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Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI) Cardiac

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

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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 <u>CMS Medicare Coverage Database</u> for the most current applicable CMS National Coverage.¹⁻⁵

- <u>National Coverage Determination (NCD) 220.2. Magnetic Resonance</u>
 <u>Imaging</u>
- Local Coverage Determination (LCD) L38396. Cardiology Non-Emergent
 Outpatient Stress Testing
- Local Coverage Determination (LCD) L35083. Cardiology Non-Emergent
 Outpatient Stress Testing
- <u>Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing</u>
 (A56423)
- <u>Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing</u>
 (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.²
- 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.¹
- 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. $^{l\!l}$

• 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 cardiomyopathy[™]; **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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