use of positron emission tomography (PET) myocardial perfusion imaging (MPI) as a way to non-invasively measure myocardial blood flow reserve (MBFR). One goal of the study was to determine whether MBFR could identify patients with a survival benefit after revascularization, which could help guide post-test management. A total of 12,594 patients who underwent Rb82 rest/stress PET MPI were included. The MBFR observed on PET MPI correlated with overall mortality risk and can be used to pinpoint individuals who would potentially derive survival advantages from early revascularization as opposed to medical management alone. The authors concluded that utilization of the metric can inform decision-making regarding revascularization strategies. However, further validation through prospective studies is warranted.⁴⁵

Gulati et al. (2021) recommended PET as a reasonable choice over SPECT when available for intermediate- to high-risk patients with stable chest pain and no known CAD for whom rest/stress nuclear MPI is selected, to improve diagnostic accuracy and decrease the rate of nondiagnostic test results.³⁰

Swart et al. (2018) performed a multicenter study to enhance the accuracy of ¹⁸F-Fluorodeoxyglucose (FDG) positron-emission tomography/computed tomography (PET/CT) in patients suspected of having prosthetic heart valve endocarditis (PVE). Notably, FDG-PET is not appropriate to image suspected endocarditis of the native valve, as sensitivity for detecting native valve endocarditis has been reported at 0%.²⁹ The study identified and eliminated potential confounding factors using visual and standardized quantitative evaluations. A total of 160 patients with a prosthetic heart valve were included (median age 62; 68% male; 82 mechanical valves; 62 biological; 9 transcatheter aortic valve replacements; 7 other). All patients underwent FDG PET/CT for suspicion of PVE. Early integration of FDG PET/CT into the diagnostic protocol may mitigate the potential confounding impact of low inflammatory activity (for example, in patients receiving prolonged antibiotic treatment).³⁵

Chen et al. (2017) conducted the CORE320 Multicenter Study to compare the prognostic significance of combined CT angiography and CT myocardial stress perfusion imaging versus a combination of invasive coronary angiography (ICA) and stress single photon emission CT myocardial perfusion imaging. The study also addressed the time to major adverse cardiovascular events (MACE). Results indicated that the combined use of CT angiography and CT myocardial perfusion demonstrated similar predictive ability for 2-year MACE-free survival as compared to ICA and single photon emission CT perfusion imaging.²¹

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Policy Revision History/Information

Original Date: October 3, 2024		
Review History		
Version 1.1	04/21/2025	Revised per CMS update for 3/20/2025. Updated revision date, links, and references.
Version 2	10/02/2025	Annual review. Embedded criteria for MPI-SPECT; added documented need for further imaging or contraindication to MPI-SPECT into this policy to encourage lower-risk imaging via MPI-SPECT. These criteria essentially supplant the previous version of the policy. FDG PET/CT: Removed nonspecific indications and replaced with more specific indications for malignancy and benign processes (infection, vasculitis, intracardiac mass). Cardiac sarcoidosis indication augmented to provide more specific criteria and better capture the appropriate patient population, including delineation between known and suspected cardiac sarcoidosis Defined ischemic heart failure with respect to myocardial viability assessment by providing a specific ejection fraction value Removed relative non-indications for myocardial perfusion PET (other than chest trauma, which remains).

		Simplified clinical harms/benefits section due to existence of relevant NCD/LCDs.
Version 2.1	03/18/2026	Revision. Updated links and references for the following: A56848, L39521, A59318, A56476, A56423, A56952.



Cohere Medicare Advantage Policy – Positron Emission Tomography (PET), Cardiac

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

Important Notices

Notices & Disclaimers:

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Medical Necessity Criteria

Service: Positron Emission Tomography (PET), Cardiac

Benefit Category

Diagnostic Tests (Other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻¹³

- [National Coverage Determination \(NCD\). FDG PET for Myocardial Viability \(220.6.8\)](#)
- [National Coverage Determination \(NCD\). PET for Perfusion of the Heart. \(220.6.1\)](#)
- [National Coverage Determination \(NCD\). Positron Emission Tomography \(FDG\) for Oncologic Conditions. \(220.6.17\)](#)
- [Local Coverage Determination \(LCD\). Multiple Imaging in Oncology \(L35391\)](#)
- [Local Coverage Determination \(LCD\). Positron Emission Tomography \(PET\) Scan for Inflammation and Infection \(L39521\).](#)
- [Local Coverage Determination \(LCD\) Cardiac Radionuclide Imaging. \(L33457\).](#)
- [Local Coverage Determination \(LCD\) Cardiology Non-Emergency Outpatient Stress Testing. \(L35083\).](#)
- [Local Coverage Determination \(LCD\) Cardiology Non-Emergent Outpatient Stress Testing. \(L38396\).](#)
- [Billing and Coding: Multiple Imaging in Oncology. \(A56848\).](#)
- [Billing and Coding: Positron Emission Tomography \(PET\) Scan for Inflammation and Infection \(A59318\).](#)
- [Billing and Coding: Cardiac Radionuclide Imaging \(A56476\).](#)
- [Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing. \(A56423\).](#)

- [Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing. \(A56952\).](#)

Recommended Clinical Approach

Cardiac PET is considered advanced imaging, and it is best utilized per institutional internal medicine and cardiology protocols. Radiologic and cardiology guidelines from the American Society of Nuclear Cardiology (ASNC), American College of Radiology (ACR), American College of Cardiology (ACC), Society of Nuclear Medicine and Molecular Imaging (SNMMI), and European Association of Nuclear Medicine (EANM) may be consulted prior to ordering.

Cardiac PET is specifically optimized for the evaluation of myocardial perfusion and viability. It may also be utilized to evaluate infection and inflammation. Myocardial perfusion in the setting of suspected or known coronary artery disease (CAD) can be evaluated with cyclotron-produced (^{13}N -ammonia) or generator-produced (^{82}Rb) PET agents.¹⁴⁻²⁹

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of cardiac PET. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of PET imaging, including cumulative radiation exposure, allergy, and harm to breast milk.³⁰
- Potential danger to pregnancy: PET imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.³¹ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.³¹
- Increased healthcare costs and complications from the inappropriate

use of additional interventions.³²

The clinical benefits of using these criteria include:

- Noninvasive: As an imaging modality, cardiac PET is noninvasive; it is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers. It also utilizes no injected contrast agent, conferring an inherent safety benefit.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Positron emission tomography (PET) cardiac or PET cardiac with stress testing** is considered appropriate if **ANY** of the following is **TRUE**:

◆ **Rubidium (⁸²Rb) cardiac PET or PET/CT** for **ANY** of the following¹⁵:

- The patient is asymptomatic with known CAD or a high pretest probability (PTP) of CAD (See the [Pre-Test Probability of CAD](#) published by the CAD Consortium) with **ANY** of the following:
 - Equivocal prior coronary CT angiography (CCTA, with 40–90% stenosis); **OR**
 - Equivocal exercise stress test; **OR**
 - History of coronary artery bypass grafting more than 5 years prior and no stress test performed in the last 2 years; **OR**

- History of percutaneous coronary intervention and no stress test performed in the last 2 years prior; **OR**
- Coronary artery calcium score equal to or above 400; **OR**
- New or worsening left ventricular dysfunction (ejection fraction [EF] less than or equal to 45%); **OR**
- New or previously unrecognized or uninterpretable ECG, as qualified by **ANY** of the following:
 - Complete left bundle branch block; **OR**
 - Ventricular paced rhythm; **OR**
 - Pre-excitation pattern such as Wolff-Parkinson-White; **OR**
 - A less than 1 millimeter ST segment depression; **OR**
 - Left ventricular hypertrophy (LVH) with repolarization abnormalities; **OR**
 - Patients on beta blocker, calcium channel blocker, and/or antiarrhythmic medication; **OR**
 - Physical inability to perform a maximum exercise workload; **OR**
- The patient is symptomatic with suspected or known coronary artery disease (CAD) and imaging is recommended for **ANY** of the following reasons:
 - Detection of obstructive CAD with myocardial ischemia in patients with chest pain (acute but stabilized or chronic); **OR**
 - Intermediate or high pretest probability; **OR**
 - For clarification of equivocal or discordant prior tests and **ANY** of the following is **TRUE**:
 - ◆ Presence of anomalous coronary arteries with suspected ischemia; **OR**
 - ◆ Presence of borderline obstructive lesions on coronary angiography (50–70% non-left main stenosis or CCTA (40–90% stenosis); **OR**
 - New heart failure diagnosis without previous assessment for CAD with **ANY** of the following:
 - ◆ Heart failure with preserved ejection fraction (intermediate or high-risk of CAD); **OR**

- ◆ Ejection fraction less than 45% (any clinical risk of CAD)¹⁶; **OR**
 - Pre-operative risk assessment before high-risk surgical procedures (e.g., vascular surgery, solid organ transplantation); **OR**
 - Post-operative assessment of reimplanted coronary arteries (e.g., surgically corrected transposition of the great arteries); **OR**
 - Evaluation or surveillance for **ANY** of the following:
 - For assessment of myocardial blood flow in suspected microvascular disease; **OR**
 - Myocardial viability for detection of hibernating or stunned myocardium; **OR**
 - Transplant coronary artery disease (TCAD) or cardiac allograft vasculopathy (CAV) in patients with a history of organ transplantation; **OR**
 - Hypertrophic cardiomyopathy; **OR**
 - New-onset atrial fibrillation with no prior cardiac evaluation; **OR**
 - Patients without clear cardiac symptoms in the presence of an elevated cardiac troponin; **OR**
 - Patients who will be treated with interleukin-2 products for various malignant disorders; **OR**
 - Evidence or high suspicion of ventricular arrhythmias; **OR**
 - Syncope for patients with an intermediate or high CHD risk (ATP III risk criteria) and where cardiac etiology is suspected based on an initial evaluation, including history, physical examination, or ECG, and patient is unable to exercise; **OR**
 - Worsening or continuing symptoms after normal or submaximal exercise stress test with suspicion of a false negative result; **OR**
 - History of false positive exercise stress test; **OR**
- ◆ **FDG PET/CT** and **ANY** of the following is **TRUE**²⁵:
- Evaluation of cardiac sources of infection or inflammation, as indicated by **ALL** of the following⁵:
 - Documented suspicion on clinical exam and laboratory evaluation; **AND**

- Non-specific or inconclusive imaging from echocardiography and/or CT; **AND**
- The patient is being evaluated for **ANY** of the following conditions:
 - ◆ Infective endocarditis with a prosthetic valve; **OR**
 - ◆ Suspected cardiac device infection (pacemaker, defibrillators, LVAD, metallic implants); **OR**
 - ◆ CTA or MRA are inconclusive or nondiagnostic for **ANY** of the following:
 - Aortitis; **OR**
 - Systemic vasculitis; **OR**
 - Vascular graft infection; **OR**
 - ◆ Cardiac sarcoidosis with **ANY** of the following:
 - Risk factors (such as systemic sarcoidosis); **OR**
 - Patient less than 60 years old with unexplained, new onset conduction system disease; **OR**
 - Heart failure without explanation; **OR**
 - Idiopathic sustained ventricular tachycardia unexplained by other causes; **OR**
- Neoplastic conditions for **ANY** of the following:
 - Initial staging; **OR**
 - Treatment planning; **OR**
 - Response assessment; **OR**
 - Restaging or treatment monitoring, and **ANY** of the following is **TRUE**^{4,33}:
 - ◆ The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
 - ◆ Suspected recurrence/progression; **OR**
 - ◆ Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy)

and/or 6–8 weeks since the prior imaging evaluation); **OR**

- An abnormality considered indeterminate by another imaging modality to determine whether glucose metabolism in that abnormality favors a benign or malignant process; **OR**
 - Cardiomyopathy (inflammatory or restrictive) and ischemic cardiomyopathy have been excluded²⁶; **OR**
 - Ventricular arrhythmia (frequent PVCs, non-sustained ventricular tachycardia, sustained ventricular tachycardia, or cardiac arrest)^{27–28}; **OR**
 - Myocardial viability assessment prior to revascularization¹; **OR**
 - Nontraumatic chest wall pain with a normal chest radiography and **ANY** of the following³⁴:
 - History of prior chest intervention; **OR**
 - Known or suspected malignancy; **OR**
 - Suspected infectious or inflammatory condition; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Positron emission tomography (PET), cardiac** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The imaging request is for **myocardial perfusion PET** and **ANY** of the following is **TRUE**:
 - Acute nonspecific chest pain with a low probability of CAD²⁰; **OR**

- Asymptomatic patients with less than an intermediate risk for CAD who may benefit from CT coronary calcium or coronary CT angiography; **OR**
- Chest trauma^{18,35}; **OR**
- Nonischemic myocardial disease (excluding sarcoidosis)¹⁷⁻¹⁸; **OR**
- Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ The imaging request is for FDG PET/CT with **ANY** of the following:
 - If used as first-line diagnostic test; **OR**
 - If **ANY** of the following tests have already been done or are planned as part of diagnostic evaluation without documented medical necessity:
 - Labeled WBC scan; **OR**
 - 67Ga SPECT/CT; **OR**
 - Cardiac MRI; **OR**
 - Endocarditis in a native valve; **OR**
 - If used for monitoring response to treatment with the exception of cardiac sarcoidosis; **OR**
 - Acute chest pain with suspected aortic dissection; **OR**
 - Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
 - The use of PET scan for inflammation and infection of other conditions not specifically addressed in the indications will be considered investigational.

*NOTE: PET in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

**NOTE: PET scans should be scheduled at least 4–6 weeks after radiation therapy or surgery to avoid false positives due to inflammation from recent treatments.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and

the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{[36-37](#)}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{[36-37](#)}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{[36-37](#)}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{[36-37](#)}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
78429	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study; with concurrently acquired computed tomography transmission scan
78430	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall

	motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography (CT) transmission scan
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability)
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography (CT) transmission scan
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study
78491	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic)
78492	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic)
78811	Positron emission tomography (PET) imaging; limited area (e.g., of chest, head/neck)

Medical Evidence

Patel et al. (2020) assess the use of positron emission tomography (PET) myocardial perfusion imaging (MPI) as a way to non-invasively measure myocardial blood flow reserve (MBFR). One aim was to determine if patients with MBFR with a survival benefit after revascularization, which helps guide post-test management. A total of 12594 patients who underwent Rb82 rest/stress PET MPI were included. The MBFR observed on PET MPI correlates with overall mortality risk and can pinpoint individuals who would potentially derive survival advantages from early revascularization as opposed to medical management alone. The authors conclude that utilization of the metric can inform decision-making regarding revascularization strategies, however, further validation through prospective studies is warranted.³⁸

Gulati et al. (2021) recommended for intermediate-high risk patients with stable chest pain and no known CAD for whom rest/stress nuclear MPI is selected, PET is reasonable in preference to SPECT, if available to improve diagnostic accuracy and decrease the rate of nondiagnostic test results.³⁹

Swart et al. (2018) performed a multicenter study to enhance the accuracy of ¹⁸F-Fluorodeoxyglucose (FDG) positron-emission tomography/computed tomography (PET/CT) in patients suspected of having prosthetic heart valve endocarditis (PVE). Notably, FDG-PET is not appropriate to image suspected endocarditis of the native valve, as sensitivity for detecting native valve endocarditis has been reported at 0%.²⁹ The study identified and eliminated potential confounding factors using visual and standardized quantitative evaluations. A total of 160 patients with a prosthetic heart valve were included (median age 62; 68% male; 82 mechanical valves; 62 biological; 9 transcatheter aortic valve replacements; 7 other). All patients underwent FDG PET/CT for suspicion of PVE. Early integration of FDG PET/CT into the diagnostic protocol is shown to mitigate the potential impact of low inflammatory activity (for example, that induced by prolonged antibiotic treatment).⁴⁰

Chen et al. (2017) conducted the CORE320 Multicenter Study (NCT00934037) to compare the prognostic significance of combined CT angiography and CT myocardial stress perfusion imaging vs a combination of invasive coronary

angiography (ICA) and stress single photon emission CT myocardial perfusion imaging. The study also addressed the time to major adverse cardiovascular events (MACE). Results indicate that the combined use of CT angiography and CT myocardial perfusion demonstrates comparable predictive ability for 2-year MACE-free survival. This encompasses the necessity for myocardial revascularization procedures compared to the standard approach involving ICA and single photon emission CT perfusion imaging.²¹

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Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		



Cohere Medicare Advantage Policy – Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 3, 2024

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

Date of last literature review: 10/2/2024

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

Benefit Category

Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.^{1,61}

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.^{1,57,61-63,69}

- [National Coverage Determination \(NCD\). Positron emission tomography \(FDG\) for oncologic indications \(220.6.17\)](#)
- [National Coverage Determination \(NCD\). Positron emission tomography \(NaF-18\) to identify bone metastasis of cancer \(220.6.19\)](#)
- [Local Coverage Determination \(LCD\). Positron emission tomography \(PET\) scan for inflammation and infection \(L39521\)](#)
- [Billing and Coding: Positron emission tomography \(PET\) scan for inflammation and infection \(A59318\)](#)
- [Local Coverage Determination \(LCD\). Multiple imaging in oncology \(L35391\)](#)

Recommended Clinical Approach

Positron emission tomography (PET) is a non-invasive diagnostic imaging procedure used to evaluate the metabolic activity in tissues. This technology is particularly useful for assessing oncologic, cardiovascular diseases and neurological disorders. Before undergoing a PET scan, patients typically undergo a series of preliminary assessments, including history and physical examination, and often other imaging studies like MRI or CT scans, which guide the need for further metabolic imaging.⁵⁷⁻⁵⁸

Oncologic positron emission tomography (PET) is considered advanced imaging and best utilized per institutional oncologic protocols and oncologic

(e.g., National Comprehensive Cancer Network [NCCN]) and radiological society guidelines including the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM), and the American College of Radiology (ACR). The decision to perform oncologic PET is often made at institutional tumor board meetings after multidisciplinary oncology teams review the case. Teams may include oncologic surgeons, radiation oncologists, medical oncologists, pathologists, and radiologists.¹⁻³

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of positron emission tomography (PET)/PET computed tomography (CT). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of PET imaging, including cumulative radiation exposure, allergy, and harm to breast milk.⁶⁴⁻⁶⁶
- Potential danger to pregnancy: PET imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹⁶ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁶⁷
- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁶⁸

The clinical benefits of using these criteria include:

- Improved diagnostic accuracy: PET imaging, and in particular, PET/CT, has shown greater accuracy in evaluating patients with either known or suspected malignancy than PET or CT alone or PET and CT obtained separately but interpreted together.²
- Noninvasive: PET is a noninvasive imaging modality. It is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers. PET

also utilizes no injected contrast agent, conferring an inherent safety benefit.

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Positron emission tomography (PET) with or without concurrently acquired computed tomography (CT)(PET/CT) using fluorodeoxyglucose (FDG)** is considered appropriate if **ANY** of the following is **TRUE**^{1-3,57,61,62,63}:

- ◆ Diagnosis, staging, treatment monitoring/re-staging for **ANY** of the following primary cancer/tumor types:
 - Adrenal⁴; **OR**
 - Anal⁵; **OR**
 - Bladder⁶; **OR**
 - Bone⁷; **OR**
 - Brain/central nervous system⁸; **OR**
 - Breast (excluding initial diagnosis and/or staging of axillary lymph nodes)⁹⁻¹²; **OR**
 - Cervical (excluding initial diagnosis of cervical cancer related to anti-tumor treatment strategy)¹³⁻¹⁴; **OR**
 - Colorectal¹⁵⁻¹⁷; **OR**
 - Endometrial¹⁸⁻¹⁹; **OR**
 - Esophageal²⁰⁻²¹; **OR**
 - Gastric²²; **OR**

- Gestational trophoblastic neoplasia²³; **OR**
- Head and neck²⁴⁻²⁶; **OR**
- Lung cancer, non-small cell²⁷⁻²⁹; **OR**
- Lung cancer, small cell²⁸⁻²⁹; **OR**
- Lymphoma³⁰⁻³¹; **OR**
- Melanoma, cutaneous (excluding initial staging of regional lymph nodes)³²; **OR**
- Multiple myeloma³³; **OR**
- Ovarian³⁴⁻³⁶; **OR**
- Pancreatic³⁷⁻³⁸; **OR**
- Pleural mesothelioma³⁹; **OR**
- Prostate (excluding initial diagnosis and antitumor treatment strategy)⁴⁰⁻⁴⁴; **OR**
- Squamous cell carcinoma of the skin⁴⁵; **OR**
- Soft tissue sarcoma⁴⁶⁻⁴⁷; **OR**
- Testes (indicated for seminoma cancers only)⁴⁸⁻⁴⁹; **OR**
- Thyroid⁵⁰⁻⁵¹; **OR**
- Vulvar⁵²; **OR**

◆ **Prostate-specific membrane antigen (PSMA [using F-18 piflufolastat, F-18 flutufolastat, or Ga-68 PSMA-11]) PET and the patient has prostate cancer/tumor and **ANY** of the following positive findings⁴⁰⁻⁴⁴:**

- The patient has been treated with radical prostatectomy and **ANY** of the following is **TRUE**:
 - Serum prostate-specific antigen (PSA) elevation greater than 0.1 ng/mL; **OR**
 - Persistence of elevated PSA (failure to fall to undetectable levels); **OR**
 - Previously undetectable PSA that has been increasing on two or more occasions; **OR**
- The patient has been treated with radiation therapy or other nonsurgical treatment and **ANY** of the following:
 - An increase of PSA by 2 ng/mL or greater above the lowest post-treatment PSA; **OR**
 - PSA increasing after radiation therapy and the patient is a candidate for salvage local therapy (even if the lowest PSA value is under 2 ng/mL); **OR**

- Initial treatment planning for suspected metastatic disease; **OR**
- Staging for individuals with a diagnosis of unfavorable intermediate-risk, high-risk, or very high-risk prostate cancer; **OR**
- GA-68 PSMA-11 PET/CT before initial treatment with lutetium Lu-177 vipivotide tetraxetan (e.g., Pluvicto) for metastatic castration-resistant prostate cancer; **OR**
- ◆ **F-18 fluciclovine or choline C-11 PET/CT** and **ANY** of the following positive findings⁴⁰⁻⁴⁴:
 - The patient has been treated with radical prostatectomy, and **ANY** of the following is **TRUE**:
 - Serum prostate-specific antigen (PSA) elevation greater than 0.1 ng/ml; **OR**
 - Persistence of elevated PSA (failure to fall to undetectable levels); **OR**
 - Previously undetectable PSA that has been increasing on two or more occasions; **OR**
 - The patient has been treated with radiation therapy or other nonsurgical treatment and **ANY** of the following:
 - An increase of PSA by 2 ng/mL or greater above the lowest post-treatment PSA; **OR**
 - PSA increasing after radiation therapy and the patient is a candidate for salvage local therapy (even if the lowest PSA value is under 2 ng/mL); **OR**
- ◆ **Dotatate PET** and the patient has a well-differentiated neuroendocrine tumor and **ANY** of the following^{4,53}:
 - Diagnosis with high suspicion of neuroendocrine tumor based on prior imaging (e.g. prior CT), symptoms (e.g. intractable diarrhea) or laboratory values (e.g, High chromogranin levels) ; **OR**
 - Initial Staging; **OR**
 - Treatment planning for lutetium Lu-177 Dotatate; **OR**
 - Restaging or treatment monitoring, and **ANY** of the following is **TRUE**^{28,36}:
 - The patient is assumed to have either no known disease or disease that is stable or clinically

insignificant (every 6–12 months for an overall duration [e.g., 5 years]); **OR**

- Suspected recurrence/progression; **OR**
- Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6–8 weeks since the prior imaging evaluation); **OR**

◆ **Positron emission tomography (PET) scan for non-oncologic conditions** is considered appropriate if **ANY** of the following are **TRUE**⁵⁹⁻⁶⁰:

- **ALL** of the following are **TRUE**:

- MRI and CT are contraindicated or inconclusive; **AND**
- **ANY** of the following is **TRUE**⁶²:

- ◆ For patients greater than or equal to 18 years of age with fever of unknown origin (FUO) and **ALL** of the following⁶²:

- Fever higher than 38.3 Celsius (101 degrees Fahrenheit); **AND**
- Present for greater than or equal to 21 days defined by fever on 2 or more occasions with repeating episodes for 2 or more weeks prior to the study; **AND**
- The patient is not immunocompromised; **AND**
- Investigation including history, physical, laboratory analysis, and standard imaging is non-diagnostic; **AND**
- The patient does not have any conditions that would limit the ability to interpret the PET scan; **OR**

- ◆ For diagnosis of equivocal cases of suspected osteomyelitis or spondylodiscitis (with abnormal radiographs or CT findings and **ALL** of the following:

- MRI cannot be performed or is non-diagnostic or inconclusive; **AND**

- The patient does not have any conditions that would limit the ability to interpret the PET (e.g., post-operative or post-traumatic conditions, uncontrolled blood sugars); **AND**
 - Not in conjunction with bone scintigraphy, leukocyte scintigraphy, and or MOAB scintigraphy; **OR**
- Evaluation of cardiac sources of infection or inflammation, as indicated by **ALL** of the following⁶²:
 - Documented suspicion on clinical exam and laboratory evaluation; **AND**
 - Non-specific or inconclusive imaging from echocardiography and/or CT; **AND**
 - The patient is being evaluated for **ANY** of the following conditions:
 - ◆ Infective endocarditis with a prosthetic valve; **OR**
 - ◆ Suspected cardiac device infection (pacemaker, defibrillators, LVAD, metallic implants); **OR**
 - ◆ CTA or MRA are inconclusive or nondiagnostic for **ANY** of the following:
 - Aortitis; **OR**
 - Systemic vasculitis; **OR**
 - Vascular graft infection; **OR**
 - ◆ Cardiac sarcoidosis with **ANY** of the following:
 - Risk factors (such as systemic sarcoidosis); **OR**
 - Patient less than 60 years old with unexplained, new onset conduction system disease; **OR**
 - Heart failure without explanation; **OR**
 - Idiopathic sustained ventricular tachycardia unexplained by other causes; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in

the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Positron emission tomography (PET), with or without concurrently acquired computed tomography (CT)(PET/CT)** is not considered appropriate if **ANY** of the following is **TRUE**:

- For **oncologic indications** and **ANY** of the following:
 - Whole-body PET or PET/CT for cancer screening purposes only; **OR**
 - Initial diagnosis or staging of axillary lymph nodes in breast cancer^{1.9-12}; **OR**
 - Initial diagnosis of cervical cancer related to anti-tumor treatment strategy^{1.13-14}; **OR**
 - Initial staging of regional lymph nodes in melanoma^{1.32}; **OR**
 - Non-seminomatous tumors of the testes⁴⁸⁻⁴⁹; **OR**
 - FDG-PET for the initial anti-tumor strategy of prostate cancer⁴⁰⁻⁴⁴; **OR**
 - F-18 sodium fluoride (NaF-18) PET for any indication, including identifying bone metastasis of cancer⁶⁹; **OR**
- For **infection/inflammation** and **ANY** of the following:
 - If used as first-line diagnostic test; **OR**
 - If **ANY** of the following tests have already been done or are planned as part of diagnostic evaluation without documented medical necessity:
 - ◆ Labeled WBC scan; **OR**
 - ◆ 67Ga SPECT/CT; **OR**
 - Endocarditis in a native valve; **OR**
 - If used for monitoring response to treatment with the exception of cardiac sarcoidosis; **OR**

- The use of PET scan for inflammation and infection of other conditions not specifically addressed in the Indications section above will be considered investigational.

*NOTE: PET/CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: PET/CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.⁵⁴

***NOTE: PET scans should be scheduled at least 4–6 weeks after radiation therapy or surgery to avoid false positives due to inflammation from recent treatments.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.⁵⁵⁻⁵⁶

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.⁵⁵⁻⁵⁶

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.⁵⁵⁻⁵⁶

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still

yields reliable diagnostic images. [55-56](#)

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
78811	Positron emission tomography (PET) imaging of chest
78812	Positron emission tomography (PET) imaging of skull base to midhigh
78813	Positron emission tomography (PET) imaging of whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging of skull base to midhigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) of whole body
79101	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
A9515	Choline c-11, diagnostic, per study dose up to 20 millicuries
A9552	Fluorodeoxyglucose f-18 fdg, diagnostic, per study dose, up to 45 millicuries

A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie
A9588	Fluciclovine f-18, diagnostic, 1 millicurie
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie
A9595	Piflufolastat f-18, diagnostic, 1 millicurie
A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie
A9597	Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified
A9607	Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie
A9608	Flotufolastat f18, diagnostic, 1 millicurie
A9609	Fludeoxyglucose f18 up to 15 millicuries
A9800	Gallium Ga-68 gozetotide, diagnostic, (Locametz), 1 millicurie
G0219	PET imaging whole body; melanoma for non-covered indications
G0235	PET imaging, any site, not otherwise specified
G0252	PET imaging, full and partial-ring scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Jadvar et al. (2017) published Appropriate Use Criteria for the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM), the American Society of Clinical Oncology (ASCO), the American College of Nuclear Medicine (ACNM) the Society for Pediatric Radiology (SPR), and the Canadian Association of Nuclear Medicine (CANM). The group focused on meta-analyses and large individual studies comparing PET or PET/CT with other imaging modalities. It stated that the physician must prioritize which modality to begin with. PET/CT is said to have a strong role in restaging cancers and determining future patient management. Clinical studies cited to support the accuracy of PET/CT in detecting recurrent disease and assessing treatment response.³

The American College of Radiology (ACR) published the ACR-ACNM-SNMMI-SPR practice parameter for performing FDG-PET/CT in oncology in 2021. The indications presented in the document include use in the staging of malignancy, monitoring response to therapy, or restaging when the patient has relapsed. Additionally, this imaging modality may help localize the site of the primary tumor in the setting of metastatic disease, clarify indeterminate results, or localize occult disease when testing such as tumor markers indicates neoplastic disease. Finally, FDG-PET/CT may be used to plan treatment goals and to guide biopsy and radiation treatment planning.²

Published by the American College of Radiology in 2023, the ACR-ACNM-SNMMI practice parameter for performing Gallium-68 and Copper-64 Dotatate PET/CT imaging for neuroendocrine tumors (NETs). This imaging modality is appropriate for diagnosing, staging, restaging, and assessing treatment response in neuroendocrine tumors. Radiotracers such as those discussed in this practice parameter, which target cell membrane expression of somatostatin receptors (SSTRs), are useful in evaluating well-differentiated NETs compared to anatomical imaging. Fused imaging with computed tomography (PET/CT) in hybrid PET scanners has shown a high level of accuracy in evaluating patients with known or suspected malignancy.⁵³

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Clinical Guideline Revision History/Information

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Cohere Medicare Advantage Policy – Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

Clinical Guidelines for Medical Necessity Review

Version: 1
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Important Notices

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Medical Necessity Criteria

Service: Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

Benefit Category

Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.^{1,61}

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.^{1,57,61-63,69}

- [National Coverage Determination \(NCD\). Positron emission tomography \(FDG\) for oncologic indications \(220.6.17\)](#)
- [National Coverage Determination \(NCD\). Positron emission tomography \(NaF-18\) to identify bone metastasis of cancer \(220.6.19\)](#)
- [Local Coverage Determination \(LCD\). Positron emission tomography \(PET\) scan for inflammation and infection \(L39521\)](#)
- [Billing and Coding: Positron emission tomography \(PET\) scan for inflammation and infection \(A59318\)](#)
- [Local Coverage Determination \(LCD\). Multiple imaging in oncology \(L35391\)](#)

Recommended Clinical Approach

Positron emission tomography (PET) is a non-invasive diagnostic imaging procedure used to evaluate the metabolic activity in tissues. This technology is particularly useful for assessing oncologic, cardiovascular diseases and neurological disorders. Before undergoing a PET scan, patients typically undergo a series of preliminary assessments, including history and physical examination, and often other imaging studies like MRI or CT scans, which guide the need for further metabolic imaging.⁵⁷⁻⁵⁸

Oncologic positron emission tomography (PET) is considered advanced imaging and best utilized per institutional oncologic protocols and oncologic

(e.g., National Comprehensive Cancer Network [NCCN]) and radiological society guidelines including the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM), and the American College of Radiology (ACR). The decision to perform oncologic PET is often made at institutional tumor board meetings after multidisciplinary oncology teams review the case. Teams may include oncologic surgeons, radiation oncologists, medical oncologists, pathologists, and radiologists.¹⁻³

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of positron emission tomography (PET)/PET computed tomography (CT). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of PET imaging, including cumulative radiation exposure, allergy, and harm to breast milk.⁶⁴⁻⁶⁶
- Potential danger to pregnancy: PET imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.¹⁶ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁶⁷
- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁶⁸

The clinical benefits of using these criteria include:

- Improved diagnostic accuracy: PET imaging, and in particular, PET/CT, has shown greater accuracy in evaluating patients with either known or suspected malignancy than PET or CT alone or PET and CT obtained separately but interpreted together.²
- Noninvasive: PET is a noninvasive imaging modality. It is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers. PET

also utilizes no injected contrast agent, conferring an inherent safety benefit.

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Positron emission tomography (PET) with or without concurrently acquired computed tomography (CT)(PET/CT) using fluorodeoxyglucose (FDG)** is considered appropriate if **ANY** of the following is **TRUE**^{1-3,57,61,62,63}:

- ◆ Diagnosis, staging, treatment monitoring/re-staging for **ANY** of the following primary cancer/tumor types:
 - Adrenal⁴; **OR**
 - Anal⁵; **OR**
 - Bladder⁶; **OR**
 - Bone⁷; **OR**
 - Brain/central nervous system⁸; **OR**
 - Breast (excluding initial diagnosis and/or staging of axillary lymph nodes)⁹⁻¹²; **OR**
 - Cervical (excluding initial diagnosis of cervical cancer related to anti-tumor treatment strategy)¹³⁻¹⁴; **OR**
 - Colorectal¹⁵⁻¹⁷; **OR**
 - Endometrial¹⁸⁻¹⁹; **OR**
 - Esophageal²⁰⁻²¹; **OR**
 - Gastric²²; **OR**

- Gestational trophoblastic neoplasia²³; **OR**
- Head and neck²⁴⁻²⁶; **OR**
- Lung cancer, non-small cell²⁷⁻²⁹; **OR**
- Lung cancer, small cell²⁸⁻²⁹; **OR**
- Lymphoma³⁰⁻³¹; **OR**
- Melanoma, cutaneous (excluding initial staging of regional lymph nodes)³²; **OR**
- Multiple myeloma³³; **OR**
- Ovarian³⁴⁻³⁶; **OR**
- Pancreatic³⁷⁻³⁸; **OR**
- Pleural mesothelioma³⁹; **OR**
- Prostate (excluding initial diagnosis and antitumor treatment strategy)⁴⁰⁻⁴⁴; **OR**
- Squamous cell carcinoma of the skin⁴⁵; **OR**
- Soft tissue sarcoma⁴⁶⁻⁴⁷; **OR**
- Testes (indicated for seminoma cancers only)⁴⁸⁻⁴⁹; **OR**
- Thyroid⁵⁰⁻⁵¹; **OR**
- Vulvar⁵²; **OR**

◆ **Prostate-specific membrane antigen (PSMA [using F-18 piflufolastat, F-18 flutufolastat, or Ga-68 PSMA-11]) PET and the patient has prostate cancer/tumor and **ANY** of the following positive findings⁴⁰⁻⁴⁴:**

- The patient has been treated with radical prostatectomy and **ANY** of the following is **TRUE**:
 - Serum prostate-specific antigen (PSA) elevation greater than 0.1 ng/mL; **OR**
 - Persistence of elevated PSA (failure to fall to undetectable levels); **OR**
 - Previously undetectable PSA that has been increasing on two or more occasions; **OR**
- The patient has been treated with radiation therapy or other nonsurgical treatment and **ANY** of the following:
 - An increase of PSA by 2 ng/mL or greater above the lowest post-treatment PSA; **OR**
 - PSA increasing after radiation therapy and the patient is a candidate for salvage local therapy (even if the lowest PSA value is under 2 ng/mL); **OR**

- Initial treatment planning for suspected metastatic disease; **OR**
- Staging for individuals with a diagnosis of unfavorable intermediate-risk, high-risk, or very high-risk prostate cancer; **OR**
- GA-68 PSMA-11 PET/CT before initial treatment with lutetium Lu-177 vipivotide tetraxetan (e.g., Pluvicto) for metastatic castration-resistant prostate cancer; **OR**
- ◆ **F-18 fluciclovine or choline C-11 PET/CT** and **ANY** of the following positive findings⁴⁰⁻⁴⁴:
 - The patient has been treated with radical prostatectomy, and **ANY** of the following is **TRUE**:
 - Serum prostate-specific antigen (PSA) elevation greater than 0.1 ng/ml; **OR**
 - Persistence of elevated PSA (failure to fall to undetectable levels); **OR**
 - Previously undetectable PSA that has been increasing on two or more occasions; **OR**
 - The patient has been treated with radiation therapy or other nonsurgical treatment and **ANY** of the following:
 - An increase of PSA by 2 ng/mL or greater above the lowest post-treatment PSA; **OR**
 - PSA increasing after radiation therapy and the patient is a candidate for salvage local therapy (even if the lowest PSA value is under 2 ng/mL); **OR**
- ◆ **Dotatate PET** and the patient has a well-differentiated neuroendocrine tumor and **ANY** of the following^{4,53}:
 - Diagnosis with high suspicion of neuroendocrine tumor based on prior imaging (e.g. prior CT), symptoms (e.g. intractable diarrhea) or laboratory values (e.g, High chromogranin levels) ; **OR**
 - Initial Staging; **OR**
 - Treatment planning for lutetium Lu-177 Dotatate; **OR**
 - Restaging or treatment monitoring, and **ANY** of the following is **TRUE**^{28,36}:
 - The patient is assumed to have either no known disease or disease that is stable or clinically

insignificant (every 6–12 months for an overall duration [e.g., 5 years]); **OR**

- Suspected recurrence/progression; **OR**
- Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6–8 weeks since the prior imaging evaluation); **OR**

◆ **Positron emission tomography (PET) scan for non-oncologic conditions** is considered appropriate if **ANY** of the following are **TRUE**⁵⁹⁻⁶⁰:

- **ALL** of the following are **TRUE**:

- MRI and CT are contraindicated or inconclusive; **AND**
- **ANY** of the following is **TRUE**⁶²:

- ◆ For patients greater than or equal to 18 years of age with fever of unknown origin (FUO) and **ALL** of the following⁶²:

- Fever higher than 38.3 Celsius (101 degrees Fahrenheit); **AND**
- Present for greater than or equal to 21 days defined by fever on 2 or more occasions with repeating episodes for 2 or more weeks prior to the study; **AND**
- The patient is not immunocompromised; **AND**
- Investigation including history, physical, laboratory analysis, and standard imaging is non-diagnostic; **AND**
- The patient does not have any conditions that would limit the ability to interpret the PET scan; **OR**

- ◆ For diagnosis of equivocal cases of suspected osteomyelitis or spondylodiscitis (with abnormal radiographs or CT findings and **ALL** of the following:

- MRI cannot be performed or is non-diagnostic or inconclusive; **AND**

- The patient does not have any conditions that would limit the ability to interpret the PET (e.g., post-operative or post-traumatic conditions, uncontrolled blood sugars); **AND**
 - Not in conjunction with bone scintigraphy, leukocyte scintigraphy, and or MOAB scintigraphy; **OR**
- Evaluation of cardiac sources of infection or inflammation, as indicated by **ALL** of the following⁶²:
 - Documented suspicion on clinical exam and laboratory evaluation; **AND**
 - Non-specific or inconclusive imaging from echocardiography and/or CT; **AND**
 - The patient is being evaluated for **ANY** of the following conditions:
 - ◆ Infective endocarditis with a prosthetic valve; **OR**
 - ◆ Suspected cardiac device infection (pacemaker, defibrillators, LVAD, metallic implants); **OR**
 - ◆ CTA or MRA are inconclusive or nondiagnostic for **ANY** of the following:
 - Aortitis; **OR**
 - Systemic vasculitis; **OR**
 - Vascular graft infection; **OR**
 - ◆ Cardiac sarcoidosis with **ANY** of the following:
 - Risk factors (such as systemic sarcoidosis); **OR**
 - Patient less than 60 years old with unexplained, new onset conduction system disease; **OR**
 - Heart failure without explanation; **OR**
 - Idiopathic sustained ventricular tachycardia unexplained by other causes; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in

the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

→ **Positron emission tomography (PET), with or without concurrently acquired computed tomography (CT)(PET/CT)** is not considered appropriate if **ANY** of the following is **TRUE**:

- For **oncologic indications** and **ANY** of the following:
 - Whole-body PET or PET/CT for cancer screening purposes only; **OR**
 - Initial diagnosis or staging of axillary lymph nodes in breast cancer^{1.9-12}; **OR**
 - Initial diagnosis of cervical cancer related to anti-tumor treatment strategy^{1.13-14}; **OR**
 - Initial staging of regional lymph nodes in melanoma^{1.32}; **OR**
 - Non-seminomatous tumors of the testes⁴⁸⁻⁴⁹; **OR**
 - FDG-PET for the initial anti-tumor strategy of prostate cancer⁴⁰⁻⁴⁴; **OR**
 - F-18 sodium fluoride (NaF-18) PET for any indication, including identifying bone metastasis of cancer⁶⁹; **OR**
- For **infection/inflammation** and **ANY** of the following:
 - If used as first-line diagnostic test; **OR**
 - If **ANY** of the following tests have already been done or are planned as part of diagnostic evaluation without documented medical necessity:
 - ◆ Labeled WBC scan; **OR**
 - ◆ 67Ga SPECT/CT; **OR**
 - Endocarditis in a native valve; **OR**
 - If used for monitoring response to treatment with the exception of cardiac sarcoidosis; **OR**

- The use of PET scan for inflammation and infection of other conditions not specifically addressed in the Indications section above will be considered investigational.

*NOTE: PET/CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

**NOTE: PET/CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.⁵⁴

***NOTE: PET scans should be scheduled at least 4–6 weeks after radiation therapy or surgery to avoid false positives due to inflammation from recent treatments.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.⁵⁵⁻⁵⁶

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.⁵⁵⁻⁵⁶

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.⁵⁵⁻⁵⁶

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still

yields reliable diagnostic images. [55-56](#)

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
78811	Positron emission tomography (PET) imaging of chest
78812	Positron emission tomography (PET) imaging of skull base to midhigh
78813	Positron emission tomography (PET) imaging of whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging of skull base to midhigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) of whole body
79101	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
A9515	Choline c-11, diagnostic, per study dose up to 20 millicuries
A9552	Fluorodeoxyglucose f-18 fdg, diagnostic, per study dose, up to 45 millicuries

A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie
A9588	Fluciclovine f-18, diagnostic, 1 millicurie
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie
A9595	Piflufolastat f-18, diagnostic, 1 millicurie
A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie
A9597	Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified
A9607	Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie
A9608	Flotufolastat f18, diagnostic, 1 millicurie
A9609	Fludeoxyglucose f18 up to 15 millicuries
A9800	Gallium Ga-68 gozetotide, diagnostic, (Locametz), 1 millicurie
G0219	PET imaging whole body; melanoma for non-covered indications
G0235	PET imaging, any site, not otherwise specified
G0252	PET imaging, full and partial-ring scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Jadvar et al. (2017) published Appropriate Use Criteria for the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM), the American Society of Clinical Oncology (ASCO), the American College of Nuclear Medicine (ACNM) the Society for Pediatric Radiology (SPR), and the Canadian Association of Nuclear Medicine (CANM). The group focused on meta-analyses and large individual studies comparing PET or PET/CT with other imaging modalities. It stated that the physician must prioritize which modality to begin with. PET/CT is said to have a strong role in restaging cancers and determining future patient management. Clinical studies cited to support the accuracy of PET/CT in detecting recurrent disease and assessing treatment response.³

The American College of Radiology (ACR) published the ACR-ACNM-SNMMI-SPR practice parameter for performing FDG-PET/CT in oncology in 2021. The indications presented in the document include use in the staging of malignancy, monitoring response to therapy, or restaging when the patient has relapsed. Additionally, this imaging modality may help localize the site of the primary tumor in the setting of metastatic disease, clarify indeterminate results, or localize occult disease when testing such as tumor markers indicates neoplastic disease. Finally, FDG-PET/CT may be used to plan treatment goals and to guide biopsy and radiation treatment planning.²

Published by the American College of Radiology in 2023, the ACR-ACNM-SNMMI practice parameter for performing Gallium-68 and Copper-64 Dotatate PET/CT imaging for neuroendocrine tumors (NETs). This imaging modality is appropriate for diagnosing, staging, restaging, and assessing treatment response in neuroendocrine tumors. Radiotracers such as those discussed in this practice parameter, which target cell membrane expression of somatostatin receptors (SSTRs), are useful in evaluating well-differentiated NETs compared to anatomical imaging. Fused imaging with computed tomography (PET/CT) in hybrid PET scanners has shown a high level of accuracy in evaluating patients with known or suspected malignancy.⁵³

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Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		



Cohere Medicare Advantage Policy – Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

Clinical Policy for Medical Necessity Review

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Next Annual Review: October 2, 2026

Important Notices

Notices & Disclaimers:

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medicare Advantage Policy - Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

Policy Number: CHP-220-3.1

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁶

- [National Coverage Determination \(NCD\). Positron emission tomography \(FDG\) for oncologic indications \(220.6.17\)](#)¹
- [National Coverage Determination \(NCD\). Positron emission tomography \(NaF-18\) to identify bone metastasis of cancer \(220.6.19\)](#)²
- [Local Coverage Determination \(LCD\). Positron emission tomography \(PET\) scan for inflammation and infection \(L39521\)](#)³
 - [Billing and Coding: Positron emission tomography \(PET\) scan for inflammation and infection \(A59318\)](#)⁴
- [Local Coverage Determination \(LCD\). Multiple imaging in oncology \(L35391\)](#)⁵
 - [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)⁶

Description

Positron emission tomography (PET) is a minimally invasive diagnostic imaging procedure used to evaluate metabolic activity in tissue. Typically, the patient is injected with a radiotracer, often fluorodeoxyglucose (FDG), which allows a scanner to detect the metabolic activity of cells. This technology is particularly useful for assessing oncologic, cardiovascular, and neurological disorders. Before undergoing a PET scan, the patient often undergoes other imaging studies, including magnetic resonance imaging (MRI) and computed tomography (CT) scans, which guide the need for further metabolic imaging.⁷

PET/CT combines functional and anatomic information and allows for precise tumor staging and evaluation of disease progression, as well as treatment planning, monitoring response to treatment and post-treatment surveillance in at-risk patients.⁸⁻⁹ Oncologic PET is considered advanced imaging and is best used per institutional oncologic protocols and oncological (e.g., National

Comprehensive Cancer Network, NCCN) and radiological society guidelines including those of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM), and the American College of Radiology (ACR). The decision to perform oncologic PET is often made at institutional tumor board meetings after multidisciplinary oncology teams review the case. Teams may include oncologic surgeons, radiation oncologists, medical oncologists, pathologists, and radiologists.¹⁰⁻¹¹

Medical Necessity Criteria

Indications

Positron emission tomography (PET) with or without concurrently acquired computed tomography (CT)(PET/CT) is considered appropriate if **ANY** of the following is **TRUE**^{1-6,10-11}:

- One fluorodeoxyglucose (FDG) PET study for initial anti-tumor treatment strategy with **ALL** of the following¹:
 - The patient has cancer(s) that are biopsy-proven or strongly suspected based on other diagnostic testing; **AND**
 - The treating physician determines that the FDG PET study is needed to determine the location and/or extent of the tumor for **ANY** of the following therapeutic purposes:
 - To determine whether the patient is an appropriate candidate for an invasive diagnostic or therapeutic procedure; **OR**
 - To determine the optimal anatomic location for an invasive procedure; **OR**
 - To determine the anatomic extent of the tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor; **AND**
 - **ANY** of the following oncologic conditions, cancers, or tumor types:
 - Colorectal²³⁻²⁵; **OR**
 - Esophagus²⁸⁻²⁹; **OR**
 - Head and neck (not thyroid, CNS)³²⁻³⁴; **OR**
 - Lymphoma³⁸⁻³⁹; **OR**
 - Non-small cell lung^{35,37}; **OR**
 - Ovary⁴²⁻⁴³; **OR**
 - Brain¹⁶; **OR**
 - Cervix (see non-indications)²¹⁻²²; **OR**
 - Small cell lung³⁶⁻³⁷; **OR**

- Soft tissue sarcoma⁵³⁻⁵⁴; **OR**
- Pancreas⁴⁴⁻⁴⁵; **OR**
- Testes⁵⁵⁻⁵⁶; **OR**
- Thyroid⁵⁷⁻⁵⁸; **OR**
- Breast (see non-indications)¹⁷⁻²⁰; **OR**
- Melanoma (see non-indications)⁴⁰; **OR**
- All other solid tumors; **OR**
- Myeloma⁴¹; **OR**
- All other cancers not listed; **OR**
- Three FDG PET scans when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy for **ANY** of the following oncologic conditions, cancers, or tumor types:
 - Colorectal²³⁻²⁵; **OR**
 - Esophagus²⁸⁻²⁹; **OR**
 - Head and neck (not thyroid, CNS)³²⁻³⁴; **OR**
 - Lymphoma³⁸⁻³⁹; **OR**
 - Non-small cell lung^{35,37}; **OR**
 - Ovary⁴²⁻⁴³; **OR**
 - Brain¹⁶; **OR**
 - Cervix²¹⁻²²; **OR**
 - Small cell lung³⁶⁻³⁷; **OR**
 - Soft-tissue sarcoma⁵³⁻⁵⁴; **OR**
 - Pancreas⁴⁴⁻⁴⁵; **OR**
 - Testes⁵⁵⁻⁵⁶; **OR**
 - Prostate⁴⁷⁻⁵¹; **OR**
 - Thyroid⁵⁷⁻⁵⁸; **OR**
 - Breast¹⁷⁻²⁰; **OR**
 - Melanoma⁴⁰; **OR**
 - All other solid tumors; **OR**
 - Myeloma⁴¹; **OR**
 - All other cancers not listed; **OR**
- Characterization of solitary pulmonary nodule (SPN) greater than 8 millimeters in diameter or greater than 8mm for the solid component of a part-solid nodule⁶⁰; **OR**
- **F-18 fluciclovine, choline C-11, or prostate-specific membrane antigen (PSMA [using F-18 piflufolastat, F-18 flutufolastat, or Ga-68 PSMA-11]) PET and ALL of the following⁴⁷⁻⁵¹:**

- The patient has prostate cancer/tumor; **AND**
- **ANY** of the following:
 - Initial staging if the patient has a diagnosis of unfavorable intermediate-risk, high-risk, or very high-risk prostate cancer; **OR**
 - The patient has been treated with radical prostatectomy and **ANY** of the following:
 - Serum prostate-specific antigen (PSA) elevation greater than 0.1 ng/ml; **OR**
 - Persistence of PSA (failure to fall to undetectable levels); **OR**
 - Previously undetectable PSA that has been increasing on two or more occasions; **OR**
 - The patient has been treated with radiation therapy and **ANY** of the following:
 - An increase of PSA by 2 ng/mL or greater above the lowest post-treatment PSA; **OR**
 - PSA increasing after radiation therapy and the patient is a candidate for salvage local therapy (even if the lowest PSA value is under 2 ng/mL); **OR**
 - Prior to initiation of androgen deprivation therapy (ADT)⁶²; **OR**
 - Three months following completion of ADT⁶²; **OR**
 - GA-68 PSMA-11 PET/CT before initial treatment with lutetium Lu-177 vipivotide tetraxetan (e.g., Pluvicto) for metastatic castration-resistant prostate cancer; **OR**
 - Restaging 12 weeks after treatment with Lu177/Pluvicto⁶⁴; **OR**
 - Known metastatic disease and concern for progression on treatment and **ALL** of the following⁶¹⁻⁶³:
 - PSMA imaging will influence treatment plan; **AND**
 - Inconclusive prior imaging; **OR**
- **Dotatate PET** with **ALL** of the following^{12,65-66}:
 - The patient has a well-differentiated neuroendocrine tumor; **AND**
 - **ANY** of the following:
 - Diagnosis ; **OR**
 - Staging; **OR**
 - Restaging; **OR**
 - Treatment planning for lutetium Lu-177 Dotatate; **OR**
- **Positron emission tomography (PET) scan for non-oncologic conditions** is considered appropriate if **ANY** of the following is **TRUE**⁶⁷⁻⁶⁸:

- The patient is greater than or equal to 18 years of age with fever of unknown origin (FUO) and **ALL** of the following³:
 - Fever higher than 38.3 Celsius (101 degrees Fahrenheit); **AND**
 - Present for greater than or equal to 21 days defined by fever on 2 or more occasions with repeating episodes for 2 or more weeks prior to the study; **AND**
 - The patient is not immunocompromised; **AND**
 - Investigation including history, physical, laboratory analysis, and standard imaging is non-diagnostic; **AND**
 - The patient does not have any conditions that would limit the ability to interpret the PET scan; **OR**
- For diagnosis of equivocal cases of suspected osteomyelitis or spondylodiscitis (with abnormal radiographs or CT findings) and **ALL** of the following³:
 - MRI cannot be performed or is non-diagnostic or inconclusive; **AND**
 - The patient does not have any conditions that would limit the ability to interpret the PET (e.g., post-operative or post-traumatic conditions, uncontrolled blood sugars); **AND**
 - Not in conjunction with bone scintigraphy, leukocyte scintigraphy, and or MOAB scintigraphy; **OR**
- **Subsequent PET scans for oncological purposes** for **ANY** of the following⁵:
 - Assessment of therapeutic effect after completion of potentially curative therapy, if additional or alternative therapy will be employed for residual or progressive disease; **OR**
 - Assessment of therapeutic effect after localized, non-surgical therapy (e.g., stereotactic radiotherapy, radiofrequency or thermal ablation) of apparently limited or clinically significant lesions; **OR**
 - Suspected recurrence/progression including **ANY** of the following:
 - New symptoms suggestive of tumor recurrence or progression; **OR**
 - New physical findings (e.g., palpable lesion) suspicious for recurrence/progression; **OR**
 - Rising tumor markers or other signs or laboratory values suggestive of paraneoplastic phenomena; **OR**
 - Findings on other imaging that are equivocal or suspicious; **OR**
 - Restaging after documentation of recurrence/progression, if extent of disease will alter therapy or if new baseline needed prior to change in therapy; **OR**

- Evaluating response to treatment, when a change in therapy is contemplated and routine imaging (e.g., CT) does not or is not expected to provide optimal information; **OR**
- Follow-up of indeterminate findings on a clinically indicated PET scan performed for restaging or suspected recurrence/progression, to assess for trends in FDG uptake within suspected lesions over time. Typically no sooner than 3 months after the indeterminate PET scan; **OR**
- PET should be employed instead of or before conventional imaging if **ANY** of the following:
 - Available data suggest that PET is likely to obviate additional advanced imaging tests or invasive procedures or is likely to be more accurate than other modalities in detection or characterization of lesions that would change patient management; **OR**
 - The patient has contrast allergy or other contraindication to contrast administration that renders other modalities less effective; **OR**
 - The patient is being monitored for known disease that either has been previously shown to be characterized on PET than on other modalities or has been shown to be adequately FDG-avid for follow-up with PET and was not previously imaged with other modalities (e.g., bone metastases well visualized on previous PET and either not as well visualized on bone scintigraphy or bone scintigraphy not done); **OR**
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

Positron emission tomography (PET), with or without concurrently acquired computed tomography (CT) (PET/CT) is not considered appropriate if **ANY** of the following is **TRUE**:

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms in the absence of established guidelines or criteria supporting more frequent imaging⁶⁹; **OR**
- For oncologic indications and **ANY** of the following:
 - As an initial screening test in asymptomatic individuals; **OR**
 - Initial anti-tumor treatment strategy in the diagnosis of breast cancer or initial staging of axillary lymph nodes¹⁷⁻²⁰; **OR**
 - Initial anti-tumor treatment strategy for diagnosis of cervical cancer²¹⁻²²; **OR**
 - Initial anti-tumor treatment strategy for evaluation of regional lymph nodes in melanoma⁴⁰; **OR**
 - Initial anti-tumor treatment strategy in adenocarcinoma of the prostate¹; **OR**
 - Non-seminoma tumors of the testes⁴⁸⁻⁴⁹; **OR**
 - F-18 sodium fluoride (NaF-18) PET for any indication, including identifying bone metastasis of cancer²; **OR**
- For infection/inflammation and **ANY** of the following³:
 - When used as first-line diagnostic test; **OR**
 - If **ANY** of the following tests have already been done or are planned as part of diagnostic evaluation without documented medical necessity:
 - Labeled WBC scan; **OR**
 - 67Ga SPECT/CT; **OR**
 - The use of PET scan for inflammation and infection of other conditions not specifically addressed in the Indications section above will be considered investigational.

^ANOTE: PET/CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

^BNOTE: PET/CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.⁷⁵

^CNOTE: PET scans should be scheduled at least 4–6 weeks after radiation therapy or surgery to avoid false positives due to inflammation from recent treatments.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.^{[70-71](#)}

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.^{[70-71](#)}

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.^{[70-71](#)}

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.^{[70-71](#)}

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
78811	Positron emission tomography (PET) imaging of chest
78812	Positron emission tomography (PET) imaging of skull base to midhigh
78813	Positron emission tomography (PET) imaging of whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging of skull base to midhigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) of whole body
79101	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
A9515	Choline c-11, diagnostic, per study dose up to 20 millicuries
A9552	Fluorodeoxyglucose f-18 fdg, diagnostic, per study dose, up to 45 millicuries
A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie
A9588	Fluciclovine f-18, diagnostic, 1 millicurie
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie
A9595	Piflufolastat f-18, diagnostic, 1 millicurie
A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie

A9597	Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified
A9607	Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie
A9608	Flotufolastat f18, diagnostic, 1 millicurie
A9609	Fludeoxyglucose f18 up to 15 millicuries
A9800	Gallium Ga-68 gozetotide, diagnostic, (Locametz), 1 millicurie
G0219	PET imaging whole body; melanoma for non-covered indications
G0235	PET imaging, any site, not otherwise specified
G0252	PET imaging, full and partial-ring scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of PET imaging, including cumulative radiation exposure, allergy, and harm to breast milk.⁷²⁻⁷⁴
- Potential danger to pregnancy: PET imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy. Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁷⁵
- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁷⁶

The clinical benefits of using these criteria include:

- Improved diagnostic accuracy: PET imaging, and in particular, PET/CT, has shown greater accuracy in evaluating patients with either known or suspected malignancy than PET or CT alone or PET and CT obtained separately but interpreted together.¹⁰
- Noninvasive: PET is a noninvasive imaging modality. It is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers. PET also utilizes no injected contrast agent, conferring an inherent safety benefit.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Evidence

Zamani-Siahkali et al. (2024) conducted a systematic review and meta-analysis of studies investigating FDG-PET in malignant melanoma.²⁷ In their final analysis, which included 100 studies and over 10,000 patients, the authors reported both sensitivity and specificity of FDG-PET in initial detection and regional lymph node and distant metastasis. The authors reported high overall patient-based sensitivity and specificity of FDG-PET at 81% and 92% respectively. However, the authors also noted different sensitivity and specificity values across clinical settings. For example, detection sensitivity was higher in the secondary (90%) compared to the initial (60%) staging setting. Moreover, sensitivity of detection of regional metastasis was low (38%), indicating that FDG-PET may have minimal utility in detecting regional metastasis in melanoma. In contrast, the authors cite other studies reporting much higher sensitivity of sentinel lymph node biopsy and ultrasound imaging in detecting metastases in melanoma.

Jadvar et al. (2017) published appropriate use criteria for PET/CT in response assessment and restaging in cancer patients for the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM), the American Society of Clinical Oncology (ASCO), the American College of Nuclear Medicine (ACNM), the Society for Pediatric Radiology (SPR), and the Canadian Association of Nuclear Medicine (CANM). The authors conducted a systematic review of published meta-analyses and large individual studies investigating PET or PET/CT in seven cancer types: breast, colorectal, lymphoma, lung, melanoma, sarcoma, and head and neck. For each of these cancer types, the authors rated the appropriateness of PET/CT in various clinical scenarios. PET/CT was rated as appropriate for several of the scenarios evaluated including restaging for local recurrence or metastases and/or treatment response evaluation in head and neck cancer, breast cancer, sarcoma, melanoma, lymphoma, lung cancer, and colorectal cancer.²⁸

The American College of Radiology (ACR) published the ACR-ACNM-SNMMI-SPR practice parameter for performing FDG-PET/CT in oncology in 2021. The indications included use in the staging of malignancy, monitoring response to

therapy, or restaging after relapse. Additionally, PET/CT may help localize the site of the primary tumor in the setting of metastatic disease, clarify indeterminate results, or localize occult disease. Finally, FDG-PET/CT may be used to plan treatment, including surgery and radiation, and guide biopsy.¹⁰

In 2023 the American College of Radiology published the ACR-ACNM-SNMMI practice parameter for performing Gallium-68 and Copper-64 Dotatate PET/CT imaging for neuroendocrine tumors (NETs). This imaging modality is appropriate for diagnosing, staging, restaging, and assessing treatment response in neuroendocrine tumors. Radiotracers such as those discussed in this practice parameter, which target cell membrane expression of somatostatin receptors (SSTRs), are useful in evaluating well-differentiated NETs compared to anatomical imaging. Fused imaging with computed tomography (PET/CT) in hybrid PET scanners has shown a high level of accuracy in evaluating patients with known or suspected malignancy.⁶⁵

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Policy Revision History/Information

Original Date: November 21, 2024		
Review History		
Version 2	11/21/2024	Added CMS verbiage related to initial tumor treatment strategy; added bullet and reference related to solitary pulmonary nodules.
Version 3	10/02/2025	Annual review. Edited FDG-PET for oncologic conditions for clarity and ease-of-use. Updated list of approved primary cancer/tumor types for initial anti-tumor treatment strategy and subsequent tumor management in accordance with NCD 220.6.17. Split indications for initial anti-tumor treatment strategy from indications for subsequent tumor management in accordance with NCD 220.6.17. Consolidated F-18 fluciclovine/choline C-11 PET/CT and PSMA indications. Simplified dotatate indications for clarity and ease-of-use. Moved evaluation of cardiac sources of infection or inflammation indications to PET Cardiac policy. Incorporated indications from LCD L35391. Added repeat imaging non-indications. Added description section. Medical evidence - added one reference.

Version 3.1	03/26/2026	Revision. Updated links and references for L39521 and A59318.



Cohere Medicare Advantage Policy – Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

Clinical Policy for Medical Necessity Review

Version: 3

Cohere Health UMC Approval Date: October 2, 2025

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Revision : Not Applicable

Next Annual Review: October 2, 2026

Important Notices

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medicare Advantage Policy - Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁶

- [National Coverage Determination \(NCD\). Positron emission tomography \(FDG\) for oncologic indications \(220.6.17\)](#)¹
- [National Coverage Determination \(NCD\). Positron emission tomography \(NaF-18\) to identify bone metastasis of cancer \(220.6.19\)](#)²
- [Local Coverage Determination \(LCD\). Positron emission tomography \(PET\) scan for inflammation and infection \(L39521\)](#)³
 - [Billing and Coding: Positron emission tomography \(PET\) scan for inflammation and infection \(A59318\)](#)⁴
- [Local Coverage Determination \(LCD\). Multiple imaging in oncology \(L35391\)](#)⁵
 - [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)⁶

Description

Positron emission tomography (PET) is a minimally invasive diagnostic imaging procedure used to evaluate metabolic activity in tissue. Typically, the patient is injected with a radiotracer, often fluorodeoxyglucose (FDG), which allows a scanner to detect the metabolic activity of cells. This technology is particularly useful for assessing oncologic, cardiovascular, and neurological disorders. Before undergoing a PET scan, the patient often undergoes other imaging studies, including magnetic resonance imaging (MRI) and computed tomography (CT) scans, which guide the need for further metabolic imaging.⁷

PET/CT combines functional and anatomic information and allows for precise tumor staging and evaluation of disease progression, as well as treatment planning, monitoring response to treatment and post-treatment surveillance in at-risk patients.⁸⁻⁹ Oncologic PET is considered advanced imaging and is best used per institutional oncologic protocols and oncological (e.g., National

Comprehensive Cancer Network, NCCN) and radiological society guidelines including those of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM), and the American College of Radiology (ACR). The decision to perform oncologic PET is often made at institutional tumor board meetings after multidisciplinary oncology teams review the case. Teams may include oncologic surgeons, radiation oncologists, medical oncologists, pathologists, and radiologists.¹⁰⁻¹¹

Medical Necessity Criteria

Indications

Positron emission tomography (PET) with or without concurrently acquired computed tomography (CT)(PET/CT) is considered appropriate if **ANY** of the following is **TRUE**^{1-6,10-11}:

- One fluorodeoxyglucose (FDG) PET study for initial anti-tumor treatment strategy with **ALL** of the following¹:
 - The patient has cancer(s) that are biopsy-proven or strongly suspected based on other diagnostic testing; **AND**
 - The treating physician determines that the FDG PET study is needed to determine the location and/or extent of the tumor for **ANY** of the following therapeutic purposes:
 - To determine whether the patient is an appropriate candidate for an invasive diagnostic or therapeutic procedure; **OR**
 - To determine the optimal anatomic location for an invasive procedure; **OR**
 - To determine the anatomic extent of the tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor; **AND**
 - **ANY** of the following oncologic conditions, cancers, or tumor types:
 - Colorectal²³⁻²⁵; **OR**
 - Esophagus²⁸⁻²⁹; **OR**
 - Head and neck (not thyroid, CNS)³²⁻³⁴; **OR**
 - Lymphoma³⁸⁻³⁹; **OR**
 - Non-small cell lung^{35,37}; **OR**
 - Ovary⁴²⁻⁴³; **OR**
 - Brain¹⁶; **OR**
 - Cervix (see non-indications)²¹⁻²²; **OR**
 - Small cell lung³⁶⁻³⁷; **OR**

- Soft tissue sarcoma⁵³⁻⁵⁴; **OR**
- Pancreas⁴⁴⁻⁴⁵; **OR**
- Testes⁵⁵⁻⁵⁶; **OR**
- Thyroid⁵⁷⁻⁵⁸; **OR**
- Breast (see non-indications)¹⁷⁻²⁰; **OR**
- Melanoma (see non-indications)⁴⁰; **OR**
- All other solid tumors; **OR**
- Myeloma⁴¹; **OR**
- All other cancers not listed; **OR**
- Three FDG PET scans when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy for **ANY** of the following oncologic conditions, cancers, or tumor types:
 - Colorectal²³⁻²⁵; **OR**
 - Esophagus²⁸⁻²⁹; **OR**
 - Head and neck (not thyroid, CNS)³²⁻³⁴; **OR**
 - Lymphoma³⁸⁻³⁹; **OR**
 - Non-small cell lung^{35,37}; **OR**
 - Ovary⁴²⁻⁴³; **OR**
 - Brain¹⁶; **OR**
 - Cervix²¹⁻²²; **OR**
 - Small cell lung³⁶⁻³⁷; **OR**
 - Soft-tissue sarcoma⁵³⁻⁵⁴; **OR**
 - Pancreas⁴⁴⁻⁴⁵; **OR**
 - Testes⁵⁵⁻⁵⁶; **OR**
 - Prostate⁴⁷⁻⁵¹; **OR**
 - Thyroid⁵⁷⁻⁵⁸; **OR**
 - Breast¹⁷⁻²⁰; **OR**
 - Melanoma⁴⁰; **OR**
 - All other solid tumors; **OR**
 - Myeloma⁴¹; **OR**
 - All other cancers not listed; **OR**
- Characterization of solitary pulmonary nodule (SPN) greater than 8 millimeters in diameter or greater than 8mm for the solid component of a part-solid nodule⁶⁰; **OR**
- **F-18 fluciclovine, choline C-11, or prostate-specific membrane antigen (PSMA [using F-18 piflufolastat, F-18 flutufolastat, or Ga-68 PSMA-11]) PET and ALL of the following⁴⁷⁻⁵¹:**

- The patient has prostate cancer/tumor; **AND**
- **ANY** of the following:
 - Initial staging if the patient has a diagnosis of unfavorable intermediate-risk, high-risk, or very high-risk prostate cancer; **OR**
 - The patient has been treated with radical prostatectomy and **ANY** of the following:
 - Serum prostate-specific antigen (PSA) elevation greater than 0.1 ng/ml; **OR**
 - Persistence of PSA (failure to fall to undetectable levels); **OR**
 - Previously undetectable PSA that has been increasing on two or more occasions; **OR**
 - The patient has been treated with radiation therapy and **ANY** of the following:
 - An increase of PSA by 2 ng/mL or greater above the lowest post-treatment PSA; **OR**
 - PSA increasing after radiation therapy and the patient is a candidate for salvage local therapy (even if the lowest PSA value is under 2 ng/mL); **OR**
 - Prior to initiation of androgen deprivation therapy (ADT)⁶²; **OR**
 - Three months following completion of ADT⁶²; **OR**
 - GA-68 PSMA-11 PET/CT before initial treatment with lutetium Lu-177 vipivotide tetraxetan (e.g., Pluvicto) for metastatic castration-resistant prostate cancer; **OR**
 - Restaging 12 weeks after treatment with Lu177/Pluvicto⁶⁴; **OR**
 - Known metastatic disease and concern for progression on treatment and **ALL** of the following⁶¹⁻⁶³:
 - PSMA imaging will influence treatment plan; **AND**
 - Inconclusive prior imaging; **OR**
- **Dotatate PET** with **ALL** of the following^{12,65-66}:
 - The patient has a well-differentiated neuroendocrine tumor; **AND**
 - **ANY** of the following:
 - Diagnosis ; **OR**
 - Staging; **OR**
 - Restaging; **OR**
 - Treatment planning for lutetium Lu-177 Dotatate; **OR**
- **Positron emission tomography (PET) scan for non-oncologic conditions** is considered appropriate if **ANY** of the following is **TRUE**⁶⁷⁻⁶⁸:

- The patient is greater than or equal to 18 years of age with fever of unknown origin (FUO) and **ALL** of the following³:
 - Fever higher than 38.3 Celsius (101 degrees Fahrenheit); **AND**
 - Present for greater than or equal to 21 days defined by fever on 2 or more occasions with repeating episodes for 2 or more weeks prior to the study; **AND**
 - The patient is not immunocompromised; **AND**
 - Investigation including history, physical, laboratory analysis, and standard imaging is non-diagnostic; **AND**
 - The patient does not have any conditions that would limit the ability to interpret the PET scan; **OR**
- For diagnosis of equivocal cases of suspected osteomyelitis or spondylodiscitis (with abnormal radiographs or CT findings) and **ALL** of the following³:
 - MRI cannot be performed or is non-diagnostic or inconclusive; **AND**
 - The patient does not have any conditions that would limit the ability to interpret the PET (e.g., post-operative or post-traumatic conditions, uncontrolled blood sugars); **AND**
 - Not in conjunction with bone scintigraphy, leukocyte scintigraphy, and or MOAB scintigraphy; **OR**
- **Subsequent PET scans for oncological purposes** for **ANY** of the following⁵:
 - Assessment of therapeutic effect after completion of potentially curative therapy, if additional or alternative therapy will be employed for residual or progressive disease; **OR**
 - Assessment of therapeutic effect after localized, non-surgical therapy (e.g., stereotactic radiotherapy, radiofrequency or thermal ablation) of apparently limited or clinically significant lesions; **OR**
 - Suspected recurrence/progression including **ANY** of the following:
 - New symptoms suggestive of tumor recurrence or progression; **OR**
 - New physical findings (e.g., palpable lesion) suspicious for recurrence/progression; **OR**
 - Rising tumor markers or other signs or laboratory values suggestive of paraneoplastic phenomena; **OR**
 - Findings on other imaging that are equivocal or suspicious; **OR**
 - Restaging after documentation of recurrence/progression, if extent of disease will alter therapy or if new baseline needed prior to change in therapy; **OR**

- Evaluating response to treatment, when a change in therapy is contemplated and routine imaging (e.g., CT) does not or is not expected to provide optimal information; **OR**
- Follow-up of indeterminate findings on a clinically indicated PET scan performed for restaging or suspected recurrence/progression, to assess for trends in FDG uptake within suspected lesions over time. Typically no sooner than 3 months after the indeterminate PET scan; **OR**
- PET should be employed instead of or before conventional imaging if **ANY** of the following:
 - Available data suggest that PET is likely to obviate additional advanced imaging tests or invasive procedures or is likely to be more accurate than other modalities in detection or characterization of lesions that would change patient management; **OR**
 - The patient has contrast allergy or other contraindication to contrast administration that renders other modalities less effective; **OR**
 - The patient is being monitored for known disease that either has been previously shown to be characterized on PET than on other modalities or has been shown to be adequately FDG-avid for follow-up with PET and was not previously imaged with other modalities (e.g., bone metastases well visualized on previous PET and either not as well visualized on bone scintigraphy or bone scintigraphy not done); **OR**
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
 - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

Positron emission tomography (PET), with or without concurrently acquired computed tomography (CT) (PET/CT) is not considered appropriate if **ANY** of the following is **TRUE**:

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms in the absence of established guidelines or criteria supporting more frequent imaging⁶⁹; **OR**
- For oncologic indications and **ANY** of the following:
 - As an initial screening test in asymptomatic individuals; **OR**
 - Initial anti-tumor treatment strategy in the diagnosis of breast cancer or initial staging of axillary lymph nodes¹⁷⁻²⁰; **OR**
 - Initial anti-tumor treatment strategy for diagnosis of cervical cancer²¹⁻²²; **OR**
 - Initial anti-tumor treatment strategy for evaluation of regional lymph nodes in melanoma⁴⁰; **OR**
 - Initial anti-tumor treatment strategy in adenocarcinoma of the prostate¹; **OR**
 - Non-seminoma tumors of the testes⁴⁸⁻⁴⁹; **OR**
 - F-18 sodium fluoride (NaF-18) PET for any indication, including identifying bone metastasis of cancer²; **OR**
- For infection/inflammation and **ANY** of the following³:
 - When used as first-line diagnostic test; **OR**
 - If **ANY** of the following tests have already been done or are planned as part of diagnostic evaluation without documented medical necessity:
 - Labeled WBC scan; **OR**
 - 67Ga SPECT/CT; **OR**
 - The use of PET scan for inflammation and infection of other conditions not specifically addressed in the Indications section above will be considered investigational.

^ANOTE: PET/CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

^BNOTE: PET/CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.⁷⁵

^CNOTE: PET scans should be scheduled at least 4–6 weeks after radiation therapy or surgery to avoid false positives due to inflammation from recent treatments.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.[70-71](#)

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.[70-71](#)

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.[70-71](#)

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.[70-71](#)

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
78811	Positron emission tomography (PET) imaging of chest
78812	Positron emission tomography (PET) imaging of skull base to midhigh
78813	Positron emission tomography (PET) imaging of whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging of skull base to midhigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) of whole body
79101	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
A9515	Choline c-11, diagnostic, per study dose up to 20 millicuries
A9552	Fluorodeoxyglucose f-18 fdg, diagnostic, per study dose, up to 45 millicuries
A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie
A9588	Fluciclovine f-18, diagnostic, 1 millicurie
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie
A9595	Piflufolastat f-18, diagnostic, 1 millicurie
A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie

A9597	Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified
A9607	Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie
A9608	Flotufolastat f18, diagnostic, 1 millicurie
A9609	Fludeoxyglucose f18 up to 15 millicuries
A9800	Gallium Ga-68 gozetotide, diagnostic, (Locametz), 1 millicurie
G0219	PET imaging whole body; melanoma for non-covered indications
G0235	PET imaging, any site, not otherwise specified
G0252	PET imaging, full and partial-ring scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of PET imaging, including cumulative radiation exposure, allergy, and harm to breast milk.^{[72-74](#)}
- Potential danger to pregnancy: PET imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy. Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.^{[75](#)}
- Increased healthcare costs and complications from the inappropriate use of additional interventions.^{[76](#)}

The clinical benefits of using these criteria include:

- Improved diagnostic accuracy: PET imaging, and in particular, PET/CT, has shown greater accuracy in evaluating patients with either known or suspected malignancy than PET or CT alone or PET and CT obtained separately but interpreted together.^{[10](#)}
- Noninvasive: PET is a noninvasive imaging modality. It is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers. PET also utilizes no injected contrast agent, conferring an inherent safety benefit.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Evidence

Zamani-Siahkali et al. (2024) conducted a systematic review and meta-analysis of studies investigating FDG-PET in malignant melanoma.⁷⁷ In their final analysis, which included 100 studies and over 10,000 patients, the authors reported both sensitivity and specificity of FDG-PET in initial detection and regional lymph node and distant metastasis. The authors reported high overall patient-based sensitivity and specificity of FDG-PET at 81% and 92% respectively. However, the authors also noted different sensitivity and specificity values across clinical settings. For example, detection sensitivity was higher in the secondary (90%) compared to the initial (60%) staging setting. Moreover, sensitivity of detection of regional metastasis was low (38%), indicating that FDG-PET may have minimal utility in detecting regional metastasis in melanoma. In contrast, the authors cite other studies reporting much higher sensitivity of sentinel lymph node biopsy and ultrasound imaging in detecting metastases in melanoma.

Jadvar et al. (2017) published appropriate use criteria for PET/CT in response assessment and restaging in cancer patients for the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM), the American Society of Clinical Oncology (ASCO), the American College of Nuclear Medicine (ACNM), the Society for Pediatric Radiology (SPR), and the Canadian Association of Nuclear Medicine (CANM). The authors conducted a systematic review of published meta-analyses and large individual studies investigating PET or PET/CT in seven cancer types: breast, colorectal, lymphoma, lung, melanoma, sarcoma, and head and neck. For each of these cancer types, the authors rated the appropriateness of PET/CT in various clinical scenarios. PET/CT was rated as appropriate for several of the scenarios evaluated including restaging for local recurrence or metastases and/or treatment response evaluation in head and neck cancer, breast cancer, sarcoma, melanoma, lymphoma, lung cancer, and colorectal cancer.⁷⁸

The American College of Radiology (ACR) published the ACR-ACNM-SNMMI-SPR practice parameter for performing FDG-PET/CT in oncology in 2021. The indications included use in the staging of malignancy, monitoring response to

therapy, or restaging after relapse. Additionally, PET/CT may help localize the site of the primary tumor in the setting of metastatic disease, clarify indeterminate results, or localize occult disease. Finally, FDG-PET/CT may be used to plan treatment, including surgery and radiation, and guide biopsy.¹⁰

In 2023 the American College of Radiology published the ACR-ACNM-SNMMI practice parameter for performing Gallium-68 and Copper-64 Dotatate PET/CT imaging for neuroendocrine tumors (NETs). This imaging modality is appropriate for diagnosing, staging, restaging, and assessing treatment response in neuroendocrine tumors. Radiotracers such as those discussed in this practice parameter, which target cell membrane expression of somatostatin receptors (SSTRs), are useful in evaluating well-differentiated NETs compared to anatomical imaging. Fused imaging with computed tomography (PET/CT) in hybrid PET scanners has shown a high level of accuracy in evaluating patients with known or suspected malignancy.⁶⁵

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Policy Revision History/Information

Original Date: November 21, 2024		
Review History		
Version 2	11/21/2024	Added CMS verbiage related to initial tumor treatment strategy; added bullet and reference related to solitary pulmonary nodules.
Version 3	10/02/2025	Annual review. Edited FDG-PET for oncologic conditions for clarity and ease-of-use. Updated list of approved primary cancer/tumor types for initial anti-tumor treatment strategy and subsequent tumor management in accordance with NCD 220.6.17. Split indications for initial anti-tumor treatment strategy from indications for subsequent tumor management in accordance with NCD 220.6.17. Consolidated F-18 fluciclovine/choline C-11 PET/CT and PSMA indications. Simplified dotatate indications for clarity and ease-of-use. Moved evaluation of cardiac sources of infection or inflammation indications to PET Cardiac policy. Incorporated indications from LCD L35391. Added repeat imaging non-indications. Added description section. Medical evidence - added one reference.