Cohere Medicare Advantage Policy - Computed Tomography Angiography (CTA), Lower Extremity

Clinical Guidelines for Medical Necessity Review

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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.

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Other Notices:

Guideline Information:

Specialty Area: Diagnostic Imaging
Guideline Name: Cohere Medicare Advantage Policy - Computed Tomography Angiography (CTA), Lower Extremity

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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 following[2]:
    - Expanding hematoma[3]; **OR**
    - Major blunt trauma and the patient is hemodynamically stable[4]; **OR**
    - Neurologic deficit of lower extremity in association with trauma[5]; **OR**
    - Known or suspected knee dislocation*[6]; **OR**
    - Vascular trauma to a lower extremity[7]; **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 planned[9]; **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 contraindicated[7]; **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 completed[11]; **OR**
- Known severe post-thrombotic changes incompletely evaluated by ultrasound[11]; **OR**
- Evidence of severe venous reflux disease and **ALL** of the following[11]:
    - 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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