

Cohere Medical Policy – Cardiovascular

Clinical Guidelines for Medical Necessity Review

Consolidated Reference • 90 Policies

Updated on 05/26/2026

Cardiovascular – Consolidated Edition

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Cohere Medical Policy – Arterial Stenting, Other

Clinical Guidelines for Medical Necessity Review

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medical Policy – Arterial Stenting, Other

Literature review current through: 11/1/2024

Document last updated: 12/12/2024

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

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Medical Necessity Criteria

Service: Arterial Stenting, Other

Recommended Clinical Approach:

Arterial stent placement is indicated in a variety of clinical scenarios to treat both aneurysmal and occlusive arterial pathology. There are (2) types of arterial stents: (1) Bare metal stents; (2) Covered stents (a bare metal stent covered with fabric or graft material). Stents are further sub-classified as either balloon expandable or self-expanding. Lastly, bare metal stents may also be coated with a drug that is intended to reduce the risk of restenosis.

Generally speaking, stents are placed via a transcatheter route, but they can also be placed through an open approach (e.g., arterial cutdown). Exceptions to the scope of this policy include lower extremity arterial occlusive disease, extracranial carotid artery occlusive disease, extracranial vertebral artery occlusive disease, intrathoracic carotid artery occlusive disease, intracranial arterial occlusive disease, and coronary artery disease.

Medical Necessity Criteria

Indications

→ **Arterial stenting** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The patient has **ANY** of the following aneurysmal conditions⁶⁻⁷:
 - Any symptomatic aneurysm; **OR**
 - Asymptomatic lower extremity aneurysmal disease as indicated by **ANY** of the following:
 - An iliac artery aneurysm greater than 3 cm in diameter; **OR**
 - A common femoral artery aneurysm greater than 2.5 cm in diameter; **OR**
 - A profunda femoral artery aneurysm greater than 2 cm in diameter; **OR**
 - A superficial femoral artery (SFA) aneurysm greater than 2 times the diameter of the normal native SFA (with or without mural thrombus); **OR**

- A popliteal artery aneurysm greater than or equal to 2 cm in diameter (with or without mural thrombus) with documentation that the patient has a high surgical risk¹²; **OR**
- Asymptomatic upper extremity aneurysm; **OR**
- Asymptomatic visceral artery aneurysm as indicated by **ANY** of the following:
 - Renal artery aneurysms greater than 3 cm in diameter (and renal artery aneurysms of any size in women of childbearing age); **OR**
 - Splenic artery aneurysms greater than 3 cm in diameter (and splenic artery aneurysms of any size in women of childbearing age); **OR**
 - All splenic artery pseudoaneurysms; **OR**
 - Hepatic artery aneurysms greater than 2 cm in diameter or a hepatic artery aneurysm that enlarges by more than 0.5 cm in a year¹³; **OR**
 - Gastric, gastroepiploic, pancreaticoduodenal, and gastroduodenal aneurysms of any size¹³; **OR**
 - Superior mesenteric artery aneurysms of any size¹³; **OR**
 - Celiac artery aneurysms greater than 2 cm in diameter¹³; **OR**
- ◆ The patient has symptomatic upper extremity arterial occlusive disease indicated by **ALL** of the following:
 - Subclavian, axillary, or brachial artery stenosis (greater than 50% diameter reduction or 75% cross-sectional area stenosis); **AND**
 - **ANY** of the following:
 - Lifestyle-limiting, exercise-induced ipsilateral upper extremity fatigue; **OR**
 - Limb-threatening ischemia of the upper extremity (e.g., rest pain, ulceration, tissue loss, or gangrene); **OR**
 - Subclavian steal syndrome; **OR**
 - Subclavian artery occlusive disease causing cardiac ischemia in patients with a prior (and patent) ipsilateral internal mammary artery to coronary artery bypass; **OR**

- ◆ Visceral occlusive disease, as indicated by **ANY** of the following:
 - Symptomatic acute or chronic mesenteric ischemia; **OR**
 - Symptomatic renal artery stenosis (RAS) with **ANY** of the following³⁻⁴:
 - Bilateral RAS with **ALL** of the following:
 - ◆ Greater than 70% stenosis; **AND**
 - ◆ Intolerance to **OR** insufficient blood pressure response to guideline medical therapy (GDMT)(e.g., angiotensin-converting enzyme [ACE] inhibitors, angiotensin II receptor blockers [ARB], calcium channel blockers, diuretics); **OR**
 - Unilateral RAS with intolerance to GDMT (e.g., increased serum creatinine level upon initiation of a renin-angiotensin system inhibitor, or blood pressure does not respond to therapy); **OR**
 - Chronic end-stage renal disease (ESRD) with hemodialysis dependence less than or equal to 3 months; **OR**
 - Progressive renal functional impairment determined to be secondary to renal artery stenosis; **OR**
 - Unilateral renal artery stenosis (greater than 70%) in a uninephric patient; **OR**
 - Recurrent flash pulmonary edema or refractory heart failure secondary to renal artery occlusive disease; **OR**
- ◆ The patient has complex congenital heart disease, including but not limited to **ANY** of the following:
 - Pulmonary artery stenosis¹⁴⁻¹⁷; **OR**
 - Aortic coarctation^{14,18-21}; **OR**
 - Patent ductus arteriosus (PDA); **OR**
- ◆ Bare metal or covered stent placement may be clinically indicated in **ANY** of the following peri-procedural clinical scenarios:
 - Acute arterial occlusion; **OR**
 - Flow-limiting dissection; **OR**
 - Elastic recoil or refractory spasm; **OR**
 - Residual stenosis greater than 30%; **OR**
 - Trans-stenotic resting pressure gradient greater than 5 mmHg; **OR**

- ◆ Covered stent placement or stent graft placement may be clinically indicated in **ANY** of the following peri-procedural clinical scenarios:
 - Arterial perforation; **OR**;
 - Arterial occlusion; **OR**
 - Arterial pseudoaneurysm; **OR**
 - Arteriovenous fistula; **OR**
- ◆ Repeat or secondary stenting is appropriate if **ANY** of the following is **TRUE**^{11,18,22}:
 - Restenosis; **OR**
 - Suboptimal result; **OR**
 - Stent fracture (in association with restenosis or another complication such as pseudoaneurysm); **OR**
 - Stent recoil; **OR**
 - Re-coarctation of the aorta; **OR**
 - Impending or documented bypass graft failure; **OR**
- ◆ Asymptomatic peripheral artery occlusive disease with a documented need for intervention.

Non-Indications

→ **Arterial stenting** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Known allergic reactions to stent or stent graft material (e.g., nitinol, dacron, expanded polytetrafluoroethylene [ePTFE]).

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
37236	Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery
37237	Transcatheter placement of an intravascular stent(s)

	(except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery (List separately in addition to code for primary procedure)

Medical Evidence

The American College of Cardiology (ACC), American Heart Association (AHA), Society for Cardiovascular Angiography and Interventions (SCAI), Society of Interventional Radiology (SIR), and Society for Vascular Medicine (SVM) published the *Appropriate Use Criteria for Peripheral Artery Intervention* in 2018. Stenting is supported for the treatment of renal artery stenosis; recommendations align with evidence from the randomized CORAL trial (Stenting and Medical Therapy for Atherosclerotic Renal-Artery Stenosis). Patients with hypertension may benefit from renal stenting when outcomes are not achieved after taking the maximum dose of three prescribed antihypertensive medications. The report also notes the need for research on various modalities for in-stent stenosis and failure of arterial grafts.¹¹ Importantly, these guidelines also emphasize the relative benefits of endovascular intervention – such as stenting – over traditional open procedures. They cite, for example, that iliac artery stenting has excellent durability similar to surgical intervention but carries the additional benefit of an improved safety profile compared to surgical revascularization.

Although stenting is considered comparable to surgical intervention in many settings, some challenges associated with stenting may occur. Restenosis occurs with variable frequency depending on the anatomical site of treatment and, if unresolved, can be a life-limiting complication for patients who suffer critical limb ischemia and subsequent limb loss and the associated cardiovascular consequences. Frequent clinical reassessment is recommended to promote limb salvage and mitigate mortality.

The Society for Cardiovascular Angiography and Interventions (SCAI) published an *Expert Consensus Statement for Renal Artery Stenting Appropriate Use*. Clinical trials support stenting, including the CORAL trial. The procedure has a low complication rate and positive outcomes.⁴ The SCAI also published *Appropriate Use Criteria for Peripheral Arterial Interventions: An Update*. The document also discusses aorto-iliac, femoral-popliteal, infra-popliteal, and renal arterial circulation.⁶

As a final note, lower extremity occlusive peripheral artery disease – particularly mild or asymptomatic diseases – is not considered within this

guideline because stenting is not an effective or adequate treatment as compared to lifestyle modification with pharmacological therapy or surgical therapy for more advanced disease.

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Clinical Guideline Revision History/Information

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Review History		
Version 2	12/12/2024	Annual policy review and restructure: • Updated recommended clinical approach to the current format. • Consolidated upper extremity bullet points. • Consolidated aneurysmal indications into one bullet. • Replaced prior mesenteric ischemia indication with appropriate (e.g., non-emergent, non-acute) criteria. • Added indication for secondary or repeat stenting. • Removed one non-indication which was already covered by the choice of CPT codes. • Updated medical evidence section. • Updated references.



Cohere Medical Policy – Cardiac Ablation

Clinical Guidelines for Medical Necessity Review

Version: 3
Effective Date: January 9, 2025

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medical Policy - Cardiac Ablation

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

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Medical Necessity Criteria

Service: Cardiac Ablation

Recommended Clinical Approach:

Catheter ablation is a procedural approach to cardiac rhythm control. It is used to treat atrial fibrillation, atrial flutter, supraventricular tachycardia (SVT), and ventricular arrhythmias. Cardiac ablation involves the transcatheter access of tissue where inappropriate electrical activity originates (i.e., pulmonary veins, coronary sinuses, posterior wall, etc.) and the administration of cryothermal energy, electricity, radiofrequency or pulsed field energy to ablate the surrounding area. In effect, this electrically isolates the problematic site and prevents the inappropriate impulse (which causes arrhythmias) from traveling. Catheter ablation is particularly useful for patients who have exhausted conservative medical therapy, though it can be a first-line treatment for certain groups, such as patients with SVT and atrial fibrillation. Cardiac ablation generally has a high success rate with few complications, although repeat ablation is necessary for some patients. Importantly, AV nodal ablation is a palliative treatment for persistent atrial fibrillation that is symptomatic, has failed rhythm and rate control, and may be causing tachyarrhythmia-induced heart failure. AV node ablation is not considered a first-line treatment; it is a palliative treatment with distinct indications separate from other therapeutic cardiac ablations.

Medical Necessity Criteria

Indications

→ **Cardiac ablation** is considered appropriate if **ANY** of the following is **TRUE**:

◆ The procedure is for atrial fibrillation and **ANY** of the following is **TRUE** ^{10-12,17}:

- Symptomatic atrial fibrillation (AF) in whom antiarrhythmic drugs have been ineffective, contraindicated, not tolerated, or not preferred, and continued rhythm control is desired;
- OR**

- Repeat ablation after recurrent symptomatic atrial fibrillation, which reoccurs beyond the blanking period (at least 3 months after the initial ablation), when antiarrhythmic drugs have been ineffective, contraindicated, not tolerated, or not preferred, and continued rhythm control is desired¹⁷; **OR**
 - Symptomatic AF and heart failure with reduced ejection fraction (HFrEF) on guideline-directed medical therapy (GDMT); **OR**
 - Symptomatic AF and heart failure with preserved ejection fraction (HFpEF); **OR**
- ◆ The procedure is for atrioventricular node ablation, and **ALL** of the following are **TRUE**^{1,2,13}:
- Persistent or permanent atrial fibrillation; **AND**
 - Pharmacologic rate control has been unsuccessful due to rhythm refractoriness or patient intolerance; **AND**
 - The patient has a permanent pacemaker implanted or is an appropriate candidate for ventricular pacing with plans to implant a pacemaker prior to (or on the same day as) ablation; **AND**
 - Known or suspected tachycardia-induced cardiomyopathy; **OR**
- ◆ The procedure is for atrial flutter (AFL) and **ANY** of the following is **TRUE**^{1,2,10,11}:
- Symptomatic atrial flutter that has become refractory or intolerant to treatment with a Class I or III antiarrhythmic; **OR**
 - Atrial flutter that is favorable for ablation as a first-line therapy versus antiarrhythmic medication; **OR**
 - Recurrent episodes of symptomatic atrial flutter; **OR**
 - Recurrent atrial flutter with a reasonable expectation of success with a redo procedure; **OR**
- ◆ The procedure is an electrophysiology study (EPS)/cardiac ablation for supraventricular tachycardia (SVT) and **ANY** of the following is **TRUE**:
- Symptomatic or sustained SVT; **OR**
 - Wolff-Parkinson-White (WPW) pattern with syncope¹⁵; **OR**
 - Episode of pre-excited atrial fibrillation¹⁵; **OR**

- New cardiomyopathy likely caused by focal atrial tachycardia; **OR**
- For evaluation of asymptomatic patients with ventricular preexcitation pattern to determine **ANY** of the following:
 - Inducibility of atrioventricular reentrant tachycardia (AVRT); **OR**
 - Rapidity of antegrade conduction as a risk factor for sudden cardiac arrest; **OR**
- For the presence of manifest ventricular preexcitation which would interfere with certain types of employment (including, but not limited to, pilots, military service, firefighters, competitive athletes, etc.)¹⁵; **OR**
- ◆ The procedure is for ventricular arrhythmia and **ANY** of the following is **TRUE**:
 - Symptomatic premature ventricular complexes (PVCs) with frequency of greater than 15% of beats in a patient refractory to or intolerant to antiarrhythmic therapy; **OR**
 - High PVC frequency (greater than 15% of beats and predominately of one morphology²) associated with symptoms or diminished left ventricular ejection fraction (less than 50%) on cardiac imaging; **OR**
 - When a PVC of similar morphology is a trigger for other arrhythmias, such as ventricular fibrillation (VF); **OR**
 - Frequent PVCs refractory to medical therapy, which are interfering with the effectiveness of biventricular pacing; **OR**
 - Sustained symptomatic monomorphic ventricular tachycardia (VT) in a structurally normal heart; **OR**
 - Episodes of VT causing excess appropriate ICD shocks (e.g., in arrhythmogenic right cardiomyopathy, Brugada syndrome, sarcoidosis); **OR**
 - Recurrent sustained monomorphic VT in a patient with structural heart disease that is refractory to or intolerant to antiarrhythmic therapy⁹; **OR**
 - Cardiomyopathy with VT storm; **OR**
 - Sustained monomorphic VT in repaired tetralogy of Fallot⁸; **OR**
 - In other forms of congenital heart disease (CHD) with sustained VT, which have undergone appropriate

evaluation and treatment for anatomic and hemodynamic etiologies.^{8,16}

Non-Indications

→ **Cardiac ablation** is not considered appropriate if **ANY** of the following is **TRUE**.^{1,2,11}

- ◆ The procedure is for AV node ablation, and **ANY** of the following is **TRUE**:
 - The patient is a candidate for pharmacologic rhythm control; **OR**
 - The patient is taking a pharmacologic agent that is successfully achieving rate control; **OR**
 - The patient is not a candidate for permanent pacing; **OR**
- ◆ The procedure is an electrophysiology study/ablation for SVT and the patient has nonsustained, asymptomatic SVT; **OR**
- ◆ The procedure is cardiac ablation for ventricular arrhythmia and **ANY** of the following is **TRUE**:
 - The patient has infrequent nonsustained VT; **OR**
 - The patient has torsades de pointes or other sustained polymorphic VT; **OR**
 - After the patient has experienced VF arrest.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93613	Intracardiac electrophysiologic three-dimensional mapping
93631	Intraoperative epicardial and endocardial pacing and mapping to localize the site of tachycardia or zone of slow conduction for surgical correction
93650	Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block

93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, with attempted induction of arrhythmia, with right atrial pacing and recording, with treatment of supraventricular tachycardia by ablation
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, with attempted induction of arrhythmia, with right atrial pacing and recording, with focus of ventricular ectopy
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia
93656	Comprehensive electrophysiologic evaluation with transseptal catheterization, with insertion and repositioning of multiple electrode catheters, with attempted induction of arrhythmia, with atrial pacing and recording
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation

Medical Evidence

January et al. (2014) published an evidence-based, systematic review and subsequent guidelines for the American Heart Association, American College of Cardiology, and the Heart Rhythm Society, for the management of patients with atrial fibrillation. A number of recommendations were made or revised for optimal management of atrial fibrillation. Atrioventricular (AV) nodal ablation with permanent ventricular pacing was recommended to control heart rate when pharmacological therapy has not been effective and rhythm control could not be achieved.²

Joglar et al. (2024) published an updated guideline addressing the diagnosis and management of atrial fibrillation. The guideline recognized lifestyle and risk factor modification as a pillar of AF management to prevent progression, and adverse outcomes, as well as to emphasize the importance of early and continued maintenance of sinus rhythm and reduced AF burden. Catheter ablation of AF received a Class I indication as first-line therapy in selected patients based on recent randomized studies that have demonstrated the superiority of catheter ablation over drug therapy for rhythm control. Many patients require both pharmacological and interventional therapy, but catheter cardiac ablation was endorsed among those patients who would receive the greatest early benefit. Generally, optimal patients for first-line catheter ablation are younger and have few comorbidities.¹⁷

In 2021, a retrospective review of pediatric cardiac ablation was published by Walsh et al. This 20-year longitudinal study evaluated the use of cardiac ablation among children with supraventricular tachycardia. The authors concluded that cardiac ablation is safe and clinically successful for children with SVT, and that, from an overall cohort of 7,069 cases, the rate of major complications was low. Only 12 cases of complete heart block (necessitating pacemaker insertion) occurred in the cohort. Although repeat ablation was required for a proportion of patients, the authors note that technological advances are likely to improve the overall safety profile as children continue to be treated with cardiac ablation and other interventional cardiovascular procedures.²⁵

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Clinical Guideline Revision History/Information

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Version 2	July 29, 2024	Re-formatted document updated indications and non-indications/references
Version 3	January 9, 2025	Annual policy review and restructure: • Updated recommended clinical approach to the current format. • Condensed the detail in the recommended clinical approach section to better align with other similar policies. • Removed redundant indications and non-indications that were already covered by existing language. • Wordsmithed for clarity and to better reflect the cited references. • Expanded examples of high-risk employment. • Updated references. • Updated medical evidence section. • Clarified repeat ablation criteria based on current ACC guidelines. • Removed non-indication for paroxysmal atrial fibrillation. • Removed CPT code 93662 – not in scope of

		policy.



Cohere Medical Policy – Cardiac Catheterization

Clinical Policy for Medical Necessity Review

Version: 1

Effective Date: June 26, 2025

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Cardiac Catheterization

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

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Medical Necessity Criteria

Service: Cardiac Catheterization

Description

Cardiac catheterization is an invasive cardiac evaluation method. It allows for direct evaluation of hemodynamics, cardiac pressure, and cardiac output.^{1,3} Left heart catheterization involves the insertion of a catheter into an artery in the arm, groin, or wrist. Generally, femoral artery access is more commonly used than radial artery access for left heart catheterization. The catheter is guided to the left ventricle of the heart to measure left ventricular pressures or to obtain an angiogram (left ventriculogram, ventriculography). Left heart catheterization is sometimes performed with coronary angiography, a method of assessing the coronary arteries that supply the muscle of the heart. Depending on the clinical situation, each type of catheterization may be performed concomitantly or separately as stand-alone procedures.¹⁻⁴

Medical Necessity Criteria

Indications

Cardiac catheterization is considered appropriate if **ALL** of the following are **TRUE**:

- **Coronary/bypass angiography with or without left heart catheterization, and ANY of the following¹⁻⁴:**
 - This section is not applicable (service not requested); **OR**
 - Acute coronary syndromes (ACS), including elevated troponin or non-ST elevation myocardial infarction (NSTEMI); **OR**
 - Worsening or limiting ischemic symptoms^A or stable angina despite guideline-directed medical treatment (GDMT)^B with **ANY** of the following high-risk findings^{2,3}:
 - Severe resting left ventricular (LV) dysfunction (left ventricular ejection fraction [LVEF] is less than 40%) that is not readily explained by noncoronary causes; **OR**
 - Reversible perfusion abnormalities that encompass greater than or equal to 10% of the myocardium (SDS = 10) in patients without prior history or evidence of myocardial infarction (MI); **OR**

- Stress electrocardiography (ECG) findings, including **ANY** of the following:
 - Greater than or equal to 2 mm of ST-segment depression at low workload; **OR**
 - Greater than or equal to 2 mm of ST-segment depression that persists into recovery; **OR**
 - Exercise-induced ST-segment elevation of greater than 1.5mm; **OR**
 - Exercise-induced ventricular tachycardia or ventricular fibrillation (VT/VF); **OR**
- Stress-induced LV dysfunction (peak exercise LVEF is less than 40% or drop in LVEF with stress is greater than or equal to 10%); **OR**
- Stress-induced perfusion abnormalities encumbering greater than or equal to 10% of the myocardium; **OR**
- Stress segmental scores indicating multiple vascular territories with abnormalities; **OR**
- Stress-induced LV dilation; **OR**
- Inducible wall motion abnormality (involving more than 2 segments or 2 coronary beds); **OR**
- Wall motion abnormality developing at a low dose of dobutamine (less than or equal to 10 mg/kg/min) or at a low heart rate (less than 120 beats/min); **OR**
- Coronary artery calcium (CAC) score greater than 400 Agatston units; **OR**
- Multivessel obstructive coronary artery disease (CAD) in two or more major coronary arteries (greater than or equal to 70% stenosis) on coronary computed tomography angiography (CCTA); **OR**
- Left main stenosis (greater than or equal to 50% stenosis) on CCTA; **OR**
- FFR-CT less than or equal to 0.80⁵⁻⁹; **OR**
- Congenital heart disease with **ANY** of the following¹⁰:
 - Invasive cardiovascular procedure is planned, requiring pre- or post-operative catheterization or angiographic imaging (e.g., for pressure or gradient measurements); **OR**
 - Noninvasive imaging is inconclusive or discordant with findings on physical exam; **OR**
- Hypertrophic cardiomyopathy (HCM) with **ANY** of the following¹¹:
 - Symptomatic HCM after noninvasive imaging; **OR**

- Evidence of myocardial ischemia; **OR**
- Prior to septal myectomy; **OR**
- Symptomatic congestive heart failure (CHF) and **ALL** of the following^{1,12}:
 - Ejection fraction is less than 40%; **AND**
 - Echocardiogram is inadequate to determine the cause of dysfunction or the extent of coronary disease; **AND**
 - Contraindications to cardiac computed tomography angiography (CCTA) exist; **AND**
 - No cardiac catheterization, single photon emission computed tomography (SPECT), cardiac positron emission tomography (PET), or stress echocardiogram (ECG) has been performed since the diagnosis of congestive heart failure or cardiomyopathy; **OR**
- Ventricular fibrillation or sustained ventricular tachycardia; **OR**
- The patient has survived sudden cardiac arrest or life-threatening ventricular arrhythmia¹³; **OR**
- Preoperative assessment before **ANY** of the following:
 - Heart valve surgery; **OR**
 - Lung transplant; **OR**
 - Liver transplant; **OR**
- The patient is being considered for or has received a heart transplant; **AND**
- The procedure is a **left heart catheterization with left ventricular angiogram (ventriculogram)**, and **ANY** of the following is **TRUE**^{1,3,4}:
 - This section is not applicable (service not requested); **OR**
 - Assessment of left ventricular systolic function; **OR**
 - Assessment of the degree of mitral regurgitation; **OR**
 - Assessment for a ventricular septal defect, other intracardiac shunts, or other congenital heart abnormalities; **OR**
 - Pericardial tamponade; **OR**
 - Hemodynamic assessment of the aortic valve, only if noninvasive imaging is inadequate²; **OR**
 - Measurement of the left ventricular end-diastolic pressure; **OR**
 - Constrictive or restrictive pericarditis; **AND**
- The procedure is a **right cardiac catheterization**, and **ANY** of the following is **TRUE**^{1,10,11,14,15}:
 - This section is not applicable (service not requested); **OR**
 - Preoperative assessment before valvular surgery; **OR**
 - Left ventricular dysfunction disproportional to the severity of the

- valvular disease; **OR**
- Pulmonary hypertension disproportional to the severity of the valvular disease; **OR**
- Clinical uncertainty between (or suspicion of) constrictive versus restrictive physiology; **OR**
- Suspected pericardial tamponade; **OR**
- Suspected cardiomyopathy of unknown etiology with symptoms (LVEF less than 40%); **OR**
- The patient is being considered for or has received a heart transplant; **OR**
- Patients with stable ischemic heart disease who develop symptoms and signs of heart failure; **OR**
- Known congenital heart disease when non-invasive tests are inconclusive or discordant with clinical assessment; **OR**
- Assessing any shunt inside the heart or lungs; **OR**
- Partial anomalous pulmonary venous connection to define vascular connections; **OR**
- Cor pulmonale; **OR**
- For assessment of atrial baffle function (suspected obstruction or leak) after Mustard/Senning operation.

Non-Indications

Cardiac catheterization is not considered appropriate if **ANY** of the following is **TRUE**¹:

- Coagulopathy; **OR**
- Fever; **OR**
- Systemic infection; **OR**
- Evaluation of syncope¹⁶; **OR**
- Radiopaque contrast agent allergies in patients who have not been appropriately premedicated.
- Acute or chronic kidney disease; **OR**
- Uncontrolled arrhythmia; **OR**
- Pregnancy; **OR**
- Normal coronary angiogram or CCTA within the last two years and with no stenosis or plaque (for certain left heart catheterization scenarios)¹⁻⁴; **OR**
- Normal stress test (given adequate stress) within the last year (for certain left heart catheterization scenarios).¹⁻⁴

Definitions

- **Ischemic Equivalent:** Chest pain syndrome, anginal equivalent, or ischemic electrocardiogram (ECG) abnormalities are 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 CAD may also be considered an ischemic equivalent.¹⁻⁴
- **Guideline-Directed Medical Treatment (GDMT)** includes the following, as appropriate³:
 - Diet, weight loss, and regular physical activity
 - Smoking cessation (if patient is a smoker)
 - Aspirin 75–162 mg daily
 - A statin medication in moderate dosage
 - Antihypertensive medication to achieve a blood pressure level <140/90 mm Hg (if patient is hypertensive)
 - Appropriate glycemic control (if patient is diabetic)

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93451	Right heart catheterization
93452	Left heart catheterization with intraprocedural injection for left ventriculography
93453	Combined right and left heart catheterization with intraprocedural injection for left ventriculography
93454	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and

	interpretation
93455	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with catheter placement in bypass graft, with intraprocedural injections for bypass graft angiography
93456	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with right heart catheterization
93457	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with catheter placement in bypass graft, with intraprocedural injection for bypass graft angiography and right heart catheterization
93458	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with left heart catheterization, with intraprocedural injection for left ventriculography
93459	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision and interpretation, with left heart catheterization, catheter placement in bypass graft, with bypass graft angiography
93460	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with right and left heart catheterization
93461	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with right and left heart

	catheterization, catheter placement in bypass graft, with bypass graft angiography
93462	Left heart catheterization by transseptal puncture through intact septum or by transapical puncture
93593	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; normal native connections
93594	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; abnormal native connections
93595	Left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone, normal or abnormal native connections
93596	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); normal native connections
93597	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); abnormal native connections

Medical Evidence

A study of more than 96,000 patients undergoing left heart catheterization examined the concomitant use of left ventriculography. Approximately 82% (78,705) of patients underwent left ventriculography in addition to left heart catheterization. Use was pronounced among younger patients. Upon cohort analysis of a subgroup comprised of patients who had a very recent ejection fraction assessment (within the last 30 days) and who had no intervening diagnosis (i.e., no new heart failure, no myocardial infarction, no hypotension, no shock), nearly 88% underwent left ventriculography, a total of 32,798 patients that was also higher than the rate observed in the overall cohort. The authors noted that this pattern constituted overuse of left ventriculography, particularly for subgroup patients for whom new information was very unlikely to be obtained. They stated that the reputation of left ventriculography as an “add-on” procedure to cardiac catheterization may confer risks ranging from increased patient morbidity to excess care cost.¹⁷

A 2016 study compared invasive left ventriculography with two other modalities: 2D echocardiography and quantitative gated single-photon emission computed tomography. All patients underwent each of the three imaging techniques within three months of each other to evaluate chest pain of unclear etiology. The authors concluded that, although invasive left ventriculography is considered the gold standard for the evaluation of symptomology thought to be of cardiac origin, noninvasive imaging may be an adequate substitution due to the strongly positive correlation associated with each of the three imaging modalities for measuring left ventricular ejection fraction. Therefore, invasive left ventriculography may be better utilized among patients who can accept the medical risk of radiation exposure and contrast-induced kidney injury.¹⁸

A review was published in 2022 on the role of right heart catheterization in patients (RHC) with heart failure. The procedure is a fundamental diagnostic tool for patients experiencing refractory heart failure or cardiogenic shock. The procedure is also crucial for evaluating eligibility for – and managing patients post-implantation of – mechanical circulatory assist devices or heart transplantation. While RHC is not typically suggested for patients with decompensated heart failure, it may benefit those whose condition does not

improve with initial therapy, as well as those with uncertain volume status and persistent hypoperfusion or those being evaluated for advanced cardiac support. It serves an important role in the early, accurate detection of primary graft dysfunction among heart transplant recipients, which is also the leading cause of death among this cohort.¹⁹

Choi et al. (2023) conducted a retrospective, single-center, observational study to evaluate the discriminatory and prognostic significance of invasively measured left ventricular end-diastolic pressure in patients suspected of having heart failure with preserved ejection fraction (HFpEF). The authors focused on patients with intermediate scores on the Heart Failure Association Pre-test Assessment, Echocardiography and Natriuretic Peptide, Functional Testing, Final Etiology (HFA-PEFF) scale. A total of 404 patients were included; all patients exhibited symptoms of heart failure and had a left ventricular ejection fraction of greater than or equal to 50%. Patients underwent left heart catheterization (LHC). Exclusion criteria included patients who presented without definitive HF symptoms or with acute coronary syndrome (ACS), primary cardiomyopathies, significant valvular heart disease (beyond mild stenosis or moderate left-sided regurgitation), pulmonary arterial hypertension, heart transplantation, constrictive pericarditis, or stress-induced cardiomyopathy. Elevated left ventricular end-diastolic pressure (LVEDP) was linked to a significantly higher 10-year risk of all-cause death or HF readmission in patients suspected of having HFpEF, especially among those with intermediate HFA-PEFF scores. This association remained even after adjusting for multiple variables, including the HFA-PEFF score. (Clinicaltrial.gov, NCT04505449).²⁰

Otto et al. (2021) reviewed published guidelines from the American College of Cardiology (ACC) and the American Heart Association (AHA) on the management of patients with valvular heart disease. When noninvasive testing results are inconclusive, especially in symptomatic patients, or when there is a discrepancy between noninvasive tests and clinical findings, cardiac catheterization with direct intracardiac measurements is recommended. Cardiac catheterization provides valuable direct measurements of transvalvular pressure gradients and cardiac output. Contrast angiography may be helpful for semiquantitative assessment, especially when noninvasive results conflict with physical examination findings. Cardiac catheterization offers the advantage of measuring

intracardiac pressures and pulmonary vascular resistance, aiding in decision-making regarding valve intervention.¹⁴

A 2020 study examined 289 transplanted donor hearts with invasive coronary angiography with the aim of determining the prevalence of post-transplant CAD and cardiac allograft vasculopathy (CAV). Invasive coronary angiography was successfully completed in all transplanted donor hearts. Donor hearts that were diagnosed with moderate CAD did not affect transplant recipient survival and did not accelerate the development of CAV. The authors concluded that there is an application for invasive coronary angiography in the routine evaluation of transplanted donor hearts.²¹

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Clinical Guideline Revision History/Information

Original Date: June 26, 2025		
Review History		
Version 1	06/26/2025	Combined three cardiac catheterization policies (left heart catheterization with coronary angiography/bypass angiography, right heart catheterization with left ventriculogram, combined right-left heart catheterization) into one cardiac catheterization policy, titled "cardiac catheterization". Wordsmithing throughout that did not affect the meaning of the criteria unless otherwise stated below Removed redundant criteria that were already captured by prior indications Provided definition of guideline-directed medical therapy (GDMT) for stable ischemic heart disease References to "suspected" disease were removed (i.e. - indications which stated "known or suspected" were amended to simply say "known")



Cohere Medical Policy – Cardiac Implantable Devices

Clinical Guidelines for Medical Necessity Review

Version: 4
Effective Date: December 19, 2024

Important Notices

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Medical Necessity Criteria

Service: Cardiac Implantable Devices

Recommended Clinical Approach:

Pacemaker implantation is indicated for various symptomatic cardiac conduction system abnormalities, such as sinus node dysfunction (SND), atrioventricular (AV) block, and atrial fibrillation (AF) with a slow ventricular heart rate response whether due to intrinsic conduction system disease, secondary to medications, or produced by an AV node ablation¹. Depending on clinical status and comorbidities, the patient may require either single-site or multiple-site pacing, added defibrillator function if appropriate (e.g., heart failure with reduced ejection fraction [HFrEF]), or cardiac resynchronization therapy (CRT) without a defibrillator (CRT-P) or with a defibrillator (CRT-D). CRT is also known as biventricular (BiV) pacing.

New techniques for CRT bring about questions of optimal patient selection, indications, and follow-up for conduction system pacing (CSP) versus CRT via BiV pacing.¹⁷ Pacing is frequently required after a surgical Maze procedure when much of the normal electrical impulses from the atria are disrupted.¹ Adequate atrial pacing may reduce the frequency of atrial tachyarrhythmic events. Many antiarrhythmics used to control atrial flutter/fibrillation can exacerbate sick sinus syndrome, which may require pacing to prevent symptomatic bradycardia.²⁻³

Implantable cardioverter-defibrillators (ICDs) may be used for the prevention of sudden cardiac death (SCD) in patients at high risk.⁴ Permanent pacing is typically performed for symptomatic bradyarrhythmias. It may also be used for patients, regardless of symptoms, with an acquired second-degree Mobitz type II atrioventricular block, high-grade atrioventricular block, or third-degree atrioventricular block not attributable to reversible or physiologic causes⁶. Nocturnal bradycardia is not in itself an indication of permanent pacing.⁵ Atrial fibrillation should only be the primary indication for pacemaker implantation when performed in concert with AV node ablation. Isolated pacemaker insertion should not be requested with AF or atrial flutter as the only associated diagnosis. Pacing is a treatment for symptomatic

bradycardic rhythms. Leadless pacemakers are beyond the scope of this policy.

Medical Necessity Criteria

Indications

→ A **cardiac implantable device** is considered appropriate if **ANY** of the following are **TRUE**^{1,3,5-6}:

◆ The device is an **implantable single or dual-chamber pacemaker**, and **ANY** of the following is **TRUE**^{2-7,13,17,19}:

- Symptomatic persistent or permanent atrial fibrillation (AF) and is a candidate for AV node ablation^{2-7,13,17,19}; **OR**
- Permanent AF with symptomatic bradycardia^{2-7,13,17,19}; **OR**
- Atrial flutter with **ANY** of the following^{2-7,13,17,19}:
 - Associated sinus node dysfunction; **OR**
 - AV node dysfunction; **OR**
 - Symptomatic bradycardia, with or without antiarrhythmic treatment²⁻³; **OR**
- Symptomatic bradycardia, sinus node dysfunction, or AV node dysfunction, with or without antiarrhythmic treatment or guideline-directed management and therapy, for which there is no alternative treatment and continued treatment is clinically necessary⁵; **OR**
- Tachy-brady (tachycardia-bradycardia) form of sick sinus syndrome and symptoms attributable to bradycardia, permanent pacing is reasonable to increase heart rate and reduce symptoms attributable to hypoperfusion⁵; **OR**
- Symptomatic chronotropic incompetence, permanent pacing with rate-responsive programming is reasonable to increase exertional heart rates and improve symptoms⁵; **OR**
- Acquired second-degree Mobitz type II atrioventricular block, high-grade atrioventricular block, or third-degree atrioventricular block not attributable to reversible or physiologic causes, permanent pacing is recommended regardless of symptoms⁵; **OR**
- Marked first-degree or second-degree Mobitz type I (Wenckebach) AV block with symptoms that are clearly attributable to the AV block, permanent pacing is reasonable^{2-7,13,17,19}; **OR**

- Alternating BBB^{2-7,13,17,19}; **OR**
- Syncope and BBB with an HV interval 70 ms or greater or evidence of infranodal block at EPS^{2-7,13,17,19}; **OR**
- Vasovagal syncope with **ALL** of the following when all other transient causes have been excluded⁷:
 - The patient is 40 years of age or older; **AND**
 - Recurrent vasovagal syncope; **AND**
 - Prolonged pauses that are documented as greater than or equal to 3 seconds correlated with syncope; **OR**
- Replacement of a previously implanted pacemaker and **ANY** of the following is **TRUE**^{2-7,13,17,19}:
 - Infection that is related to leads or device; **OR**
 - Battery life depleted; **OR**
 - Malfunction of lead or device; **OR**
 - Manufacturer recall of device; **OR**
 - Revision to a dual chamber pacemaker for patients in sinus rhythm with a single chamber ventricular pacemaker who develop pacemaker syndrome; **OR**
- ◆ The device is an **implantable cardioverter-defibrillator (ICD)**, and **ANY** of the following is **TRUE**^{2,4,7-8,18}:
 - Primary prevention of sudden cardiac death (SCD) and **ANY** of the following is true^{2,4,7-8}:
 - LVEF of 35% or less with **ALL** of the following⁴:
 - ◆ Ischemic heart disease⁴; **AND**
 - ◆ NYHA class I-III HF⁴; **AND**
 - ◆ **ANY** of the following:
 - 40 or more days post-MI⁴; **OR**
 - 90 or more days post-revascularization⁴; **OR**
 - Documented prior MI with non-sustained ventricular tachycardia (NSVT), LVEF less than or equal to 40%, and ventricular fibrillation (VF) or ventricular tachycardia (VT) that was induced during an electrophysiology (EP) study; **OR**
 - Heart failure with reduced ejection fraction (HFrEF) who is a candidate for cardiac transplantation or a left ventricular assist device (LVAD)^{4,7}; **OR**

- Nonischemic cardiomyopathy (NICM), HF with NYHA class I–III symptoms and an LVEF of 35% or less, despite GDMT; **OR**
- Neuromuscular disorder (Duchenne, Becker, Emery–Dreifuss, Myotonic type 1, and limb–girdle types 1B, 2C, 2F, and 2I), HF with NYHA class I–III symptoms, and an LVEF of 35% or less, despite GDMT^{4,7}; **OR**
- NICM due to a lamin A/C (LMNA) gene mutation who have 2 or more risk factors (NSVT, LVEF less than 45%, non-missense mutation, male sex)⁴; **OR**
- Arrhythmogenic right ventricular cardiomyopathy and an additional marker of increased risk of SCD (resuscitated SCA, sustained VT, significant ventricular dysfunction with RVEF or LVEF less than or equal to 35%)^{4,7}; **OR**
- Hypertrophic cardiomyopathy (HCM) and **ANY** of the following¹⁸:
 - ◆ Maximum LV wall thickness greater than or equal to 30 mm¹⁸; **OR**
 - ◆ SCD in 1 or more first-degree (e.g., parent, sibling, child) relatives presumably caused by HCM¹⁸; **OR**
 - ◆ One or more episodes of unexplained syncope within the preceding 6 months¹⁸; **OR**
 - ◆ NSVT¹⁸; **OR**
 - ◆ An abnormal blood pressure response with exercise¹⁸; **OR**
- Cardiac sarcoidosis and **ANY** of the following^{2,4,7–8}:
 - ◆ LVEF greater than 35% with inducible sustained VA on EP study; **OR**
 - ◆ Syncope; **OR**
 - ◆ Evidence of myocardial scar by cardiac MRI/PET scan; **OR**
 - ◆ An indication for permanent pacing; **OR**
- In patients with prior heart transplant and severe allograft vasculopathy with LV less than 45%²²; **OR**
- In patients with myotonic dystrophy type 1^{4,7}; **OR**

- In high-risk patients with symptomatic long QT syndrome in whom a beta blocker is ineffective or not tolerated^{4,7}; **OR**
- Adult congenital heart disease with severe ventricular dysfunction (LVEF less than 35%), and either additional risk factors or symptoms of HF despite GDMT or additional risk factors^{4,7}; **OR**
- Secondary prevention of SCD with **ANY** of the following^{2-5,7-8,18}:
 - Patients with ischemic heart disease, who either survive SCA due to VT/VF or who experience hemodynamically unstable VT or stable sustained VT not due to reversible causes; **OR**
 - Patients with ischemic heart disease and unexplained syncope who have inducible sustained monomorphic VT on EP; **OR**
 - Patients with ischemic heart disease and unexplained syncope who have an LVEF less than or equal to 35%; **OR**
 - Patients with NICM who either survive SCA due to VT/VF, or who experience hemodynamically unstable VT or stable sustained VT; **OR**
 - In patients with NICM who experience syncope presumed to be due to VA; **OR**
 - Arrhythmogenic right ventricular cardiomyopathy and syncope presumed due to VA; **OR**
 - HCM with **ANY** of the following¹⁸:
 - ◆ Survivor of SCA due to VT or VF; **OR**
 - ◆ Spontaneous sustained VT causing syncope or hemodynamic compromise; **OR**
 - In patients with giant cell myocarditis with VF or hemodynamically unstable VT treated according to GDMT; **OR**
 - Cardiac sarcoidosis and **ANY** of the following:
 - ◆ Sustained VT; **OR**
 - ◆ Survivors of SCA; **OR**
 - ◆ LVEF of 35% or less; **OR**
 - Patients with an LVAD and sustained VA; **OR**

- Patients resuscitated from SCA due to coronary artery spasm in whom medical therapy is ineffective or not tolerated; **OR**
- In patients resuscitated from SCA due to coronary artery spasm, an ICD in addition to medical therapy; **OR**
- Cardiac channelopathy (i.e., long QT syndrome, catecholaminergic polymorphic ventricular tachycardia, Brugada syndrome, early repolarization syndrome, and short QT syndrome) and prior SCA^{4,7}; **OR**
- Hemodynamically unstable VT; **OR**
- Stable sustained VT not associated with MI; **OR**
- Unexplained syncope, and ischemic heart disease with inducible sustained monomorphic VT on EP study; **OR**
- Diagnosed condition with high risk of life-threatening VT (familial/inherited); **OR**
- In patients with catecholaminergic polymorphic ventricular tachycardia, and either recurrent sustained VT or syncope, while receiving adequate or maximally tolerated beta blocker; **OR**
- Brugada syndrome with spontaneous type 1 Brugada electrocardiographic pattern and cardiac arrest, sustained VA, or a recent history of syncope presumed due to VA; **OR**
- Early repolarization pattern on ECG, and either cardiac arrest or sustained VA; **OR**
- In patients with short QT syndrome who have a cardiac arrest or sustained VA; **OR**
- Patients resuscitated from SCA due to idiopathic polymorphic VT or VF; **OR**
- Congenital heart disease with **ANY** of the following:
 - ◆ Hemodynamically unstable VT after evaluation and appropriate treatment for residual lesions/ventricular dysfunction; **OR**
 - ◆ SCA due to VT or VF in the absence of reversible causes; **OR**

- ◆ Repaired tetralogy of Fallot physiology and either inducible VT/VF or spontaneous sustained VT; **OR**
- ◆ Repaired moderate or severe complexity congenital heart disease with unexplained syncope and at least moderate ventricular dysfunction or marked hypertrophy; **OR**
- ◆ The device is a **subcutaneous implantable cardioverter-defibrillator system** and **ALL** of the following⁴ are **TRUE**:
 - An indication for primary or secondary prevention of SCD; **AND**
 - **ANY** of the following is **TRUE**:
 - Transvenous defibrillation unable or failed to be placed; **OR**
 - Vascular access is limited; **OR**
 - Congenital heart disease that either limits venous access to the heart or requires intracardiac shunt²¹; **OR**
 - Prior transvenous ICD infection²¹; **OR**
 - On hemodialysis²¹; **OR**
 - Immunocompromise; **OR**
 - At high risk for bacteremia (e.g., prior bacteremia, chronic indwelling catheters); **OR**
 - Endocarditis; **OR**
- ◆ The device is for **cardiac resynchronization therapy (CRT) without a defibrillator (CRT-P) or with a defibrillator (CDT-D, when cardioverter-defibrillator function is indicated)** when **ANY** of the following is **TRUE**^{5,9-14}:
 - For initial CRT when **ANY** of the following is **TRUE**:
 - LVEF less than or equal to 35% (with ischemic or non-ischemic cardiomyopathy) and **ALL** of the following^{9,10} are **TRUE**:
 - ◆ Sinus rhythm; **AND**
 - ◆ LBBB (QRS duration greater than or equal to 120 ms)⁵; **AND**
 - ◆ NYHA class II, III or ambulatory IV HF on maximally tolerated GDMT for at least 3 months²⁰; **OR**

- LVEF less than or equal to 30% (ischemic), and **ALL** of the following are **TRUE**:
 - ◆ Sinus rhythm **AND**
 - ◆ LBBB (QRS duration greater than or equal to 120 ms)⁵; **AND**
 - ◆ NYHA class I HF on maximally tolerated GDMT for at least 3 months²⁰; **OR**
- Atrial fibrillation (AF) and **ALL** of the following^{19,20}:
 - ◆ **ANY** of the following:
 - AV nodal ablation (AVNA)^{19,20}; **OR**
 - Pharmacological rate control will allow near 100% ventricular pacing with CRT^{19,20}; **AND**
 - ◆ With an LVEF less than or equal to 35% on maximally tolerated GDMT for at least 3 months^{19,20}; **OR**
- High degree or complete heart block and EF 36% to 50% (**applies to CRT-P only**); **OR**
- HCM and **ALL** of the following²⁰:
 - ◆ Existing or prior ICD²⁰; **AND**
 - ◆ NYHA class II to ambulatory class IV HF despite GDMT for at least 3 months²⁰; **AND**
 - ◆ LBBB (QRS duration greater than or equal to 120 ms)⁵; **AND**
 - ◆ **ANY** of the following²⁰:
 - LVEF less than 35%; **OR**
 - LVEF less than 50% and expected high burden of ventricular pacing; **OR**
- New pacemaker implantation with **ALL** of the following:
 - ◆ LVEF less than or equal to 35% on GDMT; **AND**
 - ◆ Anticipated requirement for significant (greater than 40%) ventricular pacing; **OR**
- For upgrade to a CRT device when **ALL** of the following are **TRUE**^{9,14}:
 - The patient is being paced from the RV more than 40% of the time; **AND**
 - **ANY** of the following:
 - ◆ LVEF less than or equal to 35% on GDMT; **OR**

- ◆ LVEF less than 50% and expected high burden of ventricular pacing; **OR**
- For replacement of an existing CRT device when **ANY** of the following is **TRUE**^{9,14}:
 - Battery life depleted; **OR**
 - Elective replacement indicator (ERI); **OR**
 - Malfunction of lead or device.

Non-Indications

→ A **cardiac implantable device** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Symptoms are due to a transient cause (e.g., acute myocardial infarction [MI], drug toxicity, or electrolyte imbalance) with no other indication present; **OR**
- ◆ The device is an **implantable pacemaker**, and **ANY** of the following is **TRUE**:
 - Active systemic or local infection; **OR**
 - Permanent or persistent AF in whom a rhythm control strategy is not planned and implantation of an atrial lead should not be performed; **OR**
 - The patient has a first-degree AV block or second-degree Mobitz type I (Wenckebach) or 2:1 AV block, which is believed to be at the level of the AV node, without symptoms or symptoms that do not temporally correspond to the atrioventricular block; **OR**
 - Prevention of AF⁶; **OR**
 - Treatment of sleep apnea¹⁵; **OR**
 - Asymptomatic bradycardia during sleep⁸; **OR**
 - Syncope of undetermined cause¹⁶; **OR**
- ◆ The device is an **implantable defibrillator**, and **ANY** of the following is **TRUE**:
 - Active systemic or local infection; **OR**
 - NYHA class IV patients with HF not responsive to medication who are not candidates for cardiac transplantation or LVAD^{4,8}; **OR**
 - Physiological shock of any etiology; **OR**
 - Non-cardiac disease, such as cancer or liver failure, that is associated with the possibility of less than 1 year of meaningful survival; **OR**

- ◆ The device is a **subcutaneous implantable cardioverter-defibrillator system**, and **ANY** of the following is true:
 - In patients with an indication for bradycardia pacing or CRT; **OR**
 - Antitachycardia pacing for VT termination is required; **OR**
- ◆ The device is for **cardiac resynchronization therapy (CRT)** and **ANY** of the following is **TRUE**^{9-10,14}:
 - QRS less than 120 ms; **OR**
 - EF greater than 50%; **OR**
 - Non-ambulatory NYHA IV HF symptoms; **OR**
 - With LVAD in place; **OR**
 - Active systemic or local infection.

Level of Care Criteria

Outpatient or Inpatient.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33206	Insertion of permanent atrial pacemaker with transvenous electrode
33207	Insertion of permanent ventricular pacemaker with transvenous electrode
33208	Insertion of permanent atrial and ventricular pacemaker with transvenous electrode
33210	Insertion or replacement of temporary transvenous single chamber cardiac electrode or pacemaker catheter (separate procedure)
33211	Insertion or replacement of temporary transvenous dual chamber pacing electrodes (separate procedure)
33212	Insertion of pacemaker pulse generator with connection to existing single lead
33213	Insertion of pacemaker pulse generator with connection to existing dual leads
33214	Conversion of single chamber implanted pacemaker

	system to dual chamber system
33216	Insertion of transvenous electrode of permanent pacemaker
33217	Insertion of 2 transvenous electrodes of permanent cardioverter-defibrillator
33221	Insertion of pacemaker pulse generator with existing multiple leads
33224	Transvenous insertion of pacing electrode for left ventricular pacing, with connection to existing pacemaker
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system) (List separately in addition to code for primary procedure)
33226	Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of existing generator)
33227	Removal and replacement of permanent pacemaker pulse generator in single lead system
33228	Removal and replacement of permanent pacemaker pulse generator in dual lead system
33229	Removal and replacement of permanent pacemaker pulse generator in multiple lead system
33230	Insertion of implantable defibrillator pulse generator only; with existing dual leads
33231	Insertion of implantable defibrillator pulse generator only; with existing multiple leads
33233	Removal of permanent pacemaker pulse generator
33234	Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular
33235	Removal of transvenous pacemaker electrode(s); dual lead system
33240	Insertion of implantable defibrillator pulse generator only;

	with existing single lead
33241	Removal of implantable defibrillator pulse generator only
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system
33264	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; multiple lead system
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed
33271	Insertion of subcutaneous implantable defibrillator electrode
33272	Removal of subcutaneous implantable defibrillator electrode
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed

33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed
93640	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement;
93641	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement; with testing of single or dual chamber pacing cardioverter-defibrillator pulse generator
93642	Electrophysiologic evaluation of single or dual chamber transvenous pacing cardioverter-defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
C1721	Cardioverter-defibrillator, dual chamber (implantable)
C1722	Cardioverter-defibrillator, single chamber (implantable)
C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)
C1779	Lead, pacemaker, transvenous VDD single pass
C1785	Pacemaker, dual chamber, rate-responsive (implantable)

C1786	Pacemaker, single chamber, rate-responsive (implantable)
C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)
C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
C1898	Lead, pacemaker, other than transvenous VDD single pass
C1899	Lead, pacemaker/cardioverter-defibrillator combination (implantable)
C1900	Lead, left ventricular coronary venous system
C2619	Pacemaker, dual chamber, non-rate-responsive (implantable)
C2620	Pacemaker, single chamber, non-rate-responsive (implantable)
C2621	Pacemaker, other than single or dual chamber (implantable)
0571T	Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed
0572T	Insertion of substernal implantable defibrillator electrode
0573T	Removal of substernal implantable defibrillator electrode
0574T	Repositioning of previously implanted substernal implantable defibrillator-pacing electrode
0577T	Electrophysiologic evaluation of implantable cardioverter-defibrillator system with substernal electrode (includes defibrillation threshold evaluation,

	induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
0580T	Removal of substernal implantable defibrillator pulse generator only
0614T	Removal and replacement of substernal implantable defibrillator pulse generator

Medical Evidence

The American College of Cardiology (ACC), in association with the American Heart Association (AHA), the American College of Clinical Pharmacy (ACCP), and the Heart Rhythm Society (HRS), has published several guidelines for the management of various cardiac rhythm disorders. The most recent were published in 2024 and 2023, covering hypertrophic cardiomyopathy (HCM) and atrial fibrillation (AF), respectively. Per the ACC's recommendation, HCM may be appropriately treated with implantable cardioverter-defibrillators (ICDs) such as an implantable cardiac defibrillator to reduce the risk of sudden cardiac death (SCD). Patients with an existing ICD may be eligible to receive cardiac resynchronization therapy based on symptoms of worsening heart failure (HF) (left bundle branch block [LBBB], left ventricle ejection fraction [LVEF] under 50%, New York Heart Association [NYHA] class II to ambulatory class IV symptoms). The 2024 guidelines direct the optimal treatment of patients with HF with reduced ejection fraction (HFrEF) – the ACC verifies that guideline-directed medical therapy (GDMT) is generally attempted for a period of at least 3 months before ventricular function is reassessed for potential augmentation by device therapy.¹⁸⁻²⁰

Kusumoto et al. (2018) published recommendations for the treatment of bradycardia in a multi-society guideline. They strongly recommended permanent pacing regardless of symptoms in patients with acquired second-degree Mobitz type II atrioventricular block, high-grade atrioventricular block, or third-degree atrioventricular block not attributable to reversible or physiologic causes. Strong recommendations were made for other patients with AV block, including those with neuromuscular disease and symptomatic bradycardia.⁵

Calkins et al. (2017) published an expert consensus statement with the HRS, the European Heart Rhythm Association (EHRA), and the European Cardiac Arrhythmia Society (ECAS) to update guidelines based on advances in AF ablation since the previous publication. It was recommended that the amount of time an individual spends in AF (24-hour AF burden) is essential to address when ablation is being considered. This is due largely to the increase in the use of implantable loop recorders, pacemakers, and ICDs.¹

Al-Khatib et al. (2017) published guidelines on behalf of the AHA, ACC, and the HRS regarding the management of patients with ventricular arrhythmias (VAs) and the prevention of SCD. Various types of defibrillators were discussed, and their effectiveness in terminating life-threatening VAs. Survivors of cardiac arrest, patients with ventricular tachycardia (VT) and structural heart disease, and those with significant left ventricle (LV) dysfunction may benefit greatly from defibrillator implantation.⁴

January et al. (2014) published an evidence-based, systematic review and subsequent guidelines for the AHA, ACC, and HRS on the *Management of Patients with Atrial Fibrillation*. A number of recommendations were made or revised for optimum management of AF. Pacemakers are recommended in AF patients for the treatment of symptomatic bradycardia, which is often related to sick sinus syndrome. The authors stated that antiarrhythmic therapy may exacerbate sick sinus syndrome, requiring pacemaker implantation. Permanent pacing was not recommended by the group for the prevention of AF in patients without other indications for pacemaker placement. Implanted defibrillators are not recommended for AF rhythm control.⁶

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Clinical Guideline Revision History/Information

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Version 3	4/26/2024	
Version 4	12/19/2024	Annual policy review and restructure: • Updated recommended clinical approach to the current format. • Overall reformatting to align with current editorial standards. • Removal of redundant indications • Condensed indications where applicable for clarity. • Updated medical evidence section. • Updated references.

Cohere Medical Policy – Cardiac Implantable Rhythm Management Devices

Clinical Policy for Medical Necessity Review

CHP-307-5 Version 5

Cohere Health UMC Approval Date January 15, 2026

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Important Notices

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Procedure Codes (CPT/HCPCS)

Cardiac Implantable Rhythm Management Devices	
CPT/HCPCS Code	Code Description
33206	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial
33207	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular
33208	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular
33210	Insertion or replacement of temporary transvenous single chamber cardiac electrode or pacemaker catheter (separate procedure)
33211	Insertion or replacement of temporary transvenous dual chamber pacing electrodes (separate procedure)
33212	Insertion of pacemaker pulse generator only; with existing single lead
33213	Insertion of pacemaker pulse generator only; with existing dual leads
33214	Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator)
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator

33221	Insertion of pacemaker pulse generator only; with existing multiple leads
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system) (List separately in addition to code for primary procedure)
33226	Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of existing generator)
33227	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; single lead system
33228	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; dual lead system
33229	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; multiple lead system
33230	Insertion of implantable defibrillator pulse generator only; with existing dual leads
33231	Insertion of implantable defibrillator pulse generator only; with existing multiple leads
33233	Removal of permanent pacemaker pulse generator only
33234	Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular
33235	Removal of transvenous pacemaker electrode(s); dual lead system
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead

33241	Removal of implantable defibrillator pulse generator only
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system
33264	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; multiple lead system
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed
33271	Insertion of subcutaneous implantable defibrillator electrode
33272	Removal of subcutaneous implantable defibrillator electrode
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed
93640	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of

	arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement;
93641	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement; with testing of single or dual chamber pacing cardioverter-defibrillator pulse generator
93642	Electrophysiologic evaluation of single or dual chamber transvenous pacing cardioverter-defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
C1721	Cardioverter-defibrillator, dual chamber (implantable)
C1722	Cardioverter-defibrillator, single chamber (implantable)
C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)
C1779	Lead, pacemaker, transvenous VDD single pass
C1785	Pacemaker, dual chamber, rate-responsive (implantable)
C1786	Pacemaker, single chamber, rate-responsive (implantable)
C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)
C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
C1898	Lead, pacemaker, other than transvenous VDD single pass

C1899	Lead, pacemaker/cardioverter-defibrillator combination (implantable)
C1900	Lead, left ventricular coronary venous system
C2619	Pacemaker, dual chamber, non-rate-responsive (implantable)
C2620	Pacemaker, single chamber, non-rate-responsive (implantable)
C2621	Pacemaker, other than single or dual chamber (implantable)
0571T	Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed
0572T	Insertion of substernal implantable defibrillator electrode
0573T	Removal of substernal implantable defibrillator electrode
0574T	Repositioning of previously implanted substernal implantable defibrillator-pacing electrode
0577T	Electrophysiologic evaluation of implantable cardioverter-defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
0580T	Removal of substernal implantable defibrillator pulse generator only
0614T	Removal and replacement of substernal implantable defibrillator pulse generator

Cardiac Implantable Rhythm Management Devices - Description

Cardiac implantable rhythm management devices, including pacemakers, cardioverter-defibrillators, and cardiac resynchronization therapy devices, are permanently implanted devices that deliver electrical stimulation to the heart for rhythm management.¹

A pacemaker consists of a pulse generator, which is placed under subcutaneous tissue on the upper chest, and pacemaker leads terminating in small electrodes, which are anchored to the myocardium. An implantable cardioverter-defibrillator (ICD) is similarly made up of a pulse generator and leads. However, the leads in an ICD have shocking coils to allow for defibrillation. Subcutaneous ICDs have no leads and instead have shock electrodes attached to the generator that tunnel through the subcutaneous tissue. Devices for cardiac resynchronization therapy typically consist of a pacing ICD in the right ventricle, along with an additional pacing lead in the left ventricle to improve dyssynchrony.

Implantable cardioverter-defibrillators (ICDs) are often used to prevent sudden cardiac death (SCD) in high-risk patients.⁴ ICDs were initially implanted for secondary prevention after a sudden cardiac arrest. Their use has since been expanded to primary prevention in patients with ischemic and non-ischemic cardiomyopathies.

Service: Implantable Single or Dual-chamber Pacemaker - Medical Necessity Criteria

Administrative Guidelines for Medical Necessity Review

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity.

Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When multiple diagnostic or therapeutic procedures are requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Indications

- A **cardiac implantable rhythm management device - implantable single or dual-chamber pacemaker** is considered appropriate if **ALL** of the following are **TRUE**^{1-6,13,3-11}:
 - **ANY** of the following conditions requiring a pacemaker:
 - Documented non-reversible symptomatic bradycardia due to sinus node dysfunction; **OR**
 - Documented non-reversible symptomatic bradycardia due to second-degree and/or third-degree atrioventricular (AV) block; **OR**
 - Prior to a planned catheter ablation of the AV node³⁻¹¹; **OR**
 - Symptomatic bradycardia with cardiac transplant⁶; **OR**
 - Sinus node dysfunction or AV node dysfunction with **ALL** of the following⁶:
 - There is no alternative treatment; **AND**
 - Continued treatment is clinically necessary; **OR**
 - Any degree of AV or fascicular block in a patient diagnosed with a progressive neuromuscular disease known to involve the heart (e.g., myotonic muscular dystrophy, Kearns-Sayre syndrome, Erb dystrophy, peroneal muscular atrophy)^{12-14,16}; **OR**
 - Alternating bundle branch block (BBB)³⁻¹¹; **OR**

- Syncope/presyncope symptoms with **ANY** of the following:
 - BBB with **ANY** of the following at electrophysiological study (EPS)³⁻¹¹:
 - ▲ His-ventricular (HV) interval greater than or equal to 70 ms; **OR**
 - ▲ Evidence of infranodal block; **OR**
- Cardioinhibitory vasovagal syncope with **ALL** of the following⁸:
 - All other transient causes have been excluded; **AND**
 - The patient is greater than or equal to 40 years of age; **AND**
 - **ANY** of the following³⁵:
 - ▲ Spontaneous documented symptomatic asystolic pauses greater than 3 seconds; **OR**
 - ▲ Asymptomatic pauses greater than 6 seconds due to sinus arrest and/or AV block; **OR**
- **ANY** of the following at EPS:
 - HV interval greater than or equal to 100 ms¹⁵; **OR**
 - Intra- or infra-Hisian block; **OR**
- Hypertrophic cardiomyopathy with **ALL** of the following^{14,33,37}:
 - Symptomatic left ventricular outflow tract (LVOT) obstruction (e.g., chest pain, dyspnea on exertion, lightheadedness, palpitations, syncope or near-syncope); **AND**
 - Unresponsive to optimal medical therapy, septal ablation, and surgical myectomy; **OR**
- Transcatheter aortic valve repair (TAVR) or surgical aortic valve repair with high risk of worsening AV conduction disease^{6,34,14,10}; **OR**
- Removal/replacement or removal in isolation of a previously implanted generator and/or leads with **ANY** of the following³⁻¹¹:
 - Infection related to leads or device; **OR**
 - Battery life depleted; **OR**
 - Malfunction of the lead or device; **OR**
 - **ALL** of the following:
 - ▲ Manufacturer or FDA recall of device; **AND**
 - ▲ Documentation that replacement is medically necessary; **OR**
 - Addition of an atrial lead for a patient with **ALL** of the following:
 - ▲ Some evidence of intermittent sinus rhythm; **AND**
 - ▲ A single chamber ventricular pacemaker; **AND**
 - ▲ Develops pacemaker syndrome; **AND**
- **ANY** of the following pacemaker types:
 - The patient requires a **leadless cardiac pacemaker** as indicated by **ANY** of the following^{14,16,38,39}:
 - No upper extremity venous access¹⁶; **OR**
 - High risk of device pocket infection (e.g., active or previous systemic/device infection, on hemodialysis)¹⁶; **OR**

- A conventional transvenous pacing system is otherwise considered difficult, high-risk, or not sufficient for effective therapy³⁹; **OR**
- The patient has or is planned to have a tricuspid valve intervention; **OR**
- The patient requires a **transvenous pacemaker**.

Non-Indications

- A **cardiac implantable rhythm management device** is not considered appropriate if **ANY** of the following is **TRUE**^{2,3,5,6,12-14}:
 - Symptoms are due to a reversible cause (e.g., acute MI, drug toxicity, electrolyte imbalance) with no other indication; **OR**
 - The device is an **implantable pacemaker**, and **ANY** of the following:
 - Active systemic or local infection; **OR**
 - Permanent or persistent AF when a rhythm control strategy is not planned and implantation of an atrial lead should not be performed; **OR**
 - First-degree AV block or second-degree Mobitz type I (Wenckebach) or 2:1 AV block, which is believed to be at the level of the AV node, without symptoms or symptoms that do not temporally correspond to the AV block; **OR**
 - Prevention of AF³; **OR**
 - Treatment of sleep apnea²⁸; **OR**
 - Asymptomatic bradycardia during sleep¹⁷; **OR**
 - Syncope of undetermined cause²⁹; **OR**
 - The device is a **leadless cardiac pacemaker** and **ANY** of the following^{40,41}:
 - A dual-chamber leadless pacemaker is considered investigational and is not appropriate for any clinical scenario; **OR**
 - The patient has a co-implanted cardioverter-defibrillator (ICD)⁴²; **OR**
 - Known intolerance to the tissue-contacting materials in the device (e.g., titanium, nickel, Nitinol titanium-nickel alloy, epoxy resin)⁴³; **OR**
 - Implanted vena cava filter⁴³; **OR**
 - Reversible causes of bradycardia (e.g., electrolyte abnormalities, medications, drugs, hypothermia)^{6,44}; **OR**
 - Asymptomatic first-degree AV block^{6,44}; **OR**
 - Asymptomatic sinus bradycardia^{6,44}; **OR**
 - Asymptomatic sino-atrial block¹⁶; **OR**
 - Asymptomatic sinus arrest¹⁶; **OR**
 - Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium) without symptomatic bradycardia¹⁶; **OR**
 - Syncope of undetermined cause⁴⁵; **OR**
 - Bradycardia during sleep⁶; **OR**
 - Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block⁶; **OR**
 - Asymptomatic bradycardia in post-myocardial infarction patients about to initiate long-term beta-blocker drug therapy⁶; **OR**

- Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of tachycardia^{46,47}; **OR**
- A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged^{6,44}; **OR**
- The device is an **implantable defibrillator**, and **ANY** of the following:
 - Active systemic or local infection; **OR**
 - Physiological shock of any etiology; **OR**
 - Non-cardiac disease, such as cancer or liver failure, that is associated with the possibility of less than 1 year of meaningful survival; **OR**
 - Supraventricular tachycardia (e.g., atrial fibrillation) with a poorly controlled ventricular rate; **OR**
 - Significant irreversible brain damage; **OR**
 - The patient is not clinically stable (e.g., in shock, from any etiology); **OR**
 - LVEF not measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI) or catheter angiography; **OR**
- The device is a **subcutaneous implantable cardioverter-defibrillator system**, and **ANY** of the following³⁶:
 - Symptomatic bradycardia; **OR**
 - Incessant ventricular tachycardia; **OR**
 - Spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing; **OR**
- The device is for **cardiac resynchronization therapy (CRT)** and **ANY** of the following^{23,24,26}:
 - Non-ambulatory NYHA IV HF symptoms; **OR**
 - With LVAD in place; **OR**
 - Active systemic or local infection.

Service: Implantable Cardioverter-Defibrillator (ICD) - Medical Necessity Criteria

Administrative Guidelines for Medical Necessity Review

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity.

Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When multiple diagnostic or therapeutic procedures are requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Indications

- A **cardiac implantable rhythm management device - implantable cardioverter-defibrillator (ICD)** is considered appropriate if **ALL** of the following are **TRUE**^{1-8,12,13,17,18}:
 - **ANY** of the following conditions requiring an ICD:
 - Necessary replacement of an existing ICD due to **ANY** of the following⁴⁸:
 - End of battery life^{48,49}; **OR**
 - Elective replacement indicator (ERI)⁴⁸; **OR**
 - Device/lead malfunction⁴⁸; **OR**
 - **ALL** of the following⁵⁰:
 - ▲ Manufacturer or FDA recall of device; **AND**
 - ▲ Documentation that replacement is medically necessary; **OR**
 - Personal history of sustained ventricular tachyarrhythmia (VT) or cardiac arrest due to ventricular fibrillation (VF) and **ANY** of the following⁵:
 - An episode of sustained VT (spontaneous or induced by an electrophysiological study [EPS]) with **ALL** of the following⁵¹:
 - ▲ Not associated with an acute myocardial infarction (MI); **AND**
 - ▲ Not due to a transient or reversible cause; **OR**
 - An episode of cardiac arrest due to VF, not due to a transient or reversible cause^{5,48}; **OR**

- ☐ The patient survived a sudden cardiac arrest due to coronary artery spasm, and medical therapy is ineffective, not tolerated, or insufficient^{4-8,14,17,18,52}; **OR**
- Ischemic heart disease with unexplained syncope and **ANY** of the following^{4-8,14,17,18}:
 - ☐ Inducible sustained monomorphic VT on EPS; **OR**
 - ☐ Left ventricular ejection fraction (LVEF) less than or equal to 35%; **OR**
- Syncope presumed to be due to ventricular arrhythmia (VA) with **ANY** of the following^{4-8,14,17,18}:
 - ☐ Non-ischemic cardiomyopathy (NICM); **OR**
 - ☐ Arrhythmogenic right ventricular cardiomyopathy; **OR**
- Prior MI with **ALL** of the following^{4,7,8,17}:
 - ☐ Measured LVEF less than or equal to 30%; **AND**
 - ☐ Does not have New York Heart Association (NYHA) classification IV heart failure (HF); **AND**
 - ☐ **ANY** of the following:
 - ▲ The patient meets criteria for a cardiac pacemaker and is receiving the combined devices in the same procedure; **OR**
 - ▲ **ALL** of the following:
 - △ No coronary artery bypass graft (CABG) within the past 3 months; **AND**
 - △ No percutaneous coronary intervention (PCI) with angioplasty or stenting within the past 3 months; **AND**
 - △ No MI within the past 40 days; **AND**
 - △ No clinical symptoms or findings making the patient a candidate for coronary revascularization; **OR**
- Severe, ischemic, dilated cardiomyopathy with no personal history of sustained VT or cardiac arrest due to VF and **ALL** of the following^{24,54}:
 - ☐ NYHA class II or III heart failure; **AND**
 - ☐ LVEF less than or equal to 35%; **AND**
 - ☐ **ANY** of the following:
 - ▲ The patient meets criteria for a cardiac pacemaker and is receiving the combined devices in the same procedure; **OR**
 - ▲ **ALL** of the following:
 - △ No coronary artery bypass graft (CABG) within the past 3 months; **AND**
 - △ No percutaneous coronary intervention (PCI) with angioplasty or stenting within the past 3 months; **AND**
 - △ No MI within the past 40 days; **AND**
 - △ No clinical symptoms or findings making the patient a candidate for coronary revascularization; **OR**
- The patient has severe, non-ischemic, dilated cardiomyopathy with no personal history of sustained VT or cardiac arrest due to VF with **ALL** of the following^{24,53}:
 - ☐ NYHA Class I-III heart failure; **AND**
 - ☐ LVEF less than or equal to 35%; **AND**
 - ☐ On optimal medical therapy for greater than or equal to 3 months; **AND**
 - ☐ **ANY** of the following:
 - ▲ The patient meets criteria for a cardiac pacemaker and is receiving the combined devices in the same procedure; **OR**
 - ▲ **ALL** of the following:
 - △ No coronary artery bypass graft (CABG) within the past 3 months; **AND**

- △ No percutaneous coronary intervention (PCI) with angioplasty or stenting within the past 3 months; **AND**
 - △ No MI within the past 40 days; **AND**
 - △ No clinical symptoms or findings making the patient a candidate for coronary revascularization; **OR**
- The patient has a documented, congenital, familial, or genetic disorder with a high risk of life-threatening tachyarrhythmias (sustained VT or VF) (e.g., long QT syndrome, hypertrophic cardiomyopathy, adult congenital heart disease with severe ventricular dysfunction)^{18,27}; **OR**
- Primary prevention in a patient without a history of sudden cardiac arrest and **ANY** of the following^{4,7,8,17}:
 - Heart failure with reduced ejection fraction (HFrEF) and the patient is a candidate for **ANY** of the following:
 - ▲ Cardiac transplantation; **OR**
 - ▲ A left ventricular assist device (LVAD)^{4,8}; **OR**
 - Neuromuscular disorder (e.g., Duchenne, Becker, Emery-Dreifuss, myotonic type 1, and limb-girdle types 1B, 2C, 2F, and 2I) with **ALL** of the following^{4,8}:
 - ▲ Heart failure (HF) with NYHA class I–III symptoms; **AND**
 - ▲ LVEF of 35% or less, despite GDMT; **OR**
 - Nonischemic cardiomyopathy (NICM) due to a lamin A/C (LMNA) gene mutation with any high-risk feature (e.g., NSVT, LVEF less than 45%, non-missense mutation, male sex)⁴; **OR**
 - Arrhythmogenic right ventricular cardiomyopathy and any high-risk feature (e.g., resuscitated sudden cardiac death [SCD], sustained VT, significant ventricular dysfunction with right ventricular ejection fraction [RVEF] or LVEF less than or equal to 35%)^{4,8}; **OR**
 - Cardiac sarcoidosis and **ANY** of the following^{4,7,8,17}:
 - ▲ LVEF less than 35% with inducible sustained ventricular arrhythmia (VA) on EPS; **OR**
 - ▲ Syncope; **OR**
 - ▲ Evidence of myocardial scar by cardiac magnetic resonance imaging (MRI)/positron emission tomography (PET) scan; **OR**
 - ▲ An indication for permanent pacing; **OR**
 - Prior heart transplant and severe allograft vasculopathy with left ventricular dysfunction^{19,4}; **AND**
- **ANY** of the following implantable defibrillator types:
 - The patient requires a **subcutaneous implantable cardioverter-defibrillator system** as indicated by **ANY** of the following¹⁻⁶:
 - Transvenous defibrillator unable or failed to be placed; **OR**
 - Vascular access is limited; **OR**
 - Congenital heart disease that either limits venous access to the heart or requires intracardiac shunt²²; **OR**
 - Prior transvenous ICD infection²²; **OR**
 - On hemodialysis²²; **OR**
 - Immunocompromised; **OR**
 - At high risk for bacteremia (e.g., prior bacteremia, chronic indwelling catheters); **OR**
 - Endocarditis; **OR**
 - To preserve vascular structure for future needs²²; **OR**
 - The patient requires a **transvenous implantable cardioverter-defibrillator**.

Non-Indications

- A **cardiac implantable rhythm management device** is not considered appropriate if **ANY** of the following is **TRUE**^{2,3,5,6,12-14}.
 - Symptoms are due to a reversible cause (e.g., acute MI, drug toxicity, electrolyte imbalance) with no other indication; **OR**
 - The device is an **implantable pacemaker**, and **ANY** of the following:
 - Active systemic or local infection; **OR**
 - Permanent or persistent AF when a rhythm control strategy is not planned and implantation of an atrial lead should not be performed; **OR**
 - First-degree AV block or second-degree Mobitz type I (Wenckebach) or 2:1 AV block, which is believed to be at the level of the AV node, without symptoms or symptoms that do not temporally correspond to the AV block; **OR**
 - Prevention of AF³; **OR**
 - Treatment of sleep apnea²⁸; **OR**
 - Asymptomatic bradycardia during sleep¹⁷; **OR**
 - Syncope of undetermined cause²⁹; **OR**
 - The device is a **leadless cardiac pacemaker** and **ANY** of the following^{40,41}:
 - A dual-chamber leadless pacemaker is considered investigational and is not appropriate for any clinical scenario; **OR**
 - The patient has a co-implanted cardioverter-defibrillator (ICD)⁴²; **OR**
 - Known intolerance to the tissue-contacting materials in the device (e.g., titanium, nickel, Nitinol titanium-nickel alloy, epoxy resin)⁴³; **OR**
 - Implanted vena cava filter⁴³; **OR**
 - Reversible causes of bradycardia (e.g., electrolyte abnormalities, medications, drugs, hypothermia)^{6,44}; **OR**
 - Asymptomatic first-degree AV block^{6,44}; **OR**
 - Asymptomatic sinus bradycardia^{6,44}; **OR**
 - Asymptomatic sino-atrial block¹⁶; **OR**
 - Asymptomatic sinus arrest¹⁶; **OR**
 - Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium) without symptomatic bradycardia¹⁶; **OR**
 - Syncope of undetermined cause⁴⁵; **OR**
 - Bradycardia during sleep⁶; **OR**
 - Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block⁶; **OR**
 - Asymptomatic bradycardia in post-myocardial infarction patients about to initiate long-term beta-blocker drug therapy⁶; **OR**
 - Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of tachycardia^{46,47}; **OR**
 - A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged^{6,44}; **OR**
 - The device is an **implantable defibrillator**, and **ANY** of the following:
 - Active systemic or local infection; **OR**

- Physiological shock of any etiology; **OR**
- Non-cardiac disease, such as cancer or liver failure, that is associated with the possibility of less than 1 year of meaningful survival; **OR**
- Supraventricular tachycardia (e.g., atrial fibrillation) with a poorly controlled ventricular rate; **OR**
- Significant irreversible brain damage; **OR**
- The patient is not clinically stable (e.g., in shock, from any etiology); **OR**
- LVEF not measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI) or catheter angiography; **OR**
- The device is a **subcutaneous implantable cardioverter-defibrillator system**, and **ANY** of the following³⁶:
 - Symptomatic bradycardia; **OR**
 - Incessant ventricular tachycardia; **OR**
 - Spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing; **OR**
- The device is for **cardiac resynchronization therapy (CRT)** and **ANY** of the following^{23,24,26}:
 - Non-ambulatory NYHA IV HF symptoms; **OR**
 - With LVAD in place; **OR**
 - Active systemic or local infection.

Service: Cardiac Resynchronization Therapy (CRT) - Medical Necessity Criteria

Administrative Guidelines for Medical Necessity Review

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity.

Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When multiple diagnostic or therapeutic procedures are requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Indications

- A **cardiac implantable rhythm management device - cardiac resynchronization therapy (CRT)** without a defibrillator (CRT-P) or with a defibrillator (CRT-D, when cardioverter-defibrillator function is indicated) is considered appropriate if **ANY** of the following is **TRUE**^{1-6,9,16,23-26}:
 - Initial CRT or upgrade to CRT for **ANY** of the following:
 - LVEF less than or equal to 35% and **ALL** of the following^{23,24}:
 - Ischemic or non-ischemic cardiomyopathy; **AND**
 - LBBB (QRS duration greater than or equal to 120 ms)⁶; **AND**
 - NYHA class II, III or ambulatory IV HF on maximally tolerated GDMT for at least 3 months²⁷; **OR**
 - LVEF less than or equal to 30% (ischemic), and **ALL** of the following:
 - LBBB (QRS duration greater than or equal to 120 ms)⁶; **AND**
 - NYHA class I HF on maximally tolerated GDMT for at least 3 months²⁷; **OR**
 - Atrial fibrillation (AF), and **ALL** of the following^{11,27}:
 - **ANY** of the following:
 - ▲ AV nodal ablation (AVNA); **OR**
 - ▲ Pharmacological rate control will allow near 100% ventricular pacing with CRT; **AND**
 - LVEF less than or equal to 35% on maximally tolerated GDMT for at least 3 months; **OR**
 - High degree or complete heart block and EF 36% to 50% (applies to CRT-P only); **OR**
 - Narrow QRS (less than 120 ms) and **ALL** of the following^{23,26,14}:

- ☐ NYHA class I - ambulatory IV; **AND**
- ☐ The patient is being paced from the RV more than 40% of the time; **AND**
- ☐ LVEF less than or equal to 35% on GDMT; **OR**
- Replacement of an existing CRT generator or leads for **ANY** of the following^{23,26}:
 - Battery life depleted; **OR**
 - Elective replacement indicator (ERI); **OR**
 - Malfunction of lead or device; **OR**
 - **ALL** of the following:
 - ☐ Manufacturer or FDA recall of device; **AND**
 - ☐ Documentation that replacement is medically necessary.

Non-Indications:

- A **cardiac implantable rhythm management device** is not considered appropriate if **ANY** of the following is **TRUE**^{2,3,5,6,12-14}:
 - Symptoms are due to a reversible cause (e.g., acute MI, drug toxicity, electrolyte imbalance) with no other indication; **OR**
 - The device is an **implantable pacemaker**, and **ANY** of the following:
 - Active systemic or local infection; **OR**
 - Permanent or persistent AF when a rhythm control strategy is not planned and implantation of an atrial lead should not be performed; **OR**
 - First-degree AV block or second-degree Mobitz type I (Wenckebach) or 2:1 AV block, which is believed to be at the level of the AV node, without symptoms or symptoms that do not temporally correspond to the AV block; **OR**
 - Prevention of AF³; **OR**
 - Treatment of sleep apnea²⁸; **OR**
 - Asymptomatic bradycardia during sleep¹⁷; **OR**
 - Syncope of undetermined cause²⁹; **OR**
 - The device is a **leadless cardiac pacemaker** and **ANY** of the following^{40,41}:
 - A dual-chamber leadless pacemaker is considered investigational and is not appropriate for any clinical scenario; **OR**
 - The patient has a co-implanted cardioverter-defibrillator (ICD)⁴²; **OR**
 - Known intolerance to the tissue-contacting materials in the device (e.g., titanium, nickel, Nitinol titanium-nickel alloy, epoxy resin)⁴³; **OR**
 - Implanted vena cava filter⁴³; **OR**
 - Reversible causes of bradycardia (e.g., electrolyte abnormalities, medications, drugs, hypothermia)^{6,44}; **OR**
 - Asymptomatic first-degree AV block^{6,44}; **OR**
 - Asymptomatic sinus bradycardia^{6,44}; **OR**
 - Asymptomatic sino-atrial block¹⁶; **OR**
 - Asymptomatic sinus arrest¹⁶; **OR**
 - Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium) without symptomatic bradycardia¹⁶; **OR**
 - Syncope of undetermined cause⁴⁵; **OR**

- Bradycardia during sleep⁶; **OR**
- Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block⁶; **OR**
- Asymptomatic bradycardia in post-myocardial infarction patients about to initiate long-term beta-blocker drug therapy⁶; **OR**
- Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of tachycardia^{46,47}; **OR**
- A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged^{6,44}; **OR**
- The device is an **implantable defibrillator**, and **ANY** of the following:
 - Active systemic or local infection; **OR**
 - Physiological shock of any etiology; **OR**
 - Non-cardiac disease, such as cancer or liver failure, that is associated with the possibility of less than 1 year of meaningful survival; **OR**
 - Supraventricular tachycardia (e.g., atrial fibrillation) with a poorly controlled ventricular rate; **OR**
 - Significant irreversible brain damage; **OR**
 - The patient is not clinically stable (e.g., in shock, from any etiology); **OR**
 - LVEF not measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI) or catheter angiography; **OR**
- The device is a **subcutaneous implantable cardioverter-defibrillator system**, and **ANY** of the following³⁶:
 - Symptomatic bradycardia; **OR**
 - Incessant ventricular tachycardia; **OR**
 - Spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing; **OR**
- The device is for **cardiac resynchronization therapy (CRT)** and **ANY** of the following^{23,24,26}:
 - Non-ambulatory NYHA IV HF symptoms; **OR**
 - With LVAD in place; **OR**
 - Active systemic or local infection.

Lange et al. (2025) compared the clinical characteristics and outcomes of patients receiving cardiac resynchronization therapy (CRT) with either a pacemaker (CRT-P) or a defibrillator (CRT-D).³⁰ Of the 1603 patients receiving CRT, 95.8% (1536 patients) received a CRT-D system. Patients receiving CRT-P were significantly older, had more comorbidities, had significantly better left ventricular systolic function, and were less likely to have a history of myocardial infarction. CRT-P patients were also more likely to have a preexisting pacemaker and a history of non-ischemic cardiomyopathy. Mortality at 1-year follow-up was higher in patients treated with CRT-P than in patients treated with CRT-D for patients with ischemic cardiomyopathy only; for patients with non-ischemic cardiomyopathy, there were no differences in mortality at 1-year follow-up.

Felix et al. (2025) conducted a systematic review and meta-analysis on the use of cardiac resynchronization therapy (CRT) in patients with chronic Chagas cardiomyopathy (CCC).³¹ The authors noted that while CRT has been shown to be effective in treating both ischemic and nonischemic cardiomyopathy, its utility in patients with CCC has not been specifically investigated. Their final analysis included four observational cohort studies and 250 patients. During follow-up (mean duration 30 months), the all-cause mortality rate was 38%, cardiac death rate 29%, and noncardiac death rate 4%. A substantial proportion of patients reported relief from severe HF symptoms. The authors concluded that while CRT improved LVEF and symptomatic and functional burden, overall mortality remained high.

Gold et al. (2023) assessed the long-term safety and efficacy of subcutaneous implantable cardioverter-defibrillator (S-ICD) systems in 1,643 patients.³² The median follow-up period was 4.2 years, with 66 patients completing 5 years of follow-up. Overall defibrillation success for termination of VT/VF was high at over 98% with no reported differences across any of the assessed predictors, indicating broad utility across patients. Moreover, defibrillation success was maintained throughout the 5-year period for both discrete and storm episodes, and complication rates were low.

In collaboration with seven other societies, including the American Heart Association (AHA), the American College of Cardiology (ACC) issued the 2025 appropriate use criteria (AUC) for implantable cardioverter-defibrillators, cardiac resynchronization therapy, and pacing.¹⁴ These AUC replace the 2013 AUC, consist of over 335 indications rated according to appropriateness (appropriate, may be appropriate, rarely appropriate), and cover several device types and clinical scenarios, including sections on genetic conditions and comorbidities that may influence treatment decisions. For example, amongst patients with unexplained syncope, nonischemic heart disease, and LV hypertrophy, the appropriateness of implanting an ICD is determined by LVEF: an ICD is appropriate in patients with an LVEF less than or equal to 35%, sometimes appropriate in patients with an LVEF between 36% and 49%, and is rarely appropriate in patients with an LVEF greater than or equal to 50%.

The ACC, in association with the AHA, the American College of Clinical Pharmacy (ACCP), and the Heart Rhythm Society (HRS), has published several guidelines for the management of various cardiac rhythm disorders, including a 2024 guideline on hypertrophic cardiomyopathy (HCM) and a 2023 guideline on atrial fibrillation (AF). Per the ACC's recommendation, HCM may be appropriately treated with implantable cardioverter-defibrillators (ICDs) such as an implantable cardiac defibrillator to reduce the risk of sudden cardiac death (SCD). Patients with an existing ICD may be eligible to receive cardiac resynchronization therapy based on symptoms of worsening heart failure (HF) (left bundle branch block [LBBB], left ventricular ejection fraction [LVEF] under 50%, New York Heart Association [NYHA] class II to ambulatory class IV symptoms). The 2024 guidelines direct the optimal treatment of patients with HF with reduced ejection fraction (HFrEF) - the ACC verified that guideline-directed medical therapy (GDMT) is generally attempted for a period of at least 3 months before ventricular function is reassessed for potential augmentation by device therapy.^{11,18,27}

In 2021, the pediatric and congenital electrophysiological society (PACES), along with seven other medical societies, including the ACC, AHA, and the heart rhythm society published an expert consensus statement on indications and management of cardiovascular implantable electronic devices in pediatric patients.^{12,13} The guidelines contain indications for the use of permanent pacemakers, implantable cardioverter-defibrillators, and insertable cardiac monitors. The authors note that while indications for pacemaker implantation in adolescents and older children are often similar to those in adults, indications for infants and young children may be profoundly different. For example, a heart rate of 45 is within the normal range in an adolescent, but indicates

profound bradycardia in an infant. Several indications are therefore stated relative to age-appropriate norms. For example, permanent atrial or dual chamber pacemaker implantation is indicated for a patient with isolated sinus node dysfunction where there is a correlation of symptoms with age-appropriate bradycardia.

Kusumoto et al. (2018) published recommendations for the treatment of bradycardia in a multi-society guideline. They strongly recommended permanent pacing regardless of symptoms in patients with acquired second-degree Mobitz type II atrioventricular (AV) block, high-grade AV block, or third-degree AV block not attributable to reversible or physiologic causes. Strong recommendations were made for other patients with AV block, including those with neuromuscular disease and symptomatic bradycardia.⁶

Calkins et al. (2017) published an expert consensus statement with the HRS, the European Heart Rhythm Association (EHRA), and the European Cardiac Arrhythmia Society (ECAS) to update guidelines based on advances in AF ablation since the previous publication. It was recommended that the amount of time an individual spends in AF (24-hour AF burden) is essential to address when ablation is being considered. This is due largely to the increase in the use of implantable loop recorders, pacemakers, and ICDs.²

Al-Khatib et al. (2017) published guidelines on behalf of the AHA, ACC, and the HRS regarding the management of patients with ventricular arrhythmias (VAs) and the prevention of SCD. Various types of defibrillators were discussed, and their effectiveness in terminating life-threatening VAs. Survivors of cardiac arrest, patients with ventricular tachycardia (VT) and structural heart disease, and those with significant left ventricular (LV) dysfunction may benefit greatly from defibrillator implantation.⁴

January et al. (2014) published an evidence-based, systematic review and subsequent guidelines for the AHA, ACC, and HRS on the management of patients with atrial fibrillation. A number of recommendations were made or revised for optimum management of AF. Pacemakers are recommended in AF patients for the treatment of symptomatic bradycardia, which is often related to sick sinus syndrome. The authors stated that antiarrhythmic therapy may exacerbate sick sinus syndrome, requiring pacemaker implantation. Permanent pacing was not recommended by the group for the prevention of AF in patients without other indications for pacemaker placement. Implanted defibrillators are not recommended for AF rhythm control.³

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Policy Revision History/Information

Clinical Guideline Version	Date	Review History
Version 1	01/17/2024	Original version created
Version 2	03/15/2024	Policy criteria reviewed and updated per medical literature
Version 3	04/26/2024	Policy criteria reviewed and updated per medical literature
Version 4	12/19/2024	Annual policy review and restructure. Updated recommended clinical approach to the current format. Overall reformatting to align with current editorial standards. Removal of redundant indications. Condensed indications where applicable for clarity. Updated medical evidence section. Updated references.
Version 5	01/15/2026	Annual review. Policy name changed (formerly "Cohere Medical Policy - Cardiac Implantable Devices"). Incorporated indications for leadless cardiac pacemakers from retired Cohere policy "Leadless Cardiac Pacemakers". Added indications (pacemaker in patient with: sinus rhythm with long first-degree AV block, AV/fascicular disease, progressive neuromuscular disease, HV interval greater than 100 ms, intra- or infra- Hisian block; after failed CRT/CRT nonresponder, prior to catheter ablation of AV junction; ICD: after recent TAVR, with laminopathy, with long-QT syndrome and other risk factor for sudden cardiac death, left ventricular systolic dysfunction due to ischemic heart disease, dilated cardiomyopathy). Updated medical evidence section, including 3 peer-reviewed studies and 2 medical society guidelines.



Cohere Medical Policy – Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR)

Clinical Policy for Medical Necessity Review

Version: 2

Cohere Health UMC Approval Date: July 31, 2025

Last Annual Review: July 31, 2025

Revision: Not Applicable

Next Annual Review: July 31, 2026

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Commercial Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR)

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

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Medical Necessity Criteria

Service: Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR)

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity.

Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Carotid artery stenting (CAS) or transcarotid artery revascularization (TCAR) are less invasive procedures than carotid endarterectomy (CEA) and may be superior to CEA in patients in some clinical scenarios. These procedures must be supported by comprehensive imaging and neurological assessments and involve detailed shared decision-making to ensure optimal patient outcomes.

Medical Necessity Criteria

Indications

Carotid artery stenting (CAS) and/or transcarotid artery revascularization (TCAR) is considered appropriate if **ALL** of the following are **TRUE**^{1,2}:

- The patient has **ANY** of the following:
 - Within the past 6 months, the patient had **ALL** of the following:
 - **ANY** of the following:
 - Onset of neurologic symptoms as documented by a neurologist; **OR**
 - Documented radiographic evidence of a neurologic event; **AND**
 - The patient has **ALL** of the following:
 - Carotid artery stenosis between 50–99% by invasive or noninvasive imaging³; **AND**
 - An FDA-approved carotid stent and/or embolic protection device is being used; **OR**
 - The patient is asymptomatic with **ALL** of the following:
 - Carotid artery stenosis between 70–99% by invasive or noninvasive imaging⁴; **AND**
 - The patient has **ANY** of the following:
 - Ipsilateral stroke or TIA occurred more than 6 months ago; **OR**
 - The patient never had a neurological event; **AND**
 - Stenosis greater than or equal to 70% by invasive or noninvasive imaging; **AND**
- Imaging evaluation of carotid artery stenosis, including **ANY** of the following:
 - **ALL** of the following:
 - Duplex ultrasound demonstrates significant disease (greater than or equal to 50% for symptomatic patients, greater than or equal to 70% for asymptomatic patients); **AND**

- Degree of stenosis is confirmed by advanced imaging (computed tomography angiography [CTA] or magnetic resonance angiography [MRA])⁵⁻⁸; **OR**
- CTA, MRA, or intra-arterial digital subtraction (catheter) angiography demonstrates significant disease (greater than or equal to 50% for symptomatic patients, greater than or equal to 70% for asymptomatic patients).

Non-Indications

Carotid artery stenting (CAS) and/or transcarotid artery revascularization (TCAR) is not considered appropriate if **ANY** of the following is **TRUE**:

- A non-FDA-approved stent or embolic protection device is requested; **OR**
- Carotid artery stenosis is less than 50% (stroke or TIA within the last 6 months)⁹; **OR**
- Carotid artery stenosis less than 70% (no stroke or TIA within past 6 months)⁹; **OR**
- Chronic carotid artery stenosis of 100%; **OR**
- Severe disability caused by cerebral infarction that precludes preservation of useful function, if applicable¹⁰; **OR**
- Carotid artery stenosis determined by Duplex alone.

Level of Care Criteria

Inpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; with distal embolic protection
37216	Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; without distal embolic protection.

37217	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation
37218	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery, open or percutaneous antegrade approach, including angioplasty, when performed, and radiological supervision and interpretation

Medical Evidence

Hamouda et al. (2025) conducted a multi-institutional study on the utilization of distal embolic protection (DEP) during transcarotid artery revascularization (TCAR) with flow reversal versus transfemoral carotid artery stenting with DEP (TFCAS-DEP). Of the 99,030 patients enrolled in the study, 67% underwent TCAR followed by TFCAS-DEP (31%), TCAS-DEP (0.9%), and TFCAS-PBO (0.8%). Survival rates were higher, and postoperative neurological outcomes were lower with TCAR versus transfemoral carotid artery stenting (TFCAS) with DEP. Future research should compare TCAR with transcarotid artery stenting with DEP (TCAS-DEP).¹¹

Stonko et al. (2022) conducted a retrospective cohort study to measure the utilization of carotid revascularization procedures and the risks associated with each. Carotid endarterectomy (CEA), TFCAS, and TCAR were included in the study, which included 108,676 patients with carotid artery stenosis. Data from January 1, 2015, through December 31, 2019, were obtained from the Vascular Quality Initiative database. The most performed procedure was CEA (81,508 or 75%), followed by TFCAS (15,578 or 14.3%), and TCAR (11,590 or 10.7%). The authors noted that between 2015 and 2019, utilization of CEA decreased from 84.9% in 2015 to 64.8% in 2019. Performance of TFCAS slightly decreased between 2015 and 2019 (14.4% to 13.3%) while TCAR increased from 0.8% to 13.3%. The study demonstrated that TCAR was favored for patients at high-risk of stroke, cardiovascular events, or cranial nerve injury. In 2015, the FDA approved the first TCAR device, which also contributed to higher utilization.¹²

Nazari et al. (2021) reported on the efficacy of DEPs during carotid artery stenting (CAS) placement with respect to major adverse cardiovascular events (MACE) (e.g., death, stroke, myocardial infarction/arrhythmia) within 30 days. The American College of Surgeons National Surgical Quality Improvement Program database identified 1200 adult patients undergoing CAS between 2011 and 2018. Of the total, 23.8% did not have a DEP. Preoperative antiplatelets were used less frequently among patients without DEPs. Patients also experienced an increased need for urgent carotid artery stent placement, along with a higher incidence of major adverse cardiovascular events and strokes. The absence of DEPs during CAS placement increases the risk of perioperative stroke by four times. Despite

this, nearly 25% of patients in a national quality improvement program had the procedure without such protection. Enhanced efforts to promote the use of DEPs are necessary.¹³

Halliday et al. (2021) performed an international multicenter randomized controlled trial (RCT). The Asymptomatic Carotid Surgery Trial (ACST-2) study CAS with CEA in asymptomatic patients with severe carotid artery stenosis. Both procedures aim to reduce the risk of stroke in these patients. The trial involved 3625 patients from 130 centers, randomly assigned to either CAS or CEA. Over a mean follow-up of 5 years, both procedures showed similar rates of disabling stroke or death within 30 days of the intervention (1% each). Non-disabling procedural stroke was slightly higher with CAS compared to CEA. The 5-year rates of non-procedural stroke, including fatal or disabling strokes, were similar between the two groups. The study suggested that CAS and CEA are similarly effective in reducing the risk of long-term fatal or disabling stroke in asymptomatic patients with severe carotid artery stenosis.¹⁴

Malas et al. (2019) conducted a prospective, single-arm trial titled "Safety and Efficacy Study for Reverse Flow Used During Carotid Artery Stenting Procedure (ROADSTER)". The study reports on the one-year outcomes of a novel trans carotid neuroprotection system (NPS) called ENROUTE. The trial evaluated the safety of TCAR and its effectiveness over a year. It was a prospective, single-arm clinical trial conducted across 14 centers, enrolling patients with high-risk factors for CEA. Results showed that TCAR with the ENROUTE system was safe and effective, with a low incidence of ipsilateral stroke at one year (0.6%) and a mortality rate of 4.2%, none of which were neurologic in origin. Most patients were asymptomatic (79.9%) and had various anatomic and medical high-risk factors. TCAR demonstrated favorable outcomes perioperatively and at 1-year follow-up, suggesting it is a safe and durable option for high-risk patients compared to traditional CEA. The study attributes the promising results to the novel cerebral protection offered by the ENROUTE system and the advantages of the trans-carotid approach in avoiding aortic arch manipulation and minimizing embolization. (ClinicalTrials.gov NCT01685567).¹⁵

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Policy Revision History/Information

Original Date: April 19, 2024		
Review History		
Version 2	07/31/2025	Annual review. Rearranged bullets for improved usability and organization. Clarified the indications for onset of neurologic symptoms for improved usability and organization. Included an indication for “FDA-approved carotid stent and/or embolic protection device”. Clarified the indications for an asymptomatic patient. • Revised one indication to read “with carotid artery stenosis (CAS) between 70–99% by invasive or noninvasive imaging”. • Removed the indication for “institution and surgeon complication rates (stroke or death) is less than 3% at 30 day”. • Removed indication for “presence of anatomic or medical conditions that increase the risk for carotid endarterectomy surgery, including...carotid restenosis, radiation-induced stenosis, or surgically inaccessible lesion.” Also removed indication for “life expectancy of at least 5 years.”

		Added indications for “imaging evaluation” to include ANY of the following: • Duplex ultrasound demonstrates significant disease (greater than or equal to 50% for symptomatic patients, greater than or equal to 70% for asymptomatic patients) and the degree of stenosis is confirmed by advanced imaging CTA or MRA; OR • CTA, MRA, or intra-arterial digital subtraction (catheter) angiography demonstrates significant disease (greater than or equal to 50% for symptomatic patients, greater than or equal to 70% for asymptomatic patients). Clarified the non-indications for improved usability and organization. Added non-indications for: • A non-FDA-approved stent or embolic protection device is requested; • Carotid artery stenosis is less than 50% (stroke or TIA within the last 6 months); • Carotid artery stenosis less than 70% (no stroke or TIA within past 6 months); • Chronic carotid artery stenosis of 100%; • Severe disability caused by cerebral infarction that precludes preservation of useful function, if applicable. Added CPT 37216. Literature review – Medical Evidence section updated (Hamouda et al., 2025; Stonko et al., 2022; Nazari et al., 2021).



Cohere Medical Policy – Carotid Endarterectomy (CEA)

Clinical Policy for Medical Necessity Review

Version: 2

Cohere Health UMC Approval Date: July 10, 2025

Last Annual Review: July 10, 2025

Revision: Not Applicable

Next Annual Review: July 10, 2026

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Carotid Endarterectomy (CEA)

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

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Medical Necessity Criteria

Service: Carotid Endarterectomy (CEA)

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity.

Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Carotid endarterectomy (CEA) is a surgical procedure involving the removal of fat deposits, plaques, or the artery itself in patients whose carotid arteries may have been narrowed by atherosclerosis or carotid artery stenosis.¹ The procedure is considered standard of care for symptomatic patients and can be performed in those classified as high-risk.^{2,3}

Medical Necessity Criteria

Indications

A **carotid endarterectomy (CEA)** is appropriate if **ANY** of the following is **TRUE**⁴:

- The patient is symptomatic (defined as a stroke or transient ischemic attack [TIA] within 6 months, ideally within 14 days), with **ALL** of the following⁵⁻⁷:
 - Carotid artery stenosis between 50–99% by invasive or noninvasive imaging⁵; **AND**
 - An FDA-approved carotid stent and/or embolic protection device is being used; **OR**
- The patient is asymptomatic with carotid artery stenosis between 70–99% by invasive or noninvasive imaging.⁹

Non-Indications

A **carotid endarterectomy (CEA)** is not considered appropriate if **ANY** of the following is **TRUE**:

- The patient has an implantable device that sends electrical signals to the carotid artery (e.g., Barostim)¹⁰; **OR**
- Severe disability caused by cerebral infarction that precludes preservation of useful function.⁴

Level of Care Criteria

Inpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
35301	Thromboendarterectomy, including patch graft, if

	performed; carotid, vertebral, subclavian, by neck incision

Medical Evidence

Vasavada et al (2023) conducted a meta-analysis and systematic review to compare carotid endarterectomy (CEA) and carotid artery stenting (CAS) using research conducted between 2015 and 2023. Results indicated that CEA demonstrated better outcomes in terms of stroke events and the combined incidence of stroke or death. Conversely, CAS shows a lower incidence of myocardial infarctions compared to CEA. Overall, CEA appears to be more effective in reducing stroke events and the combined incidence of stroke or death, while CAS is associated with fewer cases of myocardial infarctions.¹

Mohd et al (2023) analyzed treatment modalities encompassing medical and surgical options such as CEA and CAS. The selection between surgical intervention and conservative management hinges on individual patient characteristics and risk profiles. The authors reviewed the pathophysiology of carotid artery stenosis, associated risk factors, the importance of timely diagnosis and treatment, and the approaches of CEA and CAS. Evidence indicated that CEA offers notable advantages to patients with moderate to severe stenosis. Efficacy appears limited in patients exhibiting less than 50% stenosis. CEA demonstrated pronounced efficacy among patients with severe stenosis, particularly in cases of high-grade severity. The advantage of CEA diminishes with prolonged intervals following the initial ischemic event, with a more notable effect observed in female patients. Recent guidelines for secondary stroke prevention recommend scheduling CEA within a two-week window for individuals who have encountered a transient ischemic attack (TIA) or minor stroke.¹¹

AbuRahma et al (2022) performed a meta-analysis of the guidelines published by the Society for Vascular Surgery. The guidelines were based on several randomized trials comparing CEA and CAS. Since then, additional studies and systematic reviews have been published to reaffirm the importance of medical management alongside surgical interventions. Key areas explored were CEA versus maximal medical therapy for low-risk patients and CEA versus transfemoral CAS for low-surgical-risk patients with symptomatic carotid artery stenosis greater than 50%. The guidelines also address the timing of carotid intervention for patients presenting with acute

stroke, screening for carotid artery stenosis in asymptomatic patients, and the optimal sequence of intervention for patients with combined carotid and coronary artery disease (CAD). The primary treatment for symptomatic low-risk surgical patients (with stenosis of 50–99% and 70–99% if asymptomatic) is CEA. The perioperative CEA risk of stroke and death in asymptomatic patients should be less than 3% to ensure benefits. For patients with recent stable stroke, carotid revascularization is considered appropriate for those with greater than 50% stenosis and should be performed once the patient is neurologically stable after 48 hours but less than 14 days after symptom onset. For patients requiring both CEA and coronary artery bypass grafting (CABG), CEA is suggested before or concurrent with CABG to reduce the risk of stroke and stroke/death potentially. The sequencing of intervention depends on clinical presentation and institutional experience.⁵

Routine screening for asymptomatic carotid artery stenosis in patients without cerebrovascular symptoms or significant risk factors is not recommended unless significant stenosis is detected.⁵ For asymptomatic patients, social and demographic factors such as age, sex, life expectancy, and comorbidities should be carefully considered prior to carotid revascularization. Surgical benefits for asymptomatic patients may now be less than previously anticipated in earlier randomized trials (from the 1990s and 2000s), and the 3% complication rate should be interpreted with consideration for current advances in medical therapy.⁴

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Policy Revision History/Information

Original Date: April 5, 2024		
Review History		
Version 2	07/10/2025	Annual review. No additions to medical necessity criteria or procedure codes. Removed indication for a symptomatic patient - "acceptable institution and surgeon complication rate of less than 6%". Removed indication for an asymptomatic patient - "there is documentation that the patient prefers surgery over medical management and risk factor modification." Removed indication for an asymptomatic patient - "acceptable institution and surgeon complication rates (less than 3%)." Removed indication for an asymptomatic patient - "acceptable long-term survival (greater than or equal to 5 years)." Removed non-indication for a patient who is at high-risk for perioperative complications, including ANY of the following: • Left ventricular ejection fraction less than 30%; OR

		• NYHA class III/IV heart failure; OR • Severe coronary artery disease (CAD); OR • Severe pulmonary disease Added non-indication - "The patient has an implantable device that sends electrical signals to the carotid artery (e.g., Barostim)."



Cohere Medical Policy – Carotid Sinus Stimulators

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: December 19, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Carotid Sinus Stimulators

Date of last literature review: 12/18/2024
Document last updated: 12/18/2024
Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Carotid Sinus Stimulators

Recommended Clinical Approach

This service is clinically unproven and not medically necessary. This policy addresses carotid sinus nerve stimulators for hypertension and heart failure only; however, there may be indications in other specialties where this treatment is considered medically necessary and supported by the medical literature.

Medical Necessity Criteria

Indications

- **Carotid sinus stimulators** are 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

- **Carotid sinus stimulators** are not considered appropriate if **ANY/ALL** of the following is **TRUE**:
- ◆ This is not applicable, as there are no indications.

Level of Care Criteria

None

Procedure Codes (HCPCS/CPT)

HCPCS/CPT Code	Code Description
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)

0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)
0269T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)
0270T	Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)
0271T	Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)
0272T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (e.g., battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day);
0273T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (e.g., battery status, lead impedance,

	pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming
C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)

Medical Evidence

Autonomic nervous system modulation has been developed to diminish excessive sympathetic response that characterizes disease conditions such as uncontrolled hypertension and heart failure. Trials with direct vagal nerve and spinal cord stimulation have shown poor performance. Increased vagal tone through carotid sinus baroreflex activation systems was developed as an improved approach. The BAROSTIM NEO system CVRx was developed and subsequently approved by the US Food and Drug Administration (FDA) for first in man trial BeAT-HF trial (NCT 02627196).¹

In the INOVATE-HF trial (Gold et al, 2016) baroreceptor activation therapy (BAT) did not improve rates of death or heart failure (HF) events. The BeAT-HF trial in 2020 was a randomized, non-blinded study of 408 patients (Zile et al., 2020) that showed improvement in symptoms and quality of life; however, it was not designed to measure changes in mortality or CHF hospitalization.²

Societies such as the American College of Cardiology have published recommendations regarding BAT. The 2022 guideline for the American College of Cardiology/American Heart Association/Heart Failure Society of America (ACC/AHA/HFSA) by Heidenreich et al. concluded that while early results to date were promising, the largest trial published in 2020 did not show a reduction in mortality or heart failure hospitalizations.³

Additionally, the 2021 guidelines for the European Society of Cardiology for diagnosing and treating acute and chronic HF (McDonagh et al.) state that baroreflex therapy shows potential for improved quality of life, reduced mortality, and reduced rates of hospitalization. However, it was concluded that current evidence was insufficient to support guideline recommendations given the lack of evidence showing a reduction in CHF hospitalization or mortality.⁴

On behalf of the American Heart Association (AHA), Carey et al. published a 2018 scientific statement on detecting, evaluating, and managing resistant hypertension. A randomized trial of 322 patients with resistant hypertension

failed to meet the primary trial end point; however, the device was found to be safe and efficacious in the long term for resistant hypertension.⁵

The National Institute for Health and Care Excellence (NICE) published guidance on *Implanting a Baroreceptor Stimulation Device for Resistant Hypertension*. Based on current evidence, the efficacy of the treatment is not yet proven. The reviewing committee considered separate evidence for unilateral and bilateral implantation, with much of the available evidence at the time based upon bilateral usage. The committee also noted that medication non-compliance is an important factor to consider in resistant hypertension trials.⁶

In total, there is insufficient evidence to date that baroreflex activation therapy (BAT) therapy with carotid sinus stimulators improves hard clinical outcomes in the setting of other proven therapies such as guideline-directed medical therapy (GDMT) and cardiac resynchronization therapy.

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Clinical Guideline Revision History/Information

Original Date: August 30, 2023		
Review History		
Version 2	12/19/2024	Annual review. No changes to medical necessity criteria or procedure codes.



Catheter-Based Angiogram, Lower Extremity Arteries – Single Service

Clinical Guidelines for Medical Necessity Review

Version: 1.0
Effective Date: May 23, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Catheter-Based Angiogram, Lower Extremity Arteries (Single Service)

Literature review current through: 5/20/2024

Document last updated: 5/24/2024

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

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Medical Necessity Criteria

Service: Catheter-Based Angiogram, Lower Extremity Arteries

General Guidelines

- **Units, Frequency, & Duration:** Once.
- **Criteria for Subsequent Requests:** Repeat imaging may be appropriate if there is a significant clinical change since the initial imaging study/intervention.
- **Recommended Clinical Approach:**
 - Catheter-based angiography may be appropriate as the initial advanced imaging modality when the clinician determines that there is a high likelihood that the patient is a candidate for a minimally invasive intervention (e.g., angioplasty, atherectomy, or stent placement).¹
 - The ordering clinician must provide appropriate documentation of clinical indication. This should include a pertinent history to justify the request.
 - Multi-view fluoroscopy usually provides adequate imaging of the arterial anatomy to plan and perform arterial interventions.
 - IVUS can provide additional anatomic information (i.e., vessel diameter and plaque anatomy), which can improve the effectiveness of arterial interventions.
- **Exclusions:** None.

Medical Necessity Criteria

Indications

- **Catheter-based angiogram, lower extremities** is considered appropriate if **ANY** of the following are **TRUE**^{1,2}:
- ◆ The patient is experiencing **chronic limb-threatening ischemia** and **ANY** of the following is **TRUE**³:
 - Gangrene is present; **OR**
 - The patient is experiencing pain at rest*; **OR**
 - The patient has a wound that has not healed (50% or greater healing achieved from appropriate medical therapy of at least four weeks' duration) related to ischemia; **OR**
 - ◆ The patient is experiencing **non-limb-threatening** peripheral artery disease (PAD); **AND**

- The patient fails to show significant clinical improvement despite documented compliance with optimal medical care, including **ALL** of the following^{4,5}:
 - Smoking cessation (attempted or achieved); **AND**
 - Weight management; **AND**
 - Glycemic control; **AND**
 - Statin therapy; **AND**
 - Blood pressure management; **AND**
 - Supervised exercise program; **AND**
 - Pharmacotherapy (anti-platelet, cilostazol); **AND**
- The patient reports their symptoms to be lifestyle-limiting; **AND**
- Revascularization is being considered; **AND**
- **ANY** of the following is **TRUE**:
 - MRA, CTA, Doppler testing is abnormal (suggesting greater than 75% stenosis) or has not achieved diagnostic results; **OR**
 - Noninvasive testing is unavailable; **OR**
 - Invasive angiogram has been considered an appropriate initial test; **OR**
 - Noninvasive studies for anatomic assessment (e.g., CTA and/or MRA) are perceived to be a greater risk to the patient than invasive angiography.²

*Ischemic rest pain is typically described as affecting the forefoot and is often made worse with recumbency while being relieved by dependency. It should be present for greater than 2 weeks and be associated with one or more abnormal hemodynamic parameters. These parameters include an ankle-brachial index (ABI) less than 0.4 (using higher of the dorsalis pedis [DP] and posterior tibial [PT] arteries), absolute highest AP less than 50 mm Hg, absolute TP less than 30 mm Hg, transcutaneous partial pressure of oxygen (TcPO₂) less than 30 mm Hg, and flat or minimally pulsatile pulse volume recording (PVR) waveforms (equivalent to Wifl ischemia grade 3).³

Non-Indications

- **Catheter-based angiogram, lower extremities** is not considered appropriate if **ANY** of the following is **TRUE**¹⁻⁶:
- ◆ The patient is unwilling to undergo interventional therapy if angiography discovers disease; **OR**
 - ◆ The risk of the procedure is judged to be high because of concurrent medical problems.

NOTE: Catheter-based angiogram, lower extremities may not be considered appropriate if **ANY** of the following is **TRUE**^{1,7}:

- ◆ Severe allergy to contrast media; **OR**

- ◆ Severe renal insufficiency; **OR**
- ◆ The patient is pregnant; **OR**
- ◆ The patient uses metformin; **OR**
- ◆ There was prior vascular surgery at the proposed access site (e.g., femoral access at the site of a prior femoral reconstruction); **OR**
- ◆ There is a known or suspected arterial aneurysm or significant vascular anomaly (e.g., AV fistula) at the proposed access site.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description/Definition
36245	Insertion of catheter into first order abdominal branch of artery, within a vascular family
36246	Insertion of catheter into initial second order abdominal branch of artery, within a vascular family
36247	Insertion of catheter into initial third order abdominal branch of artery, within a vascular family
37252	Radiologic supervision and interpretation with the IVUS procedure and are used for procedures involving both arteries and/or veins. Reported once per procedure for the first vessel studied with IVUS.
37253	Radiologic supervision and interpretation with the IVUS procedure and are used for procedures involving both arteries and/or veins. Each initial vessel.
75716	Angiography, extremity, bilateral, radiological
75710	Angiography, extremity, unilateral, radiological

Medical Evidence

Gerhard-Herman et al. (2017) developed the 2016 AHA/ACC guideline for the management of patients with lower extremity peripheral artery disease. Invasive angiography is recommended in a patient with critical limb ischemia in whom revascularization is considered. This was a Class I (Strong) recommendation with Level of Evidence as Expert Opinion. Use of noninvasive imaging can create a delay in crucial treatment for the patient. A Class IIa (Moderate Strength of Recommendation) Level of Evidence Expert Opinion rating was given to invasive angiography in patients with lifestyle-limiting claudication with an inadequate response to guideline-directed medical treatment (GDMT) when revascularization is being considered. The risk of invasive angiography can be less than noninvasive studies, particularly in the setting of advanced chronic kidney disease, as the contrast dose is lower in the invasive scenario. The committee concluded that invasive and noninvasive angiography is not recommended in asymptomatic peripheral arterial disease (Class of Recommendation: Harm; Level of Evidence B-R (Randomized)).²

Woo and colleagues (2022) published the Society of Vascular Surgery appropriate use criteria for management of intermittent claudication. 2280 unique intermittent claudication treatment scenarios were rated. Invasive treatment recommendations were made for patients who have completed exercise therapy, are nonsmokers, and are on optimal medical therapy with severe lifestyle limitations. The group stated that there is unclear benefit and possible harm related to invasive intervention in the infrapopliteal segment for intermittent claudication.³

Conte et al. (2019) developed global vascular guidelines for the management of chronic limb-threatening ischemia. The group proposed a new anatomic scheme for threatened limbs, the Global Limb Anatomic Staging System (GLASS). This integrated, limb-based approach is based on a set of clinical assumptions and simplified approaches to stratification. They make a strong recommendation for revascularization to all average-risk patients with advanced limb-threatening conditions and significant perfusion deficits. There was a weak recommendation for revascularization in average-risk patients with intermediate limb threat (based on a scoring tool such as Wlfi).

It is stated that more in-depth study is required regarding the relationship between regional ischemia and patterns of infrapopliteal and pedal disease.³

References

1. Patel MR, Bailey SR, Bonow RO, et al. ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/ HRS/SCCM/SCCT/SCMR/STS 2012 appropriate use criteria for diagnostic catheterization: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society of Critical Care Medicine, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. 2012;59(22):1995–2027. doi:10.1016/j.jacc.2012.03.003.
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Clinical Guideline Revision History/Information

Original Date: May 23, 2024	
Review History	



Cohere Medical Policy – Catheter-Based Angiogram, Lower Extremity Arteries

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: August 6, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medical Policy – Catheter-Based Angiogram, Lower Extremity Arteries

Literature review current through: 8/6/2024

Document last updated: 8/6/2024

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

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Medical Necessity Criteria

Service: Catheter-Based Angiogram, Lower Extremity Arteries

General Guidelines

- **Units, Frequency, & Duration:** Once.
- **Criteria for Subsequent Requests:** Repeat imaging may be appropriate if there is a significant clinical change since the initial imaging study/intervention.
- **Recommended Clinical Approach:**
 - Catheter-based angiography may be appropriate as the initial advanced imaging modality when the clinician determines that there is a high likelihood that the patient is a candidate for a minimally invasive intervention (e.g., angioplasty, atherectomy, or stent placement).¹
 - The ordering clinician must provide appropriate documentation of clinical indication. This should include a pertinent history to justify the request.
 - Multi-view fluoroscopy usually provides adequate imaging of the arterial anatomy to plan and perform arterial interventions.
 - IVUS can provide additional anatomic information (i.e., vessel diameter and plaque anatomy), which can improve the effectiveness of arterial interventions.
- **Exclusions:** None.

Medical Necessity Criteria

Indications

- **Catheter-based angiogram, lower extremities** is considered appropriate if **ANY** of the following is **TRUE**^{1,2}:
- ◆ The patient is experiencing chronic limb-threatening ischemia or acute limb ischemia, and **ANY** of the following is **TRUE**³:
 - Wound due to arterial insufficiency that has not healed despite wound care, and documentation of **ANY** of the following:
 - Stenosis greater than or equal to 75% by CT or MR angiography; **OR**
 - PSV greater than or equal to 300 cm/sec or PSV ratio greater than or equal to 4; **OR**
 - ABI less than or equal to 0.4; **OR**
 - Flat or minimally pulsatile PVR (pulse volume recording) waveforms; **OR**

- Ischemic rest pain with pain in the forefoot relieved with dependency and lasting more than 2 weeks, and **ANY** of the following is **TRUE**³:
 - ABI less than or equal to 0.4; **OR**
 - Highest ankle pressure of less than or equal to 50 mm Hg; **OR**
 - Absolute toe pressure of less than or equal to 30 mm Hg; **OR**
 - TcPO₂ (transcutaneous partial pressure of oxygen less than or equal to 30 mm Hg; **OR**
 - Flat or minimally pulsatile PVR (pulse volume recording) waveforms; **OR**
- Gangrene is present; **OR**
- Acute limb ischemia (sudden loss of blood supply typically due to embolization or dissection); **OR**
- ◆ The patient is experiencing intermittent claudication, and **ALL** of the following are **TRUE**:
 - The patient fails to show significant clinical improvement despite documented compliance with optimal medical care, including **ALL** of the following^{4,5}:
 - **ANY** of the following:
 - ◆ Smoking cessation (attempted or achieved); **OR**
 - ◆ The patient is a non-smoker; **AND**
 - Weight management; **AND**
 - Glycemic control; **AND**
 - Statin therapy; **AND**
 - Blood pressure management; **AND**
 - Supervised exercise program; **AND**
 - Pharmacotherapy (anti-platelet, cilostazol); **AND**
 - Revascularization is being considered; **AND**
 - The patient reports their symptoms to be lifestyle-limiting; **AND**
 - **ANY** of the following is **TRUE**:
 - ABI's are equal to or less than 0.4; **OR**
 - Stenosis greater than or equal to 75% by CT or MR angiography; **OR**
 - PSV greater than or equal to 300 cm/sec or PSV ratio greater than or equal to 4; **OR**
 - Examination of pulses shows strong evidence of femoral level and below disease (no pulses felt at the femoral level); **OR**
- ◆ The patient has **ANY** of the following:
 - Aneurysm; **OR**
 - Pseudoaneurysm; **OR**

- Dissection; **OR**
- Symptomatic or asymptomatic in-stent restenosis (greater than or equal to 50%); **OR**
- Threatened bypass graft and **ANY** of the following (approve only for PTA/stenting) is **TRUE**:
 - Drop in ABI of 0.15 or greater; **OR**
 - Stenosis in graft/inflow or outflow of greater than 50% by LEAD; **OR**
 - Symptomatic or asymptomatic.
- Planned procedure requiring vascular access when there is a significant stenosis (ex. Access for EVAR or TAVR)

Non-Indications

→ **Catheter-based angiogram, lower extremities** is not considered appropriate if **ANY** of the following is **TRUE**¹⁻⁶:

- ◆ The patient is unwilling to undergo interventional therapy if angiography discovers disease; **OR**
- ◆ The risk of the procedure is judged to be high because of concurrent medical problems.

NOTE: Catheter-based angiogram, lower extremities may not be considered appropriate if **ANY** of the following is **TRUE**^{1,7}:

- ◆ Severe allergy to contrast media; **OR**
- ◆ Severe renal insufficiency; **OR**
- ◆ The patient is pregnant; **OR**
- ◆ The patient uses metformin; **OR**
- ◆ There was prior vascular surgery at the proposed access site (e.g., femoral access at the site of a prior femoral reconstruction); **OR**
- ◆ There is a known or suspected arterial aneurysm or significant vascular anomaly (e.g., AV fistula) at the proposed access site.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description/Definition
36245	Insertion of catheter into first order abdominal branch of artery, within a vascular family
36246	Insertion of catheter into initial second order abdominal

	branch of artery, within a vascular family
36247	Insertion of catheter into initial third order abdominal branch of artery, within a vascular family
37252	Radiologic supervision and interpretation with the IVUS procedure and are used for procedures involving both arteries and/or veins. Reported once per procedure for the first vessel studied with IVUS.
37253	Radiologic supervision and interpretation with the IVUS procedure and are used for procedures involving both arteries and/or veins. Each initial vessel.
75716	Angiography, extremity, bilateral, radiological
75710	Angiography, extremity, unilateral, radiological

Medical Evidence

Gerhard-Herman et al. (2017) developed the 2016 AHA/ACC guideline for the management of patients with lower extremity peripheral artery disease. Invasive angiography is recommended in a patient with critical limb ischemia in whom revascularization is considered. This was a Class I (Strong) recommendation with Level of Evidence as Expert Opinion. Use of noninvasive imaging can create a delay in crucial treatment for the patient. A Class IIa (Moderate Strength of Recommendation) Level of Evidence Expert Opinion rating was given to invasive angiography in patients with lifestyle-limiting claudication with an inadequate response to guideline-directed medical treatment (GDMT) when revascularization is being considered. The risk of invasive angiography can be less than noninvasive studies, particularly in the setting of advanced chronic kidney disease, as the contrast dose is lower in the invasive scenario. The committee concluded that invasive and noninvasive angiography is not recommended in asymptomatic peripheral arterial disease (Class of Recommendation: Harm; Level of Evidence B-R (Randomized)).²

Woo and colleagues (2022) published the Society of Vascular Surgery appropriate use criteria for management of intermittent claudication. 2280 unique intermittent claudication treatment scenarios were rated. Invasive treatment recommendations were made for patients who have completed exercise therapy, are nonsmokers, and are on optimal medical therapy with severe lifestyle limitations. The group stated that there is unclear benefit and possible harm related to invasive intervention in the infrapopliteal segment for intermittent claudication.³

Conte et al. (2019) developed global vascular guidelines for the management of chronic limb-threatening ischemia. The group proposed a new anatomic scheme for threatened limbs, the Global Limb Anatomic Staging System (GLASS). This integrated, limb-based approach is based on a set of clinical assumptions and simplified approaches to stratification. They make a strong recommendation for revascularization to all average-risk patients with advanced limb-threatening conditions and significant perfusion deficits. There was a weak recommendation for revascularization in average-risk patients with intermediate limb threat (based on a scoring tool such as Wlfi).

It is stated that more in-depth study is required regarding the relationship between regional ischemia and patterns of infrapopliteal and pedal disease.³

References

1. Patel MR, Bailey SR, Bonow RO, et al. ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/ HRS/SCCM/SCCT/SCMR/STS 2012 appropriate use criteria for diagnostic catheterization: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society of Critical Care Medicine, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. 2012;59(22):1995–2027. doi:10.1016/j.jacc.2012.03.003.
2. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease. *J Am Coll Cardiol*. 2017;69 (11). <http://dx.doi.org/10.1016/j.jacc.2016.11.007>.
3. Conte MS, Bradbury AW, Kolh P, et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. *J Vasc Surg*. 2019;69(6):3S–125S.e40. doi:10.1016/j.jvs.2019.02.016.
4. Klein AJ, Jaff MR, Gray BH, et al. SCAI appropriate use criteria for peripheral arterial interventions: an update. *Catheter Cardiovasc Interv*. 2017;90(4): E90–E110.
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Clinical Guideline Revision History/Information

Original Date: May 23, 2024		
Review History		
Version 2	8/6/2024	Updated indications, non-indications, references



Cohere Medical Policy – Coronary Atherectomy

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: January 2, 2025

Important Notices

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Guideline Information:

Disease Area: Cardiovascular Disease

Guideline Name: Coronary Atherectomy

Date of last literature review: 10/24/2024

Document last updated: 01/02/2025

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

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Medical Necessity Criteria

Service: Coronary Atherectomy

Recommended Clinical Approach

Coronary atherectomy is a percutaneous coronary intervention (PCI) that removes or ablates atheromatous (composed of fatty material) coronary plaque by cutting, drilling, shaving, pulverizing, lasing, or sanding to achieve improved compliance of the wall of the blood vessel and patency of the treated lumen. Three atherectomy devices are approved and are characterized by their mode of action: 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 stand-alone treatments. 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 eccentric lesions, 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 atherectomy devices (cutting and scoring balloons) and intracoronary lithotripsy.¹⁴⁻¹⁷

In patients with multivessel coronary artery disease (CAD) with multiple vessels requiring treatment, treatment of additional coronary lesions may be needed over several procedures. Staging may be needed if: 1) the patient has chronic kidney disease and it is necessary to limit contrast dose; or 2) if the initial procedure reached the recommended limit of contrast dose or radiation exposure; or 3) if there is a complication during the initial procedure that requires a delay in treatment of subsequent lesions.

An atherectomy is usually performed as a single service; however, under certain circumstances, one or more additional services may be needed within 1-2 months.

Medical Necessity Criteria

Indications

→ A **coronary atherectomy** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The patient is undergoing percutaneous coronary intervention (PCI) and **ANY** of the following is **TRUE**:
 - After successful wire crossing to treat balloon uncrossable lesions; **OR**
 - Lesions in which the balloon fails to expand or dilate the lesion (including chronic total occlusions [CTOs]) to facilitate successful PCI [6,10-11,18](#); **OR**
 - Rotational atherectomy to treat **ANY** of the following:
 - PCI of fibrotic or heavily calcified lesions to achieve plaque modification to improve procedural success [1-2-3,7,10-11](#); **OR**
 - In-stent restenosis lesions to facilitate successful PCI [8-11,18](#); **OR**
 - Aorto ostial or branch ostial stenoses (bifurcations) to debulk lesions and facilitate successful PCI [10-11,18-19](#); **OR**
 - Under-expanded stents in lesions previously treated with stents to allow full expansion and reduce subsequent cardiac events (stent thrombosis or restenosis) [10-13](#); **OR**
 - Orbital atherectomy for a patient undergoing PCI of fibrotic or heavily calcified lesions to achieve plaque modification to improve procedural success [14-6,18](#); **OR**
 - Excimer laser atherectomy to treat **ANY** of the following:
 - In-stent restenosis lesions to facilitate successful PCI [8-11,18](#);
 - Aorto ostial or branch ostial stenoses (bifurcations) to debulk lesions and facilitate successful PCI [10-11,18-19](#); **OR**
 - Under-expanded stents in lesions previously treated with stents to allow full expansion and reduce subsequent cardiac events (stent thrombosis or restenosis) [10-13](#); **OR**
 - Saphenous vein graft lesions or to treat large thrombus burden in native coronary arteries [18](#); **OR**
 - The patient is undergoing PCI of fibrotic or heavily calcified lesions to achieve plaque modification to improve procedural success. [14-6,18](#)

Non-Indications

→ **A coronary atherectomy** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The patient does not have an indication for coronary artery revascularization; **OR**
- ◆ The facility where the procedure is to be performed does not meet **ANY** of the following²⁰:
 - There is no emergency cardiac surgery backup; **OR**
 - Absence of a transfer agreement with a cardiac surgery facility; **OR**
 - Absence of a proven plan to transfer to a facility with cardiac surgery back up within an acceptable time frame; **OR**
- ◆ The procedure is intended to be performed in the setting of a significant coronary artery dissection; **OR**
- ◆ The lesion is not successfully crossed by a guidewire; **OR**
- ◆ The patient is undergoing routine atherectomy and **ANY** of the following is **TRUE**:
 - The lesion is not heavily calcified by angiography; **OR**
 - Does not meet the criteria by intravascular ultrasound (IVUS) or optical coherence tomography (OCT) that predicts 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 under expansion)²¹⁻²²; **OR**
 - Has not been first treated with full inflation and expansion of an appropriately sized balloon; **OR**
- ◆ Orbital atherectomy is performed in **ANY** of the following:
 - A previously stented lesion (in-stent restenosis); **OR**
 - A saphenous vein graft lesion; **OR**
 - The setting of large clot burden; **OR**
- ◆ Rotational atherectomy is performed in **ANY** of the following:
 - A saphenous vein graft lesion; **OR**
 - The setting of large clot burden; **OR**
- ◆ The patient can be managed medically; **OR**
- ◆ The patient has **ANY** of the following:

- Presence of comorbid conditions (e.g., advanced malignancy, active bleeding, acute renal failure, acute systemic infections); **OR**
- Stable coronary artery disease (CAD) and chronic kidney disease (CKD), and the patient is asymptomatic with no compelling indication.¹

Level of Service Criteria

Inpatient or outpatient

Procedure Codes (CPT/HCPCS)

CPT/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
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)
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
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)
C1724	Catheter, transluminal atherectomy, rotational

Medical Evidence

Khan et al. (2019) conducted a meta-analysis to compare the safety and efficacy of rotational atherectomy (RA) performed using trans-radial (TR) and transfemoral (TF) access to evaluate the widespread reluctance to use TR access for complex percutaneous coronary intervention (PCI), including RA, for heavily calcified coronary lesions. The meta-analysis includes 5 retrospective studies with 3315 patients undergoing RA via TR access and 5838 patients undergoing RA via TF access. TR access was associated with lower major access site bleeding (OR: 0.45, 95% CI: 0.31–0.67, P less than 0.001) and radiation exposure (MD: -16.1, 95% CI: -25.4--6.7 Gy cm², P equal to 0.0007). No significant differences were observed in all-cause in-hospital mortality, major adverse cardiac events (MACE), stent thrombosis, myocardial infarction, hospital stay, procedure time, or procedure success between the two groups.²⁴

Schwarz et al. (2022) conducted a systematic review and meta-analysis to compare periprocedural characteristics and outcomes of planned atherectomy (PA), bailout atherectomy (BA), and RA. PA is defined as RA performed immediately prior to balloon pre-dilation, while BA is defined as RA after failure to expand a pre-dilating balloon. Pooling 2120 patients from 5 studies, the authors found no difference in procedural success (PA vs BA risk ratio [RR] 1.03; 95% confidence interval [95% CI] 0.99–1.07), major adverse cardiovascular events on follow-up (RR 1.04, 95% CI 0.62–1.74), death (RR 0.98, 95% CI 0.59–1.64), myocardial infarction (MI) (RR 1.16, 95% CI 0.62–2.18), target vessel re-vascularization (RR 1.40, 95% CI 0.83 to 2.36), stroke (RR 1.50, 95% CI 0.46–4.86), or stent thrombosis (RR 0.82, 95% CI 0.06–10.74). However, compared to BA, PA was associated with shorter procedural times (mean difference [MD] -25.88 min, 95% CI -35.55 to -16.22), fewer coronary dissections (RR 0.50, 95% CI 0.26–0.99), fewer stents (MD -0.20, 95% CI -0.29 to -0.11), and a trend toward less periprocedural MI (RR 0.77, 95% CI 0.54–1.11).²⁵

Abusnina et al. (2022) conducted a systematic review to evaluate the clinical outcomes of atherectomy in treating coronary artery calcification (CAC) in patients with reduced left ventricular ejection fraction (LVEF). The review includes 7 studies involving 2,238 unique patients with a median follow-up duration of 22.4 months. Comparing patients with severely reduced LVEF

compared to those with moderately reduced or preserved LVEF, the authors found the risk ratio (RR) of in-hospital all-cause mortality using atherectomy was 5.28 (95% CI 1.65–16.84; *P* equal to 0.005) and RR for long term all-cause mortality was 2.84 (95% CI 1.16–6.95; *P* equal to 0.02). The results indicate that treating severe CAC with atherectomy in patients with severely reduced LVEF had significantly higher in-hospital and long-term all-cause mortality risks compared to the patients with moderate or preserved LVEF. While there was no significant difference in in-hospital cardiac mortality between the two groups, long-term cardiac mortality was significantly higher in patients with severe CAC and severely reduced LVEF who underwent atherectomy.^{[26](#)}

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Clinical Guideline Revision History/Information

Original Date: July 1, 2023		
Review History		
Version 2	01/02/2025	• Version 1 of this policy included coronary artery atherectomy and intracoronary lithotripsy. • Intracoronary lithotripsy (non-covered) was split into a separate policy – see policy <i>Coronary Intravascular Lithotripsy (IVL)</i>. • This annual review builds upon the 2023 atherectomy draft. • The policy was restructured according to updated guidelines. • Medical evidence was added. • Indications were updated and restructured for rules conversion: ○ “ANY of the following” was added in this indication statement: “Rotational atherectomy to treat ANY of the following:” ○ New references were added: Khan et al, 2019 (for rotational atherectomy), Lawton et al, 2021 (ACC guidelines); Abusinina et al, 2022. ○ All abbreviations were expanded at first use. • Clinical approach was updated. • All existing references were updated and new references added. • Updates to CPT/HCPCS procedure codes.



Cohere Medical Policy - Coronary Intravascular Lithotripsy (IVL)

Clinical Policy for Medical Necessity Review

Version: 3

Policy Number: CHP-308-3

Cohere Health UMC Approval Date: January 15, 2026

Last Annual Review: January 15, 2026

Revision: Not Applicable

Next Annual Review: January 15, 2027

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Coronary Intravascular Lithotripsy (IVL)

Policy Number: CHP-308-1

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

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Medical Necessity Criteria

Service: Coronary Intravascular Lithotripsy (IVL)

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

This service is clinically unproven and not medically necessary. The current coronary intravascular lithotripsy (IVL) device received premarket approval for use on severely calcified, stenotic de novo coronary artery lesions. Coronary lithotripsy is intended to disrupt calcified coronary plaques with sonic pressure waves to facilitate coronary stenting. Because IVL does not yet have long-term efficacy results, nor a diverse range of randomized, controlled, double-blinded trials of statistical rigor, it is considered premature to presume clinical outcomes and benefits.¹⁻¹⁶

Medical Necessity Criteria

Indications

Coronary intravascular lithotripsy 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

Coronary intravascular lithotripsy may not be 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
92972	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)
C1761	Catheter, transluminal intravascular lithotripsy, coronary

Medical Evidence

The Society for Cardiovascular Angiography Interventions (2024) published an expert consensus statement to guide the management of calcified coronary lesions. The statement discussed intravascular lithotripsy (IVL) in a number of clinical capacities and concluded that IVL is safe and effective, with the explicit caveat that there is presently limited available data and no comparative studies. IVL is included in their treatment algorithm for calcified coronary disease alongside atherectomy and specialty balloons. Several multicenter studies, including randomized controlled trials, are currently underway to examine the use of IVL and will further elucidate its role in high-risk patient populations. Although IVL will likely become an adjunct tool in the management of challenging calcified coronary disease, it lacks the long-term safety and efficacy data necessary to recommend its use at this time.^{12,13}

A 2024 study examining sex differences between 454 IVL patients (75% males, 25% females) found relative parity of procedural success and adverse events. At one year post-procedure, 13% of all patients had experienced a major adverse cardiac event (e.g., cardiac death, myocardial infarction, target vessel repeat revascularization). Other plaque disruption techniques were employed in 17% of all patients.⁶

Mhanna et al. (2022) performed a meta-analysis evaluating the utility of adjunctive intravascular lithotripsy for treating calcified coronary lesions. Eight single-arm observational studies with 980 patients (1011 lesions) were included. Almost half of the patients had a diagnosis of acute coronary syndrome. Severe calcification was found in 97% of all lesions. The authors note that additional studies should focus on evaluating IVL against other calcium/plaque-modifying techniques.²

Sattar et al. (2022) evaluated the use of IVL for calcified lesions in 760 patients in seven studies. While positive outcomes were reported, limitations were identified. One single-arm observational study was included. The authors noted the need for randomized, double-blind studies. They also noted that a definition of 'severe calcification' is needed to bring uniformity to the studies

(e.g., imaging use, including intravascular ultrasounds and optical coherence tomography). Adjunct therapy was not included.³

A 2020 study of 57 patients found a 98% rate of procedural success, despite lithoplasty balloons rupturing in 13% of cases, and two patients experiencing significant dissection. In addition, more than 75% of lesions were dilated before and after lithotripsy with the current standard technology of either rotational atherectomy or cutting/scoring balloons, limiting the conclusions that can be drawn about the effect of IVL itself.⁵

Kereiakes et al. (2020) reported on the design and rationale for the Disrupt CAD III trial (ClinicalTrials.gov identifier NCT03595176). The study assessed the Shockwave Coronary IVL catheter, the only current FDA-approved device that is indicated to optimize coronary stent deployment in patients with de novo calcified coronary stenoses. Follow-up continued for two years after enrollment ended in 2020. The authors noted that limitations included a lack of a concurrent control group and a non-randomized study design.¹ The preliminary results of this study were published in 2020, which found no major adverse cardiac event in 92% of patients at 30 days following IVL. At one year post-procedure, that number decreased to 86.2%. At 2 years, 81.1% of patients remained free of major adverse cardiac events. Target lesion failure had occurred in 16.1% of patients at this time. In 2023, a larger post-approval study was published by the same study team involving 1,212 patients. The authors found a 0.25% mortality rate, lower than the predicted 0.31% rate, but acknowledged the study's weakness of lacking long-term data. A 2024 review of post-IVL in-hospital events, published by the same team, studied 17,681 higher-risk patients who were excluded from the prior post-approval study, with a total population of 18,893. 21.7% of patients also required atherectomy; post-procedure residual stenosis was observed at a rate of $4.0 \pm 12\%$. In-hospital mortality and major procedural complications remained low ($<1\%$), but no long-term data was presented.⁷⁻¹¹

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Policy Revision History/Information

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Version 2	12/19/2024	Policy criteria reviewed and updated per medical literature.
Version 3	01/15/2026	Annual review. Code 0715T was deleted as part of the 10/1/2025 AMA code update. Minor copy-edits made to Description and Medical Evidence sections. References reformatted and updated. Reference #4 added.



Cohere Medical Policy – Descending and Abdominal Aortic Aneurysm Repair

Clinical Guidelines for Medical Necessity Review

Version: 2

Cohere Health UMC Approval Date: July 31, 2025

Last Annual Review: July 31, 2025

Revision: Not Applicable

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Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Descending and Abdominal Aortic Aneurysm Repair

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

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Medical Necessity Criteria

Service: Descending and Abdominal Aortic Aneurysm Repair

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity.

Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the

patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

The descending and abdominal aorta are the part of the aorta that travels downward from the aortic arch, passing through the belly and bifurcating into the iliac arteries in the pelvis. An aortic aneurysm occurs when the wall of the aorta becomes weakened and expands outward. Because the aorta is the largest artery in the body and is highly pressurized, the aneurysmal portion may rupture – or dissect – and cause serious, life-threatening sequelae, such as rapid blood loss or poor perfusion of extremities and vital organs that may result in death. To mitigate this risk, aortic aneurysms are often prophylactically repaired. Depending on the type of repair, the patient may or may not be placed on mechanical cardiopulmonary bypass during the operation in order to survive an extended interruption of blood flow to the vital organs while the surgeon is working on the aorta. In an open surgical repair (OSR), the surgeon directly visualizes and repairs/excises the aneurysm. Endovascular aortic repair (EVAR) is a minimally invasive method of repairing the aorta and is known as TEVAR (thoracic EVAR) when it occurs in the thoracic region. The surgeon accesses the aorta by placing a catheter in the groin and deploying a stent graft to the affected portion of the aorta. The stent graft self-expands to support the diseased aorta, prevent dissection, and restore blood flow. Hybrid repair may also be performed, involving a combination of both open and endovascular techniques. The surgeon is best positioned to choose the most appropriate treatment (OSR, EVAR/TEVAR, or hybrid repair) for the patient based on their individual anatomic and clinical factors. Importantly, aortopathy may be syndromic or familial in nature. Marfan syndrome, Vascular Ehlers-Danlos syndrome (VEDS), Loeys-Dietz syndrome, and Turner syndrome are among the genetic conditions associated with aortic disease. The most common pathogenic mutation occurs on the ACTA2 gene. Other affected genes include the FBN1 and SMAD3 genes.¹⁻⁴

Medical Necessity Criteria

Indications

Descending thoracic and abdominal aortic repair (open surgical repair [OSR], EVAR/TEVAR, or hybrid repair) or endovascular arterial repair is considered appropriate if **ALL** of the following are **TRUE**:

- An FDA-approved device will be used; **AND**
- **ANY** of the following:
 - **ANY** of the following pathologies, provided that the treating clinician deems the patient to be an appropriate candidate for repair:
 - Symptomatic or ruptured aneurysms²⁻⁴; **OR**
 - Pseudoaneurysms²⁻⁴; **OR**
 - Intramural hematomas²⁻⁴; **OR**
 - Penetrating ulcers²⁻⁴; **OR**
 - Abdominal aortic aneurysm (AAA), including **ANY** of the following²⁻⁴:
 - Asymptomatic fusiform abdominal aortic aneurysms (greater than 5.5 cm in males or greater than 5 cm in females); **OR**
 - All saccular aneurysms in patients with a reasonable life expectancy; **OR**
 - Aneurysm that expands by more than 1.0 cm within 12 months or by more than 0.5 cm in 6 months; **OR**
 - The patient has a concomitant AAA and iliac artery aneurysm with **ALL** of the following:
 - AAA at appropriate size for repair (i.e., at least 4.5 cm in men; at least 4.0 cm in women); **AND**
 - Iliac artery aneurysm (IAA) with **ANY** of the following²⁻⁴:
 - Rapidly expanding IAA (at least 7 mm in six months or at least 1 cm in 12 months); **OR**
 - Asymptomatic IAA of at least 3.5 cm⁵⁻⁷; **OR**
 - Asymptomatic fusiform descending thoracic or thoracoabdominal aneurysm with **ANY** of the following²⁻⁴:
 - A fusiform aortic diameter greater than 5.5 cm; **OR**
 - A saccular aneurysm; **OR**
 - Any surgical risk at a diameter of 5.5 cm; **OR**
 - Patients who require chemotherapy, radiation therapy, or solid organ transplant, and who are deemed to be at low to moderate

- perioperative risk (with a reasonable life expectancy) with **ANY** of the following²⁻⁴:
- A fusiform aortic aneurysm measuring between 4 and 5.4 cm; **OR**
 - A saccular aneurysm; **OR**
 - Documented rapid thoracic or thoracoabdominal expansion defined as **ANY** of the following²⁻⁴:
 - Greater than or equal to 0.5 cm in 12 months; **OR**
 - Greater than or equal to 0.3 cm in 12 months for those with heritable thoracic aortic disease (including but not limited to Marfan syndrome, Vascular Ehlers-Danlos syndrome [VEDS], Loeys-Dietz syndrome, or Turner syndrome) or bicuspid aortic valve (BAV); **OR**
 - Patients with genetically mediated aortic diseases or bicuspid aortic valves with an aortic diameter of less than 5.5 cm (the specific threshold diameter depends on the underlying medical condition)²⁻⁴; **OR**
 - Traumatic aortic disruptions, including **ANY** of the following:
 - Grade I: Small intimal defect; observation versus repair; **OR**
 - Grade II: Intramural hematoma; TEVAR within 24 hours; **OR**
 - Grade III: Pseudoaneurysms; immediate TEVAR; **OR**
 - Grade IV: Evidence of contained or frank aortic rupture; immediate TEVAR; **OR**
 - Complications from a previous aortic repair (CPT 33886) (e.g., endoleak, graft failure, need for graft extension, etc.)²⁻⁴; **OR**
 - Infected/mycotic aneurysm²⁻⁴; **OR**
 - Aneurysm associated with aortitis²⁻⁴; **OR**
 - Open repair following EVAR of acute type B aortic dissection with genetically mediated aortic diseases²⁻⁴; **OR**
 - **ALL** of the following:
 - The patient meets above criteria for fenestrated EVAR; **AND**
 - The patient has concomitant visceral artery aneurysm in need of repair⁸.

Non-Indications

Descending thoracic and abdominal aortic repair (OSR, EVAR/TEVAR, and hybrid repair) is not considered appropriate if **ANY** of the following is **TRUE**:²⁻⁴

- Aortic aneurysm size less than 3 cm (excluding saccular and symptomatic aneurysms), unless otherwise stated; **OR**
- Limited life expectancy; **OR**
- Prohibitive surgical risk for open surgical repair; **OR**
- The request is for a non FDA-approved indication (e.g., distal aortic stenosis without significant aneurysm).

Level of Care Criteria

Inpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33875	Descending thoracic aorta graft, with or without bypass
33877	Repair of thoracoabdominal aortic aneurysm with graft, with or without cardiopulmonary bypass
33880	Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin
33881	Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); not involving coverage of left

	subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin
33883	Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); initial extension
33884	Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); each additional proximal extension (List separately in addition to code for primary procedure)
33886	Placement of distal extension prosthesis(s) delayed after endovascular repair of descending thoracic aorta
34701	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34702	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the

	level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for rupture, including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34703	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac endograft, including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34704	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac endograft, including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34705	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-bi-iliac endograft, including pre-procedure sizing and device selection, all non selective catheterization(s), all

	associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34706	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-bi-iliac endograft, including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34830	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; tube prosthesis
34831	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; aorto-bi-iliac prosthesis
34832	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; aorto-bifemoral prosthesis
34841	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer,

	intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac, or renal artery)
34842	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34843	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34844	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34845	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm,

	dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac, or renal artery)
34846	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34847	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34848	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or

	modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprotheses (superior mesenteric, celiac and/or renal artery[s])

Medical Evidence

Sharples et al. (2022) conducted a prospective study to evaluate the management and timing of intervention for patients with untreated thoracic aortic aneurysms. From 2014 to 2018, a prospective study was carried out on adult patients with new or existing arch or descending thoracic aortic aneurysms with a diameter of at least 4 centimeters. A total of 886 patients were enrolled and monitored until death, intervention, or withdrawal from the study. Various outcomes were evaluated, including aneurysm growth, survival, quality of life, and hospital admissions. Findings indicated that the maximum aneurysm diameter was predominantly in the descending aorta among 82% of patients, with an annual growth rate of 0.2 cm. Throughout the follow-up period, 129 patients died, with 64 deaths attributed to aneurysm-related events. After adjusting for age, sex, and New York Heart Association dyspnea index, the risk of death escalated with aneurysm size at baseline and with aneurysmal growth. Additionally, hospital admissions rose with aneurysm size. While quality of life decreased annually with age and current smoking, there was no association between aneurysm size and changes in quality of life. The study proposed that international guidelines contemplate extending monitoring intervals to 12 months for small aneurysms and raising intervention thresholds. Decisions regarding surveillance and intervention should be tailored, taking into consideration individual factors such as age, sex, size, growth, patient characteristics, and surgical risk.⁷

McCarthy et al. (2021) performed a systematic meta-analysis to assess and compare the efficacy of endovascular stent grafting (ESG) versus open surgical repair (OSR) in managing arch or descending thoracic aortic aneurysms (TAA). A comprehensive search of relevant studies compared ESG and OSR, encompassing randomized controlled trials (RCTs), quasi-randomized trials, and non-RCTs. Five comparative cohort studies were included, with a total of 3,955 ESG and 21,197 OSR patients. A comprehensive review of unadjusted short-term (30-day) all-cause mortality indicated a preference for ESG. Upon conducting sensitivity analysis on four studies focused solely on descending TAA, no statistical significance was found, although moderate heterogeneity persisted. When adjusted, the meta-analysis of short-term all-cause mortality favored ESG, with no

observed heterogeneity. In longer-term follow-ups (beyond 30 days), survival from all-cause mortality favored OSR in larger studies while favoring ESG in smaller ones. Additionally, freedom from reintervention in the longer term favored OSR. Studies reporting on short-term non-fatal complications suggested a lower incidence following ESG. The authors stressed the need for high-quality evidence alongside society guidelines, as available research is limited and increasingly outdated. They also noted the importance of individualized patient counseling, particularly for aortic disease of hereditary etiology, as these patients are recommended for OSR on current society guidelines.⁹

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Policy Revision History/Information

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Cohere Medical Policy – Descending Thoracic and Abdominal Aortic Aneurysm Repair

Clinical Guidelines for Medical Necessity Review

CHP-161-2.1 Version 2.1

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Specialty: Cardiovascular Disease

Population Type: Adult (18+ years old), Pediatric (0-17 years old)

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Procedure Codes (CPT/HCPCS)

Service: Descending Thoracic and Abdominal Aortic Aneurysm Repair	
Code	Description
33875	Descending thoracic aorta graft, with or without bypass
33877	Repair of thoracoabdominal aortic aneurysm with graft, with or without cardiopulmonary bypass
33880	Endovascular repair of thoracic aorta, including pre-procedure sizing and device selection, nonselective catheterization(s), all associated radiological supervision and interpretation; by deployment of an aorto-aortic tube endograft covering the left subclavian artery and all aortic tube endograft extension(s) proximally in the aortic arch and ascending aorta and distally to the celiac artery, when performed
33881	Endovascular repair of thoracic aorta, including pre-procedure sizing and device selection, nonselective catheterization(s), all associated radiological supervision and interpretation; by deployment of an aorto-aortic tube endograft not involving coverage of the left subclavian artery origin and all endograft extension(s) placed from the level of the left subclavian carotid artery to the celiac artery
33882	Endovascular repair of the thoracic aorta by deployment of a branched endograft multipiece system involving an aorto-aortic tube device with a fenestration for the left subclavian artery stent graft(s) and all aortic tube endograft extension(s) placed from the level of the left common carotid artery to the celiac artery, including pre-procedure sizing and device selection, all target zone angioplasty, all nonselective catheterization(s) and left subclavian artery selective catheterization(s), and all associated radiological supervision and interpretation
33883	Delayed placement of proximal extension prosthesis(es) not involving coverage of the left subclavian artery origin, after endovascular repair of the thoracic aorta, including pre-procedure sizing and device selection, nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed
33886	Delayed placement of distal extension prosthesis(es) from the level of the left subclavian artery to the celiac artery, after endovascular repair of descending thoracic aorta, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation
34701	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34702	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34703	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft

	extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34704	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34705	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-bi-iliac endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34706	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-bi-iliac endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34830	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; tube prosthesis
34831	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; aorto-bi-iliac prosthesis
34832	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; aorto-bifemoral prosthesis
34841	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)
34842	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34843	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34844	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34845	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and

	interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)
34846	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34847	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34848	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])

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Service: Descending Thoracic and Abdominal Aortic Aneurysm Repair - Description

The descending and abdominal aorta are the part of the aorta that travels downward from the aortic arch, passing through the belly and bifurcating into the iliac arteries in the pelvis. An aortic aneurysm occurs when the wall of the aorta becomes weakened and expands outward. Because the aorta is the largest artery in the body and is highly pressurized, the aneurysmal portion may rupture - or dissect - and cause serious, life-threatening sequelae, such as rapid blood loss or poor perfusion of extremities and vital organs that may result in death. To mitigate this risk, aortic aneurysms are often prophylactically repaired. Depending on the type of repair, the patient may or may not be placed on mechanical cardiopulmonary bypass during the operation in order to survive an extended interruption of blood flow to the vital organs while the surgeon is working on the aorta. In an open surgical repair (OSR), the surgeon directly visualizes and repairs/excises the aneurysm. Endovascular aortic repair (EVAR) is a minimally invasive method of repairing the aorta and is known as TEVAR (thoracic EVAR) when it occurs in the thoracic region. The surgeon accesses the aorta by placing a catheter in the groin and deploying a stent graft to the affected portion of the aorta. The stent graft self-expands to support the diseased aorta, prevent dissection, and restore blood flow. Hybrid repair may also be performed, involving a combination of both open and endovascular techniques. The surgeon is best positioned to choose the most appropriate treatment (OSR, EVAR/TEVAR, or hybrid repair) for the patient based on their individual anatomic and clinical factors. Importantly, aortopathy may be syndromic or familial in nature. Marfan syndrome, Vascular Ehlers-Danlos syndrome (VEDS), Loeys-Dietz syndrome, and Turner syndrome are among the genetic conditions associated with aortic disease. The most common pathogenic mutation occurs on the ACTA2 gene. Other affected genes include the FBN1 and SMAD3 genes.¹⁻⁴

Service: Descending Thoracic and Abdominal Aortic Aneurysm Repair – Medical Necessity Criteria

Administrative Guidelines for Medical Necessity Review

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Indications

- **Descending thoracic and abdominal aortic repair (open surgical repair [OSR], EVAR/TEVAR, or hybrid repair) or endovascular arterial repair** is considered appropriate if **ALL** of the following are **TRUE**:
 - An FDA-approved device will be used; **AND**
 - **ANY** of the following:
 - **ANY** of the following pathologies, provided that the treating clinician deems the patient to be an appropriate candidate for repair:
 - Symptomatic or ruptured aneurysms²⁻⁴; **OR**
 - Pseudoaneurysms²⁻⁴; **OR**
 - Intramural hematomas²⁻⁴; **OR**
 - Penetrating ulcers²⁻⁴; **OR**
 - Abdominal aortic aneurysm (AAA), including **ANY** of the following²⁻⁴:
 - Asymptomatic fusiform abdominal aortic aneurysms (greater than 5.5 cm in males or greater than 5 cm in females); **OR**
 - All saccular aneurysms in patients with a reasonable life expectancy; **OR**
 - Aneurysm that expands by more than 1.0 cm within 12 months or by more than 0.5 cm in 6 months; **OR**
 - The patient has a concomitant AAA and iliac artery aneurysm with **ALL** of the following:
 - ▲ AAA at appropriate size for repair (i.e., at least 4.5 cm in men; at least 4.0 cm in women); **AND**

- ▲ Iliac artery aneurysm (IAA) with **ANY** of the following²⁻⁴:
 - △ Rapidly expanding IAA (at least 7 mm in six months or at least 1 cm in 12 months); **OR**
 - △ Asymptomatic IAA of at least 3.5 cm⁵⁻⁷; **OR**
- Asymptomatic fusiform descending thoracic or thoracoabdominal aneurysm with **ANY** of the following²⁻⁴:
 - A fusiform aortic diameter greater than 5.5 cm; **OR**
 - A saccular aneurysm; **OR**
 - Any surgical risk at a diameter of 5.5 cm; **OR**
- Patients who require chemotherapy, radiation therapy, or solid organ transplant, and who are deemed to be at low to moderate perioperative risk (with a reasonable life expectancy) with **ANY** of the following²⁻⁴:
 - A fusiform aortic aneurysm measuring between 4 and 5.4 cm; **OR**
 - A saccular aneurysm; **OR**
- Documented rapid thoracic or thoracoabdominal expansion defined as **ANY** of the following²⁻⁴:
 - Greater than or equal to 0.5 cm in 12 months; **OR**
 - Greater than or equal to 0.3 cm in 12 months for those with heritable thoracic aortic disease (including but not limited to Marfan syndrome, Vascular Ehlers-Danlos syndrome [VEDS], Loeys-Dietz syndrome, or Turner syndrome) or bicuspid aortic valve (BAV); **OR**
- Patients with genetically mediated aortic diseases or bicuspid aortic valves with an aortic diameter of less than 5.5 cm (the specific threshold diameter depends on the underlying medical condition)²⁻⁴; **OR**
- Traumatic aortic disruptions, including **ANY** of the following:
 - Grade I: Small intimal defect; observation versus repair; **OR**
 - Grade II: Intramural hematoma; TEVAR within 24 hours; **OR**
 - Grade III: Pseudoaneurysms; immediate TEVAR; **OR**
 - Grade IV: Evidence of contained or frank aortic rupture; immediate TEVAR; **OR**
- Complications from a previous aortic repair (CPT 33886) (e.g., endoleak, graft failure, need for graft extension, etc.)²⁻⁴; **OR**
- Infected/mycotic aneurysm²⁻⁴; **OR**
- Aneurysm associated with aortitis²⁻⁴; **OR**
- Open repair following EVAR of acute type B aortic dissection with genetically mediated aortic diseases²⁻⁴; **OR**
- **ALL** of the following:
 - The patient meets above criteria for fenestrated EVAR; **AND**
 - The patient has concomitant visceral artery aneurysm in need of repair⁸.

Non-Indications

- **Descending thoracic and abdominal aortic repair (OSR, EVAR/TEVAR, and hybrid repair)** is not considered appropriate if **ANY** of the following is **TRUE**:²⁻⁴
 - Aortic aneurysm size less than 3 cm (excluding saccular and symptomatic aneurysms), unless otherwise stated; **OR**
 - Limited life expectancy; **OR**
 - Prohibitive surgical risk for open surgical repair; **OR**
 - The request is for a non FDA-approved indication (e.g., distal aortic stenosis without significant aneurysm).

Medical Evidence

Sharples et al. (2022) conducted a prospective study to evaluate the management and timing of intervention for patients with untreated thoracic aortic aneurysms. From 2014 to 2018, a prospective study was carried out on adult patients with new or existing arch or descending thoracic aortic aneurysms with a diameter of at least 4 centimeters. A total of 886 patients were enrolled and monitored until death, intervention, or withdrawal from the study. Various outcomes were evaluated, including aneurysm growth, survival, quality of life, and hospital admissions. Findings indicated that the maximum aneurysm diameter was predominantly in the descending aorta among 82% of patients, with an annual growth rate of 0.2 cm. Throughout the follow-up period, 129 patients died, with 64 deaths attributed to aneurysm-related events. After adjusting for age, sex, and New York Heart Association dyspnea index, the risk of death escalated with aneurysm size at baseline and with aneurysmal growth. Additionally, hospital admissions rose with aneurysm size. While quality of life decreased annually with age and current smoking, there was no association between aneurysm size and changes in quality of life. The study proposed that international guidelines contemplate extending monitoring intervals to 12 months for small aneurysms and raising intervention thresholds. Decisions regarding surveillance and intervention should be tailored, taking into consideration individual factors such as age, sex, size, growth, patient characteristics, and surgical risk.⁷

McCarthy et al. (2021) performed a systematic meta-analysis to assess and compare the efficacy of endovascular stent grafting (ESG) versus open surgical repair (OSR) in managing arch or descending thoracic aortic aneurysms (TAA). A comprehensive search of relevant studies compared ESG and OSR, encompassing randomized controlled trials (RCTs), quasi-randomized trials, and non-RCTs. Five comparative cohort studies were included, with a total of 3,955 ESG and 21,197 OSR patients. A comprehensive review of unadjusted short-term (30-day) all-cause mortality indicated a preference for ESG. Upon conducting sensitivity analysis on four studies focused solely on descending TAA, no statistical significance was found, although moderate heterogeneity persisted. When adjusted, the meta-analysis of short-term all-cause mortality favored ESG, with no observed heterogeneity. In longer-term follow-ups (beyond 30 days), survival from all-cause mortality favored OSR in larger studies while favoring ESG in smaller ones. Additionally, freedom from reintervention in the longer term favored OSR. Studies reporting on short-term non-fatal complications suggested a lower incidence following ESG. The authors stressed the need for high-quality evidence alongside society guidelines, as available research is limited and increasingly outdated. They also noted the importance of individualized patient counseling, particularly for aortic disease of hereditary etiology, as these patients are recommended for OSR on current society guidelines.⁹

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Clinical Policy Revision History/Information

Clinical Policy Version	Date	Review History
Version 1	05/28/2024	Original Date.
Version 2	07/31/2025	Annual policy review & restructuring. Clarification for FDA-approved device usage/non usage. Indications and non-indications clarified and streamlined. Indication created for approval of AAA with concomitant iliac artery aneurysm. Description, medical evidence, and references reviewed and updated.
Version 2.1	02/26/2026	Revision. CPT code added: 33882. CPT code deleted per 1/1/2026 AMA code update: 33884. CPT code descriptions updated per 1/1/2026 AMA code update: 33880, 33881, 33883, 33886. No content changes.



Cohere Medical Policy – Electrophysiological Study (EPS)

Clinical Policy for Medical Necessity Review

Version: 2

Cohere Health UMC Approval Date: July 10, 2025

Last Annual Review: July 10, 2025

Revision: Not Applicable

Next Annual Review: July 10, 2026

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Electrophysiological Study (EPS)

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

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Medical Necessity Criteria

Service: Electrophysiological Study (EPS)

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity.

Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

An electrophysiology study (EPS) is a procedure used to evaluate the electrical activity within the heart. It involves inserting catheters into the heart to measure electrical signals and to diagnose and treat various cardiac arrhythmias (abnormal heart rhythms).

Medical Necessity Criteria

Indications

An **electrophysiological study (EPS)** is considered appropriate if **ANY** of the following is **TRUE**:

- Symptomatic or significant bradycardia (e.g., sinus node dysfunction, atrioventricular [AV] block) with inconclusive 30 days of non-invasive evaluation(s) (e.g., extended ECG monitoring, stress testing)¹; **OR**
- Focal atrial tachycardia, which is the likely etiology of new cardiomyopathy; **OR**
- Supraventricular tachycardia (SVT) with **ANY** of the following:
 - Ebstein anomaly (with or without pre-excitation or SVT) and no prior surgical intervention on the tricuspid valve^{2,3}; **OR**
 - Symptomatic or sustained SVT⁴; **OR**
- For risk stratification of Brugada syndrome with spontaneous or induced type I ECG pattern⁵; **OR**
- Wolff-Parkinson-White (WPW) pattern with syncope and **ANY** of the following related to ventricular pre-excitation⁶:
 - The patient's employment would be impacted (e.g., pilots, military service)⁷; **OR**
 - The patient is asymptomatic, and EPS is needed to determine **ANY** of the following:
 - Inducibility of atrioventricular reentrant tachycardia (AVRT); **OR**
 - The rapidity of antegrade conduction is a risk factor for sudden cardiac arrest; **OR**
- **ANY** of the following related to syncope:
 - Evaluation following myocardial infarction if 30 days of non-invasive monitoring is unrevealing; **OR**
 - Unexplained syncope with 30 days of inconclusive non-invasive evaluation(s) (e.g., extended ECG monitoring, stress testing) with **ANY** of the following:
 - Asymptomatic sinus node dysfunction is suspected; **OR**

- Bifascicular block suspected⁸; **OR**
 - Ventricular arrhythmia suspected¹; **OR**
- Congenital heart disease (CHD) with **ANY** of the following:
 - Complex CHD with nonsustained ventricular tachycardia⁹; **OR**
 - Complex CHD with unexplained syncope⁹; **OR**
 - **ALL** of the following:
 - All evaluations were inconclusive, including comprehensive ECG monitoring and stress testing; **AND**
 - **ANY** of the following symptoms of significant rhythm abnormalities:
 - Palpitations; **OR**
 - Shortness of breath; **OR**
 - Syncope; **OR**
- Ischemic cardiomyopathy with **ALL** of the following¹⁰:
 - Ejection fraction (EF) less than or equal to 40%; **AND**
 - Non-sustained ventricular tachycardia (NSVT) to determine inducibility of sustained VT or ventricular fibrillation; **AND**
 - Need for ICD implant; **OR**
- Pre-surgical surgical intervention on the tricuspid valve and the patient has an Ebstein anomaly^{2,3}; **OR**
- Tachyarrhythmia and **ANY** of the following are being considered¹⁰:
 - Automatic ICD; **OR**
 - Mapping and ablation; **OR**
- Ventricular arrhythmia(s) with an indication for invasive evaluation of other conduction diseases¹; **OR**
- Ventricular pre-excitation pattern in an asymptomatic patient and EPS is to determine **ANY** of the following:
 - Inducibility of atrioventricular reentrant tachycardia (AVRT); **OR**
 - The rapidity of antegrade conduction as a risk factor for sudden cardiac arrest.

Non-Indications

An **electrophysiological study (EPS)** is not considered appropriate if **ANY** of the following is **TRUE**:

- **ANY** of the following, as indicated by symptoms with other outpatient testing:
 - Symptomatic AV block; **OR**
 - Symptomatic sinus bradycardia (arrest)¹⁰; **OR**

- Syncope associated with arrhythmias that are indications for pacemaker or ICD implantation¹⁰; **OR**
- Tachyarrhythmias associated with syncope or near syncope and coronary intervention may be needed in the near future¹⁰; **OR**
- Non-sustained, asymptomatic supraventricular tachycardia; **OR**
- Risk assessment for an implantable cardioverter defibrillator (ICD) indication and the patient has heart failure with an ejection fraction (EF) less than or equal to 35%¹; **OR**
- Any clinical scenario or documented arrhythmia that is a class I or class II indication for pacemaker or ICD implantation.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93462	Left heart catheterization by transseptal puncture through intact septum or by transapical puncture (List separately in addition to code for primary procedure)
93600	Bundle of His recording
93602	Intra-atrial recording
93603	Right ventricular recording
93610	Intra-atrial pacing
93612	Intraventricular pacing
93613	Intracardiac electrophysiologic 3-dimensional mapping (List separately in addition to code for primary procedure)
93618	Induction of arrhythmia by electrical pacing
93619	Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia

93620	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording
93623	Programmed stimulation and pacing after intravenous drug infusion (List separately in addition to code for primary procedure)
93624	Electrophysiologic follow-up study with pacing and recording to test effectiveness of therapy, including induction or attempted induction of arrhythmia
93631	Intra-operative epicardial and endocardial pacing and mapping to localize the site of tachycardia or zone of slow conduction for surgical correction
93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left

	atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including left ventricular pacing and recording, when performed
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure)
93662	Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure)

Medical Evidence

Oliveira et al. (2023) performed a retrospective study to identify predictors associated with the lack of referral for catheter ablation (CA) as the initial treatment option in supraventricular tachycardia (SVT) patients. Various clinical and demographic factors were treated as independent variables, while non-referral for CA as the primary treatment was considered the dependent variable in a stepwise logistic regression analysis. Out of 350 patients, 20 clinical-demographic variables were examined, with 10 initially included in the logistic regression analysis: age, gender, presence of pre-excitation on ECG, palpitations, dyspnea, chest discomfort, number of antiarrhythmic drugs prior to ablation, number of concomitant symptoms, duration of symptoms, and emergency room visits due to SVT. Following multivariable adjusted analysis, age, chest discomfort during SVT, and the number of antiarrhythmic drugs administered before ablation emerged as independent predictors positively associated with the lack of referral for CA as the first-line treatment for SVT. Overall, the study suggests that certain independent predictors contribute to the underutilization of catheter ablation as the initial treatment option for SVT.¹¹

Waldmann et al. (2023) conducted a prospective multicenter study to systematically evaluate electrophysiological studies (EPS) using programmed ventricular stimulation in tetralogy of Fallot (TOF) patients undergoing assessment for pulmonary valve replacement (PVR) between January 2020 and December 2021. A uniform stimulation protocol was implemented across all participating centers. A cohort included 120 patients (mean age of 39.2 ± 14.5 years; 53.3% males). SVT was induced in 27 (22.5%) patients. The critical isthmus most frequently implicated (90.0%) was identified between the ventricular septal defect patch and the pulmonary annulus. Factors independently associated with inducible ventricular tachycardia included a history of atrial arrhythmia and pulmonary annulus diameter greater than 26 mm. EPS findings prompted significant management alterations in 23 (19.2%) cases, including CA in 18 (15.0%), surgical cryoablation during PVR in 3 (2.5%), and defibrillator implantation in 9 (7.5%) cases. During a follow-up period of 13 (6.1–20.1) months, no patients experienced sustained ventricular arrhythmias. The authors conclude that the

systematic performance of programmed ventricular stimulation in TOF patients undergoing evaluation for PVR reveals a notable rate of inducible ventricular tachycardia and holds the potential to influence treatment strategies. Further research is warranted to ascertain whether adopting a standardized treatment approach based on EPS outcomes will translate into improved clinical outcomes.¹²

Adhaduk et al. (2022) conducted a meta-analysis and systematic review of 52 articles and 8 studies to evaluate the role of electrophysiology studies in risk stratification of patients with cardiac sarcoidosis (CS). The studies included 298 patients; most studies did not include patients with coronary artery disease (CAD). Use of immunosuppression ranged from 35.8–88%; the mean left ventricle ejection fraction (LVEF) was 34–66.3%. Limitations of the analysis included heterogeneity due to differing diagnostic criteria for CS, including patients with VT. Also, some studies did not include patients with systolic heart failure. The authors concluded that the high sensitivity and specificity of EPS make it a valuable risk stratification tool for patients with CS.¹³

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Policy Revision History/Information

Original Date: April 12, 2024		
Review History		
Version 2	07/10/2025	Annual review. Rearranged bullets for improved usability and organization. Added sub-indications for supra-ventricular tachycardia (SVT): • Ebstein anomaly (with or without pre-excitation or SVT) and no prior surgical intervention on the tricuspid valve; OR • Symptomatic or sustained SVT Added sub-indications for Wolff-Parkinson-White (WPW) pattern with syncope related to ventricular pre-excitation (patient's employment would be impacted, or the patient is asymptomatic and EPS is needed to determine inducibility of atrioventricular reentrant tachycardia [AVRT] or rapidity of antegrade conduction is a risk factor for sudden cardiac arrest). Under the "syncope" indication, added "30 days" to the indications for evaluation and unexplained syncope. Also added "asymptomatic sinus node dysfunction is suspected" under the indication for unexplained syncope.

		Clarified the indications for “congenital heart disease” for improved usability and organization. Removed the following indications: • Following an episode of pre-excited atrial fibrillation; OR • Implantable cardioverter defibrillator (ICD) indications are not met due to ANY of the following: ○ Adult congenital heart disease; OR ○ Ischemic cardiomyopathy; OR • Nonischemic cardiomyopathy; OR • Manifest ventricular pre-excitation, which would interfere with certain types of employment (e.g., pilots, military service). Added non-indication for “any clinical scenario or documented arrhythmia that is a class I or class II indication for pacemaker or ICD implantation.” Added CPT 93613. Literature review – Medical Evidence section updated (Adhaduk et al., 2022).



Cohere Medical Policy - External Cardiac Monitoring Devices

Clinical Policy for Medical Necessity Review

Version: 5

Policy Number: CHP-006-5

Cohere Health UMC Approval Date: January 15, 2026

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Next Annual Review: January 15, 2027

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - External Cardiac Monitoring Devices

Policy Number: CHP-006-5

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

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Medical Necessity Criteria

Service: External Cardiac Monitoring Devices

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation or those that do not align with the provided clinical information—such as mismatched laterality, body part, or CPT code—may be denied due to a lack of medical necessity resulting from insufficient or inconsistent clinical information.
- When multiple diagnostic or therapeutic procedures are requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request.
 - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed.
 - How the results will impact patient management or treatment decisions
- Duplicate exams or requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed and/or treated with a single study or procedure.

Description

An external cardiac monitoring device is a portable device that detects and records cardiac activity while the patient is engaged in ordinary daily activities outside of a medical setting.¹ These devices are used to detect and identify cardiac abnormalities that may not be detected on a standard in-clinic electrocardiogram (ECG/EKG). For example, irregular, transient, or setting-specific anomalies. Modern devices typically consist of three components: the wearable sensor or electrode that collects cardiac data, the communication interface (monitor or smartphone application), and an analytics platform that stores and analyzes the data.² The first of these devices to be developed was the Holter monitor, which continuously monitors cardiac activity for up to 48 hours. Newer devices, including patch-based single-lead and multi-lead ECG systems, extended-duration continuous monitors, and mobile cardiac telemetry, can monitor cardiac activity for longer periods. Continuous monitors record continuously throughout the monitoring period, while event-triggered monitors only capture data when triggered by a cardiac event or by the patient.³

Medical Necessity Criteria

Indications

An **external cardiac monitoring device** is considered appropriate if **ALL** of the following are **TRUE**^{1,4,5}:

- **ALL** of the following^{6,7}:
 - Statement from a provider specifying the requested monitor type and explanation of its appropriateness; **AND**
 - A standard 12-lead electrocardiograph (ECG), complete cardiac history, and cardiac exam has not satisfactorily explained the patient's cardiac complaints; **AND**
 - Testing will provide diagnostic information that will assist in developing or changing a treatment plan for a patient at risk for cardiac arrhythmias; **AND**
- For **ANY** of the following device types^{1,8}:
 - A Holter monitor (CPT codes 93224-93227) if symptoms experienced at least once per 48 hours, including **ANY** of the following^{1,9,10}:
 - Confusional state thought to be related to cerebral hypoperfusion¹¹; **OR**
 - Dyspnea (no known trigger or with exertion); **OR**

- Heart failure symptoms^{11,12}; **OR**
- Palpitations⁸; **OR**
- Syncope/presyncope (lightheadedness or fainting)^{13,14}; **OR**
- Transient dizziness⁸; **OR**
- Transient lightheadedness⁸; **OR**
- A 30-day event monitor (CPT codes 93268, 93270–93272) or an extended-wear continuous ECG patch monitor (CPT codes 93241–93248) if symptoms experienced at least once per 21 days, including **ANY** of the following¹:
 - Confusional state thought to be related to cerebral hypoperfusion¹⁴; **OR**
 - Dyspnea (no known trigger or with exertion); **OR**
 - Heart failure symptoms; **OR**
 - Palpitations; **OR**
 - Syncope/presyncope (lightheadedness or fainting)^{13,14}; **OR**
 - Transient dizziness; **OR**
 - Transient lightheadedness; **OR**
- **Mobile cardiac telemetry (MCT)** (CPT codes 93228–93229) if **ALL** of the following:
 - The patient wore an event monitor or extended-wear continuous ECG patch monitor for at least 14 days without any diagnostic findings^{1,15}; **AND**
 - **ANY** of the following:
 - Recurrent, unexplained syncope^{13,14}; **OR**
 - Suspected atrial fibrillation (AF) in a patient with cryptogenic stroke, where anticoagulation will be implemented if diagnosed¹⁶; **OR**
 - Suspected ventricular arrhythmias that would require immediate intervention.^{9,10}

Non-Indications

An **external cardiac monitoring device** is not considered appropriate if **ANY** of the following is **TRUE**^{17,18}:

- Symptoms are suggestive of angina or clinically significant coronary artery obstruction, and monitoring would delay other needed testing or intervention^{17,19,20}; **OR**
- Implantable cardiac device capable of acquiring clinical data of a similar or equivalent quality; **OR**
- Little or no potential for new clinical data beyond what has been obtained from a previous test (e.g., a standard ECG has already established a diagnosis)^{18,9}; **OR**
- Other tests are better suited to obtain clinical data relevant to the patient's condition^{18,9}; **OR**
- The patient requires acute treatment for an arrhythmia²¹; **OR**
- The request is for mobile cardiac telemetry (MCT) and **ANY** of the following¹⁵:
 - Within 6 months of a previous MCT; **OR**
 - Symptoms of undetermined origin occurring daily (or near daily).

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93224	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional
93225	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)
93226	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report
93227	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified health care professional
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation

93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation
93268	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; includes transmission, review and interpretation by a physician or other qualified health care professional
93270	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)
93271	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis
93272	External patient and, when performed, auto activated

	electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; review and interpretation by a physician or other qualified health care professional
93228	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional
93229	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional

Medical Evidence

Kim et al. (2025) compared the diagnostic efficacy of a 72-hour ECG patch monitor with that of a conventional 24-hour Holter monitor in 47 patients with suspected cardiogenic vertigo. They reported no differences in the detection of arrhythmia events: the 72-hour patch monitor detected 10 of 47 events compared to 8 of 47 events for the 24-hour Holter monitor. Patients reported a preference for the patch monitor, suggesting that patient compliance may be higher with this class of devices.²⁴

Reynolds et al. (2024) evaluated arrhythmia encounter diagnosis at 3 months, repeat ambulatory cardiac monitor testing at 6 months, all-cause 90-day emergency department and inpatient utilization, and cost associated with five types of ambulatory cardiac monitoring devices using Medicare claims data from 2017 to 2018. Their final analysis, consisting of data from 287,789 patients, revealed that the Zio XT 14-day patch long-term continuous monitor had the highest odds of diagnosis and the lowest odds of retesting. They also reported that, across all monitor types, a new arrhythmia diagnosis was observed in approximately 40% of cases. Moreover, retesting was common, occurring in approximately 30% of cases. The authors concluded that long-term continuous monitoring may be preferable for many patients, with the exception of those experiencing symptoms very frequently, for whom a Holter monitor may be sufficient. Patients with potentially high-risk conditions, including syncope or suspected conduction abnormalities, may prefer monitoring by real-time mobile cardiac telemetry (MCT).²⁵

Feuerborn et al. (2024) reported no differences in median time to ablation, median days to new cardiac implantable electronic device implantation, initiation of anticoagulation, or time to first emergency department visit or hospitalization between patients monitored with real-time event notification versus Holter devices in their cohort of 20,259 patients. The authors concluded that the widespread use of real-time notification devices may not be warranted due to the increased burdens associated with data management, analysis, and interpretation required for real-time event notification monitoring. For example, the authors state that while there is a clear benefit to real-time monitoring in a patient with a paroxysmal atrioventricular block, a

2- to 4-week delay may not be impactful for a patient under consideration for anticoagulation medication for atrial fibrillation.¹⁵

The 2025 Japanese Heart Rhythm Society/Japanese Circulation Society consensus statement on the appropriate use of ambulatory and wearable electrocardiographs covers several wearable ambulatory external electrocardiograph devices.³ The document first reviews lead-based, patch, garment-based, and handheld devices, as well as the storage and security of the data recorded by these devices. The consensus document compares these non-invasive external devices to internal loop recorders (ILRs), which are ECG devices that are implanted subcutaneously on the anterior chest. It notes that external recording devices cannot completely replace ILRs for patients with syncope or silent cerebral infarction, citing a study that found significantly higher diagnosis of unexplained loss of consciousness in patients monitored for one year with an ILR compared to patients monitored with external recorders. However, the document also notes that external devices may have utility in patients reluctant to consent to the more invasive ILRs, suggesting a strategy of initially using an external device for these patients, pivoting to an ILR if no diagnosis is achieved within a few weeks.

In the 2024 American College of Cardiology (ACC) expert decision pathway on practical approaches for arrhythmia monitoring after stroke, Spooner et al. present a three-step pathway for monitoring patients after a stroke. The final step involves selecting a monitoring strategy that optimizes accuracy and practicality, and minimizes barriers to care and follow-up. In adult patients with stroke of presumed cardiac origin who require anticoagulation, the consensus document recommends monitoring only when arrhythmia detection will influence treatment decisions, for example, if stopping coagulation medications is being considered. In patients with ischemic stroke presumed to be due to small- or large-vessel disease, monitoring is recommended for 2-4 weeks. In patients with embolic stroke of undetermined source who are candidates for long-term anticoagulation if atrial fibrillation is identified, monitoring for 2-4 weeks is recommended.²⁶

In the 2024 Heart Rhythm Society expert consensus statement on arrhythmias in the athlete, Lampert et al. note that ambulatory ECG monitoring is beneficial in athletes with unexplained syncope or when arrhythmic syncope

is suspected. Specific recommendations include: wire-based Holter monitors when symptoms are frequent (daily); external loop/event monitors when symptoms are less frequent (weekly to monthly); patch continuous monitors when symptoms occur daily, near daily, or weekly; ILRs when symptoms potentially leading to syncope are very infrequent (monthly to yearly); mobile cardiac telemetry when palpitations occur weekly to monthly; and commercially available wearables including fitness trackers when palpitations last long enough to manually record.²⁷

Joglar et al. (2023) discuss the guidelines for the diagnosis and management of atrial fibrillation by the American College of Cardiology (ACC), American Heart Association (AHA), American College of Clinical Pharmacy (ACCP), and the Heart Rhythm Society (HRS). Key clinical trials are also reviewed. The EMBRACE (30-day Event Monitoring Belt for Recording Atrial Fibrillation After a Cerebral Ischemic Event) trial included 572 randomized patients aged 55 years or older who had a recent transient ischemic attack (TIA) or cryptogenic stroke. The patients were randomized and received either a 30-day external loop recorder (ELR) or conventional 24-hour Holter monitoring. At 90-day follow-up, detection of atrial fibrillation (AF) was higher with extended monitoring.⁸

Kusumoto et al. (2019) cite support from the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society (HRS) for the use of external wearable devices for temporary pacing scenarios. These guidelines cover short-term cardiac pacing support during surgery or in the acute setting of a cardiac event. External monitors are typically selected as the primary diagnostic tools to seek potential correlations between bradycardia and symptoms.²⁸

The 2017 International Society for Holter and Noninvasive Electrocardiology (ISHNE)-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry describes the various available recording devices according to several characteristics: whether recording is continuous, event-triggered, or auto-triggered; the number of leads; the type of recording system; and the available analyses. Clinical indications for these devices include the diagnosis of syncope, palpitations, chest pain, and coronary ischemia.¹

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Policy Revision History/Information

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Version 2	09/26/2023	Policy criteria reviewed and updated per medical literature.
Version 3	12/29/2023	Policy criteria reviewed and updated per medical literature.
Version 4	01/09/2025	Annual review. No changes to medical necessity criteria or procedure codes. Reviewed boolean logic. Literature review – Medical Evidence section updated (including references).
Version 5	01/15/2026	Annual review. Policy name changed. Formerly “External Wearable Devices”. No code additions. Added requirements for (all monitor types): statement specifying monitor type and explanation; standard exams not diagnostic; results will develop/ change treatment plan. Added CPT codes for each monitor type to relevant indications.

		Added indications for dyspnea to Holter Monitor/extended-wear monitors. Added non-indications: Little/no potential for new clinical data; Other tests are better suited; MCT in patients with symptoms of undetermined origin occurring daily (or near daily). Added description section. Expanded the Medical Evidence section; added 6 references.



Cohere Medical Policy – External Wearable Devices

Clinical Guidelines for Medical Necessity Review

Version: 4
Effective Date: January 9, 2025

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medical Policy – External Wearable Devices

Date of last literature review: 12/10/2024

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

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Medical Necessity Criteria

Service: External Wearable Devices

Recommended Clinical Approach

External wearable devices are recommended for patients with palpitations, syncope, presyncope, transient dizziness, lightheadedness, or heart failure symptoms¹. The most appropriate device is selected based on clinical history (including symptom frequency and suspected duration of the episodes), physical exam, and 12-lead electrocardiogram (ECG). Daily symptoms may be evaluated using a 24-48 hour Holter monitor. Less frequent or asymptomatic events are more likely to be captured with extended monitoring such as a 30-day loop recorder/event monitor, extended-wear continuous ECG patch device, or mobile cardiac telemetry (MCT). Consideration of the patient's ability to trigger a device effectively may guide device selection in favor of those with more passive event recording capability.^{2,3}

Medical Necessity Criteria

Indications

→ An **external wearable device** is considered appropriate if **ANY** of the following is **TRUE**²⁻⁴:

- ◆ A Holter monitor if the patient has experienced symptoms at least once per 48 hours, including **ANY** of the following:
 - Palpitations; **OR**
 - Syncope; **OR**
 - Presyncope; **OR**
 - Transient dizziness; **OR**
 - Transient lightheadedness; **OR**
 - Heart failure symptoms; **OR**
 - Confusional state thought to be related to cerebral hypoperfusion; **OR**
- ◆ A 30-day event monitor or an extended-wear continuous ECG patch monitor if the patient has experienced symptoms at least once per 21 days, including **ANY** of the following:

- Palpitations; **OR**
- Syncope; **OR**
- Presyncope; **OR**
- Transient dizziness; **OR**
- Transient lightheadedness; **OR**
- Heart failure symptoms; **OR**
- Confusional state thought to be related to cerebral hypoperfusion; **OR**
- ◆ Mobile cardiac telemetry (MCT) is considered appropriate if **ALL** of the following are **TRUE**:
 - The patient wore an event monitor or extended-wear continuous ECG patch monitor for at least 14 days without any diagnostic findings; **AND**
 - **ANY** of the following is **TRUE**:
 - Recurrent, unexplained syncope; **OR**
 - Suspected atrial fibrillation (AF) in a patient with cryptogenic stroke, where anticoagulation will be implemented if diagnosed; **OR**
 - Suspected ventricular arrhythmias that would require immediate intervention.

Non-Indications

- An **external wearable device** is not considered appropriate if **ANY** of the following is **TRUE**⁵⁻⁶:
- ◆ Symptoms are suggestive of angina or clinically significant coronary artery obstruction, and monitoring would delay other needed testing or intervention⁵; **OR**
 - ◆ The patient has an implantable cardiac device capable of acquiring clinical data of a similar or equivalent quality to an external cardiac monitor; **OR**
 - ◆ The patient requires acute treatment for an arrhythmia; **OR**
 - ◆ Mobile cardiac telemetry (MCT) is not considered appropriate if MCT has already been used once in the last 6 months.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
Holter Monitoring	
93224	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified healthcare professional
93225	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)
93226	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report
93227	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified healthcare professional
Extended-Wear Patch Monitor/Long-Term Continuous Cardiac Rhythm Monitors	
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording

	and storage; scanning analysis with report
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation
93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation
Event Monitors	
93268	External patient and, when performed, auto-activated electrocardiographic rhythm-derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; includes transmission, review, and interpretation by a physician or other qualified healthcare professional
93270	External patient and, when performed, auto-activated electrocardiographic rhythm-derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)

93271	External patient and, when performed, auto-activated electrocardiographic rhythm-derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis
93272	External patient and, when performed, auto-activated electrocardiographic rhythm-derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; review and interpretation by a physician or other qualified healthcare professional
Mobile Cardiac Telemetry (MCT)	
93228	Other qualified health care professionals review and interpretation with report of external mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real-time data analysis, and greater than 24 hours of accessible electrocardiogram (ECG) data storage (retrievable with query) with ECG triggered and patient-selected events transmitted to a remote attended surveillance center for up to 30 days
93229	Technical support for connection and patient instructions for use, attended surveillance for up to 30 days, analysis and other qualified health care professional prescribed transmission of daily and emergent data reports of external mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real-time data analysis, and greater than 24 hours of accessible electrocardiogram (ECG) data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center

Medical Evidence

Joglar et al. (2023) discussed the guidelines for the diagnosis and management of atrial fibrillation by the American College of Cardiology (ACC), American Heart Association (AHA), American College of Clinical Pharmacy (ACCP), and the Heart Rhythm Society (HRS). Key clinical trials were also included. The EMBRACE (30-Day Event Monitoring Belt for Recording Atrial Fibrillation After a Cerebral Ischemic Event) trial included 572 randomized patients aged 55 years or older who had a recent transient ischemic attack (TIA) or cryptogenic stroke. The patients were randomized and received either a 30-day external loop recorder (ELR) or conventional 24-hour Holter monitoring. At 90-day follow-up, detection of atrial fibrillation (AF) was higher with extended monitoring.⁷

In addition, Joglar et al. (2023) discussed the CRYSTAL-AF (Cryptogenic Stroke and Underlying AF) trial that included 441 patients aged 40 or older with recent TIA or cryptogenic stroke. Patients were randomized to receive cardiac monitoring with conventional follow-up ECGs or an implantable loop recorder (ILR). Detection of AF was higher with recorders than ECG at 6 months (8.9% versus 1.4%), 12 months (12.4% versus 2.0%), and 3 years (30% versus 3%).⁷

Buck et al. (2021) reported on the PER DIEM randomized control trial (RCT), which compared the efficacy of 12 months of ILR monitoring to 30 days of conventional ELR monitoring in detecting AF or atrial flutter in patients with a recent ischemic stroke. A total of 300 patients were included who had an ischemic stroke within 6 months and did not have known AF. Three hundred participants were randomly equally assigned to ILR monitoring or ELR monitoring. Follow-up visits occurred at 30 days, 6 months, and 12 months. Implantable electrocardiographic monitoring for 12 months, compared to prolonged external monitoring for 30 days, detected a more significant proportion of patients with AF over 12 months among those with ischemic stroke and no prior evidence of AF. Further research is needed to assess clinical outcomes and cost-effectiveness associated with these monitoring strategies.⁸

Kusumoto et al. (2019) cite support from the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society

(HRS) for the use of external wearable devices for temporary pacing scenarios. This includes short-term cardiac pacing support during surgery or in the acute setting of a cardiac event. External monitors are typically selected as the primary diagnostic tools to seek potential correlations between bradycardia and symptoms.¹

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Clinical Guideline Revision History/Information

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Version 4	1/9/2025	• Annual review. • No changes to medical necessity criteria or procedure codes. • Reviewed boolean logic. • Literature review – Medical Evidence section updated (including references).

Cohere Medical Policy – Implantable Pulmonary Artery Pressure Sensors (IPAPS) for Heart Failure Management

Clinical Policy for Medical Necessity Review

CHP-044-5 Version 5

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Procedure Codes (CPT/HCPCS)

Service: Implantable Pulmonary Artery Pressure Sensors (IPAPS) for Heart Failure Management

Code	Description
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

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Service: Implantable Pulmonary Artery Pressure Sensors (IPAPS) for Heart Failure Management - Description

The implantable pulmonary artery pressure sensors (IPAPS) for heart failure management device is implanted in a pulmonary artery branch to remotely manage heart failure (HF). It allows earlier intervention to reduce congestive heart failure (CHF) exacerbations and hospitalizations. The effectiveness of using an implanted hemodynamic monitor for wireless pulmonary artery pressure monitoring to lower the risk of future HF hospitalizations continues to be debated. The New York Heart Association (NYHA) classification system is used to determine heart failure.

Service: Implantable Pulmonary Artery Pressure Sensors (IPAPS) for Heart Failure Management - Medical Necessity Criteria

Administrative Guidelines for Medical Necessity Review

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation or those that do not align with the provided clinical information—such as mismatched laterality, body part, or CPT code—may be denied due to a lack of medical necessity resulting from insufficient or inconsistent clinical information.
- When multiple diagnostic or therapeutic procedures are requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request.
 - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed.
 - How the results will impact patient management or treatment decisions
- Duplicate exams or requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed and/or treated with a single study or procedure.

Indications

- **Implantable pulmonary artery pressure sensors (IPAPS) for heart failure management** are considered appropriate if **ALL** of the following are **TRUE**:
 - New York Heart Association (NYHA) class II or III heart failure (HF) within the past 30 days¹⁻⁹; **AND**
 - Diagnosis of HF greater than 3 months ago²⁻⁴; **AND**
 - Age greater than or equal to 18 years³; **AND**
 - **ANY** of the following:
 - History of HF hospitalization or urgent HF visit (e.g., emergency room or other outpatient visit requiring intravenous diuretic therapy) within the past 12 months¹⁻⁹; **OR**
 - Elevated B-type natriuretic peptide (BNP or NT-proBNP) levels with **ALL** of the following:
 - Testing within the last 30 days^{3-5,9,10}; **AND**
 - BNP or NT-proBNP is elevated [as determined by ejection fraction and BMI^A](#); **AND**
 - Optimal or maximally-tolerated guideline-directed medical therapy (GDMT), including **ALL** of the following¹:
 - **ANY** of the following:
 - Sodium-glucose cotransporter-2 inhibitors (SGLT2i) for greater than or equal to 3 months; **OR**
 - Intolerant to SGLT2i; **AND**
 - **ANY** of the following:

- ☐ Angiotensin-converting enzyme inhibitors (ACE-I)/angiotensin receptor blocker (ARB)/angiotensin receptor-neprilysin inhibitor (ARNi) for greater than or equal to 3 months; **OR**
- ☐ Intolerant to ACE-I/ARB/ARNi; **AND**
- **ANY** of the following:
 - ☐ Mineralocorticoid receptor antagonists (MRA) for greater than or equal to 3 months; **OR**
 - ☐ Intolerant to MRA; **AND**
- **ANY** of the following:
 - ☐ Ejection fraction (EF) greater than or equal to 50%; **OR**
 - ☐ Evidence-based beta-blockers such as bisoprolol, sustained release metoprolol, or carvedilol for 3 months; **OR**
 - ☐ Intolerant to beta blockers; **AND**
- **ANY** of the following:
 - ☐ Diuretics as required; **OR**
 - ☐ Intolerant to diuretics; **AND**
- Evaluation for implantable cardioverter defibrillator (ICD)/cardiac resynchronization therapy (CRT) and **ANY** of the following:
 - Appropriate candidate for device and **ALL** of the following:
 - ☐ **ANY** of the following devices:
 - ▲ Cardiac resynchronization therapy-defibrillator (CRT-D)^{2,3}; **OR**
 - ▲ Cardiac resynchronization therapy-pacemaker (CRT-P)^{2,3}; **OR**
 - ▲ ICD³; **AND**
 - ☐ Implantation for at least 3 months; **OR**
 - Not an appropriate candidate for an implantable device; **AND**
- Access to reliable internet connectivity to ensure daily collection and submission of IPAPS data⁴; **AND**
- **ANY** of the following^{2-4,6,7}:
 - BMI greater than 35 kg/m² with a chest circumference less than 65 inches; **OR**
 - BMI less than or equal to 35 kg/m².

Non-Indications

- **Implantable pulmonary artery pressure sensors (IPAPS) for Heart Failure Management** is not considered appropriate if **ANY** of the following is **TRUE**:
 - Major cardiovascular event (e.g., unstable angina, percutaneous coronary intervention [PCI], myocardial infarction, open heart surgery, stroke, etc.) within the previous 3 months^{2,3}; **OR**
 - The patient cannot take dual antiplatelet or anticoagulants for 1 month post-implant^{2,3,7}; **OR**
 - PAPS implantation occurring during hospital admission for an acute HF episode; **OR**
 - Intolerance to all neuro-hormonal antagonists (i.e., intolerance to ACE-I, ARB, ARNi, hydralazine/isosorbide dinitrate and beta-blockers)^{3,4}; **OR**
 - Likely to undergo heart transplantation or ventricular assist device (VAD) within the next 12 months^{2-4,6}; **OR**
 - Existing heart transplantation or VAD^{3,4}; **OR**
 - American College of Cardiology (ACC)/American Heart Association (AHA) Stage D HF^{3,4}; **OR**
 - NYHA class IV HF patients^{3,4}; **OR**
 - Implanted with mechanical right-sided heart valves^{2-4,6,7}; **OR**
 - Unrepaired severe valvular disease^{3,4}; **OR**
 - Pregnant or planning to become pregnant in the next 12 months^{3,4}; **OR**

- Anticipated life expectancy of less than 12 months^{3,4}; **OR**
- Any condition that, in the opinion of the reviewer, would not allow for utilization of IPAPS to manage the subject using information gained from hemodynamic measurements to adjust medications^{3,4}; **OR**
- Presence of severe pulmonary hypertension (e.g., trans-pulmonary gradient greater than 15) at implant right heart catheterization (RHC)^{3,4}; **OR**
- A history of non-compliance^{3,4}; **OR**
- Any other condition that would preclude CardioMEMS PA Sensor implantation.^{3,4}

Definitions and Notes

^A Adjusted [NT-proBNP and BNP Thresholds According to Ejection Fraction and BMI](#).⁵

Medical Evidence

Lindenfield et al. (2024) conducted a meta-analysis to analyze the efficacy of hemodynamic monitors for managing heart failure and reduced ejection fraction (HFrEF). The authors examined the results from the GUIDE-HF (Hemodynamic-Guided Management of Heart Failure) study, the CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients) study, and the LAPTOP-HF (Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy) study. A total of 1350 patients were included in the analysis of hospitalization rates over 12 months and survival at 12- and 24-month follow-ups. The authors conclude that hospitalizations for HF improved due to hemodynamic monitors. At 24-month follow-up, hospitalizations decreased by 36%. Mortality varied by study: GUIDE-HF demonstrated "no reduction in mortality," while the CHAMPION study showed a trend of reduced mortality, and the LAPTOP-HF study demonstrated a 44% decrease.⁸

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Shavelle et al. (2020) conducted a multi-center, prospective, open-label, observational, single-arm trial to determine the efficacy of pulmonary artery pressure-guided therapy. A total of 1200 patients who had NYHA class III HF with at least one hospitalization in the last 12 months due to HF were included. A 57% reduction of HFH was reported among patients; for all causes, HFH was reduced by 27% post-implantation. Patients with ejection fraction saw a 50% reduction in HFH; no differences were identified among subgroups for sex, race, and cause of HF. (ClinicalTrials.gov Identifier NCT02279888).⁶

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1. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18):e895-e1032. doi: 10.1161/CIR.0000000000001063. PMID: 35363499
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9. Lindenfeld J, Zile MR, Desai AS, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): A randomised controlled trial. *Lancet*. 2021;398(10304):991-1001. doi: 10.1016/S0140-6736(21)01754-2. PMID: 34461042

Policy Revision History/Information

Clinical Policy Version	Date	Review History
Version 1	05/22/2023	Original Date.
Version 2	03/22/2024	Policy criteria reviewed and updated per medical literature.
Version 3	03/06/2025	Annual review. Added an indication requiring enrollment in a CMS-approved Coverage with Evidence Development (CED) study, including any of the following: - CardioMEMS HF System Coverage with Evidence Development Study (NCT06779552, Abbott); OR - Real-World Effectiveness of The Cordella Pulmonary Artery (PA) Sensor System in Patients With Chronic Heart Failure: A Comparative Analysis to Standard of Care Pharmacologic Therapy (LOWER-PAP) (NCT06783335, Edwards Lifesciences). Updated the indication for "New York Heart Association (NYHA) class II or III HF" to include "within the past 30 days, before pulmonary artery pressure sensor (PAPS) implantation, regardless of left ventricular ejection fraction (LVEF)." Updated the indication for "history of HF hospitalization" to include "or urgent HF visit (e.g, emergency room or other outpatient visit requiring intravenous diuretic therapy) within the past 12 months." Added indication for "the patient has been evaluated for and received, if appropriate, an implantable cardioverter defibrillator (ICD), CRT-defibrillator (CRT-D), cardiac resynchronization therapy (CRT)-pacemaker (CRT-P) for at least 3 months before PAPS implantation (CMS, 2025; Heidenreich et al., 2022). Added indication for "no major cardiovascular events within the last 3 months before PAPS implantation (e.g., myocardial infarction, unstable angina, percutaneous coronary intervention, open heart surgery, or stroke) (CMS, 2025). Added indication to "have access to reliable connectivity to ensure daily collection and submission of IPAPS data." Added indication that the patient "must not have PAPS implantation occur during hospital admission for an acute HF episode." Added indication for "elevated brain natriuretic peptide (BNP or NT-proBNP) levels within the last 30 days" to include "thresholds for NT-proBNP and BNP (for LVEF less than or equal to 40% and LVEF greater than 40%) must be corrected for body mass index (BMI) using a 4% reduction per BMI unit over 25 kg/m2." Updated time frame from 6 to 12 months for the non-indication related to the patient is "likely to undergo heart transplantation or ventricular assist device (VAD)." Added non-indication for "eExisting heart transplantation or VAD." Rewrote the Medical Evidence section (Lindenfeld et al., 2024; Lindenfeld et al., 2021; and Shavelle et al., 2020).
Version 3.1	08/04/2025	Revision Corrected version dates in the Clinical Guideline Revision History/Information table. Added CPT 93264. No criteria changes.
Version 4	12/11/2025	Revision. Changed policy title from "Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)" to "Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS)". Simplified description. Removed CED approval criteria. No other criteria changes.

Version 5	03/10/2026	Annual review. Policy title changed to Implantable Pulmonary Artery Pressure Sensors (IPAPS) for Heart Failure Management (formerly Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS)). Simplified description. Updated GDMT indication. Removed redundant indication for "No major cardiovascular events within the last 3 months." Condensed duplicate indications for Elevated B-type brain natriuretic peptide (BNP or NT-proBNP) levels. Moved and clarified indication regarding implantation during hospital admission for an acute HF episode to non-indication section. Clarified language and rearranged bullets to improve usability and organization. Updated definition for Adjusted NT-proBNP and BNP Thresholds.



Cohere Medical Policy – Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS)

Clinical Guidelines for Medical Necessity Review

Version: 4

Cohere Health UMC Approval Date: December 11, 2025

Last Annual Review: March 6, 2025

Revision: December 11, 2025

Next Annual Review: March 6, 2026

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS)

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

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Medical Necessity Criteria

Service: Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS)

Description

The Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS) device is implanted in a pulmonary artery branch to remotely manage heart failure (HF). It allows earlier intervention to reduce congestive heart failure (CHF) exacerbations and hospitalizations. The effectiveness of using an implanted hemodynamic monitor for wireless pulmonary artery pressure monitoring to lower the risk of future HF hospitalizations continues to be debated. Specifically, this includes adult patients with New York Heart Association (NYHA) class II or III HF, a history of HF hospitalization within the past year, or elevated natriuretic peptide levels despite being on maximally tolerated stable doses of guideline-directed medical therapy (GDMT) and receiving optimal device therapy.

Medical Necessity Criteria

Indications

Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS) is considered appropriate if **ALL** of the following are **TRUE**¹⁻⁹:

- New York Heart Association (NYHA) class II or III HF within the past 30 days, before pulmonary artery pressure sensor (PAPS) implantation, regardless of left ventricular ejection fraction (LVEF); **AND**
- The patient was diagnosed with heart failure (HF) more than 3 months ago; **AND**
- Age greater than or equal to 18 years; **AND**
- **ANY** of the following:
 - History of HF hospitalization or urgent HF visit (e.g., emergency room or other outpatient visit requiring intravenous diuretic therapy) within the past 12 months; **OR**
 - Elevated natriuretic peptides within the past 30 days; **AND**

- Optimal or maximally-tolerated GDMT before PAPS implantation, including **ANY** of the following¹:
 - For EF less than or equal to 40% on beta-blockers for 3 months; ACE/ARB/ARNI, SGLT2i, MRA, or diuretics for more than 1 month; or none if intolerant^A; **OR**
 - For EF 41–49% on beta-blockers on ACE/ARB/ARNI, SGLT2i, MRA, or diuretics for more than 1 month or none if intolerant^B; **OR**
 - For EF greater than or equal to 50% on beta-blockers, ACE/ARB/ARNI, SGLT2i, MRA, or diuretics for more than 1 month, or none if intolerant^C; **AND**
- The patient has been evaluated for and received, if appropriate, an implantable cardioverter defibrillator (ICD), CRT-defibrillator (CRT-D), cardiac resynchronization therapy (CRT)–pacemaker (CRT-P) for at least 3 months before PAPS implantation¹; **AND**
- No major cardiovascular events within the last 3 months before PAPS implantation (e.g., myocardial infarction, unstable angina, percutaneous coronary intervention, open heart surgery, or stroke); **AND**
- Have access to reliable connectivity to ensure daily collection and submission of IPAPS data; **AND**
- **ANY** of the following:
 - Must not have PAPS implantation occur during hospital admission for an acute HF episode; **OR**
 - Elevated brain natriuretic peptide (BNP or NT-proBNP) levels within the last 30 days are **ANY** of the following:
 - LVEF less than or equal to 40%: NT-proBNP greater than or equal to 1000 pg/mL (or BNP greater than or equal to 250 pg/mL)*⁵; **OR**
 - LVEF greater than 40%: NT-proBNP greater than or equal to 700 pg/mL (or BNP greater than or equal to 175 pg/mL)*⁵; **OR**
 - Thresholds for NT-proBNP and BNP (for LVEF less than or equal to 40% and LVEF greater than 40%) must be corrected for body mass index (BMI) using a 4% reduction per BMI unit over 25 kg/m²⁵; **AND**
- **ANY** of the following^{6–7}:
 - BMI greater than 35 kg/m² with a chest circumference less than 65 inches; **OR**
 - BMI less than or equal to 35.

^A Heidenreich et al. (2022), section 7.3. *Pharmacological Treatment for HFrEF*.

^B Heidenreich et al. (2022), section 7.6.1. *HF With Mildly Reduced Ejection Fraction (HFmrEF)*.

^c Heidenreich et al. (2022), section 7.7.1. *HF With Preserved Ejection Fraction*.

* [NT-proBNP and BNP Thresholds According to Ejection Fraction and BMI](#).²

Non-Indications

Implantable Pulmonary Artery Pressure Sensors for Heart Failure

Management (IPAPS) is not considered appropriate if **ANY** of the following is **TRUE**^{4,7-8}:

- A major cardiovascular event (e.g., unstable angina, percutaneous coronary intervention[PCI], myocardial infarction, open heart surgery, stroke, etc.) within the previous 3 months; **OR**
- The patient cannot take dual antiplatelet or anticoagulants for 1 month post-implant; **OR**
- Intolerance to all neuro-hormonal antagonists (i.e., intolerance to angiotensin-converting enzyme inhibitors [ACE-I], angiotensin receptor blockers [ARB], angiotensin-neprilysin inhibitors [ARNi], hydralazine/isosorbide dinitrate and beta-blockers); **OR**
- Likely to undergo heart transplantation or ventricular assist device (VAD) within the next 12 months; **OR**
- Existing heart transplantation or VAD; **OR**
- ACC/AHA Stage D refractory HF (including having received or currently receiving pharmacologic circulatory support with inotropes); **OR**
- NYHA class IV HF patients; **OR**
- Implanted with mechanical right heart valve(s); **OR**
- Unrepaired severe valvular disease; **OR**
- Pregnant or planning to become pregnant in the next 12 months; **OR**
- Anticipated life expectancy of less than 12 months; **OR**
- Any condition that, in the opinion of the reviewer, would not allow for utilization of the CardioMEMS™ HF System to manage the subject using information gained from hemodynamic measurements to adjust medications; **OR**
- Presence of unexpectedly severe pulmonary hypertension (e.g., trans-pulmonary gradient greater than 15) at implant right heart catheterization (RHC); **OR**
- A history of non-compliance; **OR**
- Any other condition that would preclude CardioMEMS PA Sensor implantation.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

Medical Evidence

Lindenfield et al. (2024) conducted a meta-analysis to analyze the efficacy of hemodynamic monitors for managing heart failure and reduced ejection fraction (HFrEF). The authors examined the results from the GUIDE-HF (Hemodynamic-Guided Management of Heart Failure) study, the CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients) study, and the LAPTOP-HF (Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy) study. A total of 1350 patients were included in the analysis of hospitalization rates over 12 months and survival at 12- and 24-month follow-ups. The authors conclude that hospitalizations for HF improved due to hemodynamic monitors. At 24-month follow-up, hospitalizations decreased by 36%. Mortality varied by study: GUIDE-HF demonstrated “no reduction in mortality,” while the CHAMPION study showed a trend of reduced mortality, and the LAPTOP-HF study demonstrated a 44% decrease.⁸

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References

1. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022 May 3;145(18):e895–e1032. doi: 10.1161/CIR.0000000000001063. PMID: 35363499.
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9. Lindenfeld J, Zile MR, Desai AS, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): A randomised controlled trial. *Lancet*. 2021 Sep 11;398(10304):991-1001. doi: 10.1016/S0140-6736(21)01754-2. PMID: 34461042.

Clinical Guideline Revision History/Information

Original Date: May 22, 2023		
Review History		
Version 2	03/22/2024	Policy criteria reviewed and updated per medical literature.
Version 3	03/06/2025	Annual review. Added an indication requiring enrollment in a CMS-approved Coverage with Evidence Development (CED) study, including any of the following: • CardiMEMS HF System Coverage with Evidence Development Study (NCT06779552, Abbott); OR • Real-World Effectiveness of The Cordella Pulmonary Artery (PA) Sensor System in Patients With Chronic Heart Failure: A Comparative Analysis to Standard of Care Pharmacologic Therapy (LOWER-PAP) (NCT06783335, Edwards Lifesciences). Updated the indication for “New York Heart Association (NYHA) class II or III HF” to include “within the past 30 days, before pulmonary artery pressure sensor (PAPS) implantation, regardless of left ventricular ejection fraction (LVEF).” Updated the indication for “history of HF hospitalization” to include “or urgent HF visit (e.g, emergency room or other outpatient visit

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		“likely to undergo heart transplantation or ventricular assist device (VAD).” Added non-indication for “Existing heart transplantation or VAD.” Rewrote the Medical Evidence section (Lindenfeld et al., 2024; Lindenfeld et al., 2021; and Shavelle et al., 2020).
Version 3.1	08/04/2025	Revision Corrected version dates in the Clinical Guideline Revision History/Information table. Added CPT 93264. No criteria changes.
Version 4	12/11/2025	Revision. Changed policy title from “Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)” to “Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS)”. Simplified description. Removed CED approval criteria. No other criteria changes.



Cohere Medical Policy – Internal Loop Recorders

Clinical Guidelines for Medical Necessity Review

Version: 5
Effective Date: January 16, 2025

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medical Policy – Internal Loop Recorders

Date of last literature review: 01/15/2025

Document last updated: 01/15/2025

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

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Medical Necessity Criteria

Service: Internal Loop Recorders

Recommended Clinical Approach

Noninvasive ambulatory ECG monitoring is recommended first in patients with clinical scenarios such as symptoms suggestive of an arrhythmia, unexplained syncope, and/or cryptogenic stroke (i.e., stroke of unknown cause) with a concern for atrial fibrillation (AF). Poor diagnostic yield of noninvasive monitoring in the setting of continued symptoms may lead a physician to recommend an internal loop recorder (ILR) for their patient.¹⁻⁴ This procedure is performed by a cardiac electrophysiologist (specialized cardiologist) or trained cardiologist, and referral to a center that supports this service is required.

A single outpatient procedure is typical, and the implant's specific battery life determines the length of effectiveness. Periodic recordings are actively or passively transmitted for interpretation by a physician. Subsequent requests may be considered with documentation of device malfunction, an infection requiring removal of the initial device, or incorrect placement resulting in poor sensing, all with a documented continued need for monitoring.

Medical Necessity Criteria

Indications

→ **Internal loop recorders (ILRs)** are considered appropriate if **ANY** of the following are **TRUE**:

◆ **ALL** of the following:

- No diagnostic conclusions were achieved with non-invasive monitoring methods, including **ANY** of the following⁵⁻⁶:
 - Holter monitor; **OR**
 - Extended-wear patch monitor (e.g., long-term continuous cardiac rhythm monitor); **OR**
 - External event monitor/loop recorder; **OR**
 - Mobile cardiac outpatient telemetry (MCOT); **AND**

- The patient has no other implantable cardiac devices that can detect, record, and transmit data to a physician/cardiologist; **AND**
- The patient has **ANY** positive findings from the following list:
 - Acute (within the past six months), cryptogenic, ischemic stroke or transient ischemic attack (TIA)⁷; **OR**
 - Recurrent or unexplained infrequent syncope without documented orthostasis or autonomic dysfunction⁸⁻⁹; **OR**
 - Sporadic symptoms (for greater than or equal to 30 days) suspected to be related to ventricular arrhythmias⁹; **OR**
 - High-risk for arrhythmias due to structural or infiltrative heart disease (e.g., valvular aortic stenosis, hypertrophic cardiomyopathy, cardiac sarcoidosis, congenital heart disease, dilated ischemic or nonischemic cardiomyopathy)¹⁰⁻¹¹; **OR**
 - Palpitations that are persistent with symptoms that have not been captured by previous 14–30 day monitoring^{6,12}; **OR**
 - A systemic thromboembolic event without a known history of AF and for which maximum sensitivity to detect AF is sought¹³; **OR**
- ◆ ILR replacement may be appropriate for **ANY** of the following (based upon the continued medical necessity for the device):
 - End of battery life; **OR**
 - Device malfunction.

Non-Indications

→ **Internal loop recorders (ILRs)** may not be considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Anticoagulation decisions based on atrial fibrillation/atrial flutter burden, including post-ablation, are not presently part of the ACC/HRS guidelines. ILR placement for this purpose is not an indication of its use¹⁴; **OR**
- ◆ The patient has an existing implanted cardiac device that can provide similar clinical information; **OR**
- ◆ In the course of the workup, including wearable telemetry, a diagnosis was achieved; **OR**

- ◆ The patient has an active infection or an irreversible bleeding disorder; **OR**
- ◆ The patient has no positive clinical risk factors, presentation or history findings, or physical exam findings pertinent to remote ECG monitoring.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
33286	Removal of subcutaneous cardiac rhythm monitor

Medical Evidence

According to Al-Khatib et al. (2017), in patients with sporadic symptoms, including syncope, implantable recorders are helpful in diagnosing serious tachyarrhythmias (including ventricular arrhythmia) and bradyarrhythmias. They are generally reserved for patients in whom other ambulatory monitoring is nonrevealing due to the infrequency of events. A 25% added yield in diagnosis has been described after an unrevealing external ambulatory monitor.¹

The International Society for Holter and Noninvasive Electrocardiology (ISHNE) and Heart Rhythm Society (HRS) published a consensus statement on Ambulatory ECG (AECG) and External Cardiac Monitoring/Telemetry, which states the frequency of symptoms should dictate the type of recording: longer-term ECG monitoring is required for more infrequent events. Correlation (or lack of) of symptoms and arrhythmias is key. The most appropriate clinical workflow may include continuous (up to 7 days) AECG monitoring, which, if unsuccessful, is followed by intermittent external loop recording (long-term from weeks to months). Implantable loop recorders (ILR) may be necessary for patients remaining undiagnosed after prolonged noninvasive monitoring. The selection of appropriate technology has to take into account diagnostic power, monitoring, and risk stratification accuracy with consideration of cost-effectiveness, patient acceptance, degree of automaticity, and local availability and experience, as well as symptom frequency, the overall patient clinical condition, and the probability of life-threatening arrhythmia.⁶

Zangiabadian and colleagues (2024) published a systematic review of the predictors of pacemaker requirement in patients with an implantable loop recorder and unexplained syncope. The group concluded that heart conduction disorders, atrial arrhythmias, and underlying medical conditions were the main predictors of the need for pacemaker implantation following loop recorder installation in patients with unexplained syncope.⁸

Giancaterino et al. (2018) published a focused review that includes published reviews of major cardiovascular societies, including the AHA, ACC, and European Society of Cardiology (ESC). Guidelines emphasize the need for a

comprehensive evaluation, including prolonged cardiac monitoring, to identify underlying AF that may have gone undetected.¹²

Passman (2021) examined literature and indications for incident-based use of direct oral anticoagulation based on the use of implantable devices such as internal loop recorders and consumer-grade devices. Such devices are stated to be used to identify prolonged AF episodes that contribute to stroke risk. Two single-arm trials are described that relate to this approach, including the REACT.COM (Rhythm Evaluation for Anticoagulation with Continuous Monitoring) and TACTIC-AF (Tailored Anticoagulation for Non-Continuous Atrial Fibrillation), both studies using continuous remote monitoring from internal loop recorders. REACT.COM revealed a 94% reduction in anticoagulation use with a one-hour AF duration threshold for the administration of oral anticoagulation, and TACTIC-AF revealed a 75% reduction over a 6-minute threshold. 96 patients with 112 patient-years of follow-up were included in the study with no strokes reported. The invasive nature and expense of cardiac monitoring using insertable monitoring technology were deemed a barrier to this approach.¹³

Diederichsen et al. (2022) conducted a post hoc analysis of the LOOP randomized clinical trial (RCT) for atrial fibrillation (AF). A total of 6004 individuals were included (4503 in the control group and 1501 in the internal loop recorders [ILR]) group. Overall, screening for ILRs did not show a significant decrease in ischemic or severe strokes compared to usual care. However, there may be a potential reduction in these outcomes among participants without a prior history of stroke.¹⁵

Sagris et al. (2022) published a review on embolic stroke of undetermined source (ESUS), a subtype of ischemic stroke. Long-term continuous monitoring with cardiac implantable electronic devices, especially in selected patients with ESUS, has shown promise in improving the detection of atrial fibrillation. An extended monitoring period increases the chances of capturing infrequent or asymptomatic atrial fibrillation episodes. Unlike traditional intermittent monitoring methods, such as Holter monitoring, long-term continuous monitoring allows for a more prolonged and comprehensive assessment of the patient's cardiac rhythm. Several studies report that long-term cardiac monitoring, facilitated by implantable devices, significantly enhances the likelihood of detecting atrial fibrillation in patients with ESUS.¹⁶

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Version 4	7/19/2024	
Version 5	1/16/2025	• Annual review. • Added 2 indications on p. 5 for ILR replacement (end of battery life or device malfunction). • Literature review - Updated references- added reference for first non-indication bullet on p. 5



Cohere Medical Policy – Leadless Cardiac Pacemakers

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: December 12, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiology

Guideline Name: Cohere Medical Policy – Leadless Cardiac Pacemakers

Date of last literature review: 10/31/2024

Document last updated: 12/12/2024

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

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Medical Necessity Criteria

Service: Leadless Cardiac Pacemakers

Recommended Clinical Approach

Leadless cardiac pacemakers are self-contained pacemakers small enough to be implanted directly into the ventricle, in contrast to conventional pacemakers, which require the surgical creation of a “device pocket” and insertion of transvenous pacing leads. The elimination of these elements minimizes complications, such as the risk of pneumothorax, while providing the same clinical function with added benefits, including an improved cosmetic appearance, avoidance of hematoma, and eliminated risk of lead dislodgement or lead fracture.¹ A leadless pacemaker is implanted percutaneously via a femoral catheter, which delivers the device directly into the right atrial or ventricular wall. Dual-chamber leadless pacing systems are leveraged to modulate the contraction of both the right atrium and ventricle. Device dislodgement, though rare, may require re-implantation replacement, as would battery depletion, which is thought to occur after approximately one decade of use. Should retrieval and replacement not be feasible, leadless pacemakers can be safely abandoned and left in place. Leadless pacemakers are of special utility among patients who are at high risk of infection or upper extremity venous occlusion, as leadless devices are associated with reduced rates of these complications.²

Medical Necessity Criteria

Indications

→ A **leadless cardiac pacemaker** is appropriate if **ALL** of the following is **TRUE**:

◆ **ANY** of the following is **TRUE**:

- No upper extremity venous access exists²; **OR**
- High risk of device pocket infection (e.g., active or previous systemic/device infection, on hemodialysis, etc.)²; **OR**
- When a conventional transvenous pacing system is otherwise considered difficult, high-risk, or not sufficient for effective therapy; **AND**

◆ **ANY** of the following is true:

- Paroxysmal or permanent high-grade AV block in the presence of AF; **OR**
- Paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high-risk, or not deemed necessary for effective therapy; **OR**
- Symptomatic bradycardia-tachycardia syndrome; **OR**
- Sinus node dysfunction as evidenced by **ANY** of the following:
 - Sinus bradycardia; **OR**
 - Sinus pauses, as an alternative to atrial or dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high-risk, or not deemed necessary for effective therapy; **OR**
- Symptomatic, irreversible bradycardia caused by **ANY** of the following:
 - VDD pacing is indicated in patients with adequate sinus rates who may benefit from maintenance of AV synchrony; **OR**
 - Sick sinus syndrome (sinus node dysfunction); **OR**
 - Chronic second- or third-degree AV block; **OR**
 - Recurrent Adams-Stokes syndrome; **OR**
 - Bilateral bundle-branch block not caused by tachyarrhythmia.

Non-Indications

→ A **leadless cardiac pacemaker** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Another implant (device or otherwise) would interfere with the implantation or performance of the leadless pacemaker, in the judgment of the implanting physician; **OR**
- ◆ Known intolerance to the tissue-contacting materials in the device (e.g. – titanium, nickel, Nitinol titanium-nickel alloy, epoxy resin); **OR**
- ◆ Implanted vena cava filter; **OR**
- ◆ Mechanical tricuspid valve.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0795T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; complete system (i.e., right atrial and right ventricular pacemaker components)
0796T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)
0797T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0798T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system (i.e., right atrial and right ventricular

	pacemaker components)
0799T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right atrial pacemaker component
0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0801T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; dual-chamber system (i.e., right atrial and right ventricular pacemaker components)
0802T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right atrial pacemaker component
0803T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual chamber leadless pacemaker system)
0804T	Programming device evaluation (in person) with

	iterative adjustment of implantable device to test the function of device and to select optimal permanent programmed values, with analysis, review, and report, by a physician or other qualified health care professional, leadless pacemaker system in dual cardiac chambers
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed

Medical Evidence

In May 2023, the New England Journal of Medicine published an extensive study of the Aveir dual-chamber leadless pacemaker. This prospective, multicenter study (ClinicalTrials.gov ID NCT05252702) evaluated the safety and efficacy of the new-to-market dual-chamber leadless pacemaker when compared to the traditional transvenous model. Among 300 patients, 90.2% were free from complications at 90 days – surpassing the performance goal of 82.5%. The second performance endpoint (achievement of at least 70% AV synchrony) was accomplished in 97.3% of patients, again exceeding the performance goal of 83%. A similar study of dual-chamber leadless pacemakers found that reliable performance of the device continued through the six-month period.⁷

In April of 2024, El-Chami et al. completed a 5-year follow-up study of the Micra leadless pacemaker. A total of 1809 patients were included, with a median duration of 51.1 months. No Micra devices were removed due to infection, reinforcing the idea that leadless pacemakers are associated with less infection risk. The complication risk at 3 years, at 4.1%, was less than half the rate associated with traditional transvenous systems (8.5%). The authors endorsed the continued safety and quality of the Micra system, particularly as compared to the standard transvenous pacemaker.¹⁰

Ngo et al. (2021) performed an earlier systematic review and meta-analysis on the safety and efficacy of the Micra and the Nanostim (now discontinued) leadless pacemakers. Thirty-six observational studies were reviewed that included Nanostim (30%) and Micra (70%) leadless pacemakers. Micra was well-tolerated, with just 1.77% of patients experiencing complications at one-year follow-up. As compared to conventional transvenous pacemakers, the odds of complications with Micra were 51% less. At one-year follow-up, capture thresholds with Micra pacemakers were reported among 98.96% of patients. With this review, the authors concluded leadless pacemakers were associated with “markedly” fewer complications when compared with the standard transvenous system while maintaining clinical efficacy.⁸

Reynolds et al. (2016) reported on the Micra Transcatheter Pacing Study (ClinicalTrials.gov ID NCT02004873). This multicenter study without controls

included 719 patients who had a successful procedure. At the six-month follow-up, performance goals were met. The pacing capture threshold was adequate in 98.3% of patients, higher than the performance goal of 80%. Complications were reported in 4%, including invasive revision, termination of therapy, hospitalization or extension of hospitalization, and death.⁹

The European Society of Cardiology (ESC) published the *2021 ESC Guidelines on Cardiac Pacing and Cardiac Resynchronization Therapy*. Two recommendations were included, endorsing the use of leadless pacemakers among patients for whom no upper extremity venous access exists or for those patients with a particularly high risk of device pocket infection – including patients with prior or active systemic infection and patients on hemodialysis. The ESC also endorsed the broader sentiment that leadless pacemakers could be “considered as an alternative” to standard pacing when also weighing life expectancy and utilizing the principles of shared decision-making.²

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Cohere Medical Policy – Left Atrial Appendage Implants

Clinical Guidelines for Medical Necessity Review

Version: 3
Effective Date: January 9, 2025

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medical Policy – Left Atrial Appendage Implants

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

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Medical Necessity Criteria

Service: Left Atrial Appendage Implants

Recommended Clinical Approach

Left atrial appendage (LAA) implants (WATCHMAN Left Atrial Appendage device and AMPLATZER Amulet Occluder) are alternatives to chronic anticoagulant therapy for patients with nonvalvular atrial fibrillation (in the absence of moderate to severe mitral stenosis or a mechanical heart valve) at increased risk for a stroke. This procedure is a percutaneous catheter-based intervention that serves as an alternative to anticoagulation for patients who have become intolerant to anticoagulation, have poor drug adherence, have an increased risk of bleeding, or have had major bleeding events from recommended anticoagulant regimens.¹⁻² This procedure may also be considered for patients with high-risk occupations that place individuals at-risk for bleeding or comorbid conditions requiring treatment that are not compatible with oral anticoagulants. In patients with either (1) A CHA₂DS₂-VASc score of 3 or greater, (2) A hospitalization related to a bleeding event, or (3) A cardioembolic event while on oral anticoagulants, left atrial appendage closure devices were shown to be non-inferior to direct-acting oral anticoagulants (DOACs) at preventing of stroke, systemic embolism, significant bleeding events, and cardiovascular death.³ There is a risk of procedural complications with these implants, including peri-device leakage, perforation, pericardial tamponade, thrombosis, stroke, and death.⁴⁻⁶ Oral anticoagulation remains the preferred therapy for stroke prevention for most patients with atrial fibrillation (AF) and elevated stroke risk.¹ Current consensus guidelines favor a trial of oral anticoagulation therapy before considering primary LAA closure.

Medical Necessity Criteria

Indications

- **Left atrial appendage implant** with an FDA-approved closure device (Amplatzer Amulet, WATCHMAN FLX, WATCHMAN FLX Pro) is considered appropriate if **ALL** of the following are **TRUE**:⁵⁻⁶
 - ◆ The patient has non-valvular atrial fibrillation; **AND**

- ◆ The patient has an increased risk of stroke and systemic embolism based on **CHADS₂** score greater than or equal to 2 (Congestive heart failure, Hypertension, Age greater than 75, Diabetes, Stroke/transient ischemic attack/thromboembolism) or **CHA₂DS₂-VASc** score greater than or equal to 3 (Congestive heart failure, Hypertension, Age greater than or equal to 65, Diabetes, Stroke/transient ischemic attack/thromboembolism, Vascular disease, Sex category); **AND**
- ◆ Must be able to take short-term oral anticoagulation or antiplatelet therapy post-implantation; **AND**
- ◆ **ANY** of the following:
 - The patient has had one or more significant bleeding events requiring hospital treatment related to oral anticoagulation therapy (warfarin or direct-acting oral anticoagulants [DOACs])² related to irreversible causes; **OR**
 - The patient has a history of thromboembolic events, including TIA or stroke, despite being treated with oral anticoagulation therapy²; **OR**
 - Increased risk of bleeding, characterized by **ANY** of the following:
 - Severe bleeding due to a nonreversible cause involving the gastrointestinal, pulmonary, or genitourinary systems; **OR**
 - Spontaneous intracranial/intraspinal bleeding due to a nonreversible cause; **OR**
 - Serious bleeding related to recurrent falls when the cause of falls is not determined to be treatable.⁸

Non-Indications

- **Left atrial appendage implant** is not considered appropriate if **ANY** of the following is **TRUE**:⁵⁻⁶
- ◆ The patient has atrial fibrillation and is indicated for long-term oral anticoagulation therapy but has not had any trial of warfarin or DOACs²; **OR**
 - ◆ The patient has other medical indications for chronic oral anticoagulant therapy (valve disease, pulmonary embolism, deep vein thrombosis); **OR**

- ◆ Inability to perform transseptal puncture due to the presence of an intracardiac mass or an existing atrial septal or patent foramen ovale repair/closure device; **OR**
- ◆ LAA anatomy not amenable to percutaneous device closure; **OR**
- ◆ Known sensitivity to device components or material; **OR**
- ◆ There is a general contraindication for TEE or percutaneous catheterization procedures (patient oropharynx too small for TEE probe or conditions such as active infection or bleeding disorder); **OR**
- ◆ Use of anticoagulation therapy, aspirin or a P2Y12 inhibitor (antiplatelet drug) is contraindicated in the patient.⁶

Site of Service Criteria

Outpatient

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
33340	Percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation

Medical Evidence

January et al. (2019) published a guideline update for the American Heart Association, the American College of Cardiology, and the Heart Rhythm Society for the management of patients with atrial fibrillation. Percutaneous LAA occlusion was recommended for consideration in patients with atrial fibrillation and increased risk of stroke with contraindications to long-term anticoagulation. They state that while the FDA approval indicated that the device was restricted to patients deemed suitable for long-term warfarin, as in the inclusion criteria for the clinical trials; however, the CMS criteria indicate that the device is an alternative for patients able to tolerate short-term but not long-term warfarin.¹

Makkar et al. (2024) reviewed the post-approval study of the use of the Amulet occluder following failure of LAA occlusion. The two FDA-approved devices for LAA occlusion at the time of this publication were Amulet and WATCHMAN, with the Amulet consisting of a dual occlusive mechanism compared with the WATCHMAN device's single mechanism. The authors state that in complex LAA anatomies, failures may occur, particularly with the single mechanism devices. This post-approval study consisted of 8591 patients who underwent Amulet implantation with 244 of these patients having prior failed LAA occlusion. 88.9% of study participants with prior failed LAA occlusion had success with the Amulet implantation. Greater than 90% of patients experienced less than a 3 mm peridevice leak. There was a low rate of adverse events, and the Amulet device was found to facilitate successful closure in challenging LAA anatomies.⁹

Simon et al. (2024) conducted a retrospective study of 649 patients with a mean age of 61.3 plus or minus 10.5 years. 33.9% of the patients in the study were women, and there was a 7.1% rate of previous stroke (4.8%) or transient ischemic attack (2.3%) in the population regardless of gender. The study focused on the effect of LAA morphology on stroke incidence (cauliflower, chicken wing, swan, and windsock) with the swan morphology (4.8% of patients) indicating higher stroke risk (in addition to decreased LAA flow velocity) and the windsock shape proving to be protective against stroke (32.5% of patients).¹⁰

The US Food and Drug Administration (FDA) granted Premarket Approval (PMA) to Boston Scientific Corporation (2015) for the WATCHMAN Left Atrial Appendage Closure Device with Delivery System in addition to subsequent generation devices, the WATCHMAN FLX and WATCHMAN FLX Pro. The WATCHMAN FLX is stated to occlude a wider size range of LAAs than the first generation device, as well as allow for short-term postoperative use of a DOAC instead of warfarin, as was required with WATCHMAN.⁶

Brouwer and colleagues (2019) conducted a post-hoc analysis of the randomized PROTECT and PREVAIL trials for atrial fibrillation patients with left atrial appendage closure vs. warfarin. 1114 randomized subjects were found to have a net clinical benefit of 1.42% per year with the LAA closure. Warfarin was found to have favorable net clinical benefit early in follow-up, with trends favoring LAA closure after 1-2 years. The group concluded in favor of the long-term benefit of LAA closure due to the reduction in bleeding events and mortality.¹¹

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Clinical Guideline Revision History/Information

Original Date: December 1, 2023		
Review History		
Version 2	August 13, 2024	Updated indications, non-indications, references
Version 3	January 9, 2025	• Annual review. • No changes to procedure codes. • Removed indication p.5 related to bleeding risk from oral anticoagulation • Literature review - Medical Evidence section updated, references added.



Cohere Medical Policy – Left Heart Catheterization

Clinical Guidelines for Medical Necessity Review

Version: 4
Revision Date: March 6, 2025

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Medical Necessity Criteria

Service: Left Heart Catheterization

Recommended Clinical Approach

Left heart catheterization is an invasive cardiac evaluation method.^{1,2} It allows for direct evaluation of hemodynamics and is primarily used to assess for coronary artery disease (CAD).

Left heart catheterization involves the insertion of a catheter into an artery in the arm, groin, or wrist. Generally, femoral artery access is more commonly used than radial artery access for left heart catheterization.¹³ The catheter is guided to the left ventricle of the heart to measure left ventricular pressures or to obtain an angiogram (left ventriculogram, ventriculography). Left heart catheterization is generally performed with coronary angiography to assess left ventricular pressure and function and for the presence of valvular heart disease.

Non-emergent cardiac catheterization should be performed at a facility that offers coronary intervention and has the staffing and lab availability for a percutaneous coronary intervention (PCI) if indicated. Unless there are objective findings at the time of catheterization that make intervention uncertain, intervention should occur at the time of the catheterization.³

Medical Necessity Criteria

Indications

→ **Left cardiac catheterization** is considered appropriate if **ANY** of the following is **TRUE**^{1-11,24}:

- ◆ Congenital heart disease with **ANY** of the following²⁷:
 - Invasive cardiovascular procedure is planned, requiring pre- or post-operative catheterization or angiographic imaging (e.g., for pressure or gradient measurements); **OR**
 - Noninvasive imaging is inconclusive or discordant with findings in the physical examination; **OR**
- ◆ Hypertrophic cardiomyopathy (HCM) with **ANY** of the following²⁶:
 - Symptomatic HCM after noninvasive imaging; **OR**

- Evidence of myocardial ischemia; **OR**
- Prior to surgical myectomy; **OR**
- ◆ Newly diagnosed congestive heart failure and **ALL** of the following:
 - Ejection fraction is less than 40%; **AND**
 - Echocardiogram is inadequate to determine the cause of dysfunction or the extent of coronary disease; **AND**
 - Contraindications to cardiac computed tomography angiography (CCTA) exist; **AND**
 - No cardiac catheterization, single photon emission computed tomography (SPECT), cardiac positron emission tomography (PET), or stress echocardiogram (ECG) has been performed since the diagnosis of congestive heart failure or cardiomyopathy; **OR**
- ◆ Suspected acute coronary syndromes (ACS), including elevated troponin or non-ST elevation myocardial infarction (NSTEMI); **OR**
- ◆ Worsening or limiting ischemic symptoms^A or stable angina despite guideline-directed medical treatment (GDMT) with **ANY** of the following high-risk findings^{2,4}:
 - Severe resting left ventricular (LV) dysfunction (left ventricular ejection fraction [LVEF] is less than 40%) that is not readily explained by noncoronary causes; **OR**
 - Reversible perfusion abnormalities that encompass greater than or equal to 10% of the myocardium (SDS = 10) in patients without prior history or evidence of myocardial infarction (MI); **OR**
 - Stress electrocardiography (ECG) findings including **ANY** of the following:
 - Greater than or equal to 2 mm of ST-segment depression at low workload; **OR**
 - Greater than or equal to 2 mm of ST-segment depression that persists into recovery; **OR**
 - Exercise-induced ST-segment elevation of greater than 1.5mm; **OR**
 - Exercise-induced ventricular tachycardia or ventricular fibrillation (VT/VF); **OR**
 - Stress-induced LV dysfunction (peak exercise LVEF is less than 40% or drop in LVEF with stress is greater than or equal to 10%); **OR**

- Stress-induced perfusion abnormalities encumbering greater than or equal to 10% of the myocardium or stress segmental scores indicating multiple vascular territories with abnormalities; **OR**
- Stress-induced LV dilation; **OR**
- Inducible wall motion abnormality (involving greater than 2 segments or 2 coronary beds); **OR**
- Wall motion abnormality developing at a low dose of dobutamine (less than or equal to 10 mg/kg/min) or at a low heart rate (less than 120 beats/min); **OR**
- Coronary artery calcium (CAC) score greater than 400 Agatston units; **OR**
- Multivessel obstructive coronary artery disease in two or more major coronary arteries (CAD; greater than or equal to 70% stenosis) on CCTA; **OR**
- Left main stenosis (greater than or equal to 50% stenosis) on CCTA; **OR**
- FFR-CT less than or equal to 0.80^{18,20-23}; **OR**
- ◆ Ventricular fibrillation or sustained ventricular tachycardia; **OR**
- ◆ The patient has survived sudden cardiac arrest or potentially life-threatening ventricular arrhythmia²⁵; **OR**
- ◆ Preoperative assessment before **ANY** of the following:
 - Heart valve surgery; **OR**
 - Lung transplant; **OR**
 - Liver transplant; **OR**
- ◆ The patient is being considered for or has received a heart transplant.

^A**Ischemic Equivalent:** Chest pain syndrome, anginal equivalent, or ischemic electrocardiogram (ECG) abnormalities are 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 CAD may also be considered an ischemic equivalent.¹

Non-indications

→ **Left cardiac catheterization** is not considered appropriate if **ANY** of the following is **TRUE**^{1,24}:

- ◆ Coagulopathy; **OR**
- ◆ Fever; **OR**
- ◆ Systemic infection; **OR**
- ◆ Evaluation of syncope²⁸; **OR**
- ◆ Radiopaque contrast agent allergies in patients who have not been appropriately premedicated.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93454	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation
93455	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with catheter placement in bypass graft, with intraprocedural injections for bypass graft angiography
93458	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with left heart catheterization, with intraprocedural injection for left ventriculography
93459	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision and interpretation, with left heart catheterization, catheter placement in bypass graft, with bypass graft angiography

93595	Left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone, normal or abnormal native connections

Medical Evidence

Choi et al. (2023) conducted a retrospective, single-center, observational study to evaluate the discriminatory and prognostic significance of invasively measured left ventricular end-diastolic pressure in patients suspected of having heart failure with preserved ejection fraction (HFpEF). The authors focused on patients with intermediate scores on the Heart Failure Association Pre-test Assessment, Echocardiography and Natriuretic Peptide, Functional Testing, Final Etiology (HFA-PEFF) scale. A total of 404 patients were included. All patients exhibited symptoms of heart failure and preserved left ventricular ejection fraction (greater than or equal to 50%) and underwent left heart catheterization (LHC). Exclusion criteria included patients who presented without definitive HF symptoms, with acute coronary syndrome (ACS), primary cardiomyopathy, significant valvular heart disease (beyond mild stenosis or moderate left-sided regurgitation), pulmonary arterial hypertension, heart transplantation, constrictive pericarditis, or stress-induced cardiomyopathy. The authors noted that the diagnostic accuracy of the HFA-PEFF score in predicting HFpEF, confirmed through invasive hemodynamic measurement, is moderate, with an optimal cutoff value of 4.5. A strong correlation was identified between the HFA-PEFF score and the 10-year risk of all-cause death or HF readmission. Finally, elevated left ventricular end-diastolic pressure (LVEDP) was found to be linked to a significantly higher 10-year risk of all-cause death or HF readmission in patients suspected of having HFpEF. This association remained after adjusting for multiple variables, including the HFA-PEFF score. Invasive catheterization was found to be a useful adjunct tool, particularly among patients with intermediate HFA-PEFF scores.¹²

A 2017 study by Mustafa et al. investigated the potential health equity ramifications of limiting left heart catheterization for kidney transplant recipients. The authors examined a database of 336,354 patients with NSTEMI, of whom 742 received a kidney transplant. Kidney transplant patients were found to have been offered LHC less often than their non-transplant counterparts. Importantly, coronary angiography was associated with reduced morbidity and mortality, thereby representing an important issue of care access for patients who are disproportionately

denied LHC based on the theoretical risk of contrast-induced nephropathy.¹⁷

A 2022 publication in the *New England Journal of Medicine* investigated the utility of invasive coronary angiography for patients with stable chest pain. The DISCHARGE (Diagnostic Imaging Strategies for Patients with Stable Chest Pain and Intermediate Risk of Coronary Artery Disease) trial included 3,523 patients with completed follow-up. Patients were referred for invasive coronary angiography and had stable chest pain and intermediate pretest probability of CAD. The risk of major cardiac adverse events did not significantly differ between patients who underwent coronary angiography versus CT evaluation, with a higher rate of complications for the patients who underwent angiography. The authors concluded that these findings suggest the importance of careful patient selection for invasive coronary angiography, given the greater risk profile and limited benefits as compared to noninvasive evaluation.¹⁵

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Clinical Guideline Revision History/Information

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Version 2	11/17/2023	
Version 3	3/22/2024	
Version 4	3/6/2025	Annual Policy Review & Restructure • Recommended clinical approach modified to reflect current internal template • Rewrote medical evidence section for relevance + updated to convey current literature base • References added with updated literature review • Indications streamlined to limit redundancy (i.e., the same patient population was captured by multiple indications) and improve readability and clarity. For this reason, prior CABG indication was removed, pre-TAVR indication was removed, high-risk stress test indication was removed, intermediate-risk criteria for patients with angina were removed, ACHD indication was narrowed and streamlined. • Several non-indications were removed as they were not absolute contraindications (i.e., acute or chronic CKD, pregnancy, normal prior testing within 2 years). • Non-indication for evaluation of syncope was added based on ACC guidelines.



Cohere Medical Policy – Lower Extremity Arterial Revascularization

Clinical Policy for Medical Necessity Review

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Policy Name: Cohere Medical Policy - Lower Extremity Arterial Revascularization

Policy Number: CHP-157-4

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

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Medical Necessity Criteria

Service: Lower Extremity Arterial Revascularization

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity.

Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Lower extremity peripheral artery disease (PAD) is a condition where blood flow is restricted in the arteries of the legs due to narrowing or blockage caused by plaque build-up. Pain, numbness, and tissue damage to the legs and feet may result from a lack of blood flow, and surgical intervention may be required. Lower extremity arterial revascularization is a surgical procedure that can be performed in patients to restore blood flow to the legs and feet, improving pain and quality of life.

Medical Necessity Criteria

Indications

Lower extremity arterial revascularization (percutaneous) is considered appropriate for **ANY** of the following¹⁻⁴:

- The patient has chronic limb-threatening arterial occlusive disease (CLTI), and **ALL** of the following are **TRUE**:
 - **ANY** of the following:
 - Ischemic rest pain with **ALL** of the following:
 - Severe persistent pain in the foot or toes, typically occurring when the limb is at rest or elevated and is relieved by placing the limb in a lowered position⁵⁻⁷; **AND**
 - **ANY** of the following⁸:
 - Resting ankle pressure (AP) less than 40 mm/Hg; **OR**
 - Flat or barely pulsative ankle or metatarsal PVR; **OR**
 - Toe pressure (TP) less than 30 mm/Hg; **OR**
 - ABI less than or equal to 0.5; **OR**
 - Gangrene; **OR**
 - Ischemic wound progresses or fails to reduce in size by greater than or equal to 50% within 2-4 weeks of wound management¹; **AND**
 - The clinician determines that the patient is an appropriate candidate for intervention and provides appropriate clinical documentation supporting the clinical decision-making process, including **ANY** of the following:
 - Angiographic (CTA, MRA, invasive angiogram) lesion greater than or equal to 70%^{7,9}; **OR**
 - **ALL** of the following^{7,9}:

- Angiogram demonstrates 50–70% stenosis (i.e., the cause of limited perfusion); **AND**
- **ANY** of the following:
 - Resting intravascular pressure measurements (greater than 10 mmHg); **OR**
 - Provoked (greater than or equal to 10 mmHg) intravascular pressure measurements to determine the hemodynamic significance of lesions⁷; **OR**
- Lower extremity duplex Doppler with peak systolic velocity (PSV) greater than 3 m/s or velocity ratio 4:1⁷; **OR**
- Absent vascular flow; **AND**
- The procedure is **ANY** of the following:
 - Percutaneous transluminal angioplasty (PTA) and/or stent for aortoiliac arterial occlusive disease¹; **OR**
 - PTA and/or stent for femoral–popliteal arterial occlusive disease¹; **OR**
 - Atherectomy for femoral–popliteal arterial occlusive disease with documentation of **ANY** of the following⁴:
 - The procedure is a documented laser atherectomy for in-stent restenosis (ISR); **OR**
 - Documented moderate to severe calcification (arc of calcification extends circumferentially to greater than or equal to 180 degrees in a vessel that has failed PTA or, in the opinion of the provider, is not dilatable)¹⁰; **OR**
 - PTA in an infrapopliteal (tibial or peroneal) vessel⁴; **OR**
 - Atherectomy for infrapopliteal occlusive disease with documentation of **ANY** of the following^{*4}:
 - Documented moderate to severe calcification (i.e., arc of calcification extends circumferentially to greater than or equal to 180 degrees in a vessel that has failed PTA); **OR**
 - Documented by the provider to not be dilatable¹⁰; **OR**
 - Occlusion; **OR**
 - Aneurysm (stent); **OR**
 - Flow-limiting dissection after intervention (stent); **OR**
- The patient has non-limb threatening/intermittent claudication arterial occlusive disease, and **ALL** of the following are **TRUE**^{1–2, 6, 11}:
 - The patient fails to show significant clinical improvement despite documented compliance with optimal medical care (OMC) (e.g., smoking cessation, weight management, glycemic control, statin

- therapy, blood pressure management, supervised exercise program, pharmacotherapy [e.g., anti-platelet, cilostazol]); **AND**
- The patient reports their symptoms to be negatively affecting activities of daily living (ADLs); **AND**
 - The clinician determines that the patient is an appropriate candidate for intervention and provides appropriate clinical documentation supporting the clinical decision-making process, including **ANY** of the following:
 - Angiographic (CTA, MRA, invasive angiogram) lesion greater than or equal to 70%; **OR**
 - **ALL** of the following⁷:
 - Angiogram demonstrates stenosis of 50% to 70%; **AND**
 - **ANY** of the following:
 - Resting intravascular pressure measurements (greater than 10 mmHg); **OR**
 - Provoked (greater than or equal to 10 mmHg) intravascular pressure measurements are required to determine the hemodynamic significance of lesions⁷; **OR**
 - Lower extremity duplex Doppler with **ANY** of the following:
 - Peak systolic velocity (PSV) greater than 3 m/sec; **OR**
 - A velocity ratio greater than 4:1⁷; **OR**
 - Occlusion; **OR**
 - **ANY** of the following^{**}:
 - PTA and/or stent for aortoiliac arterial occlusive disease⁴; **OR**
 - PTA and/or stent for femoral-popliteal arterial occlusive disease⁴; **OR**
 - Atherectomy for femoral-popliteal arterial occlusive disease with documentation of **ANY** of the following⁴:
 - The procedure is a documented laser atherectomy for in-stent restenosis; **OR**
 - Documented moderate to severe calcification (i.e., arc of calcification extends circumferentially to greater than or equal to 180 degrees in a vessel that has failed PTA or, in the opinion of the provider, is not dilatable)¹⁰; **OR**
 - The procedure is considered appropriate in the presence or absence of symptoms, and **ANY** of the following is **TRUE**:
 - Bail-out stenting for flow-limiting dissection after the procedure¹; **OR**
 - Stenting for aneurysm or pseudoaneurysm¹; **OR**

- Threatened bypass graft for PTA/stenting and **ANY** of the following:
 - Drop in ABI of 0.15 or greater⁷; **OR**
 - Stenosis in graft/inflow or outflow of greater than 50% by lower extremity arterial Doppler (LEAD) or CTA/MRA.⁷

*NOTE: Infrapopliteal interventions besides a balloon angioplasty (PTA) in the setting of limb-threatening arterial occlusive disease of the extremities may be subject to prospective and/or retrospective review. Inframalleolar revascularization should be extremely rare. Multilevel arterial revascularization procedures may be indicated in the setting of limb-threatening ischemia (e.g., suprainguinal, infrainguinal, and/or infrapopliteal) with appropriate documentation.

**NOTE: Infrapopliteal interventions (endovascular or surgical) are rarely indicated in the treatment of non-limb-threatening arterial occlusive disease of the extremities. All infrapopliteal interventions in the setting of non-limb-threatening arterial occlusive disease of the extremities will be subject to review.

Non-Indications

Lower extremity arterial revascularization is not considered appropriate if **ANY** of the following is **TRUE**^{1-4, 6-7}:

- Revascularization performed in a patient with peripheral artery disease solely to prevent progression to CLTI; **OR**
- **ANY** of the following conditions¹²⁻¹⁴:
 - Pure venous ulcers; **OR**
 - Pure traumatic wounds; **OR**
 - Embolic disease; **OR**
 - Nonatherosclerotic chronic vascular conditions of the lower extremity (e.g., vasculitis, Buerger disease, radiation arteritis); **OR**
- A successful arterial intervention could increase the risk of the patient developing a limb-threatening condition or would not extend the quality or length of life, such as **ANY** of the following:
 - The patient's age or existing co-morbid conditions indicate the risk of a complication; **OR**
 - The patient is permanently non-ambulatory or the patient's activity level is severely limited; **OR**

- Evidence of occlusion without accompanying clinical symptoms (i.e., claudication); **OR**
- Isolated tibial artery occlusive disease in patients with claudication; **OR**
- **ANY** of the following procedures as they are clinically unproven and not medically necessary, as there is inconclusive evidence of their effectiveness:
 - Atherectomy for iliac disease (CPT 0238T)¹⁵; **OR**
 - Endovenous femoral–popliteal arterial revascularization (CPT 0505T); **OR**
 - Use of an eluting resorbable scaffold system for improving luminal diameter in infrapopliteal lesions (CPT C1743)

NOTE:

Rutherford/Fontaine Peripheral Arterial Disease Classification System		
Rutherford Stage	Fontaine Stage	Description/Definition
0	I	Asymptomatic
1	IIa	Mild claudication
2	IIb	Moderate claudication
3	IIb	Severe claudication
4	III	Rest pain
5	IV	Ischemic ulcers of the digits of the foot (minor tissue loss)
6	IV	Severe ischemic ulcers or gangrene (major tissue loss)

WIFI Classification System: Risk stratification based on wound, ischemia, and foot infection¹ (MILLS)

Component	Grade	Description
Wound (W)	0	No ulcer or gangrene (ischemic pain at rest)
	1	Small or superficial ulcer on leg or foot, without gangrene (SDA or SC)
	2	Deep ulcer with exposed bone, joint or tendon with or without gangrene limited to digits
	3	Deep, extensive ulcer involving forefoot and/or midfoot with or without calcaneal involvement with or without extensive gangrene (CR of the foot or nontraditional TMA)
Ischemia (I)	Grade	ABI/SBP of the ankle/TP, TcPO ₂
	0	Greater than or equal to 0.80/Greater than 100 mmHg/Greater than or equal to 60 mmHg
	1	0.6–0.79/70–100 mmHg/40–59 mmHg
	2	0.4–0.59/50–70 mmHg/30–39 mmHg
	3	Less than or equal to 0.39/Less than or equal to 50 mm/Hg/Less than 30 mmHg
Foot Infection (fi)	Grade	Description
	0	Uninfected
	1	Mild local infection, involving only the skin and subcutaneous tissue, erythema greater than 0.5 to less than or equal to 2 cm
	2	Moderate local infection, with erythema greater than 2 cm or involving deeper structures

	3	Severe local infection with signs of SIRS

Wifi = Wound, Ischemia, and foot Infection; **SDA** = simple digital amputation; **SC** = skin coverage; **MDA** = multiple digital amputations; **TMA** = transmetatarsal amputation; **CR** = complex reconstruction; **ABI** = ankle-brachial index; **SBP** = systolic blood pressure; **TP** = toe pressure (SBP of toe); **TCPO2** = transcutaneous oxygen pressure; **SIRS** = systemic inflammatory response syndrome.

TASC Classification of Femoral Popliteal Lesions	
TASC A Lesions	Single stenosis ≤ 10 cm in length Single occlusions less than ≤ 5 cm in length
TASC B Lesions	Multiple stenoses or occlusions each ≤ 5 cm Single stenosis ≤ 15 cm Heavily calcified occlusions ≤ 5 cm Single popliteal stenosis
TASC C Lesions	Multiple stenoses or occlusions totaling ≥ 15 cm Recurrent stenoses or occlusions after failing treatment (Two endovascular interventions).
TASC D Lesions	Chronic total occlusion of common femoral artery or superficial femoral artery (≥ 20 cm) Chronic total occlusion of popliteal artery and proximal trifurcation vessels.

TASC Classification of Aortoiliac Lesions	
TASC A Lesions	Unilateral or bilateral common iliac artery stenoses Unilateral or bilateral short (≤ 3 cm) external iliac artery stenosis
TASC B Lesions	Short (3 cm) stenosis of infrarenal aorta Unilateral common iliac artery occlusion External iliac artery stenosis/stenoses totaling 3–10 cm Unilateral external iliac artery occlusion
TASC C Lesions	Bilateral common iliac artery (CIA) occlusions Bilateral external iliac artery (EIA) stenoses 3–10cm long not extending into the common femoral artery (CFA) Unilateral external iliac artery (EIA) stenosis extending into the common femoral artery (CFA)

	Heavily calcified unilateral external iliac artery (EIA) occlusion
TASC D Lesions	Diffuse disease involving the aorta and both iliac arteries Diffuse multiple stenoses Unilateral occlusion of both external iliac artery (EIA) and common iliac artery (CIA) Bilateral occlusion of external iliac artery (EIA)

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
37254	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel
37256	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel
37258	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively

	catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37260	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel
37262	Intravascular lithotripsy(ies), iliac vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)
37263	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel
37265	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively

	catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel
37267	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37269	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel
37271	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when

	performed, within the same artery, unilateral; straightforward lesion, initial vessel
37273	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel
37275	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37277	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral;

	complex lesion, initial vessel
37280	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel
37282	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel
37284	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37286	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the

	lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel
37288	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37290	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel
37292	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent

	placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37294	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel
37296	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel
37298	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel
C1743	Scaffold, endovascular non-coronary, resorbable

	drug eluting, with delivery system (implantable)
0238T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion

Medical Evidence

Conte et al. (2019) developed global vascular guidelines for the management of chronic limb-threatening ischemia. The group proposed a new anatomic scheme for threatened limbs, the Global Limb Anatomic Staging System (GLASS). This integrated, limb-based approach is based on a set of clinical assumptions and simplified approaches to stratification. They made a strong recommendation for revascularization to all average-risk patients with advanced limb-threatening conditions and significant perfusion deficits. There was a weak recommendation for revascularization in average-risk patients with intermediate limb threat (based on a scoring tool such as Wlfi). It is stated that more in-depth study is required regarding the relationship between regional ischemia and patterns of infrapopliteal and pedal disease.¹

Woo and colleagues (2022) published the Society of Vascular Surgery appropriate use criteria for management of intermittent claudication. 2280 unique intermittent claudication treatment scenarios were rated. Invasive treatment recommendations were made for patients who have completed exercise therapy, are nonsmokers, and are on optimal medical therapy, with severe lifestyle limitations. The group stated that there is unclear benefit and possible harm related to invasive intervention in the infrapopliteal segment for intermittent claudication.⁶

Gerhard-Herman et al. (2017) developed the 2016 AHA/ACC guideline for the management of patients with lower extremity peripheral artery disease. Strong evidence-based recommendations were made for revascularization in the setting of CLTI to minimize tissue loss. Interdisciplinary team evaluation is strongly recommended prior to intervention. The BASIL randomized controlled trial (RCT) (Bypass versus Angioplasty in Severe Ischemia of the Leg) revealed that endovascular revascularization is an effective option for those patients with chronic limb-threatening ischemia as compared with open surgery. The group stated that multiple RCTs are ongoing that compare surgical and endovascular treatment.¹⁶

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Policy Revision History/Information

Original Date: May 28, 2024		
Review History		
Version 2	07/29/2024	Re-formatted document, updated indications and non-indications/references
Version 3	07/31/2025	Annual Review Revised indications and non-indications for clarity: Removed requirements within main bullets regarding specific Rutherford or Fontaine scoring criteria. Clarified language relating to CLTI and ischemic rest pain, upper levels of lesion stenosis reduced from 75% to 70% per current guidelines in both CLTI and non-limb threatening intermittent claudication. Clarified non-indications related to CPT 0238T and 0505T with specific language. Removed references no longer applicable: (McDermott, Bachoo, Dippel, Wang) Added references (Gornik, Hardman, Patel, Feldman) supporting revised criteria.
Version 3.1	12/18/2025	Revision. Codes deleted per AMA code update effective 01/01/2026: 37220, 37221, 37224, 37225, 37226, 37227, 37228, 37229, 37230, 37231.

		Codes added per AMA code update effective 01/01/2026: 37254, 37256, 37258, 37260, 37263, 37265, 37267, 37269, 37271, 37273, 37275, 37277, 37280, 37282, 37284, 37286, 37288, 37290, 37292, 37294.
Version 3.2	01/29/2026	Revision. Codes added as a policy scope expansion: 37262, 37296, 37298.
Version 4	05/21/2026	Revision. Added code C1743 in accordance with 04/01/2026 AMA update and added non-indication for use of an eluting resorbable scaffold system for improving luminal diameter in infrapopliteal lesions.



Cohere Medical Policy - Multiple Gated Acquisition (MUGA) Scan

Clinical Policy for Medical Necessity Review

Version: 3

Policy Number: CHP-013-3

Cohere Health UMC Approval Date: January 29, 2026

Last Annual Review: January 29, 2026

Revision: Not Applicable

Next Annual Review: January 29, 2027

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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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medical Policy - Multiple Gated Acquisition (MUGA) Scan

Policy Number: CHP-013-3

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

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Medical Necessity Criteria

Service: Multiple Gated Acquisition (MUGA) Scan

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a clinical evaluation by the treating provider, which may include a referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation or those that do not align with the provided clinical information—such as mismatched laterality, body part, or CPT code—may be denied due to a lack of medical necessity resulting from insufficient or inconsistent clinical information.
- Repeat diagnostic testing due to technical issues—such as patient motion, incomplete exams, or incorrect imaging sequences—may not be considered medically necessary, as it is the responsibility of the imaging center to deliver appropriate, high-quality studies as originally authorized. Similarly, repeat imaging requested at a different facility based solely on provider preference may not be approved for medical necessity.
- When multiple diagnostic or therapeutic procedures are requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request.
 - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed.

- How the results will impact patient management or treatment decisions.
- Duplicate exams or requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed and/or treated with a single study or procedure.
- Cohere Health evaluates imaging exams based on medical necessity, regardless of whether contrast is used. If an initial non-contrast study is completed and the radiologist later determines that contrast is needed to clarify a finding, the original authorization number may be used—provided the contrast-enhanced exam is performed at the same imaging center and within the original request's validity period, unless otherwise directed by the health plan.

Description

A multiple gated acquisition (MUGA) scan is a noninvasive nuclear medicine test used to evaluate the heart's structural and dynamic properties. A MUGA scan uses a radioactive tracer to create a computerized image of the heart as it beats. This image is used to evaluate the heart's overall ability to pump blood by calculating a left and right ventricular ejection fraction and assessing regional wall motion abnormalities.¹⁻⁵ An equilibrium MUGA scan utilizes technetium-99m (Tc-99m) pertechnetate bound to red blood cells. The technetium remains in the blood pool, allowing serial imaging over several hours. A "first-pass" study utilizes rapidly acquired image frames to observe a bolus of technetium-99m or other suitable radionuclide as it moves through the venous system into the right atrium, right ventricle, pulmonary artery, lungs, left atrium, left ventricle, and aorta.² The procedure can give a separate evaluation of right ventricular function, as well as assess for an intracardiac shunt.^{2,4}

Medical Necessity Criteria

Indications

A **multiple gated acquisition (MUGA) scan** is considered appropriate if **ANY** of the following is **TRUE**:

- An equilibrium MUGA scan and **ALL** of the following:
 - Evaluating ventricular size, wall motion, stroke volume, and ejection fraction; **AND**
 - Information is necessary to direct further evaluation and management for **ALL** of the following:¹⁻⁴
 - **ANY** of the following clinical scenarios:
 - When an assessment of ventricular function is required for management, and transthoracic echocardiography (TTE) or other imaging has proven inadequate⁵; **OR**
 - When there are conflicting results among other tests measuring ejection fraction (EF), and the results of the MUGA will help in the management of the patient; **AND**
 - For the evaluation of **ANY** of the following:
 - Accurate left ventricular ejection fraction (LVEF) in a patient with ongoing heart failure despite guideline-directed medical therapy; **OR**
 - Accurate measure of ejection fraction to determine whether to implant a defibrillator or biventricular pacemaker; **OR**
 - Monitoring and follow-up of a patient receiving any potentially cardiotoxic chemotherapy agent before or after chemotherapy³; **OR**
 - Ventricular dysfunction with post-transplant rejection²; **OR**
 - Ventricular function in a patient with myocardial disease²; **OR**
- A first pass MUGA study and **ANY** of the following²:
 - Need for assessment or identification of intracardiac shunt²; **OR**
 - Information has not been previously obtained or is unlikely to be obtained from other planned tests (e.g., echocardiography, equilibrium gated blood pool studies); **OR**
 - Assessment of right ventricular ejection fraction (RVEF) when TTE or other imaging has proven inadequate⁴; **OR**
- Repeat imaging and **ALL** of the following:
 - Repeat request follows 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

A **MUGA scan** is not considered appropriate if **ANY** of the following is **TRUE**:

- Known allergy or sensitivity to the materials used during the procedure; **OR**
- Pregnant or breastfeeding patients; **OR**
- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms.⁵

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.^{6,7}

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.^{6,7}

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.^{6,7}

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.^{6,7}

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
78466	Myocardial imaging, infarct avid, planar; qualitative or quantitative
78468	Myocardial imaging, infarct avid, planar; with ejection fraction by first pass technique
78469	Myocardial imaging, infarct avid, planar; tomographic SPECT with or without quantification
78481	Cardiac blood pool imaging (planar), first pass technique; single study, at rest or with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification
78483	Cardiac blood pool imaging (planar), first pass technique; multiple studies, at rest and with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification
78494	Cardiac blood pool imaging, gated equilibrium, SPECT, at rest, wall motion study plus ejection fraction, with or without quantitative processing
78496	Cardiac blood pool imaging, gated equilibrium, single study, at rest, with right ventricular ejection fraction by first pass technique (list separately in addition to code for primary procedure)

Medical Evidence

For decades, multiple gated acquisition (MUGA) scans have been used to detect ventricular dysfunction.⁸ However, due to concerns surrounding serial radiation exposure, echocardiography has largely superseded MUGA scans to become the primary method of medical imaging used to monitor and manage chemotherapy-induced cardiomyopathy.⁹ Patients living with breast cancer and patients receiving trastuzumab were found to be particularly vulnerable to radiation exposure and secondary cancer risk associated with repeated MUGA scans.¹⁰ However, the imaging test is still used to monitor left ventricular ejection fraction (LVEF) in clinical settings due to its high reproducibility and ease of administration.⁶

Printezi et al. (2022) conducted a systematic review examining the relative concordance between MUGA, transthoracic echocardiogram (TTE), and cardiac magnetic resonance imaging (CMR) for the monitoring of LVEF in patients with cancer therapy-related cardiac dysfunction. Twenty-two studies were included in the review, reporting on a total of 1017 patients. Overall, TTE and MUGA showed greater concordance, while the agreement between CMR and MUGA was weaker. The authors concluded that a multimodal approach to diagnostic imaging may be possible when monitoring LVEF in patients receiving treatment for cancer.⁴

Mitra et al. (2012) examined two important uses of MUGA scans in day-to-day clinical practice: serial assessment of left ventricular ejection fraction (LVEF) in patients receiving cardiotoxic chemotherapy and in patients with intractable heart failure (HF) who require an accurate determination of LVEF. Among the benefits of the test, according to the authors, are its non-invasive nature, use of low doses of radiation, and ease of administration.¹

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2445-2449

Policy Revision History/Information

Original Date: December 8, 2023		
Review History		
Version 2	01/23/2025	• Annual Review. • In indications: Deleted Infarct avid scintigraphy indication. • In non-indications: The word “lactating” has been replaced by “breastfeeding” to include a patient who has had a stillbirth and is physiologically lactating but not feeding a baby with breast milk or a patient who is formula feeding baby and is physiologically lactating but not feeding a baby with breast milk. • Removed CMS references. • Added reference on chemotherapy-induced dysfunction (reference #4)
Version 3	01/29/2026	Annual Review. Minor edits made to Description and Indications. Added repeat imaging language to Indications section. Added studies to the Medical Evidence section. Added references (5,10).



Cohere Medical Policy – Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

Clinical Guidelines for Medical Necessity Review

Version: 5
Effective Date: January 16, 2025

Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medical Policy – Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

Date of last literature review: 12/11/2024

Document last updated: 1/14/2025

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

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Medical Necessity Criteria

Service: Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

Recommended Clinical Approach

Myocardial perfusion imaging single photon emission computed tomography (MPI-SPECT) is typically appropriate for patients with chest pain (or an ischemic equivalent) and an intermediate (16–50%) or high (greater than 50%) pre-test probability (PTP) of obstructive coronary artery disease (CAD). (See the [Pre-Test Probability of CAD](#) published by the CAD Consortium). An exercise stress test is appropriate if the patient can exercise to a satisfactory workload. If the patient cannot exercise or has electrocardiogram (ECG) abnormalities that interfere with the ECG interpretation during exercise, a pharmacologic MPI-SPECT or cost-effective alternatives such as stress echocardiography or coronary computed tomographic angiography (CCTA) should be considered.

Limitations of MPI-SPECT include cost and radiation exposure. Interpretation of MPI-SPECT can be affected by attenuation artifacts related to soft tissue overlying the heart or extracardiac radioisotope (e.g., liver or gastrointestinal uptake adjacent to the heart).¹⁻² In patients with known CAD and stable symptoms, intensification of preventive measures for those with non-obstructive CAD (less than 50% stenosis) or optimization of guideline-directed medical therapy (GDMT) (including the use of beta-blockers, calcium channel blockers, long-acting nitrates, and/or ranolazine) for those with obstructive CAD (greater than or equal to 50% stenosis) should be performed with an assessment of the response and consideration to defer testing.³⁻⁴

Medical Necessity Criteria

Indications

→ **Myocardial perfusion imaging single-photon emission computed tomography (MPI-SPECT)** is considered appropriate if **ANY** of the following is **TRUE**³⁻⁴:

- ◆ The patient has chest pain (or an ischemic equivalent^A) with **ANY** of the following⁴:
 - No known coronary artery disease (CAD) with an intermediate or high pre-test probability (PTP) (as indicated by the [CAD Consortium Calculator](#)); **OR**
 - No known CAD with a low PTP (less than or equal to 15%) of CAD with a coronary calcium score of 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 following⁵:
 - ◆ 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 no prior testing and **ANY** of the following³:
 - Likely (typical) anginal symptoms^B with **ALL** of the following:
 - Age less than 50 years old; **AND**
 - 0 or 1 cardiovascular (CV) risk factor^B; **OR**
 - Less-likely anginal symptoms with **ANY** of the following:
 - Age 50 years old or above; **OR**
 - Two or more CV risk factors^B; **OR**

- ◆ No known CAD with prior testing and **ALL** of the following³:
 - Symptoms of chest pain (or an ischemic equivalent^A, see Definitions section below); **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 following are **TRUE**⁶:
 - 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 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)⁷; **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 **ANY** of the following:
 - High atherosclerotic cardiovascular disease (ASCVD) risk (more than 20% as indicated by the [ACC/AHA ASCVD Risk Estimator](#)); **OR**
 - Intermediate or high PTP (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 CAD with a history of prior myocardial infarction (MI) or coronary revascularization and **ANY** of the following³:
 - Surveillance testing and **ANY** of the following is **TRUE**:
 - 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 – 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)⁸ and **ANY** of the following:
 - Planned solid organ transplant (renal, pancreas, combined renal pancreas, liver, lung, or intestinal); **OR**
 - No known or suspected heart disease^{C,8} and **ALL** of the following:
 - 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 heart disease^{D,8} and **ANY** of the following:
 - 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); **OR**

- Prior cardiac stress testing within 3 to 8 months and **ANY** of the following:
 - High-risk vascular surgery (Table 1) with risk factors that the physician feels warrant repeat testing; **OR**
 - New findings on transthoracic echocardiogram (TTE) such as new wall motion abnormalities, new significant valvular disease, or significant drop in ejection fraction; **OR**
 - New or worsening possible cardiovascular symptoms.

^A Ischemic equivalent: Chest pain syndrome, anginal equivalent, or ischemic electrocardiogram (ECG) abnormalities are 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 CAD may also be considered an ischemic equivalent.⁹

^B Likely or typical anginal symptoms: Chest/epigastric/shoulder/arm/jaw pain, chest pressure/discomfort, when occurring with exertion or emotional stress and relieved by rest, nitroglycerin, or both.

^C No known or suspected heart disease by history, exam, or electrocardiogram⁸: 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.

^D Known or suspected heart disease by history, exam, or electrocardiogram⁸: 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 3x the upper limit of normal.

Non-Indications

→ **Myocardial perfusion imaging single-photon emission computed tomography (MPI-SPECT)** is not considered appropriate if **ANY** of the following is **TRUE**^{3-4,9}:

- ◆ The patient has undergone advanced imaging of the same body part and for the same indication within 3 months, without being on treatment; **OR**
- ◆ The patient is pregnant; **OR**
- ◆ Vasodilators (e.g., adenosine, regadenoson, and dipyridamole) are contraindicated in patients with hypotension, sinus node dysfunction, high-degree atrioventricular (AV) block (in the absence of back up pacemaker capability), and reactive airway disease; **OR**
- ◆ An active cardiac condition that has not been stabilized (e.g., uncontrolled hypertension, uncontrolled arrhythmias, undiagnosed chest pain, unstable angina); **OR**
- ◆ An active pulmonary condition that has not been stabilized (e.g., difficulty breathing, the possibility of pulmonary embolism); **OR**
- ◆ Normal coronary angiogram or CCTA with no stenosis or plaque within the last two years, and the patient has not had a significant change in symptoms⁴; **OR**
- ◆ Normal stress test (given adequate stress) without a significant change in symptoms within the last year⁴; **OR**
- ◆ HD (anatomic imaging may be indicated).

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
78451	Single-photon emission computed tomography (SPECT) myocardial perfusion imaging study with stress
78452	Multiple single-photon emission computed tomography (SPECT) myocardial perfusion imaging studies with stress
78453	Myocardial perfusion imaging, planar (including

	qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)
78454	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection

Definitions

Symptomatic/Ischemic Equivalent: Chest pain syndrome, anginal equivalent, or ischemic electrocardiogram (ECG) abnormalities are any constellation of clinical findings 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 CAD may also be considered an ischemic equivalent.¹²

Pre-Test Probability (of Obstructive CAD): Pre-test probability (PTP) of CAD is the likelihood that the patient has CAD, calculated before the test result is known. These guidelines reference the 2019 European Society of Cardiology (ESC) Guidelines for the diagnosis and management of chronic coronary syndromes model to calculate the PTP based on age, sex, and type of chest pain.^{4,13-15} Additional information such as a coronary artery calcium (CAC) score or risk factors for CAD (e.g., diabetes mellitus, smoking, family history of premature CAD [first-degree relative: male less than 55 years old or female less than 65 years old], hypertension, or dyslipidemia) can be used to improve the identification of obstructive CAD as indicated by the [CAD Consortium Calculator](#).

Table 1. Definitions of Low, Intermediate, and High-Risk Surgery²

	Surgical Risk Level		
Specialty	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	1. Bladder repair	1. Radical retropubic prostatectomy 2. Nephrectomy

	- Transurethral bladder tumor resection - Ureteral stents - Nephrostomy - Extracorporeal shock wave lithotripsy		3. Cystectomy
Gyn.	- Vaginal hysterectomy - Diagnostic gynecologic procedures (laparoscopy)	- Total abdominal hysterectomy - Bilateral salpingo-oophorectomy	-
Breast	- Diagnostic breast surgery (lumpectomy, node dissection) - Simple mastectomy	Complex breast surgery	-
Plastic Surgery	- Hand - Cosmetic procedures	- Reconstructive flaps - Post-bariatric repair abdominoplasty	-
Ear, Nose, Throat	- Diagnostic laryngoscopy - Diagnostic esophagoscopy	- Nasal septal procedures - Functional endoscopic sinus surgery	Head/neck cancer dissection (with/without laryngectomy)
Oral & Maxillofacial Surgery	Jaw reduction	Temporomandibular procedures/osteotomy	-
Podiatry	- Arthroplasty - Toe amputation - Bunion procedure	-	-
Eye	- Cataract repair - Retinal surgery - Eye muscle surgery		
Organ Transplant	-	-	- Renal Transplant - Pancreas Transplant - Kidney-Pancreas Combined Transplant - Liver - Lung - Intestinal

Medical Evidence

Huck et al. (2024) conducted a retrospective study to evaluate patients post-kidney transplant due to the risk of major adverse cardiovascular events (MACEs). The population is also at higher risk of developing cardiovascular disease (CVD). Single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), and pretransplant positron emission tomography (PET) were utilized in the study of 393 patients. Results were taken from a follow-up period of 5.9 years. Overall, PET MPI was more effective than SPECT-MPI in predicting MACEs in patients post-kidney transplant. Future research should include the effectiveness of normal PET versus SPECT when evaluating low-risk patients.¹⁶

Kelderman et al. (2022) performed a systematic review on using MPI SPECT to diagnose CVD in patients assessed for kidney transplantation. Thirteen studies that focused on MPI SPECT were identified and included in the meta-analysis of 1245 MPI SPECT scans. The pooled sensitivity was 0.66 (95% CI 0.53 to 0.77), pooled specificity was 0.75 (95% CI 0.63 to 0.84), and the area under the curve (AUC) was 0.76. The authors note that while the accuracy is not high with MPI SPECT for the diagnosis of coronary artery disease (CAD), it is recommended to screen patients at-risk.¹⁷

Patel et al. (2019) conducted a single-center randomized control trial (RCT) to determine the clinical efficacy of pharmacological MPI-SPECT and PET MPI in patients with CAD and ischemia. A total of 322 symptomatic patients were included. The following pharmacologic agents were given to patients: aspirin therapy (88.8%), beta-blockers (76.7%), and statin therapy (77.3%). Seven patients (2.2%) had a diagnostic failure at 60 days, however, no major differences in diagnostic failure rates were observed overall. Decreased utilization of coronary angiography or revascularization was noted. (ClinicalTrials.gov Identifier NCT00976053).¹⁸

A number of recent articles provided recommendations for a number of clinical scenarios. Gulati et al. (2021) provided insights into the evaluation and diagnosis of chest pain, Winchester et al. (2023) provided appropriate use criteria (AUC) for the detection and risk assessment of chronic CAD, and Doherty et al. (2024) updated a previous AUC document for the

cardiovascular evaluation for nonemergent, non-cardiac surgery, focusing more on ischemic heart disease (HD), valvular HD, and heart failure (rather than CVD in general) and their relation to the risks associated with various types of surgery (solid organ transplant, vascular, non-vascular).³⁻⁴⁸

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Clinical Guideline Revision History/Information

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Version 2	11/17/2023	
Version 3	8/2/2024	Annual review and policy restructure.
Version 4	10/29/2024	Edited repeat imaging criteria language.
Version 5	1/16/2025	• Annual review. • Added indications for preoperative clearance. • Major reorganization of the boolean logic and indication order throughout the medical necessity criteria. • Literature review - Medical Evidence section updated (including references).



Cohere Medical Policy – Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

Clinical Policy for Medical Necessity Review

Version: 7

Policy Number: CHP-012-7

Cohere Health UMC Approval Date: January 29, 2026

Last Annual Review: January 29, 2026

Revision: Not Applicable

Next Annual Review: January 29, 2027

Important Notices

Notices & Disclaimers:

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medical Policy - Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

Policy Number: CHP-012-7

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

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Medical Necessity Criteria

Service: Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a clinical evaluation by the treating provider, which may include a referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- Repeat diagnostic testing due to technical issues—such as patient motion, incomplete exams, or incorrect imaging sequences—may not be considered medically necessary, as it is the responsibility of the imaging center to deliver appropriate, high-quality studies as originally authorized. Similarly, repeat imaging requested at a different facility based solely on provider preference may not be approved for medical necessity.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request

- Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
- How the results will impact patient management or treatment decisions
- Duplicate exams or requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed and/or treated with a single study or procedure.
- Cohere Health evaluates imaging exams based on medical necessity, regardless of contrast use. If an initial non-contrast study is completed and the radiologist later determines that contrast is needed to clarify a finding, the original authorization number may be used—provided the contrast-enhanced exam is performed at the same imaging center and within the original request's validity period, unless otherwise directed by the health plan.

Description

Myocardial perfusion imaging single-photon emission computed tomography (MPI-SPECT) of the heart is a nuclear medicine test that uses gamma rays to assess blood flow and heart function. During the procedure, a small amount of a radioactive tracer is injected into the bloodstream. This tracer is taken up by healthy heart tissue, allowing gamma cameras to capture detailed, three-dimensional images of the heart. These images help medical professionals detect areas of reduced blood flow, evaluate damage from a previous heart attack, and determine whether coronary artery disease (CAD) is present. MPI-SPECT imaging can be performed at rest or after stress (either physical exercise or medication-induced) to identify regions of the heart affected by ischemia or limited blood supply due to narrowed coronary arteries.^{1,2}

Medical Necessity Criteria

Indications

Myocardial perfusion imaging single-photon emission computed tomography (MPI-SPECT) is considered appropriate if **ANY** of the following is **TRUE**^{3,4}:

- Symptoms of angina (or an anginal equivalent^A) with **ANY** of the following⁴:
 - Known coronary artery disease (CAD) with **ANY** of the following³:
 - Without improvement on best tolerated guideline-directed medical therapy (GDMT); **OR**
 - Documented unstable angina; **OR**
 - No known CAD with **ANY** of the following:
 - Intermediate or high pre-test probability (PTP)^B (as indicated by the [CAD Consortium Calculator](#) or coronary calcium score greater than or equal to 100 Agatston); **OR**
 - **ANY** of the following⁴⁻⁷:
 - Greater than 1 mm ST depression at rest; **OR**
 - 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**
 - Left bundle branch block (LBBB); **OR**
 - Left ventricular hypertrophy with ST-T abnormalities; **OR**
 - Taking digoxin; **OR**
 - Ventricular pre-excitation (Wolff-Parkinson-White pattern); **OR**
 - Ventricular-paced rhythm; **OR**
 - Prior testing with **ANY** of the following:
 - Abnormal routine stress electrocardiogram (ECG); **OR**
 - Coronary computed tomographic angiography (CCTA) with moderate stenosis 50 to 69%; **OR**
 - Equivocal plain exercise treadmill test^C; **OR**
 - Inconclusive CCTA; **OR**
 - Inconclusive routine stress ECG; **OR**
 - Invasive coronary angiography with intermediate severity (maximal coronary diameter stenosis is 40% to 69%) with no fractional flow reserve (FFR) or instantaneous wave-free ratio (iFR) performed; **OR**
 - Previous stress echocardiography had poor echocardiographic windows; **OR**

- Newly diagnosed heart failure with **ALL** of the following⁸:
 - **ANY** of the following scenarios:
 - Asymptomatic ejection fraction (EF) less than 45%; **OR**
 - Heart failure with reduced ejection fraction (HFrEF); **OR**
 - Heart failure with preserved ejection fraction (HFpEF); **AND**
 - No planned cardiac catheterization; **AND**
 - No previous evaluation for CAD; **OR**
- Evaluation of new ventricular arrhythmias without prior cardiac evaluation for ischemia as indicated by **ANY** of the following:
 - Exercise-induced ventricular tachycardia; **OR**
 - 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)⁹; **OR**
 - Sustained ventricular tachycardia; **OR**
 - Ventricular fibrillation; **OR**
- Before initiation of antiarrhythmic therapy (e.g., flecainide), and the patient has intermediate or high PTP^B of CAD; **OR**
- Syncope without an ischemic equivalent^A and the initial evaluation suggests a cardiovascular abnormality (e.g., abnormal ECG or echocardiogram); **OR**
- Surveillance testing in asymptomatic patients with **ANY** of the following:
 - Coronary artery bypass graft (CABG) at least 5 years ago and no testing within the last 5 years; **OR**
 - Percutaneous coronary intervention (PCI) at least 2 years ago and no testing within the last 2 years; **OR**
 - Coronary calcium Agatston score greater than 400^{8,10}; **OR**
 - Coronary stenosis without physiology testing, as documented by **ANY** of the following within the last 6 months:
 - Coronary angiography with stenosis greater than 50%; **OR**
 - CCTA with stenosis greater than 40%; **OR**
 - Evaluation for transplant coronary artery disease (TCAD) or cardiac allograft vasculopathy (CAV) after organ transplantation^{11,12}; **OR**
 - High-risk for silent ischemia due to **ANY** of the following within the last 5 years:
 - Chronic kidney disease^D; **OR**
 - Diabetes mellitus with known accelerated progression of CAD; **OR**

- History of **ANY** of the following and no evaluation for ischemia within the last 5 years:
 - Documented incomplete revascularization; **OR**
 - Prior myocardial infarction; **OR**
- Recent non-ST-elevation myocardial infarction (NSTEMI) and no prior ischemic evaluation; **OR**
- Preoperative testing for **ANY** of the following:
 - Planned solid organ transplant without stress testing within the last 12 months; **OR**
 - High-risk nonvascular surgery (Table 1); **OR**
 - High-risk vascular surgery (Table 1); **OR**
 - No known or suspected coronary heart disease (CHD)^E with **ALL** of the following¹³:
 - Functional status less than 4 metabolic equivalents (METs) and **ANY** of the following:
 - Intermediate risk nonvascular surgery (Table 1) with at least an intermediate (16% or greater) pre-test probability of obstructive CAD^B; **OR**
 - Intermediate risk vascular surgery (Table 1); **AND**
 - New or worsening possible cardiac symptoms; **AND**
 - No testing within the last 3–8 months; **OR**
 - Known or suspected CHD^E with **ALL** of the following¹³:
 - No stress testing within the last 3–8 months; **AND**
 - **ANY** of the following:
 - 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**
 - Greater than 4 METs with new or worsening possible cardiac symptoms; **OR**
 - Less than 4 METs with or without 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); **OR**
- Prior cardiac stress testing within 3-8 months and **ANY** of the following:
 - High-risk vascular surgery (Table 1) with risk factors that warrant repeat testing; **OR**
 - New findings on transthoracic echocardiography (TTE) (e.g., new wall motion abnormalities, new significant valvular disease, or significant drop in EF); **OR**
 - New or worsening possible cardiovascular symptoms.

Non-Indications

Myocardial perfusion imaging single-photon emission computed tomography (MPI-SPECT) is not considered appropriate if **ANY** of the following is **TRUE**^{3,4,6}:

- Active cardiac condition that has not been stabilized (e.g., uncontrolled hypertension, uncontrolled arrhythmias, unstable angina); **OR**
- Advanced imaging of the same body part for the same indication within 3 months, without intervening treatment; **OR**
- Asymptomatic patients undergoing a low-risk procedure; **OR**
- Pregnancy; **OR**
- Normal coronary angiogram or coronary computed tomographic angiography (CCTA) with no stenosis or plaque within the last 2 years, and no significant change in symptoms⁴; **OR**
- Normal stress test at 85% or greater of maximum predicted heart rate without a significant change in symptoms within the last year⁴; **OR**
- Routine screening in asymptomatic patients with or without diabetes; **OR**
- Vasodilators (e.g., adenosine, regadenoson, and dipyridamole) are contraindicated in individuals with hypotension, sinus node dysfunction, high-degree atrioventricular (AV) block (in the absence of back up pacemaker capability), and reactive airway disease.

Definitions and Notes

^A Anginal equivalent: Any constellation of clinical findings consistent with coronary artery disease (CAD) manifestations. Examples 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. These symptoms typically occur with exertion and are relieved by rest or nitroglycerin. 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.⁶

^B Pre-test probability (of obstructive CAD): The likelihood that the patient has CAD, calculated before the test result is known. These guidelines reference the 2019 European Society of Cardiology (ESC) Guidelines for the diagnosis and management of chronic coronary syndromes model to calculate the PTP based on age, sex, and type of chest pain.^{4,14-16} The [CAD Consortium Calculator](#) can be used to determine pre-test probability of CAD in patients with chest pain.

^C Equivocal plain exercise treadmill test:

- 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 metabolic equivalents (METS)

^D Chronic kidney disease: Stage 3 or above with estimated glomerular filtration rate [eGFR] of 15–59 mL/min/1.73 m² with or without albuminuria that is not treated with dialysis or kidney transplantation.¹⁷

^E No known or suspected heart disease by history, exam, or ECG: 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, valvular heart disease (VHD), or heart failure. 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, left bundle branch block (LBBB), or atrial fibrillation. B-type natriuretic peptide (BNP) or proBNP, if measured, is normal.¹³

F Known or suspected heart disease by history, exam, or electrocardiogram:

Percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG), prior infarct, cardiac risk factors (e.g., hypertension, hyperlipidemia, diabetes mellitus, tobacco use, family history of 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 ECG, left ventricular hypertrophy (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 three times the upper limit of normal.¹³

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.^{[18,19](#)}

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.^{[18,19](#)}

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.^{[18,19](#)}

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.^{[18,19](#)}

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
78451	Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)
78452	Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection
78453	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)
78454	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection

Tables

Table 1. Definitions of Low, Intermediate, and High-Risk Surgery¹⁴

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. Postbariatric 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 transplant 5. Lung transplant 6. Intestinal transplant

Medical Evidence

Arham et al. (2025) performed a systematic review and meta-analysis comparing MPI-SPECT using the Discovery NM 530c CZT-SPECT system to invasive coronary angiography (ICA), positron emission tomography (PET), magnetic resonance imaging (MRI), and coronary computed tomography (CT) angiography in patients with known or suspected coronary artery disease (CAD). Eleven prospective cohort studies enrolling 716 adult patients were included in the analysis. Results suggested MPI-SPECT provides high sensitivity (83.5%, 95% CI 77.3-88.3%), moderate specificity (75.8%, 95% CI 67.8-82.3%), and high diagnostic accuracy (area under the curve [AUC]=0.858) for detecting CAD. Authors noted that CZT SPECT may offer improved accuracy, although guidelines did not distinguish between conventional and CZT-based systems.²⁰

Huck et al. (2024) conducted a retrospective cohort study comparing myocardial perfusion imaging (MPI) single-photon emission computed tomography (SPECT) and positron emission tomography (PET) MPI in patients at risk of developing cardiovascular disease (CVD) following kidney transplant. The study included 393 patients with a median follow-up period of 5.9 years. Overall, PET MPI was more effective than MPI-SPECT at predicting major adverse cardiovascular events (MACEs) in patients following a kidney transplant. Future research should include the effectiveness of normal PET versus SPECT when evaluating low-risk patients.²¹

Kelderman et al. (2022) performed a systematic review and meta-analysis comparing the diagnostic accuracy of MPI-SPECT versus ICA for detecting CVD in patients undergoing kidney transplantation assessment. Thirteen studies reporting 1245 MPI SPECT scans were included in the meta-analysis. Results suggested that MPI-SPECT demonstrates low to moderate sensitivity (66%, 95% CI 0.53 to 0.77), specificity (75%, 95% CI 0.63 to 0.84), and diagnostic accuracy (area under the curve [AUC]=0.76). Although MPI-SPECT had modest diagnostic accuracy for detecting CAD, the authors noted that current guidelines do recommend its use for screening at-risk patients.²²

Patel et al. (2019) conducted a single-center randomized controlled trial (RCT) to compare the clinical efficacy of pharmacological stress MPI-SPECT and PET MPI in patients with CAD and ischemia. A total of 322 symptomatic

patients were included. Pharmacological stress testing was performed using dipyridamole (89%) or regadenoson (11%). Seven patients (4 MPI-SPECT [2.5%]; 3 PET MPI [1.9%]) had a diagnostic failure (defined as unnecessary angiography) at 60 days, with no difference observed between groups ($p=0.70$). However, no major differences in diagnostic failure rates were observed overall (ClinicalTrials.gov Identifier NCT00976053).²³

A number of recent articles provided recommendations for several clinical scenarios. Gulati et al. (2021) provided insights into the evaluation and diagnosis of chest pain, Winchester et al. (2023) provided appropriate use criteria (AUC) for the detection and risk assessment of chronic CAD, and Doherty et al. (2024) updated a previous AUC document for the cardiovascular evaluation for nonemergent, noncardiac surgery, focusing more on ischemic heart disease, valvular heart disease, and heart failure (rather than CVD in general) and their relation to the risks associated with various types of surgery (solid organ transplant, vascular, nonvascular).³⁴⁶

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Policy Revision History/Information

Original Date: April 29, 2022		
Review History		
Version 2	11/17/2023	Policy criteria reviewed and updated per medical literature.
Version 3	08/02/2024	Annual review and policy restructure.
Version 4	010/29/2024	Edited repeat imaging criteria language.
Version 5	01/16/2025	Annual review. Added indications for preoperative clearance. Major reorganization of the boolean logic and indication order throughout the medical necessity criteria. Literature review - Medical Evidence section updated (including references).
Version 6	05/22/2025	Combined indications regarding intermediate or high pre-test probability and coronary calcium score of greater than or equal to 100 Agatston. Updated "The patient has chest pain (or an ischemic equivalent)" to "The patient has angina (or an anginal equivalent)" and associated footnote.
Version 7	01/29/2026	Annual review. Updated repeat imaging criteria language.

		Updated code descriptions for 78451 and 78452. Added indications for prior cardiac stress testing, calcium Agatston score, evaluation of transplant coronary artery disease, and coronary stenosis without physiology testing. Updated Definitions and Notes. Expanded the Medical Evidence section; added 1 citation. Reordered references to match the order in which they first appear. Added 6 references (reference numbers 7, 11, 12, 13, 17, 20).



Cohere Medical Policy - Percutaneous Coronary Intervention

Clinical Policy for Medical Necessity Review

Version: 3

Policy Number: CHP-019-3

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Last Annual Review: January 29, 2026

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Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Percutaneous Coronary Intervention

Policy Number: CHP-019-3

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

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Medical Necessity Criteria

Service: Percutaneous Coronary Intervention

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation or those that do not align with the provided clinical information—such as mismatched laterality, body part, or CPT code—may be denied due to a lack of medical necessity resulting from insufficient or inconsistent clinical information.
- When multiple diagnostic or therapeutic procedures are requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request.
 - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed.
 - How the results will impact patient management or treatment decisions
- Duplicate exams or requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed and/or treated with a single study or procedure.

Description

Coronary artery revascularization is the process of re-establishing blood flow through the coronary arteries that vascularize the cardiac muscle. This is accomplished through a traditional, open approach (coronary artery bypass graft surgery [CABG]) or a minimally invasive approach (percutaneous coronary intervention [PCI]). In patients with stable ischemic heart disease (SIHD), a PCI is typically performed during a heart catheterization for symptomatic, significant stenosis or blockage that is refractory to optimal medical therapy, or to improve survival.

Coronary atherectomy is a PCI technique used to remove atheromatous (fatty) plaque from the coronary arteries. Atherectomy devices—such as rotational, orbital, or excimer laser systems—mechanically or thermally ablate plaque to improve vessel wall compliance and luminal patency. Coronary atherectomy is typically used as an adjunct to balloon angioplasty when fibrotic or moderate to severely calcified lesions are unlikely to be crossed or adequately expanded with balloon angioplasty alone.¹

Medical Necessity Criteria

Indications

Percutaneous coronary intervention (PCI) (e.g., percutaneous transluminal angioplasty [PTA] with or without stenting, coronary atherectomy) is considered appropriate if **ALL** of the following are **TRUE**¹⁻⁹:

- Significant coronary artery disease (CAD) defined by **ANY** of the following:
 - Significant anatomic stenosis greater than or equal to 50% left main CAD^{1,2,8}; **OR**
 - Minimal luminal area (MLA) less than 6 mm² on intravascular ultrasound (IVUS)^{2,8}; **OR**
 - Significant anatomic stenosis greater than or equal to 70% non-left main CAD¹; **OR**
 - Significant physiological stenosis: fractional flow reserve (FFR) less than or equal to 0.80 or instantaneous wave-free ratio (iFR) less than or equal to 0.89^{1,2,4,8}; **AND**
- **ANY** of the following:
 - Ventricular fibrillation (VF)¹; **OR**
 - Polymorphic ventricular tachycardia (VT)¹; **OR**
 - Prior cardiac arrest¹; **OR**

- Severe left ventricle dysfunction (ejection fraction less than or equal to 35%)²; **OR**
- Prior to structural heart interventions or high-risk vascular procedures (such as transcatheter aortic valve replacement [TAVR])^{1,10}; **OR**
- Prior to renal transplantation^{1,11}; **OR**
- Prior to liver transplantation¹²⁻¹⁴; **OR**
- Silent ischemia associated with high-risk findings (e.g., significant defects on myocardial perfusion imaging [MPI]); **OR**
- Acute ST-elevation myocardial infarction (STEMI)^{1,15,16}; **OR**
- Non-ST-elevation acute coronary syndrome (NSTEMI-ACS)^{1,3,5,15,16}; **OR**
- Unstable angina^A; **OR**
- Refractory angina (or ischemic equivalent^B) with symptoms despite optimal medical therapy (guideline-based medical therapy [GDMT], including two anti-anginal drugs or documented intolerance)⁴; **OR**
- Stable ischemic heart disease (SIHD) and **ANY** of the following:
 - Multivessel CAD with significant stenoses in the three major coronary arteries that are suitable for PCI^{1,6}; **OR**
 - **ALL** of the following^{1,2}:
 - Significant left main stenosis (greater than or equal to 50%); **AND**
 - PCI is expected to provide equivalent revascularization to coronary artery bypass graft surgery (CABG); **OR**
- In patients with STEMI or non-ST-elevation myocardial infarction (NSTEMI) after PCI of the culprit lesion, staged PCI for significant non-culprit stenosis, typically within 90 days^{1,6,17}; **OR**
- Prior heart transplant and severe cardiac allograft vasculopathy (as diagnosed by coronary angiography/IVUS) with proximal, discrete lesion(s)^{2,4,18,19}; **OR**
- **ANY** of the following (92930):
 - Two or more distinct noncontiguous lesions; **OR**
 - Bifurcation lesion; **OR**
- Chronic total occlusion with combined antegrade and retrograde approaches (92945).

Non-Indications

Percutaneous coronary intervention is not considered appropriate if **ANY** of the following is **TRUE**^{1-5,8,9,16,20}:

- Acute presentation with STEMI and **ALL** of the following:

- Totally occluded infarct-related artery greater than 72 hours after symptoms onset²¹; **AND**
- No evidence of ongoing ischemia, acute severe heart failure, or life-threatening arrhythmia¹⁶; **OR**
- Significant left main CAD with high-complexity CAD^{1,4,5}; **OR**
- Multivessel CAD with complex or diffuse CAD (e.g., SYNTAX score greater than 33)^{1,2,4,8}; **OR**
- Diabetes mellitus and multivessel CAD with the involvement of the left anterior descending artery (LAD), and an appropriate candidate for CABG.^{1-4,8}

Definitions and Notes

^AUnstable angina: Defined as at least one of the following in patients whose cardiac biomarker levels do not meet criteria for acute myocardial infarction²²:

- Prolonged rest angina (typically greater than 20 minutes)
- New onset angina of at least Canadian Cardiovascular Society (CCS) class III or higher
- Increasing angina (e.g., previously diagnosed angina that has become more frequent or severe, longer in duration, or lower in threshold)

^BIschemic equivalent: Examples 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 CAD may also be considered an ischemic equivalent.²³

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
92920	Percutaneous transluminal coronary angioplasty, single major coronary artery and/or its branch(es)
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed, single major

	coronary artery and/or its branch(es)
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); 1 lesion involving 1 or more coronary segments
92930	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); 2 or more distinct coronary lesions with 2 or more coronary stents deployed in 2 or more coronary segments, or a bifurcation lesion requiring angioplasty and/or stenting in both the main artery and the side branch
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed, single major coronary artery and/or its branch(es)
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed, single major coronary artery and/or its branches
92943	Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery branches of the bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; antegrade approach
92945	Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery branches of the bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; combined antegrade and retrograde approaches
C9600	Percutaneous transcatheter placement of drug eluting

	intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
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)
C1724	Catheter, transluminal atherectomy, rotational

Medical Evidence

The 2025 American College of Cardiology (ACC)/American Heart Association (AHA) guideline for the management of patients with acute coronary syndrome (ACS) contains several recommendations on the use of PCI in both emergent and non-emergent settings in addition to several important recommendations on appropriate medical management of patients undergoing PCI. In non-emergent settings, the guidelines recommend PCI in patients with ST-segment elevation myocardial infarction or non-ST-segment elevation ACS. The guidelines also note that the choice of revascularization method (e.g., surgical bypass vs. percutaneous) should be determined by disease complexity and any patient comorbidities.¹⁶

Similarly, the 2024 Japanese Association of Cardiovascular Interventional and Therapeutics (CVIT) expert consensus statement also recommends complete revascularization in some patients including STEMI or non-ST-elevation myocardial infarction (NSTEMI) patients with multivessel disease.¹⁵

In 2024, the Society for Cardiovascular Angiography and Interventions (SCAI) issued an expert consensus statement on treating patients with ST-elevation myocardial infarction (STEMI) through PCI. The authors acknowledge the complexity of managing multivessel disease, present in about half of patients with STEMI, and therefore recommended complete revascularization with treatment of the non-infarct stenosis. At the time of authorship of the statement, the existing guidelines recommended staged PCI among stable patients—although research in this area is ongoing with respect to the optimal timing of resolution of non-culprit lesions.⁷

Virani et al. (2023) developed a clinical practice guideline for managing patients with chronic coronary disease for the American Heart Association and the American College of Cardiology. Revascularization has a strong recommendation in patients with lifestyle-limiting angina who are currently on guideline-based medical therapy (GDMT) and who have significant coronary artery stenoses. Due to higher survival rates, coronary artery bypass grafting (CABG) is recommended over PCI in patients with chronic coronary

disease with significant left main artery involvement associated with high-complexity CAD.⁴

Abusnina et al. (2022) conducted a systematic review to evaluate the clinical outcomes of atherectomy in treating coronary artery calcification (CAC) in patients with reduced left ventricular ejection fraction (LVEF). The review includes 7 studies involving 2,238 unique patients with a median follow-up duration of 22.4 months. Comparing patients with severely reduced LVEF compared to those with moderately reduced or preserved LVEF, the authors found the risk ratio (RR) of in-hospital all-cause mortality using atherectomy was 5.28 (95% CI 1.65–16.84; P equal to 0.005) and RR for long term all-cause mortality was 2.84 (95% CI 1.16–6.95; P equal to 0.02). The results indicate that treating severe CAC with atherectomy in patients with severely reduced LVEF had significantly higher in-hospital and long-term all-cause mortality risks compared to the patients with moderate or preserved LVEF. While there was no significant difference in in-hospital cardiac mortality between the two groups, long-term cardiac mortality was significantly higher in patients with severe CAC and severely reduced LVEF who underwent atherectomy.²⁶

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 to describe the best practices of coronary artery revascularization. It recommended that, in patients with significant left main disease, traditional surgical revascularization be undertaken. Percutaneous revascularization (PCI) is a reasonable option to improve survival as 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.¹

Schwarz et al. (2022) conducted a systematic review and meta-analysis to compare periprocedural characteristics and outcomes of planned atherectomy (PA), bailout atherectomy (BA), and RA. PA is defined as RA performed immediately prior to balloon pre-dilation, while BA is defined as RA after failure to expand a pre-dilating balloon. Pooling 2120 patients from 5 studies, the authors found no difference in procedural success (PA vs BA risk ratio [RR] 1.03; 95% confidence interval [95% CI] 0.99–1.07), major adverse

cardiovascular events on follow-up (RR 1.04, 95% CI 0.62–1.74), death (RR 0.98, 95% CI 0.59–1.64), myocardial infarction (MI) (RR 1.16, 95% CI 0.62–2.18), target vessel re-vascularization (RR 1.40, 95% CI 0.83 to 2.36), stroke (RR 1.50, 95% CI 0.46–4.86), or stent thrombosis (RR 0.82, 95% CI 0.06–10.74). However, compared to BA, PA was associated with shorter procedural times (mean difference [MD] -25.88 min, 95% CI -35.55 to -16.22), fewer coronary dissections (RR 0.50, 95% CI 0.26–0.99), fewer stents (MD -0.20, 95% CI -0.29 to -0.11), and a trend toward less periprocedural MI (RR 0.77, 95% CI 0.54–1.11).²⁵

Khan et al. (2019) conducted a meta-analysis to compare the safety and efficacy of rotational atherectomy (RA) performed using trans-radial (TR) and transfemoral (TF) access to evaluate the widespread reluctance to use TR access for complex percutaneous coronary intervention (PCI), including RA, for heavily calcified coronary lesions. The meta-analysis includes 5 retrospective studies with 3315 patients undergoing RA via TR access and 5838 patients undergoing RA via TF access. TR access was associated with lower major access site bleeding (OR: 0.45, 95% CI: 0.31–0.67, *P* less than 0.001) and radiation exposure (MD: -16.1, 95% CI: -25.4--6.7 Gy cm², *P* equal to 0.0007). No significant differences were observed in all-cause in-hospital mortality, major adverse cardiac events (MACE), stent thrombosis, myocardial infarction, hospital stay, procedure time, or procedure success between the two groups.²⁴

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Original Date: December 29, 2023		
Review History		
Version 2	01/16/2025	Annual Policy Review & Restructure. Updated recommended clinical approach to the current format. Consolidated redundant indications. Reorganized order of indications for improved clarity. Added indication for cardiac allograft vasculopathy. Added indication for management of significant CAD among patients with left ventricle dysfunction. Added indication for pre-TAVR, pre-renal transplant, pre-liver transplant patients. Defined ischemic equivalent with previously-used language. Updated medical evidence. Updated references.
Version 3	01/29/2026	Annual review. Merged with previously titled "Cohere Medical Policy - Coronary Atherectomy".

		Renamed policy from “Cohere Medical Policy – Percutaneous Coronary Intervention (PCI)/Angioplasty/Stent” to “Cohere Medical Policy – Percutaneous Coronary Intervention”. Added non-indication criteria for stable STEMI. Defined unstable angina. Expanded the Medical Evidence section; added 2 citations. New codes added: 92930, 92945 Codes deleted per AMA code update effective 01/01/2026: 92921, 92925, 92929, 92934, 92944 Code descriptions revised per AMA code update effective 01/01/2026: 92920, 92924, 92928, 92933, 92937, 92943



Cohere Medical Policy - Percutaneous Coronary Intervention (PCI)/Angioplasty/Stent

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: January 16, 2025

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Percutaneous Coronary Intervention/Angioplasty/Stent

Date of last literature review: 1/9/2025

Document last updated: 1/16/2025

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

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Medical Necessity Criteria

Service: Percutaneous Coronary Intervention (PCI)/Angioplasty/Stent

Recommended Clinical Approach

Coronary artery revascularization is the process of reestablishing blood flow through the coronary arteries that vascularize the cardiac muscle. This is accomplished through a traditional, open approach (coronary artery bypass graft surgery, CABG) or a minimally invasive approach (percutaneous coronary intervention, PCI). Coronary revascularization is used to treat medical emergencies such as acute myocardial infarction or acute coronary syndrome, in contrast to less urgent environments, such as in stable ischemic heart disease (SIHD). In the latter scenario, a PCI is typically performed during a heart catheterization for symptomatic, significant stenosis or blockage that is refractory to optimal medical therapy, or to improve survival.

For patients being considered for coronary revascularization and for whom the optimal treatment strategy is unclear, a multidisciplinary heart team (which includes the cardiologist, cardiac surgeon, and other specialists) is recommended. Treatment decisions should be patient-centered, incorporate patient preferences and goals, and include shared decision-making.

Coronary angiography remains the default method to define coronary anatomy and characterize the severity of coronary arterial stenoses. A visually estimated diameter stenosis severity of greater than or equal to 70% for non-left main disease and greater than or equal to 50% for left main disease has been used to define significant stenosis and to guide revascularization strategy. An angiographically intermediate coronary stenosis is defined as a diameter stenosis severity of 40% to 69% and generally warrants additional investigation to assess physiological significance.¹ Coronary computed tomography angiography (CCTA) is gaining acceptance as an alternative to coronary angiography to define coronary anatomy.

Medical Necessity Criteria

Indications

→ **Percutaneous coronary intervention** is considered appropriate if **ANY** of the following is **TRUE**¹⁻⁹:

- ◆ The patient has significant coronary artery disease (CAD) and **ANY** of the following:
 - Ventricular fibrillation (VF); **OR**
 - Polymorphic ventricular tachycardia (VT); **OR**
 - Prior cardiac arrest; **OR**
 - Severe left ventricle dysfunction (ejection fraction less than or equal to 35%)⁴; **OR**
 - Prior to transcatheter aortic valve replacement (TAVR)¹¹⁵; **OR**
 - Prior to renal transplantation¹¹⁶; **OR**
 - Prior to liver transplantation¹⁷⁻¹⁹; **OR**
- ◆ The patient has acute ST-elevation myocardial infarction (STEMI); **OR**
- ◆ Non-ST-elevation acute coronary syndrome (NSTEMI-ACS); **OR**
- ◆ Unstable angina; **OR**
- ◆ Refractory angina (or ischemic equivalent*) and **ALL** of the following:
 - Symptoms despite optimal medical therapy (GDMT, including two anti-anginal drugs or documented intolerance)⁴; **AND**
 - Significant coronary artery stenoses as shown by **ANY** of the following:
 - Significant anatomic stenosis greater than or equal to 50% left main; **OR**
 - Significant anatomic stenosis greater than or equal to 70% non-left main CAD; **OR**
 - Significant physiological stenosis: fractional flow reserve (FFR) less than or equal to 0.80 or instantaneous wave-free ratio (iFR) less than or equal to 0.89; **OR**
- ◆ The patient has stable ischemic heart disease (SIHD) and **ANY** of the following:
 - Multivessel CAD with significant stenoses in the three major coronary arteries that are suitable for PCI; **OR**

- **ALL** of the following^{1,2}:
 - Significant left main stenosis (greater than or equal to 50%); **AND**
 - PCI is expected to provide equivalent revascularization to coronary artery bypass graft surgery (CABG); **OR**
- ◆ In stable patients with STEMI and multivessel disease, staged PCI may be performed, after successful primary PCI, for a significant non-infarct (non-culprit) artery stenosis; **OR**
- ◆ The patient has had a prior heart transplant and now has severe cardiac allograft vasculopathy (as diagnosed by coronary angiography/intravascular ultrasound) with proximal, discrete lesion(s).^{4,10-11}

***Ischemic equivalent:** Examples 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 CAD may also be considered an ischemic equivalent.¹⁴

Non-Indications

→ **Percutaneous coronary intervention** is **NOT** considered appropriate if **ANY** of the following is **TRUE**^{1-9,12-13}:

- ◆ Stable ischemic heart disease (SIHD) and **ALL** of the following:
 - The patient has an unprotected left main CAD with unfavorable anatomy for PCI; **AND**
 - The patient is a good candidate for CABG; **OR**
- ◆ Patient requires revascularization for significant left main CAD with high-complexity CAD (CABG is recommended over PCI to improve survival); **OR**
- ◆ Patient requires revascularization for multivessel CAD with complex or diffuse CAD (e.g., SYNTAX score greater than 33) (CABG is recommended over PCI to improve survival); **OR**
- ◆ Patient has diabetes and multivessel CAD with the involvement of the LAD, and is an appropriate candidate for CABG (CABG with LIMA to LAD is recommended over PCI to reduce mortality and repeat revascularizations).

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
92920	Percutaneous transluminal coronary angioplasty into single major coronary artery
92928	Percutaneous transcatheter insertion of stent into single major coronary artery
92937	Percutaneous transluminal revascularization of a single coronary artery bypass graft with angioplasty
92943	Percutaneous transluminal revascularization of chronic total occlusion of a single coronary artery branch with atherectomy, angioplasty, and insertion of stent
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
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

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 to describe the best practices of coronary artery revascularization. It recommended that, in patients with significant left main disease, traditional surgical revascularization be undertaken. Percutaneous revascularization (PCI) is a reasonable option to improve survival as 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.¹

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Version 2	January 16, 2025	Annual Policy Review & Restructure: • Updated recommended clinical approach to the current format. • Consolidated redundant indications. • Reorganized order of indications for improved clarity. • Added indication for cardiac allograft vasculopathy. • Added indication for management of significant CAD among patients with left ventricle dysfunction. • Added indication for pre-TAVR, pre-renal transplant, pre-liver transplant patients. • Defined ischemic equivalent with previously-used language. • Updated medical evidence. • Updated references.



Cohere Medical Policy – Percutaneous Ventricular Assist Devices

Clinical Guidelines for Medical Necessity Review

Version: 2
Revision Date: January 23, 2025

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medical Policy – Percutaneous Ventricular Assist Devices

Date of last literature review: 1/22/2025

Document last updated: 1/22/2025

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

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Medical Necessity Criteria

Service: Percutaneous Ventricular Assist Devices

Recommended Clinical Approach

A percutaneous ventricular assist device (pVAD) is utilized for temporary, short-term mechanical circulatory support (MCS). Use of this minimally-invasive technology may occur during a time of cardiac or cardiovascular compromise, such as during a high-risk cardiac procedure (elective use), in patients with cardiogenic shock, or in acute heart failure (emergent uses).¹⁻³ Current examples of FDA-approved pVADs include Impella and TandemHeart. pVADs have been frequently utilized instead of the more invasive intra-aortic balloon pumps during elective percutaneous coronary interventions.⁴

Medical Necessity Criteria

Indications

- **A percutaneous ventricular assist device (pVAD)** is considered appropriate as an adjunct for high-risk percutaneous coronary interventions if **ANY** of the following is **TRUE**⁵⁻⁸:
- ◆ Severe left ventricular (LV) dysfunction (EF less than 20% to 30%); **OR**
 - ◆ Complex coronary artery disease (CAD) involving a large territory (sole-remaining vessel, left main, or three-vessel disease)^{2,9-10}; **OR**
 - ◆ The planned percutaneous intervention is for a patient with a high risk for prolonged hypotension.⁴

Non-Indications

- **A percutaneous ventricular assist device (pVAD)** may not be considered appropriate if **ANY** of the following is **TRUE**^{1,8,11-12}:
- ◆ Bleeding diathesis; **OR**
 - ◆ Severe aortic or peripheral artery disease (PAD); **OR**
 - ◆ Mechanical aortic valve is present; **OR**
 - ◆ Aortic valve stenosis/calcification; **OR**
 - ◆ Atrial or ventricular septal defect.

Level of Care Criteria

Outpatient

Procedure Codes (HCPCS/CPT)

HCPCS/CPT Code	Code Description
33990	Insertion of percutaneous arterial ventricular assist device by arterial access only
33991	Insertion of percutaneous arterial ventricular assist device by arterial and venous access, with transseptal puncture, with radiological supervision and interpretation
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only

Medical Evidence

Kirklin et al. (2020) published guidelines for mechanical circulatory support on behalf of the American Association for Thoracic Surgery and the International Society for Heart and Lung Transplantation. It was recommended to fully evaluate both cardiac and non-cardiac physical function and organ systems pre-operatively. Psychosocial issues should be identified and addressed. Biventricular support should be considered for patients who remain in refractory biventricular failure or who are experiencing persistent destabilizing ventricular dysrhythmias.¹

In a 2022 clinical practice guideline on the management of heart failure for the American Heart Association and The American College of Cardiology, Heidenreich et al. granted a strong recommendation for mechanical circulatory support in emergent settings, such as in acute decompensated heart failure. Select patients with heart failure with reduced ejection fraction with New York Heart Association class IV symptoms who are dependent upon continuous intravenous inotropes or temporary mechanical circulatory support may be appropriate for durable left ventricular assist device implantation.²

Bjarnason and colleagues (2022) conducted a retrospective review of 79,176 Medicare patients undergoing PCI with either an intra-aortic balloon pump (IABP; 60% of study participants) or pVAD (40% of study participants) between 2013 and 2019. It was noted that the incidence of use of mechanical circulatory devices of either kind increased significantly (8514 in 2013 to 14,459 in 2019). They found a higher mean cost of hospitalization in patients with the pVAD compared to the IABP. The study outcome revealed there was not a lower mortality with pVAD, and there was a higher cost. It was also observed that the most critically ill patients were less likely to receive pVAD.³

Rihal et al. (2015) developed a multi-society expert consensus document for the use of percutaneous mechanical circulatory support devices in cardiovascular care. At the time of publication, a limited number of randomized clinical trials existed. The PROTECT 2 trial was discussed, which at the time was the largest single randomized trial ever performed using percutaneous mechanical circulatory support, consisting of 452 symptomatic

patients. The Impella device was studied in comparison with the intra-aortic balloon pump. Impella was found to provide superior hemodynamic support. It was noted that the most ill patients with the most significant hemodynamic compromise are not readily involved in large clinical trials.⁴

Lawton and colleagues (2022) published a clinical practice guideline related to coronary artery revascularization for the American College of Cardiology, the American Heart Association, and the Society for Cardiovascular Angiography and Interventions. Their recommendation for an appropriate hemodynamic support device for elective complex PCI to aid in preventing hemodynamic compromise during the procedure. The BCIS-1 study is cited, where there was no difference found in the primary composite outcome when hemodynamic support devices are used routinely in PCI. The study found that there were fewer major procedural complications with intra-aortic balloon counterpulsation (IABP). The PROTECT II study compared the Impella System with the IABP for high-risk PCI and concluded that Impella provided better hemodynamic support. The authors concluded that despite mixed findings in studies, hemodynamic support devices such as pVAD can be of benefit to select patients during complex PCI, including those with multivessel or left main disease.¹⁰

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12. US Food & Drug Administration (FDA). Summary of safety and probable benefit: TandemHeart Pump and Escort Controller. Published March 26, 2021. <https://www.fda.gov>.

Clinical Guideline Revision History/Information

Original Date: December 29, 2023		
Review History		
Version 2	01/23/2025	• Annual review and policy restructure • Recommended Clinical Approach section revised specifically for pVAD; other device descriptions removed • Removed all indications that are not related to prior authorization (those focusing on inpatient related or emergent conditions), including the following: ○ Section regarding NYHA Class IV heart failure and related criteria for pVAD implant in those emergent situations ○ Removed the listing of the following emergent indications: ■ Cardiogenic shock (LV, RV, or both) ■ Ischemic mitral regurgitation ■ Acute reversible cardiomyopathies (myocarditis, stress cardiomyopathy, peripartum cardiomyopathy) ■ Primary cardiac transplant allograft failure due to rejection ■ Post-transplant RV failure ■ Patients slow to wean from cardiopulmonary bypass following heart surgery ■ Refractory arrhythmias.

		- Removed all Non-Indications that are not related to prior authorization (those focusing on inpatient related or emergent conditions), including the following: - Uncontrolled sepsis - Irreversible end-organ injury/multi-organ failure, including renal, hepatic, or neurological systems, and the procedure will have no benefit. - No changes to procedure codes. - Literature review – Medical Evidence section updated to include a summary of reference number 10. - New/updated references added



Cohere Medical Policy – Peripheral Atherectomy, Non-Lower Extremity

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: December 11, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiology

Guideline Name: Cohere Medical Policy - Peripheral Atherectomy, Non-Lower Extremity

Date of last literature review: 11/27/2024

Document last updated: 12/11/2024

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

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Medical Necessity Criteria

Service: Peripheral Atherectomy, Non-Lower Extremity

Recommended Clinical Approach

This service is clinically unproven and not medically necessary. Peripheral atherectomy is an experimental/investigational endovascular procedure purported to clear heavily calcified arteries that are blocked, to achieve increased blood flow. Atherectomy is a minimally invasive procedure that removes blockages in blood vessels to re-establish normal blood flow. The procedure generally involves the removal of atheromatous plaque from within a blood vessel and uses a catheter that is fitted with a cutting blade, laser, or grinding burr.¹⁻²

This policy addresses atherectomy of peripheral arteries in the non-lower extremity. This includes, but is not limited to, upper extremity arteries, the abdominal aorta, renal arteries, the brachiocephalic trunk and its branches, and visceral arteries, including mesenteric arteries and arteries to other internal organs.

Long-term data regarding the safety and efficacy of peripheral atherectomy in arteries in the non-lower extremities are limited. A review of the literature showed no clinical trials evaluating the safety or efficacy of atherectomy in the abdominal aorta, renal artery, non-renal visceral arteries, or the brachiocephalic trunk and its branches. Societal Guidelines that address the use of atherectomy in non-lower extremity disease are lacking. Additionally, there are few published clinical papers on the effectiveness and safety of atherectomy for these clinical scenarios.

Medical Necessity Criteria

Indications

- A **peripheral atherectomy, non-lower extremity**, is considered appropriate if **ALL** of the following is **TRUE**:
 - ◆ This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

→ A **peripheral atherectomy, non-lower extremity**, is not considered appropriate if **ALL** of the following are **TRUE**:

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

Site of Service Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0234T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; renal artery
0235T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; visceral artery (except renal), each vessel
0236T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation of the abdominal aorta
0237T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; brachiocephalic trunk and branches, each vessel

Medical Evidence

Published literature and clinical guidelines predominantly focus on peripheral atherectomy of the lower extremity and do not address atherectomy of an upper extremity artery.

Aboyans et al. (2018) document diagnostic methods and therapeutic recommendations for atherosclerotic disease in several anatomic regions, including mesenteric, renal, and upper extremity arteries. For acute or chronic mesenteric artery disease (MAD), characterized by high mortality and underdiagnosis, the authors recommend endovascular surgery in most cases because a less invasive option is preferred in such patients who are often frail. In chronic MAD, open surgery provides the advantage of durability. In acute embolic occlusion, open and endovascular surgery have comparable success rates. The authors recommend first-line endovascular therapy for revascularization in patients with acute thrombotic occlusion of the superior mesenteric artery. In patients with acute embolic occlusion of the superior mesenteric artery, they recommend both endovascular therapy and open surgery. The authors note that in patients with atherosclerotic renal artery disease (RAD), defined by greater than 60% renal arterial stenosis, renal revascularization generally does not improve blood pressure or renal or cardiovascular outcomes. Upper extremity artery disease (UEAD) due to atherosclerosis is most common at the level of the brachiocephalic trunk and the subclavian and axillary arteries. Aboyans et al. note that revascularization can be proposed for severe or disabling symptoms, bilateral stenosis or stenosis with ipsilateral arteriovenous fistula for dialysis, or in patients with upcoming coronary artery bypass grafting, or patients who have already undergone such surgery with evidence of myocardial ischemia. When revascularization surgery is considered, both endovascular and open options can be proposed based on the characteristics of the lesion and the patient's risk.¹

Huber et al. (2021) provide practice guidelines for diagnosing and treating patients with chronic mesenteric ischemia (CMI) caused by atherosclerosis. The authors, including a committee of vascular surgeons, conducted a systematic review to identify the optimal technique for revascularization. The committee recommends patients with symptoms consistent with CMI should undergo an expedited workup, including a computed tomography arteriogram to exclude other potential causes of CMI. Significant arterial occlusive disease in the mesenteric vessels, particularly the superior mesenteric artery, is consistent with a diagnosis of CMI. Revascularization

should primarily target the superior mesenteric artery. Endovascular revascularization with a balloon-expandable covered intraluminal stent is recommended as the initial treatment, with open repair in select younger patients and patients who are not endovascular candidates. Long-term surveillance is recommended following revascularization and in asymptomatic patients with severe mesenteric occlusion. An endovascular-first approach is recommended if symptoms recur following revascularization due to stenoses.³

Parikh et al. (2014) report renal artery stenting has emerged as the predominant revascularization strategy in most patients with hemodynamically significant atherosclerotic renal arterial stenosis, despite considerable debate regarding the role of medical therapy versus revascularization in patients with renovascular hypertension. In the consensus statement from the Society for Cardiovascular Angiography and Interventions (SCAI), experts note that systolic and diastolic blood pressure show improvement with high safety profiles in patients with renal artery stenosis, according to prospective multicenter registries. The authors also note that although randomized controlled clinical trials comparing the efficacy of optimal medical therapy and renal stenting show limited benefit in preserving renal function following stenting, such trials often exclude patients who may benefit from renal artery stenting.⁴

Usai et al. (2020) conducted a retrospective review on patients at two institutions to evaluate the performance of less invasive endovascular stent therapy versus open surgical revascularization in patients with subclavian artery atherosclerotic disease (SAAD). Reintervention-free survival (RFS) was the primary endpoint of the study, while the secondary endpoints included primary patency (PPR) and secondary patency (SPR) rates, overall survival (OS) times, and time to reintervention. The median time to follow-up was 87 months in the surgical group versus 27 months in the endovascular group. At 98 months, RFS was significantly higher in the surgical group, although OS did not differ significantly between the two groups. Open surgical repair was also associated with a reduced reintervention rate. At 98 months, PPR was 96% in the surgery group and 65% in the endovascular group, but SPR did not differ significantly. The authors conclude that surgical treatment was associated with higher patency and lower reintervention than endovascular treatment.⁵

Diaz et al. (2020) present a case report on laser atherectomy to treat in-stent restenosis of the superior mesenteric artery in a 53-year-old male with chronic mesenteric ischemia caused by severe in-stent restenosis who experienced abdominal pain and weight loss. The authors used a 0.9 mm laser catheter with low energy and pulse rate together with balloon therapy.

Based on the patient's improved symptoms following revascularization, the authors conclude that treating severe in-stent restenosis of the superior mesenteric artery using laser atherectomy is safe and can result in a favorable outcome when conventional percutaneous therapies fail.⁶

In another case report, Valle et al. (2017) describe the use of orbital atherectomy in a renal artery in a 55-year-old male with severe renal artery stenosis and drug-refractory hypertension. The patient presented with severe calcification of the right renal artery. The authors initially used orbital atherectomy to modify the renal plaque, followed by stenting of the renal artery. Based on favorable follow-up angiography and clinical results, the authors conclude that using orbital atherectomy in the renal vasculature is safe and effective and warrants further evaluation.⁷

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Clinical Guideline Revision History/Information

Original Date: September 25, 2023		
Review History		
Version 2	12/11/2024	• Annual review. • Medical evidence rewritten to reflect CPT codes. • Aligned to the current template. • References updated. • Standardized language updated for indications and non-indications.



Cohere Medical Policy – Peripheral Intravascular Lithotripsy (IVL)

Clinical Guidelines for Medical Necessity Review

Version: 2

Cohere Health UMC Approval Date: July 10, 2025

Last Annual Review: July 10, 2025

Revision: Not applicable

Next Annual Review: July 10, 2026

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medical Policy - Peripheral Intravascular Lithotripsy (IVL)

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

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Medical Necessity Criteria

Service: Peripheral Intravascular Lithotripsy (IVL)

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity.

Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the

patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Peripheral Intravascular Lithotripsy (IVL) is a minimally invasive procedure that uses acoustic pulses to treat moderate to severe calcific peripheral arterial disease.¹⁻³ During (IVL), lithotripsy emitters, embedded in a balloon catheter, create sonic pressure waves that travel safely through soft tissue.^{4,5} The waves produce vapor bubbles that, upon collapse, create high-energy shocks to calcified plaques.⁶

Medical Necessity Criteria

Indications

Peripheral Intravascular Lithotripsy 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

Peripheral Intravascular Lithotripsy 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
C9764	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed
C9765	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes

	angioplasty within the same vessel(s), when performed
C9766	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed
C9767	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed
C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed
C9773	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
C9774	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed
C9775	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed

Medical Evidence

In their prospective, multicenter, cohort study of twelve-month outcomes of intravascular lithotripsy (IVL) treatment in patients with chronic limb-threatening ischemia, Nugteren et al. (2023) concluded that IVL showed promising safety and efficacy results. The study, which included a complex patient population of 29 patients, documented few major adverse events (4) and had a low rate of bailout stenting (12.5%). These results, according to the authors, warrant a comparison of IVL with angioplasty for popliteal and infrapopliteal arterial disease.²

According to Kereiakes et al. (2021), endovascular treatment of calcific peripheral artery disease (PAD) remains an ongoing challenge for interventionalists, as calcification in the peripheral arteries is associated with an increased risk of dissection, perforation, and increased stent rates. In addition, the presence of vascular calcification limits the success rates of endovascular interventions.³

Adams et al. (2020) conducted an observational study to assess the Shockwave Peripheral IVL System, which is labeled to treat calcified, stenotic lower limb arteries. A total of 200 patients from 18 sites were included. Follow-up occurred post-discharge. Intravascular lithotripsy was used with additional balloon-based technologies in 54% of the target lesions studied. IVL was used less often with concomitant atherectomy (19.8%) or stenting (29.9%).⁴

Armstrong et al. (2020) conducted a cohort analysis (2020) of IVL for treating calcified, stenotic iliac arteries. A total of 200 lesions were evaluated among 20 sites; 101 patients sought treatment for claudication or critical limb ischemia, and 17 sought treatment for optimization of the iliac vasculature for large-bore access. Limitations of the study included site-reported data. The study was also a single-arm study without a control arm.⁸

Madhavan et al. (2020) performed a meta-analysis on the efficacy of IVL for patients with PAD. Five prospective studies were included. The analysis included individual patient-level data that was compared to existing studies on the use of IVL for patients with PAD. A total of 336 patients were included and underwent endovascular revascularization using IVL.

Limitations include a need for comparators in single-arm studies, which did not allow for a proper comparison of the safety and efficacy of IVL in combination with other endovascular PAD treatments. Over 12% of the patients were receiving adjunctive device therapy, which makes isolating the benefits of IVL difficult. A limited number of patients were also available in key subgroups; future studies should include larger cohorts.⁹

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Policy Revision History/Information

Original Date: March 29, 2024		
Review History		
Version 2	07/10/2025	Annual Review Added procedure description (page 4). The medical evidence section has been updated to include Nugteren et al. (2023). References added (Sogbadji et al., 2025; Wong et al., 2022; Gruslova et al., 2024; Nugteren et al., 2023).



Cohere Medical Policy – Patent Foramen Ovale (PFO)/Atrial Septal Defect (ASD) Closure

Clinical Policy for Medical Necessity Review

Version: 2

Cohere Health UMC Approval Dates: July 10, 2025

Last Annual Review: July 10, 2025

Revision: Not applicable

Next Annual Review: July 10, 2026

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Patent Foramen Ovale (PFO)/Atrial Septal Defect (ASD) Closure

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

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Medical Necessity Criteria

Service: Patent Foramen Ovale (PFO)/Atrial Septal Defect (ASD) Closure

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity.

Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the

patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Closure of a patent foramen ovale (PFO) and atrial septal defect (ASD) – congenital openings between the heart's upper chambers – is performed via endovascular, minimally invasive means. During closure of a PFO, a device (often a mesh disc) is implanted in the atrial septum to seal an abnormal opening between the atria that is suspected of contributing to stroke. The procedure requires transcatheter access to a large vein, typically the femoral vein in the groin.¹⁻³ ASD closure similarly involves transcatheter insertion and implantation of occluder devices to seal an abnormal opening in the atrial septum. However, because ASDs are typically larger, the occluder devices are often larger, and their insertion is more complex, requiring more extensive imaging, balloon sizing of the defect, and a larger device delivery system.⁴

Medical Necessity Criteria

Indications

Patent foramen ovale (PFO) or atrial septal defect (ASD) closure is considered appropriate if **ANY** of the following is **TRUE**:

- **PFO closure** is considered appropriate if **ANY** of the following is **TRUE**^{1,5-9}:
 - **ALL** of the following:
 - The patient is 18 to 60 years of age with PFO with a right-to-left shunt; **AND**
 - Non-lacunar embolic stroke determined after comprehensive evaluation by a qualified radiologist or neurologist; **AND**
 - No other evident source of stroke¹⁰⁻¹⁵; **OR**
 - Systemic embolism without a prior PFO-associated stroke, in whom other embolic etiologies have been excluded^{10,11,14,16}; **OR**
 - The patient has PFO with unexplained recurrent embolic stroke despite medical therapy (without another identified cause)^{10,14}; **OR**
- **ASD closure** is considered appropriate if **ANY** of the following is **TRUE**^{1,4,8,9,18}:
 - Isolated secundum ASD and **ALL** of the following:
 - Impaired functional capacity; **AND**
 - RA or RV enlargement; **AND**
 - Hemodynamically significant net left-to-right shunt (Qp:Qs greater than or equal to 1.5:1); **OR**
 - The patient is asymptomatic and has **ALL** of the following:

- Isolated atrial septal defect (ASD); **AND**
- RA and RV enlargement; **AND**
- Net left-to-right shunt sufficiently large to cause physiological sequelae (e.g., Qp:Qs 1.5:1 or greater); **OR**
- Percutaneous closure may be considered for adults with **ANY** of the following:
 - ASD when net left-to-right shunt (Qp:Qs) is 1.5:1 or greater; **OR**
 - PA systolic pressure is 50% or more of systemic arterial systolic pressure; **OR**
 - Pulmonary vascular resistance is greater than one-third of the systemic resistance; **OR**
- Patient with a fenestrated Fontan circuit¹⁹⁻²¹; **OR**
- The patient can be considered for documented recurrent paradoxical embolization event on treatment (without another identified cause)⁹; **OR**
- Unrepaired Ebstein anomaly with moderate-severe tricuspid regurgitation and impaired exercise tolerance.²²

Non-Indications

Patent foramen ovale (PFO) or atrial septal defect (ASD) closure is not considered appropriate if **ANY** of the following is **TRUE**:

- **PFO closure** is not considered appropriate if the patient has **ANY** of the following²³:
 - Irreversible severe pulmonary hypertension (e.g., Eisenmenger physiology [net right-to-left shunt], pulmonary artery pressure or pulmonary vascular resistance greater than $\frac{2}{3}$ systemic)^{5,16}; **OR**
 - Active endocarditis, sepsis, or other untreated infection; **OR**
 - Intracardiac mass, vegetation, tumor, or thrombus at the intended site of implant; **OR**
 - PFO was discovered incidentally without associated symptoms; **OR**
 - Alternative cause of stroke identified (e.g., atherosclerotic lesions, atrial fibrillation)^{12,14}; **OR**
 - Bleeding disorder or other contraindication to antiplatelet therapy^{5,16}; **OR**
- **ASD closure** is not considered appropriate if the patient has **ANY** of the following^{4,16}
 - Irreversible severe pulmonary hypertension (pulmonary artery pressure or pulmonary vascular resistance greater than $\frac{2}{3}$ systemic); **OR**
 - Eisenmenger physiology, net right-to-left shunt; **OR**

- Bleeding disorder or other contraindication to antiplatelet therapy; **OR**
- Active endocarditis, sepsis, or other untreated infection; **OR**
- Known intracardiac thrombi.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93580	Percutaneous transcatheter closure of congenital interatrial communication (i.e., Fontan fenestration, atrial septal defect) with implant.

Medical Evidence

Amini (2025) reviewed findings on PFO and cryptogenic stroke, noting that while it may not be possible to definitively conclude whether a PFO was causally involved in a stroke, a high risk of paradoxical embolism (RoPE) score increases the likelihood that PFO was involved in the stroke. The RoPE score considers history of hypertension, diabetes, stroke, smoking, cortical infarct, and age. Similarly, the PFO-associated stroke causal likelihood (PASCAL) classification considers anatomical features of the PFO, including size of the defect and shunt type, to determine the likelihood that PFO was causally involved in a stroke. The author then reviewed studies showing that, in patients with high-risk PFOs, PFO closure decreased the recurrent stroke rate by up to 41%.¹¹

In 2020, Messe et al. updated the 2016 American Academy of Neurology's practice advisory guidelines on the treatment of patients with PFO and stroke. They recommended thorough patient evaluation prior to PFO closure. Specific recommendations included the elimination of any other cause of stroke, exercising particular caution when alternative stroke mechanisms are identified, and the importance of advising patients that PFO is common and that it is not possible to definitively determine whether the PFO was causally involved in their stroke.¹⁴ In 2019, a panel of neurologists and cardiologists published recommendations on PFO closure as a treatment for cryptogenic stroke. Their recommendations included age between 16–60, ischemic stroke within the last 6 months attributable to the PFO after examination with a stroke specialist, and specific PFO characteristics – including atrial septal aneurysm, a right-to-left shunt greater than 20 microbubbles, or a diameter at least 2 mm.¹³

Collado et al. (2018) systematically reviewed PFO closure for stroke prevention and other disorders. The evidence showed that, while approximately 25% of the adult population has a PFO, the condition itself has not been proven to increase the risk of ischemic stroke. However, up to 40% of ischemic cryptogenic strokes occur in patients with PFOs, suggesting that paradoxical embolism through a PFO may be the cause of a significant percentage of cryptogenic strokes. The authors reviewed procedural complications, including transient ST elevations, transient ischemic attack, device

dislodgement, and large residual shunt, occurring in 3% of the 307 patients evaluated. Vascular injury at the access site was found to occur in as many as 30% of cases, though only 2.4% required surgical intervention. In a study of 1355 cases, major complications occurred in 1.5% of patients, and 7.9% experienced minor complications. Device embolization was a very rare complication at 0.7% overall.¹

In the 2018 AHA/ACC guideline for the management of adults with congenital heart disease, Stout and colleagues discussed PFO in relation to Ebstein anomaly, in that an otherwise normal-appearing PFO may have a significant impact on Ebstein anomaly. Surgery for PFO or ASD, as well as tricuspid valve repair and arrhythmia surgery, may be beneficial to the patient. The committee stated that patients who do not undergo ASD closure have worse long-term outcomes, including atrial arrhythmia, eventual greater degrees of pulmonary arterial hypertension (PAH), and significantly reduced functional capacity. They stated that data suggest that ASD closure improves functional capacity, but the benefit is less clear in patients with preoperatively normal functional capacity. Until further studies are completed, the guidelines recommend closing a hemodynamically important ASD if significant PAH is absent.⁴

Kernan et al. (2014) developed guidelines for the prevention of stroke in patients with stroke and transient ischemic attack (TIA). In patients with a cryptogenic ischemic stroke or TIA who also have a PFO and no deep vein thrombosis, the available data do not support the benefits of PFO closure. Transcatheter PFO closure may be considered in the event of PFO with deep vein thrombosis (DVT), based on the risk of the DVT reoccurring.⁸ However, Kavinsky CJ et al. (2022) recommended PFO closure in patients aged 18–60 with a PFO-associated stroke but not for TIA. Also, the same guideline recommended against PFO closure in persons with a history of DVT and without a prior PFO-associated stroke.⁵

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Policy Revision History/Information

Original Date: April 5, 2024		
Review History		
Version 2	07/10/2025	Annual policy review & restructure. Minor reorganization of first PFO indication without altering the criteria itself Removed “or surgical closure” from ASD indication as this policy scope is limited to transcatheter intervention Removed qualifier of “worsening hypoxia” for patients with HLHS/Fontan palliation in adherence to society guidelines Removal of indication: orthodeoxia/platypnea syndrome. This indication was felt to be redundant and a potential area of risk if misinterpreted.



Cohere Medical Policy – Pulmonary Artery Denervation (PADN)

Clinical Policy for Medical Necessity Review

Version: 3

Cohere Health UMC Approval Date: July 24, 2025

Last Annual Review: July 24, 2025

Revision: Not Applicable

Next Annual Review: July 24, 2026

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Pulmonary Artery Denervation (PADN)

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

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Medical Necessity Criteria

Service: Pulmonary Artery Denervation (PADN)

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

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 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Pulmonary artery denervation (PADN) is a minimally invasive, catheter-based procedure to reduce pulmonary artery pressure in patients with pulmonary arterial hypertension (PAH).¹ The most common method of PADN is catheter-directed thermal ablation.

Medical Necessity Criteria

Indications

Pulmonary artery denervation (PADN) is considered appropriate if **ANY** of the following is **TRUE**^{2,3}:

- This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

Pulmonary artery denervation (PADN) is not considered appropriate if **ANY** of the following is **TRUE**^{2,3}:

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

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0793T	Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance
0632T	Percutaneous transcatheter ultrasound ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance

Medical Evidence

Pulmonary arterial hypertension (PAH) is a disease with a poor prognosis and high mortality that leads to right ventricular failure and sudden cardiac death. Chin et al. (2024) outlined the current treatment algorithm for PAH, with maximal medical therapy now involving four drugs.² Current therapy, consisting of a combination of pharmacological treatments, yields mixed results.⁴ Pulmonary artery denervation (PADN) is a relatively new, minimally invasive endovascular catheter-based interventional procedure for treating patients with PAH.¹ Most clinical studies and reviews agree that larger clinical trials are needed to define and confirm the efficacy of PADN.^{1,2,5}

Abouzid et al. (2025) conducted a meta-analysis to evaluate patients with pulmonary hypertension and the hemodynamic parameters of PADN (e.g., mean right atrial pressure [mRAP], mean pulmonary artery pressure [mPAP], and pulmonary vascular resistance [PVR]). The authors stated that while PADN may be effective, additional research is needed. Specifically, long-term results are required to understand the hemodynamic parameters' impact, safety, and efficacy. Patient selection criteria also warrant further research to ensure proper treatment.⁶

Salazar et al. (2023) and Constatine et al. (2021) also stated that additional randomized controlled trials (RCTs) are needed to establish a recommendation for the use of PADN.^{7,8} Vorla et al. (2023) published an abstract outlining the results of a meta-analysis of 8 studies (including 7 RCTs) and 577 patients. The authors noted the small sample size of trials.⁹

Zhang et al. (2022) performed an RCT on the effect of PADN among 128 patients with stable group I PAH. While results were positive, larger RCTs that include patients without an optimal response to treatment with combination pharmacotherapy are needed. Future studies should also include patients with various etiologies of PAH (e.g., idiopathic, hereditary, connective tissue disease, congenital heart disease, portal hypertension). (ClinicalTrials.gov NCT03282266).¹⁰

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Policy Revision History/Information

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Review History		
Version 2	04/26/2025	Policy criteria reviewed and updated per medical literature.
Version 3	07/24/2025	Annual Review. No changes to the indications or non-indications. Literature review - added 5 references to the Medical Evidence section (Abouzid et al., 2025; Salazar et al., 2023; Vorla et al., 2023; Zhang et al., 2022; Constantine et al., 2021).



Cohere Medical Policy – Stress Echocardiogram

Clinical Policy for Medical Necessity Review

Version: 4

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Last Annual Review: November 13, 2025

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Next Annual Review: November 13, 2026

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Stress Echocardiogram

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

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Medical Necessity Criteria

Service: Stress Echocardiogram

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Stress echocardiography is a noninvasive diagnostic tool that uses ultrasound to provide an overview of cardiac structure and function at rest and under stress. It is used to evaluate a variety of clinical presentations, including chest pain (or ischemic equivalent) and intermediate (16%–50%) or high (>50%) pretest probability of coronary artery disease (CAD).¹⁻³ During stress echocardiography, the patient is first fitted with a transducer and baseline images at rest are generated. The patient is then put under stress, either physical exercise (treadmill or stationary bicycle), pharmacologic agents (e.g., dobutamine), or stress pacing in a patient with a permanent pacemaker and images are generated when the patient's heart rate is increased. These images are used to determine cardiac function under stress including coronary heart disease and valvular defects.⁴ Stress echo results in no radiation exposure, is typically lower cost, requires a shorter patient time commitment, and provides additional information on cardiac structures (e.g., valves, ascending aorta, pericardial space) compared to myocardial perfusion imaging (MPI-SPECT). Stress echocardiography has lower diagnostic accuracy in patients with limited acoustic windows.^{2,5-6}

In patients with valvular heart disease, stress echocardiography is a useful modality to assess a patient's functional capacity, ventricular function, and severity of valve dysfunction during exercise. This information may help determine the need for, and timing of, surgical or interventional treatments. Stress echocardiography is well-tolerated in the pediatric population and is often a preferred modality, as it requires no sedation, needle sticks, or radiation exposure and has been completed in children as young as 6 years.⁷ The absence of radiation is of particular importance among groups that require serial screening, including transplant recipients, patients with a history of radiation to the chest, and patients with a history of Kawasaki disease.⁷

Medical Necessity Criteria

Indications

Stress echocardiogram is considered appropriate if **ANY** of the following is **TRUE**^{7-9,13}:

- The patient has precordial chest pain (or an ischemic equivalent^A), no known coronary heart disease, and **ANY** of the following³:
 - Intermediate or high pretest probability of coronary artery disease (CAD; according to the [CAD Consortium Calculator](#))^{10,38}; **OR**
 - A coronary calcium score of greater than or equal to 100 Agatston; **OR**
 - Prior indeterminate stress testing or cardiac computed tomography angiogram (CCTA) (e.g., heart rate did not reach 85% of age-predicted maximum heart rate)^{3,11,38}; **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 without previous evaluation for CAD³⁹; **OR**
- Evaluation of ventricular arrhythmias as indicated by **ANY** of the following^{13,14}:
 - Frequent premature ventricular contractions (PVCs) greater than 30 per hour; **OR**
 - Nonsustained ventricular tachycardia (greater than or equal to 3 consecutive beats at greater than 100 beats per minute); **OR**
 - Exercise-induced ventricular tachycardia; **OR**
 - Sustained ventricular tachycardia; **OR**
 - Ventricular fibrillation; **OR**
- Before initiation of antiarrhythmic therapy and **ANY** of the following¹³:
 - High atherosclerotic cardiovascular disease (ASCVD) risk (greater than 20% according to [ACC/AHA ASCVD Risk Estimator](#)); **OR**
 - Intermediate or high pretest probability (greater than 20%) as indicated by the [CAD Consortium Calculator](#); **OR**
- Syncope without an ischemic equivalent^A and the initial evaluation suggests a cardiovascular abnormality (e.g., regional wall motion abnormality on echo, abnormal EKG with left bundle branch block, LBBB, greater than 1 mm ST depression at rest, or left ventricular hypertrophy with ST-T abnormalities)¹³; **OR**

- Known coronary heart disease with a history of prior myocardial infarction (MI) or coronary revascularization or coronary stenosis of greater than 50% by angiography or CCTA and **ANY** of the following¹³:
 - Asymptomatic patient and **ANY** of the following:
 - The patient had a percutaneous coronary intervention (PCI) over 2 years ago and the last stress test was over 2 years ago; **OR**
 - The patient had a bypass over 5 years ago and the last stress test was over 5 years ago; **OR**
 - High risk for silent ischemia as indicated by **ANY** of the following:
 - Diabetes mellitus with accelerated progression of CAD; **OR**
 - Chronic kidney disease (CKD stage 3 or above – eGFR 15–59 mL/min/1.73 m² with or without albuminuria that is not treated with dialysis or kidney transplantation); **OR**
 - Peripheral artery disease; **OR**
 - Prior brachytherapy; **OR**
 - In-stent restenosis; **OR**
 - Saphenous vein graft intervention; **OR**
 - The patient has a history of silent ischemia; **OR**
 - Symptomatic patient with a change in clinical or functional status on adequate guideline directed medical therapy (GDMT; or documented intolerance to GDMT); **OR**
- Preoperative testing^(Table 1) for planned solid organ transplant (e.g., renal, pancreas, combined renal pancreas, liver, lung, or intestinal)^{12,15}; **OR**
- Preoperative testing with no known coronary heart disease^C and **ALL** of the following¹⁵:
 - No recent (3–8 months) testing; **AND**
 - New or worsening possible cardiac symptoms; **AND**
 - Functional status less than 4 metabolic equivalent of task (METs) and **ANY** of the following:
 - High risk vascular or nonvascular surgery^(Table 1); **OR**
 - Intermediate risk vascular surgery^(Table 1); **OR**
 - Intermediate risk nonvascular surgery^(Table 1) with at least an intermediate (16% or greater) pre-test probability of obstructive CAD according to the [CAD Consortium Calculator](#); **OR**
- Preoperative testing with known heart disease^D and **ANY** of the following¹⁵:
 - No recent (3–8 months) stress testing and **ANY** of the following:
 - High risk vascular or nonvascular surgery^(Table 1); **OR**
 - Intermediate risk vascular surgery and **ANY** of the following:

- Greater than or equal to 4 METS and **ANY** of the following:
 - [Revised Cardiac Risk](#) Index of 3 or greater (intermediate or high risk); **OR**
 - New or worsening possible cardiac symptoms; **OR**
- Less than 4 METS; **OR**
- Intermediate risk nonvascular surgery^(Table 1) and **ANY** of the following:
 - Less than 4 METS; **OR**
 - Greater than or equal to 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); **OR**
- Prior cardiac stress testing within 3 to 8 months and **ANY** of the following:
 - High risk vascular surgery^(Table 1) with risk factors that justify repeat testing; **OR**
 - New findings on transthoracic echocardiogram (TTE; e.g., wall motion abnormalities, significant valvular disease, significant drop in ejection fraction); **OR**
 - New or worsening possible cardiovascular symptoms; **OR**
- The patient has left ventricular outflow tract (LVOT) obstruction and otherwise equivocal indications for intervention¹⁶; **OR**
- To assess for exercise-induced hypertension and left ventricular (LV) function in a patient with coarctation of the aorta¹⁶; **OR**
- Post-intervention surveillance of functional capacity and efficacy following medical or surgical repair of congenital cardiac defects, including **ANY** of the following^{41,42}:
 - Atrial or ventricular left-to-right shunts; **OR**
 - Aortic coarctation⁴⁰; **OR**
 - Arterial switch; **OR**
 - Congenitally-corrected transposition of the great arteries; **OR**
 - Tetralogy of Fallot; **OR**
 - Hypoplastic left heart syndrome with Fontan palliation; **OR**
- The patient has anatomically severe aortic stenosis (AS, less than 1.0 cm²) and **ALL** of the following¹⁷:
 - Left ventricular ejection fraction (LVEF) less than 50%; **AND**

- Low transvalvular velocity and pressure gradient at rest (i.e., velocity less than 4 m/s or mean gradient less than 40 mmHg); **AND**
- Distinction between severe AS with LV systolic dysfunction and moderate AS is required; **OR**
- The patient has asymptomatic moderate or severe chronic primary mitral regurgitation¹⁷; **OR**
- The patient has asymptomatic moderate or severe aortic stenosis (stages B and C) for measurement of changes in valve hemodynamics with exercise or pharmacological stress¹⁸; **OR**
- The patient has mitral valve disease, including rheumatic mitral stenosis, with a discrepancy between clinical symptoms and resting echo findings¹⁸; **OR**
- The patient has moderate or severe aortic regurgitation (AR) for assessment of symptoms and functional capacity¹⁸; **OR**
- Discordance between clinical assessment and TTE about the severity of AR⁴³; **OR**
- In a patient with hypertrophic cardiomyopathy where a mild dynamic left ventricular outflow obstruction requires exercise provocation¹⁹; **OR**
- Preoperative diagnosis and serial long-term follow-up of high-risk patients with anomalous origin of coronaries⁷; **OR**
- Prior to a planned pregnancy in a patient with known congenital or valvular heart disease^{17,19}; **OR**
- Annual screening for **ANY** of the following:
 - Coronary aneurysms in a patient with a history of Kawasaki Disease⁷; **OR**
 - Post-cardiac transplant⁷; **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 treatment⁴⁴; **OR**
 - There is need for a one-time clarifying follow-up of a prior indeterminate finding⁴⁵; **OR**
 - In the absence of change in symptoms, there is an established need for monitoring, which would influence management.⁴⁴

Non-Indications

Stress echocardiogram is not considered appropriate if **ANY** of the following is **TRUE**^{8,20-28}:

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms^{29,44}; **OR**
- To screen for coronary artery disease in a patient with no significant signs or symptoms⁴⁶; **OR**
- A stress echocardiogram is not reasonable or necessary if performed simultaneously with **ANY** of the following additional tests⁴⁶:
 - Radionuclide ventriculography; **OR**
 - Myocardial perfusion imaging stress test (MPI-SPECT) with or without pharmacological stress; **OR**
 - A stress nuclear test for the same clinical problem; **OR**
- For screening CAD (e.g., in a patient without signs or symptoms of CAD) such as for the presence of risk factors (e.g., smoking, obesity, family history of CAD) but no personal history of vascular disease or related metabolic disorder.

Definitions

^AIschemic Equivalent: Chest pain syndrome, anginal equivalent, or ischemic electrocardiogram (ECG) abnormalities are any constellation of clinical findings that the physician believes is consistent with CAD. Examples 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; and other symptoms or 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 CAD may also be considered an ischemic equivalent.³⁰

^BLikely or typical anginal symptoms: Chest/epigastric/shoulder/arm/jaw pain, chest pressure/discomfort with exertion or emotional stress that is relieved by rest, nitroglycerin, or both.

^CNo Known or Suspected Heart Disease by History, Exam, or Electrocardiogram¹⁵: Heart disease is not suspected based on no history of prior cardiac event, lack of cardiac risk factors, or prior cardiac testing indicating no ischemic heart disease, VHD, or HF. Exam does not suggest underlying heart disease by lack of murmurs, other than functional, and no

signs of cardiac decompensation (i.e, 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.

^DKnown or Suspected Heart Disease by History, Exam, or

Electrocardiogram¹⁵: PCI, 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 ECG, 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 3x the upper limit of normal.

Table 1. Definitions of Low, Intermediate, and High-Risk Surgery¹⁵

	Surgical Risk Level		
Specialty	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	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

		6. Laparoscopic colon resection, segmental, for tumor	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.	-	1. Laminectomy	1. Spinal fusion

Spine			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	-	-	1. Renal Transplant

Transplant			2. Pancreas Transplant 3. Kidney-Pancreas Combined Transplant 4. Liver 5. Lung 6. Intestinal

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93350	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report;
93351	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with supervision by a physician or other qualified health care professional
C8928	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report
C8930	Transthoracic echocardiography, with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode

	recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with physician supervision

Medical Evidence

Woodward et al. (2025) investigated long-term outcomes in over 5,000 patients who had received a stress echocardiogram at community hospitals.³¹ Over a mean follow-up period of over 800 days, the authors found that patients with positive stress echocardiograms had a higher risk of myocardial infarction, all-cause mortality, and cardiac-related mortality. Furthermore, the authors reported that patients with no previous history of coronary artery disease who had a negative stress echocardiogram had a five-year event-free warranty period, during which they reported no major adverse cardiac events. These findings demonstrate the long-term utility of stress echocardiography in identifying patients at-risk for major cardiac events.

Ihekwa et al. (2024) conducted a systematic review and meta-analysis of long-term outcomes in patients with suspected or known CAD who underwent stress echocardiography. Their final analysis included over 16,000 patients across 6 trials who underwent either treadmill or pharmacological stress testing, with a follow-up period between 21 and 101 months. They reported that patients with positive stress echocardiography results (test results showing evidence of ischemia) had higher rates of major adverse cardiovascular events (MACE) and all-cause mortality compared to patients with negative stress echocardiography results (test results showing no evidence of ischemia). They concluded that stress echocardiography results can guide treatment, with positive results informing the need for interventions in patients with suspected coronary artery disease.³²

Lee et al. (2023) reviewed the literature on the risks and contraindications of exercise and pharmacological stress echocardiography.³³ Across 3 exercise stress studies, including a total of over 50,000 patients, the probability of a patient experiencing a life-threatening event was extremely rare, between 0.015 – 0.04 across studies. Reported complications included arrhythmias, acute myocardial infarction (AMI), and cardiac and ventricular ruptures. The probability of a life-threatening event during a pharmacological stress test was somewhat higher, though still low overall, at 0.2 for dobutamine and 0.08 for vasodilatory agents. Reported life-threatening risks included AMI and ventricular tachyarrhythmias for dobutamine, and AMI, asystole, and

hypotension for vasodilators. The authors concluded that the overall risk of life-threatening adverse events as a result of stress testing is very low. However, they also caution that certain patients, notably those with valvular dysfunction, may be at higher risk for adverse events. These patients, along with pediatric patients, pregnant patients, and patients not able to communicate easily with medical personnel, may require increased monitoring during the procedure.

Moscatelli et al. (2023) reviewed the use of stress cardiovascular imaging in pediatric patients.³⁴ They note that while coronary artery disease (CAD), the most common indication for stress testing in adult patients, is rare in pediatric patients, pediatric patients may still experience chest pain and ischemia due to several causes, including Kawasaki disease, cardiac transplantation, or coronary artery reimplantation. Stress testing may also be used in the evaluation and assessment of valvular heart diseases, cardiomyopathies, and several congenital diseases. Specific conditions that may benefit from stress echocardiography in pediatric patients include post-transplant coronary vasculopathy, anomalous origin of coronary arteries, and after cardiotoxic chemotherapy. The authors note that children younger than 8 years old may be unable to cooperate with provider instructions during exercise stress testing and may therefore need to undergo pharmacological stress testing, with the further potential need for sedation.

Pellikka et al. (2020) and the American Society of Echocardiography published echocardiography guidelines for detection and risk assessment of stable ischemic heart disease, per the 2015 American College of Cardiology/American Heart Association clinical practice guidelines.⁷ Stress echocardiography was rated as appropriate as a noninvasive diagnostic and surveillance modality for several pediatric and adult cardiac conditions. In follow-up testing for new or worsening symptoms, stress echocardiography testing was appropriate for patients with suspected stable CAD. Stress echocardiography is also the preferred imaging modality for unexplained dyspnea on exertion. Stress echocardiography is appropriate following revascularization with new cardiac symptoms, especially if refractory to guideline-directed medical therapy (GDMT). Stress echocardiography is less recommended for preoperative evaluation before noncardiac surgery and before an exercise prescription for cardiac rehabilitation. The authors noted that the absence of radiation makes this imaging modality particularly

attractive for pediatric patients, women with indications for noninvasive imaging, serial imaging scenarios, and patients with a history of radiation to the chest. Additionally, stress echocardiography is preferred to studies such as cardiovascular magnetic resonance, which involves gadolinium administration, for certain patient subsets (e.g., those with kidney disease).⁷

In 2021, Gulati and colleagues developed a multi-society guideline for the evaluation and diagnosis of chest pain. Stress echocardiography was recommended for determining the etiology of chest pain including pericardial effusion, stress cardiomyopathy, and hypertrophic cardiomyopathy. Stress echocardiography may also be used to define ischemia severity and for risk stratification after acute coronary syndrome has been ruled out.³

Stout et al. (2019), on behalf of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, developed the 2018 AHA/ACC guideline for the management of adults with congenital heart disease (ACHD). Based on clinical evidence, a strong recommendation was made to limit and monitor radiation exposure during imaging of patients with ACHD due to the potential for multiple exposures in these patients. Exercise stress testing is considered reasonable for patients with subaortic stenosis to measure exercise capacity, stress-induced arrhythmias, and ischemia. Patients with transposition of the great arteries with arterial switch are recommended to have baseline serial imaging, and if the patient is symptomatic following arterial switch.¹⁶

In the 2020 ACC/AHA guideline for the management of patients with valvular heart disease, Otto et al. state that it is reasonable to use low-dose dobutamine stress echocardiography in patients with suspected low-flow, low gradient severe aortic stenosis with normal left ventricular ejection fraction (stage D3). Stress echocardiography is also recommended in the diagnosis of chronic secondary mitral regurgitation, as well as before and during pregnancy evaluation in women with native valvular heart disease.¹⁷

The 2024 European Society of Cardiology (ESC) guidelines for the management of chronic coronary syndromes (CCS) updated and expanded the guidelines initially issued five years prior.³⁸ The authors defined CCS as a

range of clinical presentations of coronary artery disease (CAD) which can produce transient, reversible ischemia during exertion, emotion, or stress. Physical symptoms may include angina, other chest pain, or dyspnoea, or patients may be asymptomatic. The updated 2024 guidelines included a new recommendation for stress echocardiography to estimate the risk of MACEs or to diagnose myocardial ischemia in patients with suspected CCS and a moderate or high pre-test probability of obstructive coronary artery disease. The updated guidelines also recommended the use of ultrasound contrast agents to improve image quality and increase diagnostic accuracy, especially in obese patients and in patients with chronic obstructive pulmonary disease.

A number of recent articles provided recommendations for several common clinical scenarios. Gulati et al. (2021) provided insights into the evaluation and diagnosis of chest pain.³ Winchester et al (2023) provided appropriate use criteria (AUC) for the detection and risk assessment of chronic coronary disease.¹³ Doherty et al. (2024) updated a previous AUC document on cardiovascular evaluation for nonemergency, noncardiac surgery, focusing on ischemic heart disease, valvular heart disease and heart failure (rather than cardiovascular disease in general) and their relation to the risks associated with various types of surgery (solid organ transplant, vascular, non-vascular).^{15,35-37}

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Policy Revision History/Information

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Review History		
Version 2	10/29/2024	Annual review and policy restructure.
Version 3	10/31/2024	Edited repeat imaging criteria language.
Version 4	11/13/2025	Annual review. Deleted indication for ECG abnormalities that interfere with ECG diagnosis of ischemia. Simplified criteria for prior indeterminate stress testing or CCTA and for invasive angiography not done. Updated repeat imaging criteria. Removed several redundant/repetitive non-indications. Minor grammar and copy edits for clarity and usability. Added non-indication for simultaneous testing with a nuclear stress test. Updated Medical Evidence (7 references).



Cohere Medical Policy – Transcatheter Aortic Valve Replacement/Implantation (TAVR/TAVI)

Clinical Policy for Medical Necessity Review

Version: 3

Cohere Health UMC Approval Date: August 14, 2025

Last Annual Review: August 14, 2025

Revision: Not Applicable

Next Annual Review: August 14, 2026

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Transcatheter Aortic Valve Replacement/Implantation (TAVR/TAVI)

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

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Medical Necessity Criteria

Service: Transcatheter Aortic Valve Replacement/Implantation (TAVR/TAVI)

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the

patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Transcatheter aortic valve replacement/implantation (TAVR/TAVI) is an effective, minimally invasive catheter-based procedure to replace an aortic valve in patients with aortic valve stenosis. Patients considered for TAVR/TAVI include all risk cohorts (low- to high-risk). Compared to surgical aortic valve replacement (SAVR), TAVR has a lower risk of stroke, major bleeding, and atrial fibrillation, and a shorter hospital length of stay and shorter recovery.¹⁻⁸

Medical Necessity Criteria

Indications

Transcatheter aortic valve replacement/implantation using a U.S. Food and Drug Administration (FDA) approved aortic valve (e.g., the SAPIEN 3 platform, the Medtronic Evolut TAVR platform, the Abbott Navitor TAVI System) is considered appropriate if **ANY** of the following is **TRUE**:

- For patients with severe symptomatic calcific aortic stenosis and **ANY** of the following^{1,9-11}:
 - Aortic valve area is less than 1.0 cm^2 ^{1,10-11}; **OR**
 - Aortic valve area index is less than or equal to $0.6 \text{ cm}^2/\text{m}^2$ ^{1,10-11}; **OR**
 - Maximum Doppler velocity is greater than or equal to 4.0 m/s ^{1,9-11}; **OR**
 - Mean aortic valve gradient greater than or equal to 40 mm/Hg at rest^{1,9-11}; **OR**
- For asymptomatic patients with severe calcific native aortic valve stenosis as indicated by **ALL** of the following^{1,10}:
 - Peak systolic velocity of greater than or equal to 4.0 m/s or mean gradient of at least 40 mm/Hg ¹; **AND**
 - Severely restricted AV leaflet opening¹; **AND**
 - Left ventricular ejection fraction (LVEF) less than or equal to 50% ^{1,10}; **AND**
 - Age between 65 and 80¹; **OR**
- For symptomatic patients with suspected low flow/low gradient aortic stenosis and aortic valve calcium (AVC) of greater than or equal to 1300 Agaston units in women or 2000 Agaston units in men¹; **OR**
- For valve-in-valve procedures for failed prior bioprosthetic valves, including **ANY** of the following^{1,11}:

- The patient has a bioprosthetic aortic valve with aortic stenosis and/or aortic regurgitation, and **ALL** of the following are **TRUE**¹:
 - The patient has symptomatic (e.g., fatigue, dyspnea, angina, syncope, or presyncope) severe stenosis¹; **AND**
 - Improvement in hemodynamics is anticipated¹; **OR**
- The patient has a bioprosthetic aortic valve with aortic regurgitation, and **ALL** of the following are **TRUE**^{1,12}:
 - The patient has symptomatic (e.g., dyspnea, orthopnea) severe regurgitation; **AND**
 - Improvement in hemodynamics is anticipated.

Non-Indications

Transcatheter aortic valve replacement/implantation is not considered appropriate if **ANY** of the following is **TRUE**^{1,8,12-16}:

- Life expectancy less than 12 months related to a non-cardiac cause¹; **OR**
- Myocardial infarction within the last thirty days¹⁵; **OR**
- Valve with unsuitable anatomy for TAVR/TAVI, or noncalcified valve^{1,13}; **OR**
- Hypertrophic obstructive cardiomyopathy¹³; **OR**
- A short distance between the annulus and coronary ostium for an artery unprotected by a bypass graft, and concern that TAVR/TAVI may result in coronary obstruction that cannot be protected^{12,16}; **OR**
- Left ventricular ejection fraction less than 20%¹³; **OR**
- Severe pulmonary hypertension with right ventricular dysfunction determined to be not due to severe aortic stenosis and/or determined to be unlikely to improve after TAVR/TAVI¹⁴; **OR**
- Echocardiographic evidence of intracardiac mass, thrombus, or vegetation (unless completely healed)¹³; **OR**
- Severe primary mitral regurgitation without a plan to perform a transcatheter MitraClip procedure after TAVR/TAVI.⁸

Level of Care Criteria

Inpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve using percutaneous femoral

	artery approach
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve by open femoral artery approach
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve by open axillary artery approach
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve by open iliac artery approach
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve by median mediastinotomy
33366	Transcatheter aortic valve replacement (TAVR/TAVI) using prosthetic valve with transapical exposure

Medical Evidence

The severity of aortic stenosis is usually diagnosed based on echocardiographic parameters. Still, between 5 and 10% of patients with severe aortic valve stenosis do not meet these diagnostic criteria, typically patients with low-flow, low-gradient severe aortic stenosis. Sharma et al. (2023) reviewed how using ancillary testing may aid in identifying these patients, who could benefit from TAVR.¹⁰

Mesnier et al. (2022) reviewed the frequently increasing indications of TAVR. They found that indications for TAVR, which initially were confined to patients with severe symptomatic aortic stenosis, have now expanded to patients with high, intermediate, and even low surgical risk. As a result of this expansion, the number of TAVR procedures doubled compared to SAVR. They reason that the expansion of TAVR indications will continue, as several current randomized trials aim to expand TAVR indications.⁹

Otto et al. (2020) developed a guideline for the American College of Cardiology and the American Heart Association for managing patients with valvular heart disease. They state that surgical (SAVR) rather than transcatheter aortic valve replacement (TAVR) is recommended in patients less than 65 years of age due to lower surgical risk, but with a need for more extended valve durability. In patients older than 65, TAVR presents less surgical risk, pain, and hospital stay length than SAVR. At the same time, SAVR is associated with a lower risk of paravalvular leak, re-operation, and potential need for pacemaker implantation.¹

Chen and colleagues (2018) studied 2032 patients in the PARTNER 2A (Placement of Aortic Transcatheter Valve) randomized trial to determine whether prior cardiac surgery was associated with increased surgical risk. These patients with severe aortic stenosis were determined to have intermediate surgical risk and were randomized between TAVR with the Sapien XT transcatheter valve versus SAVR. 25.1% of patients had prior cardiac surgery, with 98.2% of those being coronary artery bypass grafting. No significant differences were found between patients with TAVR versus SAVR in patients with or without prior cardiac surgery in 30 days up to 2 years.³

In 2018, Spaziano et al. prospectively studied TAVR in the catheterization laboratory vs a hybrid operating room. They stated that comparisons between these two locations were scarce. The primary endpoint of the FRANCE TAVI was all-cause mortality at one year, with secondary endpoints of 30-day complications and 3-year mortality. A total of 12,121 patients with a mean age of 82.9 years, and roughly even numbers of men and women were included in the study, with 62% undergoing TAVR in a catheterization lab vs. 38% in a hybrid operating room. Major bleeding and infections were higher in the hybrid OR group. Midterm mortality was similar between the catheterization lab and the hybrid operating room; therefore, findings supported performance in either location.⁴

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Policy Revision History/Information

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Version 1	04/12/2024	New policy.
Version 2	08/13/2024	Updated indications, non-indications, and references.
Version 3	08/14/2025	Annual review. Added a new Description section. Language was revised for clarity. Additional citations were added throughout the indications section. Medical Evidence - added two new reviews.



Cohere Medical Policy – Transcatheter Mitral Valve Repair

Clinical Policy for Medical Necessity Review

Version: 2

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Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Transcatheter Mitral Valve Repair

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

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Medical Necessity Criteria

Service: Transcatheter Mitral Valve Repair

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity.

Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the

patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Percutaneous or transcatheter mitral valve repair (TMVR), also defined as mitral valve transcatheter edge-to-edge repair (TEER), is a minimally invasive procedure not requiring open heart surgery for the treatment of primary (degenerative) or secondary (functional) mitral regurgitation. It is performed by accessing a large blood vessel in either the groin or chest with a catheter, then deploying a device inside the mitral valve, often a “clip,” which alters the anatomy of the mitral valve leaflets. TMVR is indicated for symptomatic patients with moderate to severe primary mitral regurgitation (MR) equal or greater than Grade III per American Society of Echocardiography criteria,^{1,10} and for patients with high or prohibitive surgical risk for open surgical valve repair.^{1,10}

Medical Necessity Criteria

Indications

Transcatheter Mitral Valve Repair is considered appropriate if **ANY** of the following is **TRUE**^{4,6}:

- TMVR for primary (degenerative [i.e., not rheumatic]) MR is indicated by **ALL** of the following^{4,6}:
 - Moderate-Severe or Severe MR; **AND**
 - **ANY** of the following:
 - Left ventricular (LV) systolic dysfunction (left ventricular ejection fraction [LVEF] less than or equal to 60% or ESD of at least 40mm)⁴; **OR**
 - Significant symptoms (NYHA class III or IV) regardless of LV function **AND**
 - High or prohibitive surgical risk as defined by **ANY** of the following⁴:
 - Society of Thoracic Surgeons (STS) PROM equal to or greater than 8% for individuals deemed likely to undergo mitral valve replacement¹⁵; **OR**
 - STS PROM equal to or greater than 6% for individuals deemed likely to undergo mitral valve repair¹⁵; **AND**
 - Life expectancy of at least 1 year⁴; **AND**
 - Mitral valve anatomy is favorable for transcatheter repair ⁴; **OR**

- TEER for severe secondary MR with **ALL** of the following^{4,6}:
 - Left ventricular end-systolic diameter (LVESD) less than or equal to 70 mm⁶; **AND**
 - LVEF greater than or equal to 20% and less than or equal to 50%⁶; **AND**
 - Persistent symptoms while on optimal medical therapy (including cardiac resynchronization, if indicated)^{4,6}; **AND**
 - Pulmonary artery systolic pressure less than or equal to 70 mm Hg⁴; **OR**
- Percutaneous transcatheter mitral valve-in-valve implantation is indicated for a patient with **ALL** of the following¹¹:
 - Symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical bioprosthetic mitral valve, or a native mitral valve with an annuloplasty ring¹¹; **AND**
 - High or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality equal or greater than 8% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator).¹¹

Non-Indications

Transcatheter Mitral Valve Repair is not considered appropriate if **ANY** of the following is **TRUE**^{4,6,11}:

- Active endocarditis of the mitral valve⁶; **OR**
- Another cardiac surgery is planned where surgical mitral valvuloplasty can be effectively performed¹¹; **OR**
- Presence of intracardiac or venous (inferior vena cava or femoral vein) thrombosis is present⁶; **OR**
- Extensive chordal fusion or calcification⁴; **OR**
- Mitral valve insufficiency is due to a congenital cleft (transitional atrioventricular canal)⁴; **OR**
- Papillary muscle rupture⁴; **OR**
- The patient cannot tolerate anticoagulation or antiplatelet therapy post-procedure^{4,6}; **OR**
- Rheumatic mitral valve disease⁶; **OR**
- Mixed valve disease (i.e. – concomitant aortic or tricuspid dysfunction)⁴; **OR**
- Aortic aneurysm or other aortopathy wherein surgical mitral valve repair would be preferable¹⁶; **OR**
- Untreatable hypersensitivity or contraindication to contrast media or nitinol alloys (nickel and titanium)⁶; **OR**

- The patient has significant annuloplasty ring dehiscence.¹¹

Definitions

New York Heart Association (NYHA) Heart Failure Classification (NYHA, 1994):

- **I:** No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
- **II:** Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
- **III:** Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
- **IV:** Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

STS PROM: Society of Thoracic Surgery predicted risk of mortality.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33418	Transcatheter mitral valve repair with initial prosthetic valve by percutaneous approach
33419	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus
0483T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed.

Medical Evidence

Transcatheter mitral valve-in-valve is an innovative procedure authorized by the United States Food and Drug Administration (FDA) for high-risk individuals with a malfunctioning (stenosis, MR, or combined) surgical bioprosthetic mitral valve or a native mitral valve with an annuloplasty ring deemed by a heart team to pose high or greater risk for open surgical intervention.¹¹ Goel et al. (2024) performed an extensive cohort analysis of 4,243 patients from the Transcatheter Valve Therapies registry (STS/American College of Cardiology) undergoing transseptal SAPIEN 3/SAPIEN 3 Ultra transcatheter mitral valve-in-valve procedures before and after FDA approval (2015–2022). Most patients were classified as high surgical risk; however, 30-day and 1-year mortality rates were acceptable, with a significant improvement in symptoms and quality of life.¹³ Malaisrie et al. (2024), in a prospective, single-arm, multicenter study in intermediate-risk patients, found that mitral valve-in-valve with a balloon-expandable valve was associated with no mortality, no strokes, low complication rates, symptom improvements, and patient-reported quality of life improvement in a 1-year follow-up.¹² In a large multicenter study that included 5,971 patients, Eleid et al. (2025) found that three-year mortality was lowest in patients with low STS risk scores and elective procedures. They reason that it is crucial to identify patients who may benefit from mitral valve-in-valve early. Also, reintervention rates were low at three years regardless of STS risk scores.¹⁴

McCarthy et al. (2023) report on the REPAIR-MR (Primary Mitral Regurgitation) clinical trial, which began in July 2020. The trial is a prospective, randomized, parallel-controlled, open-label multicenter, noninferiority study aimed at evaluating the efficacy and safety of transcatheter edge-to-edge repair using the MitraClip compared to surgical (open-chest) mitral valve repair in patients diagnosed with severe primary MR (ClinicalTrials.gov ID NCT04198870). Participants must meet moderate surgical risk criteria and must have a diagnosis of severe MR and indications for surgery due to symptoms (NYHA class II–IV) – patients without symptoms will also be included if certain criteria is met (e.g., left ventricular ejection fraction less than or equal to 60%, pulmonary artery systolic pressure greater than 50 mm Hg, or left ventricular end-systolic diameter greater than or equal to 40 mm).

All participants are 75 years of age or older, or, less than 75 years of age with a Society of Thoracic Surgeons Predicted Risk Of Mortality score of greater than or equal to 2% for mitral repair (or Society of Thoracic Surgeons Replacement Score of greater than or equal to 4%), or having comorbidities increasing surgical risk. The trial aims to randomize 500 eligible subjects in a 1:1 ratio between the MitraClip device and surgical mitral valve repair (control group) with two co-primary endpoints evaluated at 2 years and follow-up continuing for 10 years post-enrollment.⁷

Kong et al. (2023) conducted the COAPT (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation) trial (ClinicalTrials.gov ID NCT01626079). The trial explored the occurrence and consequences of deteriorating kidney function following TEER of the mitral valve in individuals diagnosed with heart failure (HF). A total of 614 patients with diagnosed HF and severe secondary mitral regurgitation (SMR) underwent randomization to receive TEER using the MitraClip in addition to guideline-directed medical therapy (GDMT), compared to those receiving GDMT alone. In patients with HF alongside severe SMR, the occurrence of worsening renal function within 30 days was not found to be higher following TEER compared to standard GDMT alone. Despite its association with increased mortality over 2 years, worsening renal function did not diminish the efficacy of TEER in reducing mortality and HF-related hospitalizations when compared to GDMT alone.⁸

Giustino et al. (2020) performed a randomized controlled trial to compare MitraClip implantation and GDMT outcomes in patients diagnosed with SMR. Patients were stratified by their initial functional status as determined by the NYHA functional classification. The COAPT (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation) trial (ClinicalTrials.gov ID NCT01626079) included patients with HF and either moderate to severe or severe SMR who continued to experience symptoms despite receiving the maximum tolerated GDMT. A total of 613 patients were randomized – 240 (39.2%) were in the NYHA functional class II, 322 (52.5%) were in NYHA functional class III, and 51 (8.3%) were in ambulatory NYHA functional class IV. They found that the benefits of MitraClip were consistent with the NYHA functional class assessment and that

such functional assessment provides prognostic utility in patients with HF and moderate to severe or severe SMR.⁹

The FDA approved MitraClip to improve mitral insufficiency due to primary degenerative mitral valve abnormalities or functional mitral valve insufficiency due to diminished left ventricular function.¹ Other types of repair include chordal repair (NeoChord, Harpoon), edge-to-edge repair (MitraClip, PASCAL), indirect annuloplasty (ARTO, Carillon, Mitral Loop Cerclage), and direct annuloplasty (AccuCinch, Cardioband, Millipede, Mitralign).²⁻³ The MitraClip procedure avoids the need for additional extensive surgical valve repair (or replacement) with decreased morbidity and mortality.

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Policy Revision History/Information

Original Date: April 5, 2024		
Review History		
Version 2	07/10/2025	Annual review. Deleted indications for patient enrollment in experimental studies (not covered by any payor policy examined). Changed indication: "Moderate to severe mitral regurgitation (MR)" to "Moderate-Severe or Severe MR." Added indication, "Percutaneous transcatheter mitral valve-in-valve implantation is indicated for patients with ALL of the following: Symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical bioprosthetic mitral valve, or a native mitral valve with an annuloplasty ring; AND High or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality equal or higher than 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator)." Expanded indication: "High or prohibitive surgical risk" to "High or prohibitive surgical risk as defined by ANY of the

		following: 1) STS PROM equal to or greater than 8% for individuals deemed likely to undergo mitral valve replacement¹⁵; OR STS PROM equal to or greater than 6% for individuals deemed likely to undergo mitral valve repair.” Added non-indication: “The patient has significant annuloplasty ring dehiscence.” Added non-indication: “Aortic aneurysm or other aortopathy wherein surgical mitral valve repair would be preferable.” Added non-indication: “The patient has significant annuloplasty ring dehiscence.” Added CPT code 33419. Added CPT code 0483T. Literature review: The Medical Evidence section (including references) for the FDA-approved Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valve systems was updated.



Cohere Medical Policy – Transesophageal Echocardiography (TEE)

Clinical Policy for Medical Necessity Review

Version: 4

Cohere Health UMC Approval Date: July 31, 2025

Last Annual Review: July 31, 2025

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Transesophageal Echocardiography (TEE)

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

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Medical Necessity Criteria

Service: Transesophageal Echocardiography (TEE)

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity.

Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Transeophageal echocardiography (TEE) is a procedure in which a small probe attached to a thin tube is inserted into a sedated patient's throat and esophagus.¹ Sound waves are then emitted by the probe, generating live, moving images of the heart and providing information on the health and functioning of heart structures, including the myocardium, valves, pericardium, coronary arteries, and great vessels.

TEE is often used when transthoracic echocardiography (TTE) is not feasible or insufficient, for example, in patients with atrial fibrillation, suspected thrombus, or unclear valve disease. TEE is more expensive, more invasive, and takes longer to perform than TTE, but is more sensitive, especially for patent foramen ovale and left atrial appendage. TEE can also identify the cause of stroke by detecting potential intrathoracic sources of embolism.

Superior visualization of the left atrial appendage provided by TEE can assess the safety of outpatient elective and acute inpatient cardioversions.² TEE is also valuable for evaluating other heart structures, including better imaging of mitral valve function and the atrial septum, both of which can have clinical significance for a patient with atrial fibrillation.

In valvular disease patients, TEE may be used when TTE results are inconclusive or discordant with history and physical exam.² TEE is particularly useful in patients with mitral regurgitation to assess mitral leaflet anatomy when considering the feasibility of mitral leaflet repair or the MitraClip procedure. TEE is also useful in assessing the presence of infective endocarditis or left atrial thrombus. TEE is an integral part of minimally invasive valve interventions, including TAVR and MitraClip procedures.

Medical Necessity Criteria

Indications

Transesophageal echocardiography (TEE) is considered appropriate if **ANY** of the following is **TRUE**:

- The patient has paroxysmal or persistent atrial flutter/fibrillation presenting for planned cardioversion³; **OR**
- As a follow-up procedure if **ALL** of the following are **TRUE**:
 - Initial imaging yielded an intracardiac thrombus or evidence of left atrial stasis; **AND**
 - The patient has had a minimum of 6 weeks of therapeutic anticoagulant therapy⁴; **OR**
- The patient has a CHA₂DS₂-VASc score greater than or equal to 2 (high-risk for thromboembolism) before catheter ablation if an intracardiac echocardiogram is not planned during the ablation; **OR**
- As an imaging modality to visualize atrial anatomy during or up to 45 days after catheter or surgical procedures for left atrial appendage occlusion/obliteration; **OR**
- Guidance for **ANY** of the following⁶:
 - Placement of an occlusion device (e.g., septal defect, Fontan, intra-atrial baffle fenestration); **OR**
 - Blade or balloon septostomy; **OR**
 - Creation/stenting of intraventricular communication; **OR**
 - During percutaneous valve interventions; **OR**
 - During radiofrequency ablation procedures; **OR**
 - Placement of catheter-based cardiac assist device; **OR**
- The patient is presenting with atrial flutter with any history of left atrial appendage thrombus, regardless of anticoagulation status; **OR**
- To evaluate known or suspected valvular heart disease when TTE provides insufficient or discordant information; **OR**
- Specific cardiac imaging is needed before mitral valve intervention; **OR**
- Specific cardiac imaging is needed before TAVR intervention; **OR**
- To re-evaluate suspected prosthetic valve dysfunction when it would help guide therapy; **OR**
- Within three days of a mitral valve repair, to exclude the presence of intracardiac mass, thrombus, or vegetation; **OR**

- The patient has a prior valve replacement or repair and clinical symptoms or signs suggest prosthetic valve dysfunction; **OR**
- Intraprocedural guidance for **ANY** of the following valve interventions:
 - Valve replacement or repair; **OR**
 - Transcatheter pulmonary valve replacement; **OR**
- The patient has known or suspected infectious endocarditis when it is used to guide treatment; **OR**
- The patient has a suspected cardiac mass, tumor, thrombus, or cardiac source of embolus; **OR**
- The patient has Staphylococcus aureus bacteremia with or without a known source; **OR**
- The patient has a mechanical prosthetic valve and signs or symptoms of **ANY** of the following:
 - Prosthetic valve obstruction; **OR**
 - An embolic event; **OR**
- TEE is needed for intraprocedural guidance during surgery; **OR**
- TTE provided insufficient, discordant, or nondiagnostic information; **OR**
- The patient is known or suspected to have **ANY** of the following:
 - Pericardial constriction^{5,7}; **OR**
 - Pericardial disease due to mass, malignancy, thrombus, or cardiac embolus⁷; **OR**
 - Cardiac compression by a loculated pericardial hematoma; **OR**
 - Pericardial thickening inadequately defined by a transthoracic echocardiogram (TTE)⁸; **OR**
 - The patient had a recent cardiovascular surgery or intervention and a complication is suspected; **OR**
- Anatomical or functional complications of congenital heart disease are suspected; **OR**
- The patient is pregnant and has a mechanical prosthetic valve; **OR**
- Diminished left ventricular function or dilated cardiomyopathy before a VT ablation to rule out intracardiac thrombus¹⁰; **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, for **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; **OR**
- Re-evaluation of prior TEE findings for interval change; **OR**
- Suspected aortic pathology including dissection/transection (e.g., Marfan syndrome, bicuspid aortic valve, coarctation of the aorta)⁶; **OR**
- Intra-cardiac evaluation for vegetation or suspected abscess⁶; **OR**
- Pericardial effusion or cardiac function evaluation and postoperative monitoring with open sternum or poor acoustic windows⁶; **OR**
- Evaluation of postoperative results and function⁶; **OR**
- Intraoperative monitoring of ventricular volume and function⁶; **OR**
- Monitoring of intra-cardiac/intravascular air and adequacy of cardiac de-airing⁶; **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

Transesophageal echocardiography (TEE) 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 symptoms¹⁵; **OR**
- The atrial fibrillation duration is reliably defined and is less than 48 hours in a patient with a CHA₂DS₂-VASc score of less than 2³; **OR**
- Another imaging modality (e.g., CT, MRI) is requested simultaneously to evaluate for intracardiac thrombus; **OR**
- The patient has a history of esophageal pathology (e.g., stricture, malignancy, fistula, diverticulum), recent surgery of the esophagus, or active GI bleeding; **OR**

- The patient has suspected atrioesophageal fistula following atrial fibrillation ablation; **OR**
- The patient has a history of undiagnosed dysphagia; **OR**
- Routine TEE for a patient with a prosthetic valve; **OR**
- The purpose is to screen for structural cardiac abnormalities in the absence of an established diagnosis, sign, or symptom; **OR**
- Routine reassessment of global and regional left ventricular function, especially if TTE is technically adequate; **OR**
- The patient has poor airway control.⁶

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93312	Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report
93313	Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); placement of transesophageal probe only
93314	Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); image acquisition, interpretation and report only
93315	Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report
93316	Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only
93317	Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only

93318	Echocardiography, transesophageal (TEE) for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis
93355	Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D
C8925	Transesophageal echocardiography (tee) with contrast, or without contrast followed by with contrast, real time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report
C8926	Transesophageal echocardiography (tee) with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report
C8927	Transesophageal echocardiography (tee) with contrast, or without contrast followed by with contrast, for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis

Medical Evidence

Mauriello et al. (2024) reviewed the role of echocardiography in the context of cardiac arrest and post-cardiac arrest syndrome.¹⁶ They note that TEE may be appropriate in these contexts when TTE is inconclusive or unfeasible, for example, when a patient has a vascular cannula and thoracic or pericardial drainings, or when a patient cannot be moved from a supine position. The authors note that studies have reported that, in the intensive care setting, up to half of TTEs may be inconclusive, further highlighting the value of TEE in this context.

In 2025 the American Heart Association (AHA) published a scientific statement on considerations of intraoperative transesophageal echocardiography during adult cardiac surgery.¹⁷ They reviewed several studies that have recently shown decreased mortality and improved clinical outcomes when TEE is used in the intraoperative setting. The authors also cite several other professional medical societies, including the American Society of Anesthesiology, the American College of Cardiology Foundation, the American Society of Echocardiography, the Society of Cardiovascular Anesthesiologists, and the Society of Thoracic Surgeons, that all recommend broad use of TEE during and in preparation for surgical procedures.

Joglar and colleagues (2024) developed the 2023 guideline for the diagnosis and management of atrial fibrillation for the American College of Cardiology and the American Heart Association. The authors evaluated studies and recommended TEE to assess for successful closure of the left atrial appendage (LAA), most notably in the presence of thrombus or leakage around the area of closure. Based upon the ACUTE trial (Assessment of Cardioversion Using Transesophageal Echocardiography), precardioversion anticoagulation for at least 3 weeks is recommended.⁴

In the 2017 appropriate use criteria for multimodality imaging in valvular heart disease, Doherty et al. state that TEE is rarely appropriate for initial evaluation of an asymptomatic patient, and in symptomatic patients, may be appropriate in the setting of suspected acute mitral or aortic regurgitation as

well as respiratory failure or hypoxemia of uncertain etiology. TEE is stated to be appropriate for suspected infectious endocarditis of native or prosthetic valves, endocardial leads, positive blood cultures or new murmur. The committee stated that TEE is also appropriate for suspected cardiac mass, tumor, or embolus, in certain cases of mitral and aortic regurgitation, and further evaluation of valvular masses. A number of other evidence-based appropriateness recommendations may be found in the guideline.⁵

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Policy Revision History/Information

Original Date: October 10, 2022		
Review History		
Version 2	03/22/2024	Policy criteria reviewed and updated per medical literature.
Version 3	10/31/2024	Edited repeat imaging criteria language.
Version 4	07/31/2025	Annual review Added indication - "The patient is deemed a non-surgical candidate by a surgeon". Added indications noting that TEE is appropriate for guidance during procedures including the placement of an occlusion device and blade or balloon septostomy. Added repeat imaging language to indications. Removed redundant or duplicative indications. Removed relative contraindications from non-indication section. Updated Medical Evidence section to include Mauriello et al. (2024) and Rong et al. (2025)



Transthoracic Echocardiogram (TTE)

Clinical Guidelines for Medical Necessity Review

Version: V1.0
Effective Date: September 21, 2022

Important Notices

Notices & Disclaimers:

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Guideline Information:

Disease Area: Cardiology

Care Path Group: Not applicable

Single Service Name: Transthoracic Echocardiogram (TTE)

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

Physician author: Mary Krebs, MD (Primary Care Physician), Senthil Sundaram, MD (Cardiologist), Giovanni Lorenz, MD (Radiologist)

Peer reviewed by: Russell Rotondo, MD FACC (Cardiologist)

Literature review current through: September 21, 2022

Document last updated: September 21, 2022

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Care Path Services & Medical Necessity Criteria

Service: Transthoracic Echocardiogram (TTE)

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Transthoracic echocardiography can be useful for patients with possible cardiac etiology for chest pain or shortness of breath, heart failure, palpitations, arrhythmias, lightheadedness, dizziness, syncope, TIA, stroke, or a peripheral embolic event.^{1,2} It can also be used for evaluation of suspected valvular heart disease, pericardial disease, or pulmonary hypertension. Appropriate use criteria for repeat echocardiograms are more stringent than first-time studies.
- **Exclusions:** None.

Medical Necessity Criteria

Indications

- **Transthoracic echocardiogram (TTE)** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ The patient has chest pain (or ischemic equivalent) and clinical evidence of valvular, pericardial, primary myocardial disease, or congenital heart disease.
 - ◆ The patient has chest pain (or ischemic equivalent) and an additional sign or symptom, including shortness of breath, abnormal ECG, palpitations, TIA, stroke, or a peripheral embolism.
 - ◆ Prior testing (e.g., chest X-ray, ECG, cardiac biomarkers) suggested heart disease or structural heart abnormality.
 - ◆ There is a suspicion of hypertensive heart disease.
 - ◆ The patient requires evaluation of right ventricular function with suspected pulmonary hypertension or pulmonary embolism

Non-Indications

- **TTE** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Echocardiography has no contraindications. Echocardiography may have limited benefit in patients at the extremes of adult

body weight. A thick chest wall (in obese patients) or overcrowded ribs (in underweight patients) may limit ultrasound wave penetration.^{1,2}

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
93303	Complete transthoracic echocardiography for congenital cardiac anomalies
93304	Follow-up transthoracic echocardiography for congenital cardiac anomalies
93306	Real time transthoracic echocardiography with 2-dimensional (2D) image documentation, M-mode recording with spectral Doppler echocardiography, and color flow Doppler echocardiography
93307	Complete real time transthoracic echocardiography with 2-dimensional (2D) image documentation
93308	Follow-up real time transthoracic echocardiography with 2-dimensional (2D) image documentation
C8921	Tte w or w/o fol w/cont, com
C8922	Tte w or w/o fol w/cont, f/u
C8923	2d tte w or w/o fol w/con,co
C8924	2d tte w or w/o fol w/con,fu
C8929	Tte w or wo fol wcon,doppler

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Clinical Guideline Revision History/Information

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September 21, 2022 (V.1)	Physician author: Mary Krebs, MD (Primary Care Physician), Senthil Sundaram, MD (Cardiologist), Giovanni Lorenz, MD (Radiologist) Peer reviewed by: Russell Rotondo, MD FACC (Cardiologist)



Cohere Medical Policy – Venous Stenting

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: December 12, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medical Policy - Venous Stenting

Date of last literature review: 11/20/2024

Document last updated: 12/12/2024

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

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Medical Necessity Criteria

Service: Venous Stenting

Recommended Clinical Approach

Venous stent placement is generally indicated to treat symptomatic venous occlusive disease. (e.g. symptomatic venous stenosis, compression, or post-procedure venous complications). Venous stents can be placed via a percutaneous route, but venous stents can also be placed with a combination of open and percutaneous techniques. Covered stents may also be used to treat venous conditions, including venous aneurysms, arteriovenous fistulae, and venous perforations.

Medical Necessity Criteria

Indications

→ **Venous stenting** is considered appropriate if **ANY** of the following is **TRUE**¹⁻³²:

- ◆ The patient has abdominopelvic venous disease as indicated by **ANY** of the following:
 - Symptomatic compression or obstruction of the hepatic veins (e.g., Budd-Chiari syndrome)²⁻⁴; **OR**
 - Symptomatic portal venous hypertension²⁷⁻³²; **OR**
 - Symptomatic iliac vein compression (May-Thurner or Cockett's syndrome) when **ALL** of the following are **TRUE**^{5,6}:
 - Either 50% diameter reduction or 75% cross-sectional area; **AND**
 - Skin or subcutaneous changes (healed or active ulcers (Clinical, Etiology, Anatomy, and Pathophysiology [CEAP] classes 4-6)); **AND**
 - The patient does not have a superficial venous reflux (or has previously treated superficial venous reflux);
- OR**
- Symptomatic Iliocaval or iliofemoral venous obstruction⁷ confirmed by Doppler ultrasound, CT, or magnetic resonance venography (MRV)^{8,9}; **OR**

- Symptomatic ilio caval or iliofemoral venous stenosis (greater than 50% diameter reduction of the affected vein or 75% cross-sectional area stenosis or residual stenosis of greater than 30% following angioplasty); **OR**
- Symptomatic renal vein compression (e.g., Nutcracker Syndrome) with **ANY** of the following^{14,15}:
 - Nonsurgical management has been attempted for at least six months; **OR**
 - Prior left renal vein (LRV) transposition has failed, with recurrent/unimproved symptoms and evidence of persistent stenosis on imaging; **OR**
- ◆ The patient has symptomatic thoracic venous disease, including **ANY** of the following:
 - Pulmonary vein stenosis confirmed by diagnostic imaging (eg. echocardiography, CTA) and resulting from either congenital malformation, extrinsic compression, sequelae of radiofrequency ablation (RFA), lung transplantation, or after repair of Total Anomalous Pulmonary Vein Return (TAPVR); **OR**
 - Superior or inferior vena cava obstruction, including superior vena cava syndrome, confirmed by diagnostic imaging (e.g., CT, Doppler, MRI)²⁶; **OR**
- ◆ The patient has symptomatic venous complications relating to a procedure or treatment, including **ANY** of the following:
 - Complications of arteriovenous dialysis access (e.g. stenosis, occlusion, pseudoaneurysm) ¹⁰; **OR**
 - Postprocedure venous complications, including occlusion, stenosis, perforation, or pseudoaneurysm¹¹⁻¹³; **OR**
 - Post-radiation venous stenosis confirmed by diagnostic imaging (e.g., CT, Doppler, MRI)¹⁶; **OR**
 - Postoperative venous stenosis after repair of congenital cardiac disease, as confirmed by diagnostic imaging (e.g., echocardiography, CT, Doppler, MRI); **OR**
- ◆ The patient has an arteriovenous malformation (AVM) confirmed by diagnostic imaging (CT or MRI)¹; **OR**
- ◆ The patient has idiopathic intracranial hypertension^{17,18}; **OR**
- ◆ Suboptimal or failed angioplasty and **ANY** of the following is **TRUE**:
 - Residual stenosis of greater than 30%; **OR**

- Greater than 50% diameter reduction or greater than 75% cross-sectional area stenosis; **OR**
 - Abrupt occlusion at the angioplasty site; **OR**
 - Elastic recoil or refractory spasm; **OR**
 - Perforation; **OR**
 - Intractable symptoms¹; **OR**
- ◆ Repeat or secondary stenting of any of the preceding indications is appropriate if **ANY** of the following is true:
- Suboptimal or failed stenting; **OR**
 - Symptomatic restenosis; **OR**
 - Stent fracture (in association with restenosis or occlusion); **OR**
 - Stent recoil; **OR**
 - Prevention of variceal rebleeding if more than 72 hours beyond index bleed³⁰.

Non-Indications

→ **Venous stenting** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Known allergic reactions to stent or stent graft material (e.g., nitinol, dacron, expanded polytetrafluoroethylene [ePTFE]); **OR**
- ◆ Prophylactic stenting for asymptomatic venous stenosis or compression.^{19,20}

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
37238	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein
37239	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when

	performed; each additional vein (List separately in addition to code for primary procedure)
37182	Insertion of a TIPS (Transjugular Intrahepatic Portosystemic Shunt), which includes venous access, catheterization of the hepatic and portal veins, portography, intrahepatic tract formation, stent placement, and imaging guidance
37183	Revision of a TIPS (Transjugular Intrahepatic Portosystemic Shunt), which includes venous access, catheterization of the hepatic and portal veins, portography, intrahepatic tract recanalization, stent placement, and imaging guidance
37248	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein
37249	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; each additional vein (List separately in addition to code for primary procedure)

Medical Evidence

Morris et al. (2023) performed a systematic review of the benefits of stenting for inferior vena cava (IVC). The review included 33 studies with 1575 patients; indications for stenting included IVC syndrome, thrombotic disease, Budd–Chiari syndrome, and IVC stenosis following liver transplant. IVC stenting was concluded to be safe with clinical outcomes that improved symptoms and quality of life, although the authors encourage future randomized controlled trials to refine the evidence supporting these recommendations.⁶

In 2020, the American Association for the Study of Liver Diseases (AASLD) published clinical guidance titled *Vascular Liver Disorders, Portal Vein Thrombosis, and Procedural Bleeding in Patients with Liver Disease*. The AASLD cited a randomized control trial supporting percutaneous transluminal angioplasty, with or without stenting, to restore hepatic vein outflow when obstructed.³

The Society of Interventional Radiology (2023) supports stent placement for patients with iliofemoral venous obstruction. Although the authors endorse the necessity of further research to better quantify the risks and benefits, they note that, in the meantime, stenting for such patients may proceed with careful patient selection and optimization of conservative therapy, as well as correct stent sizing with a focus on high-quality procedural technique.⁹

In 2024, the AASLD also provided guidelines for the use of the transjugular intrahepatic portosystemic shunt (TIPS) procedure for the management of portal hypertension or abnormally elevated pressure within the portal venous system. TIPS utilizes a venous stent to connect the portal vein to adjacent, lower-pressure veins. Portal hypertension is multifactorial and can result from a number of clinical conditions (cirrhosis, splenic vein thrombosis, congenital anomalies).^{30,31}

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Clinical Guideline Revision History/Information

Original Date: October 4, 2023		
Review History		
Version 2	12/12/2024	Annual policy review and restructure: • Updated recommended clinical approach to the current format. • Consolidated redundant criteria • Simplified AV fistula indication • Clarified wording of post-procedure complications indication; consolidated redundant criteria • Simplified criteria of pulmonary vein stenosis • Added indication for intracranial hypertension • Added repeat stenting indication • Corrected prophylactic non-indication • Added TIPS CPT codes + indication • Edited medical evidence section • Updated references



Cohere Medical Policy - Wearable Defibrillators

Clinical Policy for Medical Necessity Review

Version: 2

Cohere Health UMC Approval Date: July 31, 2025

Last Annual Review: July 31, 2025

Revision: Not Applicable

Next Annual Review: July 31, 2025

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Wearable Defibrillators

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

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Medical Necessity Criteria

Service: Wearable Defibrillators

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

A wearable defibrillator or wearable cardioverter-defibrillator (WCD) is an external defibrillator device worn as a garment that monitors a patient's heart rhythm. It is capable of automatic detection and treatment of ventricular tachycardia (VT) or ventricular fibrillation (VF). WCDs are designed to be worn as temporary, short-term devices for 3 months or less.¹ Since the first WCD was approved by the U.S. Food and Drug Administration (FDA) over two decades ago, other WCDs have obtained FDA approval.²⁻⁴

Medical Necessity Criteria

Indications

Wearable Defibrillators are considered appropriate if **ALL** of the following are **TRUE**:

- **ANY** of the following^{2,5-6}:
 - There is a clear indication for an ICD, but an ICD is inaccessible or transiently contraindicated (e.g., systemic infection)⁵; **OR**
 - Left ventricular ejection fraction (LVEF) less than or equal to 35% after a recent myocardial infarction (MI) during the 40-day ICD waiting period⁶; **OR**
 - After coronary artery bypass surgery or percutaneous coronary intervention with LVEF less than or equal to 35% during the 90-day ICD waiting period⁶; **OR**
 - The patient is listed for cardiac transplant⁶; **OR**
 - Recently diagnosed nonischemic cardiomyopathy with LVEF less than or equal to 35% during the 3-month waiting period⁵⁻⁶; **OR**
 - Myocarditis or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc.) in which the underlying cause is potentially treatable⁵; **OR**
 - During an interval when an ICD requires removal (e.g., device pocket infection, endocarditis)⁶; **AND**
- The patient is less than 18 years of age and **ALL** of the following are **TRUE**²:
 - The request is for ZOLL LifeVest²; **AND**
 - The patient has a chest circumference greater than or equal to 26 inches (66 centimeters)²; **AND**
 - The patient weighs more than or equal to 41.3 pounds (18.75 kilograms).²
- The request is for monthly monitoring of the device within the waiting period.

Non-Indications

Wearable Defibrillators are not considered appropriate if **ANY** of the following is **TRUE**^{2,5}:

- When an active implantable defibrillator is in place²; **OR**
- In a patient who is a candidate for an implantable cardioverter-defibrillator (ICD)²; **OR**
- VT that is amenable to catheter ablation; **OR**
- Terminal disease with a life expectancy of less than 6 months⁵; **OR**
- The request is for monthly monitoring of the device beyond the length of time of the waiting period.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
K0607	Replacement battery for automated external defibrillator, garment type only, each
K0608	Replacement garment for use with automated external defibrillator, each
K0609	Replacement electrodes for use with automated external defibrillator, garment type only, each
93292	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified healthcare professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system
93745	Initial set-up and programming by a physician or other qualified healthcare professional of wearable cardioverter-defibrillator includes initial

	programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events

Medical Evidence

In 2025, a patch-WCD received FDA premarket approval. The Jewel patch-WCD was designed to overcome and address the limitations associated with traditional garment-based WCDs in two areas: poor patient compliance and inappropriate detections and false alarms. First, the device is water-resistant and can be worn almost all the time, even while the patient is in the shower, which could improve patient compliance. Second, the software has a machine learning detection algorithm designed to improve detection and protection against sudden cardiac arrest.⁴

Hummel et al. (2024) published the results of the Jewel investigational device exemption (IDE) study, which assessed the safety and effectiveness of the patch-WCD for monitoring, detecting, and terminating sustained VT/VF. The multicenter, prospective, single-arm study enrolled 305 patients typically indicated for WCDs, who were not candidates for or refused an implantable defibrillator. Of all patients studied for the safety endpoint of <15% (to be in line with the incidence of skin-related adverse events for other commercially available WCDs), only 2.30% experienced a clinically significant cutaneous adverse event, and all clinically significant cutaneous adverse events were moderate in severity. In the current study, false alarms and inappropriate shock rates were low, which is important because Dang et al. (2024) showed that false alarms lead to sleep interruption, patient noncompliance, and generate anxiety.¹⁰ Also, they showed the effective detection and conversion of shockable events. No false alarms were experienced in 61.7% of patients, compared to only 28.3% patients who had no false alarms with the LifeVest WCD. This IDE study met the primary and secondary effectiveness and safety endpoints, and no patient deaths or device missed episodes that required external rescue. The high median wear time compliance of 23.5 hours/day exceeded the secondary endpoint of wear time compliance of >14.1 hours/day, resulting in a high number of successful lifesaving conversions.⁸

Olgin et al. (2018) conducted a trial to determine the efficacy of WCDs in preventing arrhythmic and all-cause mortality. The VEST trial (Vest Prevention of Early Sudden Death Trial) was a multicenter, randomized, controlled trial that evaluated 2,302 patients with an acute myocardial infarction and ejection fraction <35% during the period before ICDs were indicated. Two-thirds of the patients received a WCD plus guideline-directed therapy

(the device group), while one-third of the patients received only guideline-directed therapy (the control group). They found that treatment with a WCD did not result in a significantly lower rate of arrhythmic death than guideline-directed therapy only during the first 90 days. Importantly, this study was conducted several years ago when there was only one WCD device on the market.⁹

Piccini et al. (2016) developed a science advisory for the American Heart Association for WCD therapy for the prevention of sudden cardiac death. They state that there is a paucity of prospective data (published, randomized clinical trials) supporting the use of the WCD. Though early ICD placement does appear to decrease the incidence of sudden cardiac death, overall survival benefit early after MI or new cardiomyopathy diagnosis has not been proven. Wearable defibrillators are useful in the immediate post-MI period, when an implantable defibrillator may be postponed due to the potential of myocardial recovery and improved ventricular function.⁵

Duncker and Veltmann performed a systematic review in 2016 of wearable cardioverter defibrillators. It is stated that a relevant proportion of patients receiving an ICD do not meet evidence-based criteria for implantation. A study of 91 patients after MI found that 45% of patients met ICD criteria of left ventricular ejection fraction less than or equal to 35% 40 days after MI. Six of the patients significantly improved by 3 months of follow-up. The study determined that patients with recent onset non-ischemic cardiomyopathy showed no benefit from early ICD implantation.⁷

The 2017 AHA/ACC/HRS guideline for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death contains two definite recommendations for WCDs. The first WCD recommendation is for patients with an ICD, a history of sudden cardiac arrest or sustained ventricular arrhythmia, and infection or other cause necessitating ICD removal. The second recommendation is for patients at increased risk for sudden cardiac death, but who are not ineligible for an ICD, such as awaiting cardiac transplant or having an LVEF of 35% or less, and are within 40 days of an MI. This group of patients may also have newly diagnosed non-ischemic cardiomyopathy, revascularization within the past 90 days, myocarditis, secondary cardiomyopathy, or systemic infection, and thereby would be recommended for a WCD.⁶

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Policy Revision History/Information

Original Date: May 28, 2024		
Review History		
Version 1	05/28/2024	New policy.
Version 2	07/31/2025	Annual review. Added new Description section. Indication language was revised for clarity. Changed non-indication to "Terminal disease with a life expectancy of less than 6 months" (previously 1 year). Corrected as stated in reference #5, Piccini et al. Added new indication, "The request is for monthly monitoring of the device within the waiting period," and added related non-indication, "The request is for monthly monitoring of the device beyond the length of time of the waiting period." Pediatric LifeVest indication restructured without altering the medical necessity criteria. Additional citations were added throughout the indications section. No changes to the procedure codes. Medical Evidence - Added the new Jewel patch-WCD recently approved by the FDA

		(2025), as well as the investigational device exemption (IDE) study for this device. Added information on the VEST trial (Vest Prevention of Early Sudden Death Trial) (Olgin et al., 2018), which was missing in the previous version. References section updated (Cheung et al., 2021; USDA Jewel Patch Wearable Cardioverter Defibrillator, 2025; Hummel et al., 2024; Olgin et al., 2018; and Dang et al., 2024).



Cohere Medical Policy – Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)

Clinical Guidelines for Medical Necessity Review

Version: 3
Revision Date: March 6, 2025

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medicare Advantage Policy - Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)

Date of last literature review: 3/4/2025

Document last updated: 3/5/2025

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

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Medical Necessity Criteria

Service: Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)

Recommended Clinical Approach

This policy is consistent with a National Coverage Analysis (NCA) published on January 13, 2025 by the Centers for Medicare and Medicaid Services (CMS) and guidelines published in 2022 by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Failure Society of America (HFSA).¹⁻²

The CardioMEMS device is implanted in a pulmonary artery branch to remotely manage heart failure (HF). It allows earlier intervention to reduce congestive heart failure (CHF) exacerbations and hospitalizations. The effectiveness of using an implanted hemodynamic monitor for wireless pulmonary artery pressure monitoring to lower the risk of future HF hospitalizations continues to be debated. Specifically, this includes adult patients with New York Heart Association (NYHA) class II or III HF, a history of HF hospitalization within the past year, or elevated natriuretic peptide levels despite being on maximally tolerated stable doses of guideline-directed medical therapy (GDMT) and receiving optimal device therapy.

Among patients with NYHA class II or III HF with an HF hospitalization within the previous year, wireless monitoring of PA pressure by an implanted hemodynamic monitor provides uncertain value. Given this uncertainty of published recommendations, it is also reasonable and necessary to incorporate the inclusion and exclusion criteria from the two studies listed on the National Institutes of Health (NIH) website ClinicalTrials.gov. Abbott Medical Devices, the manufacturer of the CardioMEMS device, sponsored the *CardioMEMS HF System Post Approval Study* and the *Hemodynamic-GUIDEd Management of Heart Failure (GUIDE-HF) Study*.³⁻⁵ The patient must meet all inclusion criteria for approval, and no exclusion criteria should be present before consideration for prior approval.

Medical Necessity Criteria

Indications

→ **Wireless pulmonary artery pressure monitoring (CardioMEMS)** is considered appropriate if **ALL** of the following are **TRUE**²:

- ◆ The implantable pulmonary artery pressure sensor (IPAPS) is part of a Coverage with Evidence Development (CED) study approved by the Centers for Medicare and Medicaid Services (CMS) including **ANY** of the following^{1,6}:
 - CardioMEMS HF System Coverage with Evidence Development Study (NCT06779552, Abbott); **OR**
 - Real-World Effectiveness of The Cordella Pulmonary Artery (PA) Sensor System in Patients With Chronic Heart Failure: A Comparative Analysis to Standard of Care Pharmacologic Therapy (LOWER-PAP) (NCT06783335, Edwards Lifesciences)¹; **AND**
- ◆ New York Heart Association (NYHA) class II or III HF within the past 30 days, before pulmonary artery pressure sensor (PAPS) implantation, regardless of left ventricular ejection fraction (LVEF)¹; **AND**
- ◆ The patient was diagnosed with heart failure (HF) more than 3 months ago¹; **AND**
- ◆ Age greater than or equal to 18 years; **AND**
- ◆ **ANY** of the following¹:
 - History of HF hospitalization or urgent HF visit (e.g, emergency room or other outpatient visit requiring intravenous diuretic therapy) within the past 12 months; **OR**
 - Elevated natriuretic peptides within the past 30 days; **AND**
- ◆ Optimal or maximally-tolerated GDMT before PAPS implantation including **ANY** of the following¹⁻²:
 - For EF less than or equal to 40% on beta-blockers for 3 months; ACE/ARB/ARNI, SGLT2i, MRA, or diuretics for more than 1 month; or none if intolerant^A; **OR**
 - For EF 41-49% on beta-blockers on ACE/ARB/ARNI, SGLT2i, MRA, or diuretics for more than 1 month or none if intolerant^B; **OR**

- For EF greater than or equal to 50% on beta-blockers, ACE/ARB/ARNI, SGLT2i, MRA, or diuretics for more than 1 month or none if intolerant^C; **AND**
- ◆ The patient has been evaluated for and received, if appropriate, an implantable cardioverter defibrillator (ICD), CRT-defibrillator (CRT-D), cardiac resynchronization therapy (CRT)-pacemaker (CRT-P) for at least 3 months before PAPS implantation¹⁻²; **AND**
- ◆ No major cardiovascular events within the last 3 months before PAPS implantation (e.g., myocardial infarction, unstable angina, percutaneous coronary intervention, open heart surgery, or stroke)¹; **AND**
- ◆ Have access to reliable connectivity to ensure daily collection and submission of IPAPS data¹; **AND**
- ◆ **ANY** of the following:
 - Must not have PAPS implantation occur during hospital admission for an acute HF episode¹; **OR**
 - Elevated brain natriuretic peptide (BNP or NT-proBNP) levels within the last 30 days are **ANY** of the following:
 - LVEF less than or equal to 40%: NT-proBNP greater than or equal to 1000 pg/mL (or BNP greater than or equal to 250 pg/mL)*²; **OR**
 - LVEF greater than 40%: NT-proBNP greater than or equal to 700 pg/mL (or BNP greater than or equal to 175 pg/mL)*²; **OR**
 - Thresholds for NT-proBNP and BNP (for LVEF less than or equal to 40% and LVEF greater than 40%) must be corrected for body mass index (BMI) using a 4% reduction per BMI unit over 25 kg/m²²; **AND**
- ◆ **ANY** of the following⁸⁻⁹:
 - BMI greater than 35 kg/m² with a chest circumference less than 65 inches; **OR**
 - BMI less than or equal to 35.

^A Heidenreich et al. (2022), section 7.3. *Pharmacological Treatment for HFrEF*.

^B Heidenreich et al. (2022), section 7.6.1. *HF With Mildly Reduced Ejection Fraction (HFmrEF)*.

^c Heidenreich et al. (2022), section 7.7.1. *HF With Preserved Ejection Fraction*.

* [NT-proBNP and BNP Thresholds According to Ejection Fraction and BMI.⁷](#)

Non-Indications

→ **Wireless pulmonary artery pressure monitoring (CardioMEMS)** is not considered appropriate if **ANY** of the following is **TRUE**^{5,7,9}:

- ◆ A major cardiovascular event (e.g., unstable angina, PCI, myocardial infarction, open heart surgery, stroke, etc.) within the previous 3 months; **OR**
- ◆ The patient cannot take dual antiplatelet or anticoagulants for 1-month post-implant; **OR**
- ◆ Intolerance to all neuro-hormonal antagonists (i.e., intolerance to angiotensin-converting enzyme inhibitors [ACE-I], angiotensin receptor blockers [ARB], angiotensin-neprilysin inhibitors [ARNi], hydralazine/isosorbide dinitrate and beta-blockers); **OR**
- ◆ Likely to undergo heart transplantation or ventricular assist device (VAD) within the next 12 months; **OR**
- ◆ Existing heart transplantation or VAD; **OR**
- ◆ ACC/AHA Stage D refractory HF (including having received or currently receiving pharmacologic circulatory support with inotropes); **OR**
- ◆ NYHA class IV HF patients; **OR**
- ◆ Implanted with mechanical right heart valve(s); **OR**
- ◆ Unrepaired severe valvular disease; **OR**
- ◆ Pregnant or planning to become pregnant in the next 12 months; **OR**
- ◆ Anticipated life expectancy of less than 12 months; **OR**
- ◆ Any condition that, in the opinion of the reviewer, would not allow for utilization of the CardioMEMSTM HF System to manage the subject using information gained from hemodynamic measurements to adjust medications; **OR**
- ◆ Presence of unexpectedly severe pulmonary hypertension (e.g., trans-pulmonary gradient greater than 15) at implant right heart catheterization (RHC); **OR**
- ◆ A history of non-compliance; **OR**

- ◆ Any other condition that would preclude CardioMEMS PA Sensor implantation.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

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

Medical Evidence

Lindenfield et al. (2024) conducted a meta-analysis to analyze the efficacy of hemodynamic monitors for managing heart failure and reduced ejection fraction (HFrEF). The authors examined the results from the GUIDE-HF (Hemodynamic-Guided Management of Heart Failure) Study, the CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients) Study, and the LAPTOP-HF (Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy) Study. A total of 1350 patients were included in the analysis of hospitalization rates over 12 months and survival at 12- and 24-month follow-ups. The authors conclude that hospitalizations for HF improved due to hemodynamic monitors. At 24-month follow-up, hospitalizations decreased by 36%. Mortality varied by study: GUIDE-HF demonstrated “no reduction in mortality,” while the CHAMPION study showed a trend of reduced mortality, and the LAPTOP-HF study demonstrated a 44% decrease.^{[10](#)}

Lindenfield et al. (2021) performed an RCT on the effectiveness of pulmonary artery pressure monitoring to reduce mortality and HF events in patients with NYHA class II-IV HF (regardless of heart failure hospitalization [HFH] and level of natriuretic peptides). Results from the randomized arm of the GUIDE-HF trial identified a 28% reduction of HFH among the 1000 patients enrolled in the study. Compared with elevated brain natriuretic peptide (BNP) alone, patients with a previous HFH also had related benefits. (ClinicalTrials.gov Identifier NCT03387813).^{[11](#)}

Shavelle et al. (2020) conducted a multi-center, prospective, open-label, observational, single-arm trial to determine the efficacy of pulmonary artery pressure-guided therapy. A total of 1200 patients who had NYHA class III HF with at least one hospitalization in the last 12 months due to HF were included. A 57% reduction of HFH was reported among patients; for all causes, HFH was reduced by 27% post-implantation. Patients with ejection fraction saw a 50% reduction in HFH - no differences were identified among subgroups for sex, race, and cause of HF. (ClinicalTrials.gov Identifier NCT02279888).^{[8](#)}

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Clinical Guideline Revision History/Information

Original Date: May 24, 2024		
Review History		
Version 2	6/11/2024	422.101 Disclaimer added
Version 3	3/6/2025	• Annual review. • Aligned policy with CMS National Coverage Analysis (NCA) Decision Memo: Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (CAG-00466N). • Added a bullet to the harms section - "Physiologic changes: Patients may experience increased wall stress, sympathetic activation, arrhythmia, and elevated heart rate. Renal function may also decrease." • Added a bullet to the benefits section - "Reduction in complications and adverse effects: Using CardioMEMS criteria helps avoid unnecessary interventions and associated risks to safeguard the patient. Wireless pulmonary artery pressure monitoring guidelines emphasize the importance of accurate diagnostics in preventing complications." (Heidenreich et al., 2022). • Added an indication requiring enrollment in a CMS-approved Coverage with Evidence Development (CED) study including any of the following: ○ CardioMEMS HF System Coverage with Evidence Development Study (NCT06779552, Abbott); OR ○ Real-World Effectiveness of The Cordella Pulmonary Artery (PA)

		Sensor System in Patients With Chronic Heart Failure: A Comparative Analysis to Standard of Care Pharmacologic Therapy (LOWER-PAP) (NCT06783335, Edwards Lifesciences). - Deleted 7 non-indications that were relative contraindications (Cohere includes absolute contraindications only). - Rewrote the Medical Evidence section (see Lindenfeld et al., 2024; Lindenfeld et al., 2021; and Shavelle et al., 2020).



Cohere Medicare Advantage Policy – Peripheral Intravascular Lithotripsy (IVL)

Clinical Policy for Medical Necessity Review

Version: 1

Policy Number: CHP-310-1

Cohere Health UMC Approval Date: January 29, 2026

Last Annual Review: January 29, 2026

Revision: Not Applicable

Next Annual Review: January 29, 2027

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Peripheral Intravascular Lithotripsy (IVL)

Policy Number: CHP-310-1

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

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Medical Necessity Criteria

Service: Peripheral Intravascular Lithotripsy (IVL)

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 peripheral intravascular lithotripsy (IVL).

Description

Peripheral intravascular lithotripsy (IVL) is a minimally invasive procedure that uses acoustic pulses to treat moderate to severe calcific peripheral arterial disease.¹⁻³ During IVL, lithotripsy emitters, embedded in a balloon catheter, create sonic pressure waves that travel through soft tissue.^{4,5} The waves produce vapor bubbles that, upon collapse, create high-energy shocks to calcified plaques.⁶⁻¹¹

Medical Necessity Criteria

Indications

Peripheral intravascular lithotripsy 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

Peripheral intravascular lithotripsy 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
37262	Intravascular lithotripsy(ies), iliac vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)
37279	Intravascular lithotripsy(ies), femoral and popliteal vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)
C9764	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed
C9765	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
C9766	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same

	vessel(s), when performed
C9767	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed
C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed
C9773	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
C9774	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed
C9775	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed

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.

Potential Harms of applying the clinical criteria in this policy include, but are not limited to, denying opportunities to improve health outcomes for individuals and populations suffering from calcified peripheral artery disease. For example, restricting access to this procedure may increase patient and population dependence on excessive pain medication, including opioids, reduced functionality leading to additional medical problems, and a decrease in economic opportunity.

Potential Benefits of applying the clinical criteria in this policy include, but are not limited to, safeguarding patients from unproven technologies, procedures, and medical treatments until the proposed treatment's safety, efficacy are thoroughly validated via peer-reviewed scientific literature. This protects patients from balloon dislodgment, rupture, or perforation.¹²

Medical Evidence

In their prospective multicenter cohort study of 12-month outcomes of intravascular lithotripsy (IVL) treatment in patients with chronic limb-threatening ischemia, Nugteren et al. (2023) concluded that IVL showed promising safety and efficacy results. The study, which included a complex patient population of 29 patients, documented few major adverse events (4) and had a low rate of bailout stenting (12.5%). These results, according to the authors, warrant caution, as the study has several limitations, including a small patient size, the absence of a control group, and heterogeneity in the postdilatation technique.¹³

According to Kereiakes et al. (2021), endovascular treatment of calcific peripheral artery disease (PAD) remains an ongoing challenge for interventionalists, as calcification in the peripheral arteries is associated with an increased risk of dissection, perforation, and increased stenting rates. In addition, the presence of vascular calcification limits the success rates of endovascular interventions.³

Armstrong et al. (2020) conducted a cohort analysis of IVL for treating calcified, stenotic iliac arteries. A total of 200 lesions were evaluated; 101 patients sought treatment for claudication or critical limb ischemia, and 17 sought treatment for optimization of the iliac vasculature for large-bore access. The authors concluded that IVL in calcified iliac lesions was both safe and effective for the treatment of stenotic iliac disease. Limitations of the study included site-reported data. Furthermore, the study was a single-arm study without a control arm.¹⁴

Madhavan et al. (2020) conducted a meta-analysis on the efficacy of IVL for patients with PAD. Five prospective studies were included. The analysis included individual patient-level data, which were compared to existing studies on the use of IVL in patients with PAD. A total of 336 patients were included and underwent endovascular revascularization using IVL. The authors concluded that the use of IVL for significantly calcified PAD lesions is safe and effective. However, as over 12% of the study's patients received adjunctive device therapy, isolating the benefits of IVL was difficult.¹⁵

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Policy Revision History/Information

Original Date: January 29, 2026		
Review History		



Cohere Medicare Advantage Policy – Arterial Stenting

Clinical Policy for Medical Necessity Review

Version: 1.2

Policy Number: CHP-131-1.2

Cohere Health UMC Approval Date: June 26, 2025

Last Annual Review: June 26, 2025

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Next Annual Review: June 26, 2026

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy - Arterial Stenting

Policy Number: CHP-131-1.2

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

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Medical Necessity Criteria

Service: Arterial Stenting

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁴

- [Local Coverage Determination \(LCD\). Non-coronary vascular stents \(L35998\)](#)
 - [Billing and Coding: Non-coronary vascular stents \(A57590\)](#)
- [Local Coverage Determination \(LCD\). Dialysis access maintenance \(L34062\)](#)
 - [Billing and Coding: Dialysis access maintenance \(A56490\)](#)

Description

Arterial stents are placed through a transcatheter route by accessing the femoral or radial artery while the patient is sedated. In certain cases, particularly when transcatheter access is expected to be challenging or unsuccessful, arterial stents can also be placed through an open approach (e.g., arterial cutdown) wherein the artery is surgically exposed for direct placement of the stent. There are two types of arterial stents: bare metal stents and covered stents (a bare metal stent covered with fabric or graft material). Stents are further sub-classified as either balloon expandable or self-expanding. Bare metal stents may also be coated with a drug that is intended to reduce the risk of restenosis.¹⁴

Medical Necessity Criteria

Indications

Arterial stenting is considered appropriate if **ALL** of the following are **TRUE**:

- **ANY** of the following¹:
 - Stent is used for an FDA-approved indication; **OR**
 - Stent is used for any of the below indications supported by the peer-reviewed medical literature; **AND**
- **ALL** of the following:
 - The patient has undergone prior thorough medical evaluation and management of symptoms¹; **AND**
 - Surgical intervention would otherwise be considered as an alternative treatment for the patient¹; **AND**
 - **ANY** of the following¹:
 - Percutaneous transluminal angioplasty (PTA) alone is not expected to provide a durable result (such as arterial or venous occlusions that carry a high risk for distal embolization or rapid recurrence); **OR**
 - Patient has a lesion known to be unfavorable for PTA alone, such as significantly calcified lesions, eccentric lesions, lesions related to external compression (e.g., May-Thurner syndrome and malignant compression of the superior vena cava), ostial renal artery stenosis, or other such lesion; **AND**
- **ANY** of the following:
 - Upper extremity flow-limiting stenosis resulting in **ANY** of the following¹:
 - Subclavian steal syndrome; **OR**
 - Upper extremity claudication; **OR**
 - Ischemic rest pain of the arm and hand; **OR**
 - Non-healing tissue ulceration and focal gangrene; **OR**
 - Congenital pulmonary artery stenosis¹; **OR**
 - Renal artery stenting for **ANY** of the following¹:
 - Renal artery dissection; **OR**
 - Renal artery aneurysm; **OR**
 - In a transplanted kidney when renal artery atherosclerosis is greater than 50%; **OR**
 - Flash pulmonary edema or acute coronary syndrome (ACS) with severe hypertension; **OR**
 - Resistant hypertension with **ANY** of the following:

- Failure of maximally tolerated doses of at least three antihypertensive agents (including one diuretic); **OR**
- Intolerance to medications; **OR**
- Ischemic nephropathy with **ALL** of the following:
 - Chronic kidney disease (CKD) with eGFR less than 45 cc/min; **AND**
 - Global renal ischemia (unilateral significant renal artery stenosis with a solitary kidney or bilateral significant renal artery stenosis); **AND**
 - There is no other explanation for symptoms; **OR**
- Renal artery stenting may be appropriate for **ANY** of the following¹:
 - Unilateral renal artery stenosis with CKD (eGFR less than 45cc/min); **OR**
 - Unilateral renal artery stenosis with prior episodes of congestive heart failure (Stage C); **OR**
 - Anatomically challenging or high-risk lesion (early bifurcation, small vessel, severe concentric calcification, and severe aortic atheroma or mural thrombus); **OR**
- Renal artery stenting is rarely appropriate for **ANY** of the following¹:
 - Unilateral, solitary, or bilateral renal artery stenosis with controlled blood pressure (BP) and normal renal function; **OR**
 - Unilateral, solitary, or bilateral renal artery stenosis with kidney size less than 7cm in pole-to-pole length; **OR**
 - Unilateral, solitary, or bilateral renal artery stenosis with chronic end-stage renal disease on hemodialysis for more than 3 months; **OR**
 - Unilateral, solitary, or bilateral renal artery chronic total occlusion; **OR**
- The patient is experiencing critical limb-threatening ischemia (CTLI) as defined by **ANY** of the following¹:
 - Gangrene⁵⁻⁶; **OR**
 - Ischemic rest pain^{A5-6}; **OR**
 - Non-healing wounds⁵⁻⁶; **OR**
- Claudication with **ALL** of the following¹:
 - Intermittent claudication characterized by exertional muscle pain which is relieved by rest⁷; **AND**
 - Physical exam findings indicating reduced blood flow (e.g.,decreased or absent pulses)⁷; **AND**
 - Ankle-brachial index (ABI) greater than or equal to 0.90 or toe-brachial index (TBI) greater than or equal to 0.70⁷; **AND**

- Failure of medical management. Medical management of peripheral artery disease (PAD) should include Class I recommendations for antiplatelet therapy, statins, and smoking cessation (including planning, counseling/behavior modification, and pharmacotherapy if needed)¹; **AND**
- Failure of home exercise program¹; **AND**
- Ongoing, significant activity-limiting disease¹; **AND**
- Anatomically suitable lesion for intervention¹; **OR**
- Mesenteric vascular insufficiency resulting in gastrointestinal symptoms (i.e., acute mesenteric ischemia, chronic mesenteric ischemia, mesenteric thrombosis, dissection, or any other vascular insufficiency) with **ALL** of the following¹:
 - Angioplasty of the vessels would not suffice; **AND**
 - The patient has had a thorough medical evaluation and management of symptoms; **AND**
 - Surgical intervention is the likely alternative to stenting; **AND**
 - The patient has multiple documented comorbidities, which make them poor candidates for open surgical procedures; **OR**
- Stenting of the superior vena cava, innominate artery, or subclavian artery with **ANY** of the following¹:
 - Superior vena cava syndrome; **OR**
 - Post-radiation venous stenosis; **OR**
 - Congenital stenosis; **OR**
 - Thrombosis and embolism, including acute thrombophlebitis; **OR**
 - Stenting of the inflow arteries (e.g., innominate or subclavian) when they are the inflow vessels of an arteriovenous (AV) fistula for chronic hemodialysis, and they are significantly stenotic; **OR**
- Stenting of the inferior vena cava or iliofemoral veins for occlusions/stenosis due to **ANY** of the following¹:
 - Post-radiation venous stenosis; **OR**
 - Congenital stenosis or webs; **OR**
 - Extrinsic venous compression (May-Thurner syndrome); **OR**
 - Thrombophlebitis; **OR**
 - Symptomatic post-traumatic venous stenosis; **OR**
- Stenting as a last resort to salvage a dialysis access graft or fistula for **ANY** of the following scenarios³:
 - PTA-induced rupture; **OR**

- Graft salvage (e.g., PTA is unsuccessful due to elastic recoil, stenosis has recurred in less than 3 months); **OR**
- Central vein stenosis or occlusion; **OR**
- Aneurysm or pseudoaneurysm; **OR**
- The patient has **ANY** of the following aneurysmal conditions⁸:
 - Any symptomatic aneurysm; **OR**
 - Asymptomatic lower extremity aneurysmal disease as indicated by **ANY** of the following⁹⁻¹¹:
 - An iliac artery aneurysm greater than 3 cm in diameter; **OR**
 - A common femoral artery aneurysm greater than 2.5 cm in diameter; **OR**
 - A profunda femoral artery aneurysm greater than 2 cm in diameter; **OR**
 - A superficial femoral artery (SFA) aneurysm greater than 2 times the diameter of the normal native SFA (with or without mural thrombus); **OR**
 - A popliteal artery aneurysm greater than or equal to 2 cm in diameter (with or without mural thrombus) with documentation that the patient has a high surgical risk; **OR**
 - Asymptomatic upper extremity aneurysm; **OR**
 - Asymptomatic visceral artery aneurysm as indicated by **ANY** of the following¹²:
 - Splenic artery aneurysms greater than 3 cm in diameter (and splenic artery aneurysms of any size in women of childbearing age); **OR**
 - All splenic artery pseudoaneurysms; **OR**
 - Hepatic artery aneurysms greater than 2 cm in diameter or a hepatic artery aneurysm that enlarges by more than 0.5 cm in a year; **OR**
 - Gastric, gastroepiploic, pancreaticoduodenal, and gastroduodenal aneurysms of any size; **OR**
 - Superior mesenteric artery aneurysms of any size; **OR**
 - Celiac artery aneurysms greater than 2 cm in diameter.

Non-Indications

Arterial stenting is not considered appropriate if **ANY** of the following is **TRUE**:

- Known allergic reactions to stent or stent graft material (e.g., nitinol, dacron, expanded polytetrafluoroethylene [ePTFE])¹³⁻¹⁷; **OR**
- Preventive stenting (i.e., the placement of a stent in a vessel for which there is no objective-related symptom or limitation of function)¹; **OR**
- Stenting of total occlusion of AV graft due to thrombus of more than one year in duration.³

Definitions and Notes

^A Ischemic rest pain: Typically described as affecting the forefoot and is often made worse with recumbency while being relieved by dependency. It should be present for greater than 2 weeks and be associated with one or more abnormal hemodynamic parameters. These parameters include an ankle-brachial index (ABI) less than 0.4 (using higher of the dorsalis pedis [DP] and posterior tibial [PT] arteries), absolute highest AP less than 50 mm Hg, absolute TP less than 30 mm Hg, transcutaneous partial pressure of oxygen (TcPO₂) less than 30 mm Hg, and flat or minimally pulsatile pulse volume recording (PVR) waveforms (equivalent to Wifl ischemia grade 3).⁵⁻⁶

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
37236	Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery
37237	Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery (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 **arterial stenting of aneurysmal disease** may include:

- Adverse effects from delayed or denied treatment. Patients with aneurysmal conditions require prompt risk stratification, individualized plan-of-care counseling, and treatment. This is particularly important as some aneurysmal diseases are characterized by rapid growth; aneurysmal size may become dangerously large in a relatively short period, conferring a higher risk of dissection, which may result in such complications as malperfusion syndrome, limb loss, and death.^{[8.13](#)}
- Risks with inappropriate surgical procedures: Arterial stenting is not a benign procedure and, if performed on a suboptimal patient, may confer serious complications. Risks include spinal cord ischemia, infection, bleeding, injury to neurovascular structures, death, anesthetic risk, and the need for repeat or additional procedures due to complications.^{[8.13](#)}

The clinical benefits of using these criteria for **arterial stenting of aneurysmal disease** may include:

- Improved patient selection resulting in better long-term outcomes. Patients with certain disease characteristics – including aneurysmal size and location, growth rate, disease etiology, and few comorbidities – are ideal for an endovascular approach such as stenting. As a minimally invasive procedure, endovascular repair requires a shorter recovery time and is associated with fewer complications than traditional open surgery repair, which often requires substantial exposure of the affected region, as well as lengthy operating times and the potential for cardiopulmonary

bypass support. Certain patients – younger patients, those with genetically driven aortic disease – are more appropriate for open surgical repair. Surgical repair of the aneurysm may be definitive, effectively eliminating the long-term risk of rupture and subsequent morbidity and mortality.^{9,14}

- Maintenance of rigorous patient safety standards aligned to best available evidence. Patients who undergo stenting while having a known allergy to stent material, such as nitinol or dacron, are at increased risk for lifelong systemic symptoms, including pain, dermatitis, and graft or stent dysfunction – a consequence which does not usually outweigh the potential benefit of aneurysmal repair. The risk of surgery itself does not outweigh the benefit of aneurysmal repair in this population.¹⁴⁻¹⁷
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

The American College of Cardiology (ACC), American Heart Association (AHA), Society for Cardiovascular Angiography and Interventions (SCAI), Society of Interventional Radiology (SIR), and Society for Vascular Medicine (SVM) published the *Appropriate Use Criteria for Peripheral Artery Intervention* in 2018. Stenting is supported for the treatment of renal artery stenosis; recommendations align with evidence from the randomized CORAL trial (Stenting and Medical Therapy for Atherosclerotic Renal-Artery Stenosis). Patients with hypertension may benefit from renal stenting when outcomes are not achieved after taking the maximum dose of three prescribed antihypertensive medications. The report also notes the need for research on various modalities for in-stent stenosis and failure of arterial grafts. Importantly, these guidelines also emphasize the relative benefits of endovascular intervention – such as stenting – over traditional open procedures. They cite, for example, that iliac artery stenting has excellent durability similar to surgical intervention but carries the additional benefit of an improved safety profile compared to surgical revascularization.¹³

A 2021 multicenter prospective study of patients with aortic coarctation examined the long-term consequences of primary stenting to resolve the coarctation. 248 patients with aortic coarctation were enrolled, and data were collected at regular follow-up intervals for up to 60 months. Stenting was selected as a less invasive alternative to traditional open-chest surgery with the goal of reducing antihypertensive medication intake, especially for pediatric patients. A notable decrease in antihypertensive use was observed at a rate of 53% immediately after surgery; this decreased to 29% at late follow-up (between 48 and 60 months). Stent fracture was also observed among 24.4% of patients at late follow-up. The authors acknowledged the early, short-term efficacy and safety of arterial stenting for aortic coarctation, particularly if the goal of care is to allow a pediatric patient to reach a more suitable age for surviving open-chest definitive repair of their congenital heart disease.¹⁸

Although stenting is considered comparable to surgical intervention in many settings, some challenges associated with stenting may occur. Restenosis

occurs with variable frequency depending on the anatomical site of treatment and, if unresolved, can be a life-limiting complication for patients who suffer critical limb ischemia and subsequent limb loss and the associated cardiovascular consequences. Frequent clinical reassessment is recommended to promote limb salvage and mitigate mortality. In the superficial femoral artery (SFA), restenosis has been reported to occur in up to one-third of patients.¹⁹

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Policy Revision History/Information

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Version 1.1	02/02/2026	Revision. Removed Billing and Coding Article A53124- Retired 12/25/2025. Updated links and reference for L35998 per CMS update.
Version 1.2	03/16/2026	Revision. Updated links and reference for L34062 and A56460.



Cohere Medicare Advantage Policy – Cardiac Ablation

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: May 28, 2024

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Guideline Name: Cohere Medicare Advantage Policy - Cardiac Ablation

Date of last literature review: 5/26/2024

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

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Medical Necessity Criteria

Service: Cardiac Ablation

Benefit Category

Not applicable.

Recommended Clinical Approach

- Cardiac ablation for atrial fibrillation: Catheter ablation is a procedural approach to rhythm control for atrial fibrillation. As atrial fibrillation can become refractory to medication over time, ablation is often recommended for symptomatic patients who have become refractory to or intolerant of medical therapy. Ablation, at minimum, entails the isolation of tissue around pulmonary vein ostia using radiofrequency or cryothermal energy. Approach an ablation strategy with a realistic risk-benefit analysis of outcomes. Ablation of atrial fibrillation is a higher-risk proposition for a patient who is unable to be treated with anticoagulant therapy before, during, and after the ablation.
- For AV node ablation: AV nodal ablation in the context of atrial fibrillation is a palliative treatment for persistent or permanent atrial fibrillation, which is symptomatic, has failed rhythm and rate control, and may be causing tachyarrhythmia-induced heart failure. This procedure must be performed in patients with a pre-existing pacemaker or patients for whom a pacemaker implant is planned during the same procedure. AV node ablation is not considered a first-line treatment for rate control of atrial fibrillation.¹⁻³ AV nodal ablation is a palliative treatment performed and has distinct indications separate from other therapeutic cardiac ablations.
- Cardiac ablation for atrial flutter: Catheter ablation is a procedural approach to rhythm control for atrial flutter. As atrial flutter is often symptomatic and can be a trigger for atrial fibrillation, ablation is often recommended for patients who have become refractory to medical therapy. Ablation of typical flutter at minimum entails isolation of tissue involved in the macroreentrant circuit rotating around the tricuspid annulus, using radiofrequency or cryothermal energy. Alternatively, an atrial flutter circuit created by a past cardiac surgical scar can be identified using mapping techniques, and an ablation line can be drawn through this circuit to disrupt continuity.⁴ Scar-mediated atrial flutter circuits can be located in the right or left atrium, traverse across chambers, and be multiple in number.⁵ There are very few factors that make ablation of atrial flutter inappropriate. The ablation of typical

atrial flutter is low risk and is a relatively straightforward procedure. Scar-mediated flutter ablations can be more complex anatomically but still have good success rates with catheter ablation.

- Cardiac ablation for SVT: Catheter ablation is an acceptable first-line therapy for the treatment of SVT. Catheter ablation can be used before any medication because of its high success and low complication rate. Arrhythmia substrate can be approached using radiofrequency or cryothermal energy, depending on location. Cryoablation has dramatically reduced the probability of inadvertent AV block during ablation procedures.⁶
- Cardiac ablation for ventricular arrhythmias: Catheter ablation of ventricular arrhythmias is a common approach to treatment, especially when the mechanism is refractory to antiarrhythmic therapy. VT can be due to a reentrant mechanism (often related to a scar-mediated circuit) or a focal area of excitability. PVCs with a high-frequency burden on monitoring are often the cause of diminished ventricular function, which can be reversed with catheter ablation.^{7,8} In certain forms of VT, an epicardial substrate can be identified. This often requires the insertion of a mapping/ablation catheter from a subxiphoid approach to access the area where the arrhythmia originates.⁹

Medical Necessity Criteria

Indications

→ **Cardiac ablation** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The patient has symptomatic paroxysmal atrial fibrillation and has become refractory or cannot tolerate treatment with an antiarrhythmic drug or antiarrhythmic drug therapy is not preferred; **OR**
- ◆ The patient has tachy-brady syndrome (e.g., as an alternative to pacemaker implantation); **OR**
- ◆ The patient has symptomatic paroxysmal atrial fibrillation and has clinical factors that would be contraindications to taking an antiarrhythmic drug; **OR**
- ◆ The patient has symptomatic persistent atrial fibrillation and has become refractory or intolerant to an antiarrhythmic drug; **OR**
- ◆ For recurrent episodes of symptomatic atrial fibrillation, which occur greater than three months after the initial procedure (ablation); **OR**

- ◆ In selected patients (generally younger with few comorbidities) with symptomatic paroxysmal AF in whom rhythm control is desired, catheter ablation is useful as first-line therapy to improve symptoms and reduce progression to persistent AF; **OR**
- ◆ In patients (other than younger with few comorbidities) with symptomatic paroxysmal or persistent AF who are being managed with a rhythm-control strategy, catheter ablation as first-line therapy can be useful to improve symptoms; **OR**
- ◆ In selected patients (Younger patients with few comorbidities and a moderate to high burden of AF or persistent AF and AFL) with asymptomatic or minimally symptomatic AF, catheter ablation may be useful for reducing the progression of AF and its associated complications; **OR**
- ◆ In appropriate patients with AF and HFrEF who are on GDMT and with reasonable expectation of procedural benefit, catheter ablation is beneficial to improve symptoms, QOL, ventricular function, and cardiovascular outcomes; **OR**
- ◆ In appropriate patients with symptomatic AF and HFpEF with a reasonable expectation of benefit, catheter ablation can be useful to improve symptoms and improve QOL; **OR**
- ◆ The procedure is **atrioventricular node ablation** and **ALL** of the following are **TRUE**¹⁰⁻¹¹:
 - Persistent or permanent atrial fibrillation; **AND**
 - The patient is an unfavorable candidate for rhythm control, either by pharmaceutical or interventional means; **AND**
 - Pharmacologic rate control has been unsuccessful due to rhythm refractoriness or patient intolerance; **AND**
 - The patient has a permanent pacemaker implanted or is an appropriate candidate for ventricular pacing; **AND**
 - The patient is at-risk of developing or has a history of heart failure; **AND**
 - Suspected tachycardia-mediated cardiomyopathy; **OR**
- ◆ The procedure is **cardiac ablation for atrial flutter** and **ANY** of the following is **TRUE**¹²⁻¹⁴:
 - The patient has symptomatic atrial flutter and has become refractory or cannot tolerate treatment with an antiarrhythmic drug; **OR**

- The patient has new-onset atrial flutter and is determined to be a favorable candidate for ablation as a first-line therapy vs antiarrhythmic medication; **OR**
- Recurrence of atrial flutter with a reasonable expectation of success with a redo procedure; **OR**
- Recurrent episodes of symptomatic atrial flutter; **OR**
- ◆ The procedure is an **electrophysiology study (EPS)/cardiac ablation for supraventricular tachycardia (SVT)** and **ANY** of the following is **TRUE**:
 - Symptomatic or sustained SVT; **OR**
 - WPW pattern¹⁵; **OR**
 - After any episode of pre-excited atrial fibrillation¹⁵; **OR**
 - A focal atrial tachycardia which is the likely etiology of new cardiomyopathy; **OR**
 - For evaluation of asymptomatic patients with ventricular preexcitation patterns to determine **ANY** of the following:
 - Inducibility of AVRT; **OR**
 - The rapidity of antegrade conduction as a risk factor for sudden cardiac arrest; **OR**
 - For the presence of manifest ventricular preexcitation which would interfere with certain types of employment (e.g., pilots, military service)¹⁵; **OR**
- ◆ The procedure is **cardiac ablation for ventricular arrhythmia** and **ANY** of the following is **TRUE**:
 - Symptomatic premature ventricular complexes (PVCs) in a patient refractory to or intolerant to antiarrhythmic therapy; **OR**
 - High PVC frequency (greater than 15% of beats) is associated with symptoms or diminished LV function (LVEF less than 50%) on cardiac imaging; **OR**
 - When a PVC of similar morphology is a trigger for other arrhythmias, such as VF; **OR**
 - Frequent PVCs refractory to medical therapy, which are interfering with the effectiveness of biventricular pacing; **OR**
 - Sustained symptomatic monomorphic VT in the structurally normal heart; **OR**
 - Episodes of VT causing excess appropriate ICD shocks (e.g., in ARVC, Brugada Syndrome, sarcoidosis); **OR**

- Recurrent sustained monomorphic VT in a patient with structural heart disease that is refractory to or intolerant to antiarrhythmic therapy⁹; **OR**
- First episode of monomorphic sustained ventricular tachycardia (lasting 30 seconds or more) in a patient with an ICD to reduce the risk of recurrent ventricular tachycardia or ICD interventions (e.g., shock, pacing); **OR**
- Previous myocardial infarction with recurrent episodes of symptomatic sustained ventricular tachycardia (lasting 30 seconds or more) and **ALL** of the following:
 - Unsuccessful prior endocardial catheter ablation;
 - AND**
 - Evidence of subepicardial substrate (e.g., ECG, mapping, imaging); **OR**
- Nonischemic cardiomyopathy with recurrent sustained monomorphic ventricular tachycardia (lasting 30 seconds or more) where antiarrhythmic therapy has failed, is not tolerated, or is not preferred; **OR**
- In cardiomyopathy with VT storm; **OR**
- Sustained monomorphic VT in repaired Tetralogy of Fallot⁸; **OR**
- In other forms of adult congenital heart disease (ACHD) with sustained VT, which have undergone appropriate evaluation and treatment for anatomic and hemodynamic etiologies^{8,15}; **OR**
- Symptomatic frequent premature ventricular contractions (e.g., more than 15% of beats) originating from the right ventricular outflow tract in an otherwise normal heart; **OR**
- Focally triggered ventricular fibrillation, resistant to antiarrhythmic medications, initiated by a similar premature ventricular contraction; **OR**
- Idiopathic symptomatic (outflow tract or non-outflow tract) ventricular arrhythmia in otherwise normal heart and antiarrhythmic medications are ineffective, not tolerated, or not preferred; **OR**
- Re-entrant ventricular tachycardia (e.g., bundle branch, His-Purkinje, or fascicular); **OR**

- Congenital heart disease with recurrent sustained (greater than 30 seconds) ventricular tachycardia or recurrent appropriate ICD shocks; **OR**
- Sarcoidosis with recurrent ventricular tachycardia refractory to medical therapy (e.g., immunosuppressive and antiarrhythmic medications).

Non-Indications

→ **Cardiac Ablation** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ There are no published non-indications.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
+93462	Left heart catheterization by transseptal puncture through intact septum or by transapical puncture
+93613	Intracardiac electrophysiologic three-dimensional mapping
93631	Intraoperative epicardial and endocardial pacing and mapping to localize the site of tachycardia or zone of slow conduction for surgical correction
93650	Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block
93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, with attempted induction of arrhythmia, with right atrial pacing and recording, with treatment of supraventricular tachycardia by ablation
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, with attempted induction of arrhythmia, with right atrial pacing and recording, with focus of

	ventricular ectopy
+93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia
93656	Comprehensive electrophysiologic evaluation with transseptal catheterization, with insertion and repositioning of multiple electrode catheters, with attempted induction of arrhythmia, with atrial pacing and recording
+93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation
+93662	Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation

Medical Evidence

January et al. (2014) published an evidence-based, systematic review and subsequent guidelines for the American Heart Association, American College of Cardiology, and the Heart Rhythm Society for the *Management of Patients with Atrial Fibrillation*. A number of recommendations were made or revised for optimum management of atrial fibrillation. Atrioventricular (AV) nodal ablation with permanent ventricular pacing is recommended to control heart rate when pharmacological therapy has not been effective and rhythm control not achieved. Ablation not recommended as a first-line treatment; medications should be utilized first whenever possible.²

Calkins et al. (2017) published an expert consensus statement with the Heart Rhythm Society, the European Heart Rhythm Association (EHRA) and the European Cardiac Arrhythmia Society to update guidelines based on advances in atrial fibrillation ablation since their previous publication. It was recommended that the amount of time an individual spends in AF (24-hour AF burden) is essential to address when ablation is being considered. This is due largely to the increase in the use of implantable loop recorders, pacemakers, and ICDs.¹

A 2015 New England Journal of Medicine publication by Verma et al. describes catheter ablation procedures for persistent atrial fibrillation vs. paroxysmal atrial fibrillation. In this randomized trial of 589 patients, it was concluded that among patients with persistent atrial fibrillation, there was no reduction in the rate of recurrent atrial fibrillation when ablation was performed in addition to pulmonary vein isolation.¹²

Otto et al. (2021) published a Scientific Statement for the American Heart Association with recommendations for the management of valvular heart disease. Regarding intervention for secondary mitral regurgitation, successful ablation of atrial fibrillation may reduce or eliminate mitral regurgitation.¹⁴

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Cohere Medicare Advantage Policy – Cardiac Catheterization

Clinical Policy for Medical Necessity Review

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Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy - Cardiac Catheterization

Policy Number: CHP-118-1.1

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Medical Necessity Criteria

Service: Cardiac Catheterization

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁴

- [Local Coverage Determination \(LCD\). Cardiac catheterization and coronary angiography \(L33557\)](#)
 - [Billing and Coding: Cardiac catheterization and coronary angiography \(A52850\)](#)
- [Local Coverage Determination \(LCD\). Cardiac catheterization and coronary angiography \(L33959\)](#)
 - [Billing and Coding: Cardiac catheterization and coronary angiography \(A56500\)](#)

Description

Left and right heart catheterization is an invasive cardiac evaluation method. It allows for direct evaluation of hemodynamics, cardiac pressure, and cardiac output.^{1,3} Left heart catheterization involves the insertion of a catheter into an artery in the arm, groin, or wrist. Generally, femoral artery access is more commonly used than radial artery access for left heart catheterization. The catheter is guided to the left ventricle of the heart to measure left ventricular pressures or to obtain an angiogram (left ventriculogram, ventriculography). Left heart catheterization is sometimes performed with coronary angiography to assess left ventricular pressure and function and for the presence of valvular heart disease. The addition of a right cardiac catheterization to a left cardiac catheterization is needed for a hemodynamic assessment when evaluating valvular heart disease, cardiomyopathies, or pericardial disease. In some clinical situations, the performance of a right cardiac catheterization (hemodynamics and cardiac output) or a left heart catheterization/left ventricular angiogram alone may be needed.^{1,3,5}

Medical Necessity Criteria

Indications

Cardiac catheterization is considered appropriate if **ALL** of the following are **TRUE**:

- **Coronary/bypass angiography with or without left heart catheterization**, and **ANY** of the following^{1,3}:
 - This section is not applicable (service not requested); **OR**
 - **ALL** of the following:
 - **ANY** of the following:
 - Anginal syndrome with ischemia; **OR**
 - Atypical chest pain syndrome suggesting ischemia; **OR**
 - Known atherosclerotic or other coronary disease (not including coronary calcification); **AND**
 - **ANY** of the following⁶:
 - Nuclear perfusion (SPECT or PET) that demonstrates at least 10% ischemic myocardium; **OR**
 - Echocardiogram demonstrating at least 3/16 segments with **ANY** of the following:
 - Stress-induced severe hypokinesis; **OR**
 - Akinesis; **OR**
 - Wall motion index of greater than 1.1; **OR**
 - Cardiac magnetic resonance (CMR) perfusion demonstrating **ANY** of the following:
 - At least 12% ischemic myocardium and/or wall motion; **OR**
 - At least 3/16 segments with **ANY** of the following:
 - Stress-induced severe hypokinesis; **OR**
 - Akinesis; **OR**
 - Wall motion index of greater than 1.1; **OR**
 - Exercise test and **ALL** the following:
 - Clinical history of cardiac chest pain; **AND**
 - **ANY** of the following:
 - Absence of resting ST-segment depression at least 1.0 mm; **OR**
 - Confounders that render exercise ECG noninterpretable (e.g., left bundle branch block [LBBB], left ventricular

- hypertrophy with repolarization, ventricular paced rhythm);
AND
- **ALL** of the following:
 - Compared with the baseline tracing, additional exercise-induced horizontal/down-sloping ST-segment depression of **ANY** of the following:
 - At least 1.5 mm in 2 leads; **OR**
 - At least 2.0 mm in any lead; **AND**
 - ST-segment elevation greater than or equal to 1 mm in a noninfarct territory. (Both the J-point and the ST-segment depression at 80 ms need to meet criteria. When the HR is greater than 130 beats/min, the ST-segment depression at 60 ms may be used if the segment at 80 ms cannot be determined); **AND**
 - **ANY** of the following:
 - Peak workload does not exceed completion of stage 2 of a standard Bruce protocol (or no more than 7 metabolic equivalents [METs] if a non-Bruce protocol is used); **OR**
 - ST-segment criteria are met at less than 75% of the maximum predicted heart rate; **OR**
 - Congenital heart disease; **OR**
 - Following cardiac arrest suspected to be due to ischemia or infarction; **OR**
 - Myocardial infarction (including NSTEMI); **OR**
 - Suspected closure of graft or stent/percutaneous transluminal coronary angioplasty; **OR**
 - Prinzmetal's angina; **OR**
 - Coronary shunt or fistula; **OR**
 - Cardiac trauma; **OR**
 - The patient is undergoing a non-coronary cardiac surgical procedure (e.g., aortic valve or mitral valve surgery, including TAVR); **OR**
 - The patient is undergoing a renal or liver transplant; **OR**
 - The patient is undergoing a high-risk non-cardiac surgical procedure (arterial or aortic surgery, or surgery with large fluid shift) and has evidence of ischemic heart disease; **AND**
 - The procedure is a **left heart catheterization with left ventricular angiogram (ventriculogram)**, and **ANY** of the following is **TRUE**¹³:
 - This section is not applicable (service not requested); **OR**

- Assessment of mitral or tricuspid valve function; **OR**
- Constrictive or restrictive pericarditis; **OR**
- Assessment of ventricular function or morphology (including tumors and clots); **OR**
- Suspected ventricular aneurysm; **OR**
- Intracardiac shunt; **OR**
- Congenital heart disease; **OR**
- Cardiac trauma; **OR**
- In the setting of severe aortic stenosis, assessment of the aortic valve only if noninvasive imaging is inadequate⁵; **AND**
- The procedure is a **right cardiac catheterization**, and **ANY** of the following is **TRUE**^{1,3}:
 - This section is not applicable (service not requested); **OR**
 - Valvular heart disease; **OR**
 - Congestive heart failure (CHF); **OR**
 - Congenital heart disease; **OR**
 - Cor pulmonale; **OR**
 - Echocardiography suggests pulmonary hypertension (i.e., a mean pulmonary arterial pressure of at least 20 mm Hg at rest)⁷; **OR**
 - Intracardiac shunts (including septal rupture) and extracardiac vascular shunts; **OR**
 - Suspected cardiomyopathy or myocarditis; **OR**
 - Endocarditis that is anticipated to require valvular surgery; **OR**
 - Suspected rejection of a transplanted heart; **OR**
 - The patient is being considered for or has received a heart transplant; **OR**
 - Suspected pericardial tamponade or constriction.

Non-Indications

Cardiac catheterization is not considered appropriate if **ANY** of the following is **TRUE**^{1,3}:

- Right heart catheterization billed for "bedside placement" of flow-directed (Swan-Ganz type) catheter; **OR**
- Right heart catheterization for atherosclerotic heart disease without heart failure; **OR**
- Right heart catheterization for angioplasty, electrophysiologic studies, or other interventional procedures; **OR**

- Right heart catheterization solely for the purpose of inserting a temporary pacemaker, performing endomyocardial biopsy, or performing electrophysiologic studies; **OR**
- When left heart catheterization is performed for reasons other than hemodynamic evaluation or LV angiography required for patient management (i.e., when routinely performed with coronary/bypass angiography, electrophysiologic or pacing studies, or endomyocardial biopsies).

Definitions

- Anginal syndrome is defined as having **ALL** of the following characteristics^{5.8}:
 - **ANY** of the following:
 - Substernal location of chest discomfort (burning, dull, heaviness, pressure, squeezing, tightness); **OR**
 - Anginal equivalent (discomfort in the shoulders, arms, neck, back, upper abdomen, or jaw, as well as shortness of breath and fatigue); **AND**
 - Precipitated by exertion or emotional stress; **AND**
 - Prompt relief with rest or sublingual nitroglycerin (“prompt” defined as between approximately 30 seconds to 1 minute).
- Atypical chest pain syndrome suggesting ischemia is defined as having **AT LEAST 2** of the following characteristics^{5.8}:
 - **ANY** of the following:
 - Substernal location of chest discomfort (burning, dull, heaviness, pressure, squeezing, tightness); **OR**
 - Anginal equivalent (discomfort in the shoulders, arms, neck, back, upper abdomen, or jaw, as well as shortness of breath and fatigue); **OR**
 - Precipitated by exertion or emotional stress; **OR**
 - Prompt relief with rest or sublingual nitroglycerin (“prompt” defined as between approximately 30 seconds to 1 minute).
- Known atherosclerotic coronary artery disease is defined as having **ANY** of the following^{5.8}:
 - History of documented myocardial infarction; **OR**
 - Known coronary artery revascularization; **OR**

- Documented coronary artery disease or coronary anomaly by coronary angiogram or CCTA.
- Evidence of ischemic heart disease is defined as having **ANY** of the following^{5,8}:
 - History of documented myocardial infarction; **OR**
 - Known coronary artery revascularization; **OR**
 - Documented coronary artery disease or coronary anomaly by coronary angiogram or CCTA.
- Prinzmetal's angina ("variant angina", "vasospastic angina") is defined as having **ALL** of the following⁹:
 - Nitrate-responsive angina; **AND**
 - Transient ischemic electrocardiogram changes; **AND**
 - Documented coronary artery spasm.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93451	Right heart catheterization
93452	Left heart catheterization with intraprocedural injection for left ventriculography
93453	Combined right and left heart catheterization with intraprocedural injection for left ventriculography
93454	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation
93455	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with catheter placement in bypass graft, with intraprocedural injections for bypass graft

	angiography
93456	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with right heart catheterization
93457	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with catheter placement in bypass graft, with intraprocedural injection for bypass graft angiography and right heart catheterization
93458	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with left heart catheterization, with intraprocedural injection for left ventriculography
93459	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision and interpretation, with left heart catheterization, catheter placement in bypass graft, with bypass graft angiography
93460	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with right and left heart catheterization
93461	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with right and left heart catheterization, catheter placement in bypass graft, with bypass graft angiography
93462	Left heart catheterization by transseptal puncture through intact septum or by transapical puncture
93593	Right heart catheterization for congenital heart

	defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; normal native connections
93594	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; abnormal native connections
93595	Left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone, normal or abnormal native connections
93596	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); normal native connections
93597	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); abnormal native connections

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 catheterization** may include:

- Adverse effects from delayed or denied treatment for patients with anginal syndrome, atypical chest syndrome, atherosclerotic heart disease, or ischemic heart disease that is not captured by the American College of Cardiology's definitions, which were added to provide decisionable interpretations of the terms mentioned in the LCDs. Consequences could include increased symptoms and cardiovascular complications (e.g., stroke, myocardial infarction), especially in patients with a high likelihood of coronary artery disease (CAD) or those requiring hemodynamic assessment for conditions like valvular heart disease.^{5,8}

The clinical benefits of using these criteria for **cardiac catheterization** may include:

- Improved patient selection for left heart catheterization, resulting in better long-term outcomes. Proper patient selection – such as the identification of appropriate patients through evidence-based, professional society guidance – helps to avoid unnecessary, high-risk interventions, such as open-chest coronary bypass (CABG), thus safeguarding patient health.^{10,11}
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

The clinical harms of using these criteria for **left heart catheterization with or without left ventriculogram** may include:

- Adverse effects from delayed or denied treatment for patients with aortic stenosis, as invasive evaluation is reserved for patients in whom noninvasive imaging is inadequate. Consequences could include increased symptoms and cardiovascular complications (e.g., stroke, myocardial infarction), especially in patients with a high likelihood of coronary artery disease (CAD) or those requiring hemodynamic assessment for conditions like valvular heart disease.^{5,8}

The clinical benefits of using these criteria for **left heart catheterization with or without left ventriculogram** may include:

- Reduced risk of catheter-induced embolization. The Society for Cardiovascular Angiography and Interventions (SCAI) recommends caution when utilizing cardiac catheterization for patients with severe aortic stenosis due to the risk of catheter-induced embolization and neurologic deficit. Retrograde catheterization of the aortic valve has been associated with silent and clinically apparent neurologic deficits in 22% and 3% of patients, respectively. Crossing the aortic valve may result in catheter-induced embolization of valve vegetation. Therefore, SCAI recommends that left heart catheterization and left ventriculography should be performed in these patients only if noninvasive imaging is inadequate.⁵

Medical Evidence

A study of more than 96,000 patients undergoing left heart catheterization examined the concomitant use of left ventriculography. Approximately 82% (78,705) of patients underwent left ventriculography in addition to left heart catheterization. Use was pronounced among younger patients. Upon cohort analysis of a subgroup comprised of patients who had a very recent ejection fraction assessment (within the last 30 days) and who had no intervening diagnosis (i.e., no new heart failure, no myocardial infarction, no hypotension, no shock), nearly 88% underwent left ventriculography, a total of 32,798 patients that was also higher than the rate observed in the overall cohort. The authors noted that this pattern constituted overuse of left ventriculography, particularly for subgroup patients for whom new information was very unlikely to be obtained. They stated that the reputation of left ventriculography as an “add-on” procedure to cardiac catheterization may confer risks ranging from increased patient morbidity to excess care cost.¹²

A 2016 study compared invasive left ventriculography with two other modalities: 2D echocardiography and quantitative gated single-photon emission computed tomography. All patients underwent each of the three imaging techniques within three months of each other to evaluate chest pain of unclear etiology. The authors concluded that, although invasive left ventriculography is considered the gold standard for the evaluation of symptomology thought to be of cardiac origin, noninvasive imaging may be an adequate substitution due to the strongly positive correlation associated with each of the three imaging modalities for measuring left ventricular ejection fraction. Therefore, invasive left ventriculography may be better utilized among patients who can accept the medical risk of radiation exposure and contrast-induced kidney injury.¹³

A review was published in 2022 on the role of right heart catheterization in patients (RHC) with heart failure. The procedure is a fundamental diagnostic tool for patients experiencing refractory heart failure or cardiogenic shock. The procedure is also crucial for evaluating eligibility for – and managing patients post-implantation of – mechanical circulatory assist devices or heart transplantation. While RHC is not typically suggested for patients with decompensated heart failure, it may benefit those whose condition does not

improve with initial therapy, as well as those with uncertain volume status and persistent hypoperfusion or those being evaluated for advanced cardiac support. It serves an important role in the early, accurate detection of primary graft dysfunction among heart transplant recipients, which is also the leading cause of death among this cohort.¹⁴

Choi et al. (2023) conducted a retrospective, single-center, observational study to evaluate the discriminatory and prognostic significance of invasively measured left ventricular end-diastolic pressure in patients suspected of having heart failure with preserved ejection fraction (HFpEF). The authors focused on patients with intermediate scores on the Heart Failure Association Pre-test Assessment, Echocardiography and Natriuretic Peptide, Functional Testing, Final Etiology (HFA-PEFF) scale. A total of 404 patients were included; all patients exhibited symptoms of heart failure and had a left ventricular ejection fraction of greater than or equal to 50%. Patients underwent left heart catheterization (LHC). Exclusion criteria included patients who presented without definitive HF symptoms or with acute coronary syndrome (ACS), primary cardiomyopathies, significant valvular heart disease (beyond mild stenosis or moderate left-sided regurgitation), pulmonary arterial hypertension, heart transplantation, constrictive pericarditis, or stress-induced cardiomyopathy. Elevated left ventricular end-diastolic pressure (LVEDP) was linked to a significantly higher 10-year risk of all-cause death or HF readmission in patients suspected of having HFpEF, especially among those with intermediate HFA-PEFF scores. This association remained even after adjusting for multiple variables, including the HFA-PEFF score. (Clinicaltrial.gov, NCT04505449).¹⁵

Otto et al. (2021) reviewed published guidelines from the American College of Cardiology (ACC) and the American Heart Association (AHA) on the management of patients with valvular heart disease. When noninvasive testing results are inconclusive, especially in symptomatic patients, or when there is a discrepancy between noninvasive tests and clinical findings, cardiac catheterization with direct intracardiac measurements is recommended. Cardiac catheterization provides valuable direct measurements of transvalvular pressure gradients and cardiac output. Contrast angiography may be helpful for semiquantitative assessment, especially when noninvasive results conflict with physical examination findings. Cardiac catheterization offers the advantage of measuring

intracardiac pressures and pulmonary vascular resistance, aiding in decision-making regarding valve intervention.⁸

A 2020 study examined 289 donor hearts with invasive coronary angiography with the aim of determining the prevalence of post-transplant CAD and cardiac allograft vasculopathy (CAV). Invasive coronary angiography was successfully completed in all donor hearts. Donor hearts that were diagnosed with moderate CAD did not affect transplant recipient survival and did not accelerate the development of CAV. The authors concluded that there is an application for invasive coronary angiography in the routine evaluation of donor hearts.¹⁶

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Clinical Guideline Revision History/Information

Original Date: June 12, 2025		
Review History		
Version 1	6/12/2025	Combined three cardiac catheterization policies (left heart catheterization with coronary angiography/bypass angiography, right heart catheterization with left ventriculogram, combined right-left heart catheterization) into one cardiac catheterization policy, titled “cardiac catheterization”. Left ventriculogram indications replaced with verbatim current CMS language – prior version of criteria was more restrictive than CMS. One indication not addressed by CMS was retained from prior versions and supported by SCAI guidelines: “In the setting of severe aortic stenosis, assessment of the aortic valve only if noninvasive imaging is inadequate” (due to the risk of catheter-induced embolization and neurologic deficit in these patients) Defined anginal syndrome by evidence of ischemia through a number of avenues (imaging, exercise test, etc.), thereby ensuring proper patient selection for this relatively high-risk procedure Minor criteria changes for policy’s ease of use (specifying that the existing MI indication includes NSTEMI; specifying that the existing presurgical indication includes pre-transplant and TAVR; providing a definition for pulmonary hypertension;

		providing a note clarifying that combined left/right cath requires both left and right cath criteria to be met) Added non-indication directly from LCD: When performed for reasons other than hemodynamic evaluation or LV angiography required for patient management (i.e., when routinely performed with coronary/bypass angiography, electrophysiologic or pacing studies, or endomyocardial biopsies) Added one previously unaddressed LCD (L33959). Added code: 93462 (Left heart catheterization by transseptal puncture through intact septum or by transapical puncture). Updated medical evidence, including literature review and references.
Version 1.1	02/06/2026	Revision. Per CMS revisions, updated links and references for L33557, A52850, L33959, A56500.



Cohere Medicare Advantage Policy – Cardiac Implantable Devices

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: May 26, 2024

Important Notices

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Medical Necessity Criteria

Service: Cardiac Implantable Devices

Benefit Category

Prosthetic Devices

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

Recommended Clinical Approach

Pacemaker implantation is often indicated for various symptomatic cardiac conduction system abnormalities such as sinus node dysfunction (SND), atrioventricular (AV) block, and atrial fibrillation (AF) with a slow ventricular heart rate response whether due to intrinsic conduction system disease, secondary to medications, or produced by an AV node ablation². Depending on the clinical status and comorbidities of the patient, the patient may require either single-site or multiple-site pacing, added defibrillator function if there are appropriate indications [e.g., heart failure with reduced ejection fraction (HFrEF)], or cardiac resynchronization therapy (CRT) without a defibrillator (CRT-P) or with a defibrillator (CDT-D). CRT is also referred to as biventricular (BiV) pacing. Newer techniques for cardiac resynchronization therapy include conduction system pacing (CSP), which involves His bundle pacing (HBP or HBP-CRT) or left bundle branch (LBB) pacing (LBBP-CRT), also called left bundle branch area pacing (LBBAP). These techniques engage the intrinsic cardiac conduction system and may closely reproduce the native ventricular activation sequence³. These advances bring additional questions, including those regarding patient selection, indications, and follow-up for conduction system pacing (CSP) versus CRT via biventricular (BiV) pacing.⁴

There is no indication of a defibrillation function for atrial fibrillation alone. Dual-chamber pacing may assist patients with sick sinus syndrome associated with atrial fibrillation. Adequate atrial pacing may reduce the frequency of atrial fibrillation events; however, pacemaker functions that attempt to treat episodes of atrial fibrillation actively have not shown consistent effectiveness. Therefore, pacing is not recommended as a primary treatment for atrial fibrillation. Many antiarrhythmics used to control atrial

fibrillation can exacerbate sick sinus syndrome, which may merit pacing to prevent symptomatic bradycardia. Pacing is frequently required after a surgical Maze procedure when much of the normal electrical impulses from the atria are disrupted.²

Pacing has an extremely limited role in the setting of atrial flutter. Pacing may assist patients with sick sinus syndrome associated with atrial flutter and, often, atrial fibrillation. Adequate atrial pacing may reduce the frequency of atrial tachyarrhythmic events; however, pacemaker functions that attempt to actively treat episodes of atrial flutter have not shown consistent effectiveness. Many antiarrhythmics used to control atrial flutter/fibrillation can exacerbate sick sinus syndrome, which may require pacing to prevent symptomatic bradycardia.⁵⁻⁶

Implantable cardioverter-defibrillators (ICDs) may be used for secondary prevention of sudden cardiac death/sudden cardiac arrest (SCD/SCA) (e.g., after an individual has experienced such an episode). Primary prevention involves the implantation of an ICD in an individual at high-risk for SCD.⁷

Medical Necessity Criteria

Indications

→ **Cardiac implantable devices** are considered appropriate if **ANY** of the following is **TRUE**.^{2,6,8-9}

◆ The device is an **implantable single or dual-chamber pacemaker** and **ANY** of the following is **TRUE**:

- The patient has symptomatic persistent or permanent atrial fibrillation and is a candidate for AV node ablation; **OR**
- The patient has documented non-reversible symptomatic bradycardia due to sinus node dysfunction; **OR**
- The patient has documented non-reversible symptomatic bradycardia due to second-degree and/or third-degree atrioventricular block; **OR**
- Asymptomatic second-degree atrioventricular block of Mobitz Type I, and **ANY** of the following:
 - QRS complexes are prolonged; **OR**
 - Electrophysiological studies have demonstrated block is at or beyond the level of HIS Bundle (a

component of the electrical conduction system of the heart); **OR**

- Frequent or persistent supraventricular tachycardias (e.g., AV nodal reentrant tachycardia, atrial flutter, atrial fibrillation), and pacemaker is specifically for control of tachycardia¹; **OR**
- For patients with tachy-brady syndrome and symptoms attributable to bradycardia, permanent pacing is reasonable to increase heart rate and reduce symptoms attributable to hypoperfusion⁸; **OR**
- In patients with acquired second-degree Mobitz type II atrioventricular block, high-grade atrioventricular block, or third-degree atrioventricular block not attributable to reversible or physiologic causes, permanent pacing is recommended regardless of symptoms⁸; **OR**
- In patients with neuromuscular diseases associated with conduction disorders, including muscular dystrophy (e.g., myotonic dystrophy type 1) or Kearns-Sayre syndrome, who have evidence of second-degree atrioventricular block, third-degree atrioventricular block, or an HV interval of 70 ms or greater, regardless of symptoms, permanent pacing, with additional defibrillator capability if needed and meaningful survival of greater than 1 year is expected, is recommended; **OR**
- In patients with infiltrative cardiomyopathy, such as cardiac sarcoidosis or amyloidosis, and second-degree Mobitz type II atrioventricular block, high-grade atrioventricular block, or third-degree atrioventricular block, permanent pacing, with additional defibrillator capability if needed and meaningful survival of greater than 1 year is expected, is reasonable; **OR**
- In patients with lamin A/C gene mutations, including limb-girdle and Emery-Dreifuss muscular dystrophies, with a PR interval greater than 240 ms and LBBB, permanent pacing, with additional defibrillator capability if needed and meaningful survival of greater than 1 year is expected, is reasonable; **OR**
- In patients with marked first-degree or second-degree Mobitz type I (Wenckebach) atrioventricular block with

symptoms that are clearly attributable to the atrioventricular block, permanent pacing is reasonable; **OR**

- For patients in sinus rhythm with a single chamber ventricular pacemaker who develop pacemaker syndrome, revising to a dual chamber pacemaker is recommended; **OR**
 - Alternating bundle branch block; **OR**
 - In patients with Anderson-Fabry disease and QRS prolongation greater than 110 ms, permanent pacing, with additional defibrillator capability if needed and meaningful survival of greater than 1 year is expected, may be considered; **OR**
 - Syncope and bundle branch block who are found to have an HV interval 70 ms or greater or evidence of infranodal block at EPS; **OR**
 - Vasovagal syncope with **ALL** of the following¹⁰:
 - The patient is 40 years of age or older; **AND**
 - Recurrent vasovagal syncope; **AND**
 - Prolonged spontaneous pauses (documented spontaneous pauses greater than or equal to 3 seconds correlated with syncope or an asymptomatic pause greater than or equal to 6 seconds); **OR**
 - Permanent cardiac pacing is reasonable in patients with carotid sinus syndrome that is cardioinhibitory (asystole is greater than 3 seconds or if there is AV block) or mixed with a significant vasodepressor response (greater than or equal to 50 mmHg drop in systolic blood pressure); **OR**
 - Previously implanted pacemaker replacement for **ANY** of the following:
 - Infection-related to leads or device; **OR**
 - Battery life ended; **OR**
 - Malfunction of lead or device; **OR**
 - Manufacturer recall of device; **OR**
- ◆ The device is an **implantable cardioverter-defibrillator (ICD)** and **ALL** of the following^{5,7,10-11}:
- Transient or reversible causes excluded; **AND**
 - **ANY** of the following:

- **Primary prevention of sudden cardiac death (SCD)**
with **ALL** of the following:
 - ◆ The patient is expected to have meaningful survival of greater than one year; **AND**
 - ◆ **ANY** of the following^{[5,7,10-11](#)}:
 - In patients with LVEF of 30% or less that is due to ischemic heart disease who are at least 40 days post MI and at least 90 days post revascularization, and with New York Heart Association (NYHA) class I heart failure (HF) despite guideline-directed medical therapy (GDMT)^{[11](#)}; **OR**
 - In patients with LVEF of 35% or less that is due to ischemic heart disease who are at least 40 days post-MI and at least 90 days post revascularization, and with NYHA class II or III HF despite GDMT; **OR**
 - Patients with documented prior MI with nonsustained ventricular tachycardia (NSVT), LVEF less than or equal to 40%, and ventricular fibrillation (VF) or ventricular tachycardia (VT) was induced during an electrophysiology (EP) study; **OR**
 - In nonhospitalized patients with heart failure with reduced ejection fraction (HFrEF) and NYHA class IV symptoms and/or use of inotropes, and who are candidates for cardiac transplantation or an LVAD; **OR**
 - In patients with nonischemic cardiomyopathy (NICM) or neuromuscular disorders (Duchenne, Becker, Emery-Dreifuss, Myotonic type 1, and limb-girdle types 1B, 2C, 2F, and 2I) and formal shared decision-making encounter between patient and physician or qualified non-physician practitioner or neuromuscular disorders (Duchenne,

- Becker, Emery-Dreifuss, Myotonic type 1, and limb-girdle types 1B, 2C, 2F, and 2I), HF with NYHA class II-III symptoms and an LVEF of 35% or less, despite GDMT; **OR**
- In patients with NICM due to a Lamin A/C mutation who have 2 or more risk factors (NSVT, LVEF less than 45%, non-missense mutation, and male sex); **OR**
- In patients with NICM or Neuromuscular disorders (Duchenne, Becker, Emery-Dreifuss, Myotonic type 1, and limb-girdle types 1B, 2C, 2F, and 2I), HF with NYHA class I symptoms and an LVEF of 35% or less despite GDMT, an ICD may be considered; **OR**
- In patients with arrhythmogenic right ventricular cardiomyopathy and an additional marker of increased risk of SCD (resuscitated SCA, sustained VT, significant ventricular dysfunction with RVEF or LVEF less than or equal to 35%), an ICD is recommended; **OR**
- In patients with hypertrophic cardiomyopathy (HCM) or long QT syndrome, an ICD is reasonable after a formal shared decision-making encounter between patient and physician or a qualified non-physician practitioner; **OR**
- **Secondary prevention of SCD** with **ALL** of the following [5.8.10-11](#):
 - ◆ The patient is expected to have meaningful survival of greater than one year; **AND**
 - ◆ **ANY** of the following:
 - In patients with ischemic heart disease, who either survive SCA due to VT/VF or experience hemodynamically unstable VT or stable sustained VT not due to

reversible causes, an ICD is recommended; **OR**

- In patients with ischemic heart disease and unexplained syncope who have an LVEF less than or equal to 35%, an ICD is recommended; **OR**
- In patients with NICM who either survive SCA due to VT/VF or experience hemodynamically unstable VT or stable sustained VT; **OR**
- In patients with arrhythmogenic right ventricular cardiomyopathy and an additional marker of increased risk of SCD (resuscitated SCA, sustained VT, significant ventricular dysfunction with RVEF or LVEF less than or equal to 35%), an ICD is recommended; **OR**
- In patients with cardiac sarcoidosis who have sustained VT or are survivors of SCA or have an LVEF of 35% or less, an ICD is recommended; **OR**
- In patients with a cardiac channelopathy (e.g., long QT syndrome, catecholaminergic polymorphic ventricular tachycardia, Brugada syndrome, early repolarization syndrome, and short QT syndrome) and SCA, an ICD is recommended; **OR**
- Hemodynamically unstable VT; **OR**
- Stable sustained VT not associated with myocardial infarction (MI); **OR**
- In patients with catecholaminergic polymorphic ventricular tachycardia and recurrent sustained VT or syncope, while receiving adequate or maximally tolerated beta blocker, treatment intensification with either combination medication therapy (e.g., beta blocker, flecainide), left cardiac sympathetic

denervation, and/or an ICD is recommended; **OR**

- In patients with Brugada syndrome with spontaneous type 1 Brugada electrocardiographic pattern and cardiac arrest, sustained VA, or a recent history of syncope presumed due to VA, an ICD is recommended; **OR**
- In patients with early repolarization pattern on ECG and cardiac arrest or sustained VA, an ICD is recommended; **OR**
- In patients with short QT syndrome who have a cardiac arrest or sustained VA, an ICD is recommended; **OR**
- In patients resuscitated from SCA due to idiopathic polymorphic VT or VF, an ICD is recommended; **OR**
- In patients with adult congenital heart disease and hemodynamically unstable VT, an ICD is recommended after evaluation and appropriate treatment for residual lesions/ventricular dysfunction; **OR**
- In patients with adult congenital heart disease with SCA due to VT or VF in the absence of reversible causes, an ICD is recommended; **OR**
- In adults with repaired tetralogy of Fallot physiology and inducible VT/VF or spontaneous sustained VT, implantation of an ICD is reasonable; **OR**

◆ The device is a **subcutaneous implantable cardioverter-defibrillator system** and the following²:

- Indication for ICD as listed above **AND ANY** of the following:
 - Recommended (Class I indication): If pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated and **ANY** of the following:

- ◆ Vascular access is limited; **OR**
- ◆ The patient is immunocompromised; **OR**
- ◆ The patient is at high-risk for bacteremia (e.g., hemodialysis, chronic indwelling endovascular catheters); **OR**
- ◆ The patient has endocarditis; **OR**
- Reasonable (Class IIa indication): If pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated; **OR**
- ◆ The device is for **cardiac resynchronization therapy (CRT) without a defibrillator (CRT-P) or with a defibrillator (CDT-D, when cardioverter-defibrillator function is indicated)** when **ANY** of the following is **TRUE**^{3,12-16}:
 - For initial CRT when **ANY** of the following is **TRUE**:
 - LVEF less than or equal to 35% (with ischemic or non-ischemic cardiomyopathy) and **ALL** of the following^{3,12}:
 - ◆ Sinus rhythm; **AND**
 - ◆ QRS greater than or equal to 150 ms; **AND**
 - ◆ LBBB; **AND**
 - ◆ NYHA class II, III or ambulatory IV HF on maximally tolerated guideline-directed medical therapy (GDMT) for at least 3 months; **OR**
 - LVEF less than or equal to 35% and **ALL** of the following:
 - ◆ Sinus rhythm; **AND**
 - ◆ QRS greater than or equal to 150 ms; **AND**
 - ◆ Non-LBBB; **AND**
 - ◆ NYHA classes II, III, or ambulatory IV HF on maximally tolerated GDMT for at least 3 months; **OR**
 - LVEF less than or equal to 35% and **ALL** of the following:
 - ◆ Sinus rhythm; **AND**
 - ◆ QRS 120-149 ms; **AND**
 - ◆ LBBB; **AND**
 - ◆ NYHA class II, III, or ambulatory IV HF on maximally tolerated GDMT for at least 3 months; **OR**

- LVEF less than or equal to 35% and **ALL** of the following:
 - ◆ Sinus rhythm **AND**
 - ◆ QRS 120-149 ms; **AND**
 - ◆ Non-LBBB; **AND**
 - ◆ NYHA class III, or ambulatory IV HF on maximally tolerated GDMT for at least 3 months; **OR**
- LVEF less than or equal to 30% and **ALL** of the following:
 - ◆ Ischemic cause of HF; **AND**
 - ◆ Sinus rhythm **AND**
 - ◆ QRS greater than or equal to 150 ms; **AND**
 - ◆ LBBB; **AND**
 - ◆ NYHA class I HF on maximally tolerated GDMT for at least 3 months; **OR**
- Atrial fibrillation (AF) **OR** sinus rhythm and **ALL** of the following:
 - ◆ **ANY** of the following:
 - An indication for ventricular pacemaker implant including those who have or will have AV nodal ablation); **OR**
 - Very prolonged first-degree block (e.g., PR greater than 300 ms); **OR**
 - ◆ **ANY** of the following:
 - Pharmacological rate control will allow near 100% ventricular pacing with CRT; **OR**
 - Anticipated frequent ventricular pacing;**AND**
 - ◆ EF less than 50%; **AND**
 - ◆ NYHA class I, II, or III; **AND**
- The patient has a QRS less than 130 ms, and **ANY** of the following:
 - ◆ Undergoing AV nodal ablation; **OR**
 - ◆ In need of right ventricle pacing (due to second-degree or third-degree block or very long first-degree block); **OR**
- High degree or complete heart block and EF 36% to 50% (**applies to CRT-P only**); **OR**
- New pacemaker implantation with **ALL** of the following:
 - ◆ LVEF less than or equal to 35% on GDMT; **AND**

- ◆ Anticipated requirement for significant (greater than 40%) ventricular pacing; **OR**
- For upgrade to a CRT device when **ALL** of the following are **TRUE**¹²:
 - The patient is being paced from the RV greater than 40% of the time; **AND**
 - LVEF less than or equal to 40%; **AND**
 - Worsening HF symptoms (NYHA class II to IV); **OR**
- For replacement of an existing CRT device when **ANY** of the following is **TRUE**¹²:
 - Required due to end of battery life; **OR**
 - Elective replacement indicator (ERI); **OR**
 - Device malfunction (including leads).

Non-Indications

→ **Cardiac implantable devices** are not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ **Implantable pacemakers** are **NOT** considered appropriate for **ANY** of the following¹:
 - Reversible causes of bradycardia such as electrolyte abnormalities, medications or drugs, and hypothermia; **OR**
 - Asymptomatic first-degree atrioventricular block; **OR**
 - Asymptomatic sinus bradycardia; **OR**
 - Asymptomatic sino-atrial block or asymptomatic sinus arrest; **OR**
 - Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium) without symptomatic bradycardia; **OR**
 - Asymptomatic second-degree atrioventricular block of Mobitz Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His Bundle (a component of the electrical conduction system of the heart); **OR**
 - Syncope of undetermined cause; **OR**
 - Bradycardia during sleep; **OR**
 - Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent atrioventricular block; **OR**

- Asymptomatic bradycardia in post-myocardial infarction patients about to initiate long-term beta-blocker drug therapy; **OR**
 - Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of tachycardia; **OR**
 - A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged.
- ◆ **Implantable defibrillators** are **NOT** considered appropriate for **ANY** of the following:
- VT due to a completely reversible disorder (electrolyte imbalance, drug use); **OR**
 - Active systemic or local infection; **OR**
 - NYHA class IV patients with heart failure not responsive to medication and are not candidates for heart transplantation or LVAD^{7,10}; **OR**
 - Noncardiac disease such as cancer or liver failure, is associated with the possibility of survival of less than 1 year.
- ◆ **Subcutaneous implantable defibrillator systems** are **NOT** considered appropriate for **ANY** of the following:
- In patients with an indication for bradycardia pacing or CRT; **OR**
 - Anti-tachycardia pacing for VT termination is required; **OR**
- ◆ **Cardiac resynchronization therapy (CRT)** is **NOT** considered appropriate when **ANY** of the following is **TRUE**^{3,12}:
- EF greater than 50%; **OR**
 - Non-ambulatory NYHA IV HF symptoms; **OR**
 - Chronic inotropic HF therapy; **OR**
 - With an LV assist device already in place.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33206	Insertion of permanent atrial pacemaker with

	transvenous electrode
33207	Insertion of permanent ventricular pacemaker with transvenous electrode
33208	Insertion of permanent atrial and ventricular pacemaker with transvenous electrode
33210	Insertion or replacement of temporary transvenous single chamber cardiac electrode or pacemaker catheter (separate procedure)
33211	Insertion or replacement of temporary transvenous dual chamber pacing electrodes (separate procedure)
33212	Insertion of pacemaker pulse generator with connection to existing single lead
33213	Insertion of pacemaker pulse generator with connection to existing dual leads
33214	Conversion of single chamber implanted pacemaker system to dual chamber system
33216	Insertion of transvenous electrode of permanent pacemaker
33217	Insertion of 2 transvenous electrodes of permanent cardioverter-defibrillator
33221	Insertion of pacemaker pulse generator with existing multiple leads
33224	Transvenous insertion of pacing electrode for left ventricular pacing, with connection to existing pacemaker
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system) (List separately in addition to code for primary procedure)
33226	Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including

	removal, insertion and/or replacement of existing generator)
33227	Removal and replacement of permanent pacemaker pulse generator in single lead system
33228	Removal and replacement of permanent pacemaker pulse generator in dual lead system
33229	Removal and replacement of permanent pacemaker pulse generator in multiple lead system
33230	Insertion of implantable defibrillator pulse generator only; with existing dual leads
33231	Insertion of implantable defibrillator pulse generator only; with existing multiple leads
33233	Removal of permanent pacemaker pulse generator
33234	Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular
33235	Removal of transvenous pacemaker electrode(s); dual lead system
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead
33241	Removal of implantable defibrillator pulse generator only
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system
33264	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse

	generator; multiple lead system
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed
33271	Insertion of subcutaneous implantable defibrillator electrode
33272	Removal of subcutaneous implantable defibrillator electrode
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode
93640	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement;
93641	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement; with testing of single or dual chamber pacing cardioverter-defibrillator pulse generator
93642	Electrophysiologic evaluation of single or dual chamber transvenous pacing cardioverter-defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
93644	Electrophysiologic evaluation of subcutaneous

	implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
C1721	Cardioverter-defibrillator, dual chamber (implantable)
C1722	Cardioverter-defibrillator, single chamber (implantable)
C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)
C1779	Lead, pacemaker, transvenous VDD single pass
C1785	Pacemaker, dual chamber, rate-responsive (implantable)
C1786	Pacemaker, single chamber, rate-responsive (implantable)
C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)
C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
C1898	Lead, pacemaker, other than transvenous VDD single pass
C1899	Lead, pacemaker/cardioverter-defibrillator combination (implantable)
C1900	Lead, left ventricular coronary venous system
C2619	Pacemaker, dual chamber, nonrate-responsive (implantable)
C2620	Pacemaker, single chamber, nonrate-responsive (implantable)
C2621	Pacemaker, other than single or dual chamber (implantable)

0571T	Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed
0572T	Insertion of substernal implantable defibrillator electrode
0573T	Removal of substernal implantable defibrillator electrode
0574T	Repositioning of previously implanted substernal implantable defibrillator-pacing electrode
0577T	Electrophysiologic evaluation of implantable cardioverter-defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
0580T	Removal of substernal implantable defibrillator pulse generator only
0614T	Removal and replacement of substernal implantable defibrillator pulse generator

Medical Evidence

January et al. (2014) published an evidence-based, systematic review and subsequent guidelines for the American Heart Association, American College of Cardiology, and the Heart Rhythm Society, titled *Management of Patients with Atrial Fibrillation*. A number of recommendations were made or revised for optimum management of atrial fibrillation. Pacemakers are recommended in AF patients for the treatment of symptomatic bradycardia, which is often related to sick sinus syndrome. They state that antiarrhythmic therapy may exacerbate sick sinus syndrome, requiring pacemaker implantation. Permanent pacing was not recommended by the group for the prevention of AF in patients without other indications for pacemaker placement. Implanted defibrillators are not recommended for atrial fibrillation rhythm control.⁹

Calkins et al. (2017) published an expert consensus statement with the Heart Rhythm Society, the European Heart Rhythm Association (EHRA), and the European Cardiac Arrhythmia Society to update guidelines based on advances in atrial fibrillation ablation since their previous publication. It was recommended that the amount of time an individual spends in AF (24-hour AF burden) is essential to address when ablation is being considered. This is due largely to the increase in implantable loop recorders, pacemakers, and ICDs.²

Al-Khatib et al. (2017) performed a systematic review on behalf of the American Heart Association, the American College of Cardiology, and the Heart Rhythm Society regarding the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. Various types of defibrillators were discussed and their effectiveness in terminating life-threatening ventricular arrhythmias. Survivors of cardiac arrest, patients with VT and structural heart disease, and those with significant LV dysfunction may benefit greatly from defibrillator implantation.⁷

Kusumoto et al. (2018) published recommendations for the treatment of bradycardia in a multi-society guideline. They strongly recommended permanent pacing regardless of symptoms in patients with acquired second-degree Mobitz type II atrioventricular block, high-grade atrioventricular block, or third-degree atrioventricular block not attributable

to reversible or physiologic causes. Strong recommendations were made for other patients with AV block, including those with neuromuscular disease, and symptomatic bradycardia.⁸

There are two related National Coverage Determinations (NCDs) from the Centers for Medicare and Medicaid Services (CMS):

- *Implantable Automatic Defibrillators* (2023): Recommendations made for those with a history of SCD, prior MI, and EF measured at less than or equal to 30%, or heart failure without a history of arrest.¹¹
- *Cardiac Pacemakers* (2004): Contains recommendations for pacemaker implantation, both single and dual-chamber, in various chronic, recurrent arrhythmic scenarios.¹⁷

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Cohere Medicare Advantage Policy – Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR)

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 - Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR)

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

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Medical Necessity Criteria

Service: Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR)

Benefit Category

Physicians' Services, Inpatient Hospital Services

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

Recommended Clinical Approach

CAS or TCAR is an appropriate treatment option for patients with symptomatic extracranial carotid artery occlusive disease between 50%–99%. For stroke patients with symptomatic extracranial carotid artery occlusive disease, treatment can lower the risk of subsequent stroke. CAS and/or TCAR are less invasive procedures than Carotid Endarterectomy (CEA) and may be superior to CEA in patients with previous neck surgery or radiation injury. CAS is an acceptable alternative for treating asymptomatic patients with severe stenosis of the extracranial carotid circulation of 70%–99%. These procedures must be supported by comprehensive imaging and neurological assessments and involve detailed shared decision-making to ensure optimal patient outcomes.

Medical Necessity Criteria

Indications

→ **Carotid artery stenting (CAS) and/or transcarotid artery revascularization (TCAR)** is considered appropriate if **ANY** of the following is **TRUE**²⁻³:

- ◆ The patient is enrolled in an FDA-approved IDE clinical trial; **OR**
- ◆ For patients with a TIA or ischemic stroke within 6 months, and **ALL** of the following are **TRUE**:
 - ICA stenosis is between 50%–99% by invasive or noninvasive imaging⁴; **AND**
 - An FDA-approved or cleared carotid stent and embolic protection device is being used; **OR**
- ◆ The patient is asymptomatic with **ALL** of the following:

- **ANY** of the following:
 - Ipsilateral stroke or TIA occurred more than 6 months ago; **OR**
 - The patient never had a neurological event; **AND**
- ICA stenosis is between 70%-99% by invasive or noninvasive imaging; **AND**
- An FDA-approved or cleared carotid stent and embolic protection device is being used.

Non-Indications

→ **Carotid artery stenting (CAS) and/or transcarotid artery revascularization (TCAR)** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The patient had a stroke or TIA within the last 6 months with **ANY** of the following:
 - Carotid stenosis less than 50%⁴; **OR**
 - Chronic carotid stenosis of 100%; **OR**
 - Severe disability caused by cerebral infarction that precludes preservation of useful function⁵; **OR**
- ◆ The patient had a stroke or TIA more than 6 months ago, or the patient never had a neurologic event with **ANY** of the following:
 - ◆ Carotid stenosis less than 70%; **OR**
 - ◆ Chronic carotid stenosis of 100%; **OR**
 - ◆ Severe disability caused by cerebral infarction that precludes preservation of useful function (if applicable).

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; with distal embolic protection
37217	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, open ipsilateral

	cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation
37218	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery, open or percutaneous antegrade approach, including angioplasty, when performed, and radiological supervision and interpretation

Medical Evidence

Halliday et al. (2021) performed an international multicenter randomized control trial (RCT). The ACST-2 study compared carotid artery stenting (CAS) with carotid endarterectomy (CEA) in asymptomatic patients with severe carotid artery stenosis. Both procedures aim to reduce the risk of stroke in these patients. The trial involved 3625 patients from 130 centers, randomly assigned to either CAS or CEA. Over a mean follow-up of 5 years, both procedures showed similar rates of disabling stroke or death within 30 days of the intervention (1% for each). Non-disabling procedural stroke was slightly higher with CAS compared to CEA. The 5-year rates of non-procedural stroke, including fatal or disabling strokes, were similar between the two groups. The study suggests that both CAS and CEA are similarly effective in reducing the risk of long-term fatal or disabling stroke in asymptomatic patients with severe carotid artery stenosis.⁶

Malas et al. (2019) conducted a prospective, single-arm trial titled "Safety and Efficacy Study for Reverse Flow Used During Carotid Artery Stenting Procedure (ROADSTER)". The study reports on the one-year outcomes of a novel trans carotid neuroprotection system (NPS) called ENROUTE. The trial aimed to evaluate the safety of trans carotid artery revascularization (TCAR) and its effectiveness over a year. It was a prospective, single-arm clinical trial conducted across 14 centers, enrolling patients with high-risk factors for CEA. Results showed that TCAR with the ENROUTE system was safe and effective, with a low incidence of ipsilateral stroke at one year (0.6%) and a mortality rate of 4.2%, none of which were neurologic in origin. Most patients were asymptomatic (79.9%) and had various anatomic and medical high-risk factors. TCAR demonstrated favorable outcomes perioperatively and at 1-year follow-up, suggesting it is a safe and durable option for high-risk patients compared to traditional CEA. The study attributes the promising results to the novel cerebral protection offered by the ENROUTE system and the advantages of the trans-carotid approach in avoiding aortic arch manipulation and minimizing embolization. (ClinicalTrials.gov NCT01685567).⁷

In October 2023, CMS relaxed the need for CAS/TCAR only in high risk patients for CEA. In summary, this final decision memorandum, which affects National Coverage Determination (NCD) 20.7 sections B4 and D, revises Medicare coverage for PTA of the carotid arteries concurrent with stenting by⁸:

1. Expanding coverage to individuals previously only eligible for coverage in clinical trials;

2. Expanding coverage to standard surgical risk individuals by removing the limitation of coverage to only high surgical risk individuals;
3. Removing facility approval requirement;
4. Adding formal shared decision-making with the individual prior to furnishing CAS; and
5. Allowing MAC discretion for all other coverage of PTA of the carotid artery concurrent with stenting not otherwise addressed in NCD 20.7.

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Cohere Medicare Advantage Policy – Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR) without Distal Embolic Protection

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Guideline Information:

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Medical Necessity Criteria

Service: Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR) without Distal Embolic Protection

Benefit Category

Not applicable.

Recommended Clinical Approach

This service is clinically unproven and not medically necessary.

Medical Necessity Criteria

Indications

- **Carotid artery stenting (CAS) and/or transcarotid artery revascularization (TCAR) without distal embolic protection** 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

- **Carotid artery stenting (CAS) and/or transcarotid artery revascularization (TCAR) without distal embolic protection** is not 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.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
37216	Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; without distal embolic protection

Medical Evidence

Nazari et al. (2021) report on the efficacy of embolic protection devices during carotid artery stent (CAS) placement with respect to major adverse cardiovascular events (MACE) (e.g., death, stroke, or myocardial infarction/arrhythmia) within 30 days. The American College of Surgeons National Surgical Quality Improvement Program database identified 1200 adult patients undergoing CAS between 2011 and 2018. Of the total, 23.8% did not have embolic protection devices. Preoperative antiplatelets were used less frequently among patients without embolic protection devices. Patients also experienced an increased need for urgent carotid artery stent placement, along with a higher incidence of major adverse cardiovascular events and strokes. The absence of embolic protection devices during CAS placement increases the risk of perioperative stroke by four times. Despite this, nearly 25% of patients in a national quality improvement program had the procedure without such protection. Enhanced efforts to promote the use of embolic protection devices are necessary.¹

Malas et al. (2019) conducted a prospective, single-arm trial titled "Safety and Efficacy Study for Reverse Flow Used During Carotid Artery Stenting Procedure (ROADSTER)". The study reports on the one-year outcomes of a novel trans carotid neuroprotection system (NPS) called ENROUTE. The trial aimed to evaluate the safety of trans carotid artery revascularization (TCAR) and its effectiveness over a year. It was a prospective, single-arm clinical trial conducted across 14 centers, enrolling patients with high-risk factors for carotid endarterectomy (CEA). Distal embolic protection devices were also evaluated. Results showed that TCAR with the ENROUTE system was safe and effective with favorable outcomes, however, distal protection lacked efficacy in the medical literature. (ClinicalTrials.gov NCT01685567).²

There is one related National Coverage Determination (NCD) from the Centers for Medicare and Medicaid Services (CMS):

- *Percutaneous Transluminal Angioplasty (PTA) (20.7) (2023):* CAS/TCAR are covered when used with an FDA-approved or cleared embolic protection device, except for the possible use in FDA-approved Category B investigational device exemption (IDE) clinical trial.³

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Clinical Guideline Revision History/Information

Original Date: May 28, 2024		
Review History		

Cohere Medicare Advantage Policy – Carotid Endarterectomy (CEA)

Clinical Policy for Medical Necessity Review

CHP-051-2 Version 2

Cohere UMC Approval Date: March 10, 2026

Last Annual Review: March 10, 2026

Revision Date: Not applicable

Next Annual Review: March 10, 2027

Specialty: Cardiovascular Disease

Population Type: Adult (18+ years old), Pediatric (0-17 years old)

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Procedure Codes (CPT/HCPCS)

Service: Carotid Endarterectomy (CEA)	
Code	Description
35301	Thromboendarterectomy, including patch graft, if performed; carotid, vertebral, subclavian, by neck incision

Important Notices

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Service: Carotid Endarterectomy (CEA) - Description

Carotid endarterectomy (CEA) is a surgical procedure involving the removal of fat deposits, plaques, or the artery itself in patients whose carotid arteries may have been narrowed by atherosclerosis or carotid artery stenosis.²⁻⁴

Service: Carotid Endarterectomy (CEA) - 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 - Carotid Endarterectomy (CEA)* 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	N/A
LCD	No LCD Available for Jurisdiction	N/A	N/A	Use Cohere Medicare Advantage internal coverage criteria

Indications

- **Carotid endarterectomy (CEA)** is considered appropriate if **ANY** of the following is **TRUE**⁵:
 - The patient is symptomatic (defined as a stroke or transient ischemic attack [TIA] within 6 months, ideally within 14 days), with **ALL** of the following⁶⁻⁸:
 - Carotid artery stenosis between 50-99% by invasive or noninvasive imaging⁶; **AND**
 - An FDA-approved carotid stent and/or embolic protection device is being used; **OR**
 - The patient is asymptomatic with carotid artery stenosis between 70-99% by invasive or noninvasive imaging.⁹

Non-Indications

- **Carotid endarterectomy (CEA)** is not considered appropriate if **ANY** of the following is **TRUE**:
 - The patient has an implantable device that sends electrical signals to the carotid artery (e.g., Barostim)¹⁰; **OR**
 - Severe disability caused by cerebral infarction that precludes preservation of useful function.⁵

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 carotid endarterectomy (CEA) may include:

- Adverse effects from delayed or denied treatment, especially after a symptomatic event, can increase the risk of stroke and potentially worsen other outcomes.¹¹
- Reported surgical complications of CEA include hypertension, hypotension, hemorrhage, acute arterial occlusion, stroke, myocardial ischemia or infarction, venous thromboembolism, cranial nerve palsy, infection, arterial restenosis, and death. Preoperative clinical conditions and comorbidities contribute to cases of stroke or death during this procedure.¹²
- Risk of incision site infection, and of adverse reactions to anesthesia or other medications.⁵

The clinical benefits of using these criteria for carotid endarterectomy (CEA) may include:

- Improved patient selection for CEA, resulting in better long-term outcomes. Ideal candidates should have a carotid artery stenosis between 50-99%. According to a 2020 Cochrane review, CEA decreased the 5-year risk of recurrent stroke in this group of patients with risk ratios of 0.77 and 0.53 for patients with 50%-69% stenosis and 70% to 99% stenosis, respectively.¹¹
- Maintenance of rigorous patient safety standards aligned to best available evidence. Patients with an implantable device that sends electrical signals to the carotid artery who undergo CEA are at risk for temporary deterioration in baroreflex response, leading to post-operative blood pressure instability and an increased risk of myocardial infarction and stroke.¹³
- Maintenance of rigorous patient safety standards aligned to best available evidence. Patients with severe disability caused by cerebral infarction that precludes preservation of useful function who undergo CEA are at risk for perioperative stroke/death.¹⁴
- Improved patient outcomes through timely and appropriate access to a CEA procedure.^{5,11}
- Reduction in complications and adverse effects from unnecessary procedures, such as carotid artery stenting.¹¹
- CEA can reduce the risk of recurrent or subsequent stroke.^{5,11} This procedure offers improved blood flow to the brain and can improve neurological function.
- Addressing the underlying causes of stenosis and carotid artery disease can help prevent future strokes or ischemic attacks. For example, lifestyle factors such as a healthy diet and physical activity are essential for preventing recurrent stroke.⁷
- Timely performance of the CEA after a symptomatic event can maximize benefits and prevent recurrent stroke.^{5,6,11}
- Enhanced overall patient satisfaction and healthcare experience.
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Vasavada et al. (2023) conducted a meta-analysis and systematic review to compare carotid endarterectomy (CEA) and carotid artery stenting (CAS) using studies published between 2015 and 2023. Results indicated that patients who underwent CEA had better outcomes in terms of stroke events and the combined incidence of stroke or death. Conversely, patients who underwent CAS had a lower incidence of myocardial infarction compared to patients who underwent CEA. Overall, CEA appeared to be more effective in reducing stroke events and the combined incidence of stroke or death, while CAS was associated with fewer cases of myocardial infarction.²

Mohd et al. (2023) analyzed treatment modalities, including medical and surgical options such as CEA and CAS. The authors noted that the choice of surgical intervention or conservative management depends on individual patient characteristics and risk profiles. The authors reviewed the pathophysiology of carotid artery stenosis, associated risk factors, the importance of timely diagnosis and treatment, and the approaches of CEA and CAS. Evidence indicated that CEA offers notable advantages to patients with moderate to severe stenosis. Efficacy appears limited in patients with less than 50% stenosis. CEA demonstrated pronounced efficacy in patients with severe stenosis, particularly in high-grade cases. The advantage of CEA was reported to decrease with prolonged intervals following the initial ischemic event, with a more notable effect observed in female patients. Recent guidelines for secondary stroke prevention recommend scheduling CEA within a two-week window for individuals who have encountered a transient ischemic attack (TIA) or minor stroke.¹⁵

AbuRahma et al. (2022) conducted a meta-analysis of guidelines published by the Society for Vascular Surgery. The guidelines were based on several randomized trials comparing CEA and CAS. Since then, additional studies and systematic reviews have been published, reaffirming the importance of medical management alongside surgical interventions. Key areas include CEA versus maximal medical therapy for low-risk patients and CEA versus transfemoral CAS for low-surgical-risk patients with symptomatic carotid artery stenosis greater than 50%. The guidelines also address the timing of carotid intervention for patients presenting with acute stroke, screening for carotid artery stenosis in asymptomatic patients, and the optimal sequence of intervention for patients with combined carotid and coronary artery disease (CAD). The primary treatment for symptomatic low-risk surgical patients (with stenosis of 50–99% and 70–99% if asymptomatic) is CEA. The perioperative CEA risk of stroke and death in asymptomatic patients should be less than 3% to ensure benefits. For patients with recent stable stroke, carotid revascularization is considered appropriate when stenosis is greater than 50% and should be performed once the patient is neurologically stable after 48 hours but less than 14 days after symptom onset. For patients requiring both CEA and coronary artery bypass grafting (CABG), CEA is suggested before or concurrent with CABG to reduce the risk of stroke and stroke/death potentially. The sequencing of interventions depends on the clinical presentation and the institution's experience.⁶

Routine screening for asymptomatic carotid artery stenosis in patients without cerebrovascular symptoms or significant risk factors is not recommended unless significant stenosis is detected.⁶ For asymptomatic patients, social and demographic factors such as age, sex, life expectancy, and comorbidities should be carefully considered prior to carotid revascularization. Surgical benefits for asymptomatic patients may now be less than previously anticipated in earlier randomized trials (from the 1990s and 2000s), and the 3% complication rate should be interpreted with consideration for current advances in medical therapy.⁵

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Policy Revision History/Information

Clinical Policy Version	Date	Review History
Version 1	03/20/2025	Original Date.
Version 2	03/10/2026	Annual review. No changes to procedure code. 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. Expanded Harms and Benefits section. Added 6 references.



Cohere Medicare Advantage Policy – Carotid Sinus Stimulators

Clinical Policy for Medical Necessity Review

Version: 1

Cohere Health UMC Approval Date: December 18, 2025

Last Annual Review: December 18, 2025

Revision: Not Applicable

Next Annual Review: December 18, 2026

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy - Carotid Sinus Stimulators

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

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Medical Necessity Criteria

Service: Carotid Sinus Stimulators

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 carotid sinus stimulators.

Description

A carotid sinus stimulator is a device made up of activation leads, an implantable pulse generator, and an external programming system. The leads are implanted adjacent to the carotid sinus, and when activated, electronically stimulate baroreceptors. Downstream effects of baroreceptor activation include reduced sympathetic system activity and enhanced vagal activity as well as reduced heart rate, greater ventricular filling time, reduced cardiac workload and energy demands, arterial dilation, reduced cardiac afterload, and improved renal blood flow.¹² These effects may counteract symptoms of heart failure and uncontrolled hypertension.

Medical Necessity Criteria

Indications

A **carotid sinus stimulator** is considered appropriate if **ANY** of the following is **TRUE**:

- Patient is enrolled in a national clinical trial approved for Category B Investigational Device Exemption (IDE) status.³

Non-Indications

A **carotid sinus stimulator** 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
64654	Initial open implantation of baroreflex activation therapy (BAT) modulation system, including lead placement onto the carotid sinus, lead tunnelling, connection to a pulse generator placed in a distant subcutaneous pocket (ie, total system), and intraoperative interrogation and programming
64655	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; lead only
64656	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; pulse generator only
64657	Removal of baroreflex activation therapy (BAT) modulation system; total system, including lead and pulse generator

64658	Removal of baroreflex activation therapy (BAT) modulation system; lead only
64659	Removal of baroreflex activation therapy (BAT) modulation system; pulse generator only
93145	Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation system including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); without programming
93146	Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation system including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming, including optimization of tolerated therapeutic level setting
C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)

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.

Potential Harms of applying the clinical criteria in this policy include, but are not limited to, denying opportunities to improve health outcomes for individuals and populations suffering from resistant hypertension. For example, restricting access to this procedure may increase patient and population dependence on excessive pain medication, including opioids, reduced functionality leading to additional medical problems, and a decrease in economic opportunity.

Potential Benefits include safeguarding patients and populations from unproven technologies, procedures, and medical treatments until the proposed treatments' safety, efficacy, and anticipated results are thoroughly validated via peer-reviewed scientific literature. This safeguards patients from the use of a medical device that is still considered experimental or unproven for the treatment of hypertension.^{[4-6](#)}

Medical Evidence

In a post-market phase 4 study of the BAROSTIM NEO system, Zile and colleagues (2024) evaluated cardiovascular mortality and heart failure morbidity in 323 patients treated with optimal medical management, either alone or in combination with carotid baroreflex activation therapy (BAT). At median 3.6 years follow-up, there were no differences between groups, indicating that adding BAT to optimal medical management does not improve mortality or morbidity in patients with heart failure and reduced ejection fraction.⁴ Similarly, BAT did not improve mortality or heart failure (HF) events in the INOVATE-HF trial.⁵ In this study, 707 patients with heart failure and reduced ejection fraction were randomized to receive either continued medical therapy or implantation of a device to provide vagal nerve stimulation. At 16-month follow-up, there were no significant differences in primary outcome measures.

In a review of clinical trials examining BAT for treatment-resistant arterial hypertension, Jordan et al. (2024) noted that while there are a growing number of studies demonstrating that the devices have beneficial effects on several measures, including end-organ damage, quality of life (QOL), exercise capacity, and glucose capacity, there remains no evidence that mortality or morbidity are reduced.⁶ The authors also note that the blood pressure-lowering effects of BAT are highly variable across patients, with no way to prospectively determine which patients are more likely to show beneficial effects. They also note that it may not be possible to determine whether non-response to BAT is due to these individual differences or to electrode misplacement. This, along with the current absence of mortality and morbidity improvements in randomized clinical trial studies, led the authors to conclude that caution is warranted in proceeding with these invasive and costly therapies.

The 2024 European Society of Cardiology (ESC) guidelines for the management of elevated blood pressure and hypertension very briefly reviewed device-based therapies for lowering blood pressure and concluded that the evidence on their safety and efficacy is insufficient to recommend their use at this time.⁷ These recommendations apply to BAT, endovascular baroreflex amplification therapy, and carotid body ablation.

The 2024 Heart Failure Society of America (HFSA) consensus document on device-based therapies in heart failure reviewed and evaluated several device-based therapies for heart failure, including BAT, cardiac contractility modulation, implantable cardioverter-defibrillators, and cardiac resynchronization therapy.⁸ They noted that while the initially reported findings of the BeAT-HF clinical trial were promising (better outcomes in the BAT group compared to the standard-of-care group on measures of QOL, 6-meter hall walk, and NT-proBNP), more recently reported findings from the extended BeAT-HF study showed no statistical differences between treatment and control groups.

The 2022 American College of Cardiology and American Heart Association guideline for the management of heart failure noted that while some clinical trial studies have suggested improvements in QOL, exercise capacity, and NT-proBNP levels, there have yet to be any reported improvements in mortality or hospitalization rates.⁹ The 2021 European Society of Cardiology guidelines for diagnosing and treating acute and chronic HF also note that while some improvement in effort capacity and quality of life has been reported in patients treated with baroreflex therapy, current evidence is limited. The ESC concluded that no recommendations could be made for their use.¹⁰

On behalf of the American Heart Association (AHA), Carey et al. published a 2018 scientific statement on detecting, evaluating, and managing resistant hypertension. The authors discussed a randomized trial of 322 patients with resistant hypertension that, while finding that the device is safe and efficacious in treating resistant hypertension, failed to meet the primary endpoint of the trial.¹

The National Institute for Health and Care Excellence (NICE) guidance on implanting a baroreceptor stimulation device for resistant hypertension states that current evidence on the safety and efficacy of the treatment is considered inadequate. The devices are thus only recommended for research purposes. The reviewing committee considered separate evidence for unilateral and bilateral implantation, with much of the available evidence at the time based upon bilateral usage.¹¹

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Policy Revision History/Information

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Cohere Medicare Advantage Policy – Catheter-Based Angiogram, Lower Extremity Arteries

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: May 31, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medicare Advantage Policy - Catheter-Based Angiogram, Lower Extremity Arteries

Date of last literature review: 5/28/2024

Document last updated: 5/31/2024

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

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Medical Necessity Criteria

Service: Catheter-Based Angiogram, Lower Extremity Arteries

Benefit Category

Inpatient Hospital Services
Outpatient Hospital Services

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

Recommended Clinical Approach

Catheter-based angiography may be appropriate as the initial advanced imaging modality when the clinician determines that there is a high likelihood that the patient is a candidate for a minimally invasive intervention (e.g., angioplasty, atherectomy, or stent placement).¹

Medical Necessity Criteria

Indications

→ **Catheter-based angiogram** is considered appropriate if **ANY** of the following is **TRUE**²⁻³:

- ◆ Extra-cardiac angiography (e.g., injection of the abdominal aorta, carotid, iliofemoral, or renal arteries) performed for **ANY** of the following conditions with cardiac catheterization (meeting its own indications):
 - The patient has a specific medical condition that would have been appropriate to require angiography independent of cardiac catheterization (e.g., extra-cardiac angiograms would have been performed at this point in the patient's medical course even if cardiac catheterization had not been performed); **OR**
 - There are reasonably anticipated therapeutic implications for which these angiograms will be used; **OR**

- The service is specifically requested (and documented in the patient's medical record) by the treating or referring physician; **OR**
- ◆ The patient requires a **diagnostic angiography** when non-invasive tests are inconclusive or not available and **ANY** of the following is **TRUE**^{1,4}:
 - Angiography can be performed during a separate session from an interventional procedure if medically necessary to define anatomy and pathology; **OR**
 - Diagnostic angiography is preceded by non-invasive tests (e.g., duplex ultrasonography, CT angiography, MRA) when these tests are inconclusive or unavailable; **OR**
 - Repeat angiography is medically necessary with new, incapacitating symptoms; **OR**
 - Repeat angiography is medically necessary if the patient is deemed unstable and requires surgical intervention; **OR**
- ◆ The patient is experiencing **chronic limb-threatening ischemia** with **ANY** of the following⁴⁻⁵:
 - Gangrene; **OR**
 - Ischemic rest pain*; **OR**
 - Non-healing wounds; **OR**
- ◆ The patient is experiencing **non-limb-threatening peripheral artery disease (PAD)** with lifestyle-limiting symptoms **AND** all of the following:
 - The patient has failed optimal medical therapy⁴; **AND**
 - Revascularization is being considered; **AND**
 - **ANY** of the following is **TRUE**:
 - MRA, CTA, Doppler testing is abnormal (suggesting greater than 75% stenosis) or has not achieved diagnostic results; **OR**
 - Noninvasive testing is unavailable; **OR**
 - An invasive angiogram has been considered an appropriate initial test; **OR**
 - Noninvasive studies for anatomic assessment (e.g., CTA and/or MRA) are perceived to be a greater risk to the patient than invasive angiography³; **OR**
- ◆ The patient requires an **evaluation for dialysis access maintenance** if located in the lower extremity⁶; **OR**

- ◆ The patient requires **ANY** of the following for **diagnostic abdominal aortography, renal angiography, or peripheral angiography⁷**:
 - Abdominal aortography or angiography as indicated by **ANY** of the following:
 - Acute traumatic abdominal injury; **OR**
 - Aneurysm and other primary vascular abnormalities; **OR**
 - Occlusive disease, including evaluation for acute or chronic intestinal ischemia; **OR**
 - Acute GI hemorrhage; **OR**
 - Congenital anomaly; **OR**
 - Prior to arterial interventional procedures or open surgical procedures; **OR**
 - Stand-alone renal angiography as indicated by **ANY** of the following:
 - Severe or difficult-to-control renal hypertension (e.g., progressive renal insufficiency, resistant hypertension); **OR**
 - Renal neoplasm; **OR**
 - Hematuria of unknown cause; **OR**
 - Abnormal kidney imaging involving radioisotopes; **OR**
 - Renal artery stenosis, aneurysm, trauma, or other intrinsic defects prior to renal arterial intervention; **OR**
 - Diagnostic renal angiography or lower extremity angiography performed at the time of an interventional procedure is separately reportable if at least one indication for medical necessity for a stand-alone lower extremity or renal angiography is met with **ANY** of the following:
 - No prior catheter-based angiographic study is available and a full diagnostic study is performed, and the decision to intervene is based on the diagnostic study; **OR**
 - A prior study is available with **ANY** of the following:
 - ◆ The patient's condition with respect to the clinical indication has changed since the prior study; **OR**
 - ◆ There is inadequate visualization of the anatomy or pathology; **OR**

- ◆ There is a clinical change during the interventional procedure that requires new evaluation outside the target area of intervention; **OR**
- Stand-alone lower extremity angiography as indicated by a pre-procedure clinical assessment that includes **ALL** of the following:
 - An invasive intervention is planned; **AND**
 - A prior non-invasive study was completed and indicates further study is needed by angiography for the planned intervention; **AND**
 - The patient has **ANY** of the following conditions:
 - ◆ Arterial embolism for **ANY** of the following:
 - Blood vessel occlusion, or embolization is needed for **ANY** of the following:
 - Laceration; **OR**
 - Blunt trauma; **OR**
 - Infection; **OR**
 - Intractable bleeding; **OR**
 - Arteriovenous fistula or malformation; **OR**
 - Treatment of malignancy (e.g., hepatic artery embolization); **OR**
 - Blood vessel occlusion, or embolization is needed for **ANY** of the following:
 - Laceration; **OR**
 - Blunt trauma; **OR**
 - Infection; **OR**
 - Intractable bleeding; **OR**
 - Arteriovenous fistula or malformation; **OR**
 - Treatment of malignancy (e.g., hepatic artery embolization); **OR**
 - ◆ Uterine artery embolization for the presence of intractable bleeding after medical therapy (hormone therapy); **OR**
 - ◆ Confirmed uterine fibroids (e.g., endometrial sampling, imaging) and **ALL** of the following:

- Individual desires uterine sparing procedure; **AND**
- Persistent symptoms lasting 3 or more consecutive months despite medical management (e.g., hormonal therapy, NSAIDs) if medically appropriate and not contraindicated; **OR**
- ◆ Prostatic artery embolism (PAE) for intractable bleeding; **OR**
- ◆ Geniculate artery embolization (GAE) for intractable knee hemarthrosis; **OR**
- ◆ Aneurysm; **OR**
- ◆ The patient has **general diagnostic needs** for **ANY** of the following involving abdominal, pelvic, or lower extremity arterial vasculature⁴:
 - Acute or chronic arterial trauma; **OR**
 - Certain vasculitis; **OR**
 - Tumor.

*Ischemic rest pain is typically described as affecting the forefoot and is often made worse with recumbency while being relieved by dependency. It should be present for greater than 2 weeks and be associated with one or more abnormal hemodynamic parameters. These parameters include an ankle-brachial index (ABI) less than 0.4 (using higher of the dorsalis pedis [DP] and posterior tibial [PT] arteries), absolute highest AP less than 50 mm Hg, absolute TP less than 30 mm Hg, transcutaneous partial pressure of oxygen (TcPO₂) less than 30 mm Hg, and flat or minimally pulsatile pulse volume recording (PVR) waveforms (equivalent to Wiffl ischemia grade 3).⁵

Non-Indications

- **Catheter-based angiogram, lower extremities** is not considered appropriate if **ANY** of the following is **TRUE**⁴:
- ◆ The patient is unwilling to undergo interventional therapy if angiography discovers disease; **OR**
 - ◆ The procedure risk is high due to concurrent medical problems (e.g., severe hypertension, uncorrectable coagulopathy, significant sensitivity to iodinated contrast material); **OR**
 - ◆ Routine non-selective renal arteriography without prior non-invasive studies; **OR**
 - ◆ For use in conditions like renal insufficiency, congestive heart failure, or certain connective tissue disorders.

NOTE: Catheter-based angiogram, lower extremities may not be considered appropriate if **ANY** of the following is **TRUE**²⁸:

- ◆ Severe allergy to contrast media; **OR**
- ◆ Severe renal insufficiency; **OR**
- ◆ The patient uses metformin; **OR**
- ◆ There was prior vascular surgery at the proposed access site (e.g., femoral access at the site of a prior femoral reconstruction); **OR**
- ◆ There is a known or suspected arterial aneurysm or significant vascular anomaly (e.g., AV fistula) at the proposed access site.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
36245	Insertion of catheter into first order abdominal branch of artery, within a vascular family
36246	Insertion of catheter into initial second order abdominal branch of artery, within a vascular family
36247	Insertion of catheter into initial third order abdominal branch of artery, within a vascular family
37252	Radiologic supervision and interpretation with the IVUS procedure and are used for procedures involving both arteries and/or veins. Reported once per procedure for the first vessel studied with IVUS.
37253	Radiologic supervision and interpretation with the IVUS procedure and are used for procedures involving both arteries and/or veins. Each initial vessel.
75710	Angiography, extremity, unilateral, radiological
75716	Angiography, extremity, bilateral, radiological

Medical Evidence

Gerhard-Herman et al. (2017) developed the 2016 AHA/ACC guideline for the management of patients with lower extremity peripheral artery disease. Invasive angiography is recommended in a patient with critical limb ischemia in whom revascularization is considered. This was a Class I (Strong) recommendation with Level of Evidence as Expert Opinion. The use of noninvasive imaging can create a delay in crucial treatment for the patient. A Class IIa (Moderate Strength of Recommendation) Level of Evidence Expert Opinion rating was given to invasive angiography in patients with lifestyle-limiting claudication with an inadequate response to guideline-directed medical treatment (GDMT) when revascularization is considered. The risk of invasive angiography can be less than in noninvasive studies, particularly in advanced chronic kidney disease, as the contrast dose is lower in the invasive scenario. The committee concluded that invasive and noninvasive angiography is not recommended in asymptomatic peripheral arterial disease (Class of Recommendation: Harm; Level of Evidence B-R (Randomized)).³

Woo and colleagues (2022) published the Society of Vascular Surgery appropriate use criteria for the management of intermittent claudication. 2280 unique intermittent claudication treatment scenarios were rated. Invasive treatment recommendations were made for patients who have completed exercise therapy, are nonsmokers, and are on optimal medical therapy with severe lifestyle limitations. The group stated unclear benefits and possible harms related to invasive intervention in the infrapopliteal segment for intermittent claudication.⁹

Conte et al. (2019) developed global vascular guidelines for the management of chronic limb-threatening ischemia. The group proposed a new anatomic scheme for threatened limbs, the Global Limb Anatomic Staging System (GLASS). This integrated, limb-based approach is based on a set of clinical assumptions and simplified approaches to stratification. They make a strong recommendation for revascularization to all average-risk patients with advanced limb-threatening conditions and significant perfusion deficits. There was a weak recommendation for revascularization in average-risk patients with intermediate limb threat (based on a scoring tool such as Wlfi).

It is stated that a more in-depth study is required regarding the relationship between regional ischemia and patterns of infrapopliteal and pedal disease.¹⁵

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Clinical Guideline Revision History/Information

Original Date: May 31, 2024		
Review History		



Cohere Medicare Advantage Policy – Catheter-Based Angiogram

Clinical Policy for Medical Necessity Review

Version: 3

Revision Date: June 26, 2025

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy – Catheter-Based Angiogram

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

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Medical Necessity Criteria

Service: Catheter-Based Angiogram

Related CMS Documents

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

- [Local Coverage Determination \(LCD\). Dialysis access maintenance \(L34062\)](#)¹
 - [Billing and Coding: Dialysis access maintenance \(A56460\)](#)²
- [Local Coverage Determination \(LCD\). Thoracic aortography and carotid, vertebral, and subclavian angiography \(L35035\)](#)³
 - [Billing and Coding: Thoracic aortography and carotid, vertebral, and subclavian angiography \(A56631\)](#)⁴
- [Local Coverage Determination \(LCD\). Diagnostic abdominal aortography and renal angiography \(L35092\)](#)⁵
 - [Billing and Coding: Diagnostic Abdominal aortography and renal angiography \(A56682\)](#)⁶
- [Local Coverage Determination \(LCD\). Aortography and peripheral angiography \(L36767\)](#)⁷
 - [Billing and Coding: Aortography and peripheral angiography \(A57056\)](#)⁸

Description

Catheter-based angiography of non-cardiac arteries is a procedure in which a catheter is inserted into blood vessels to assess vascular structures and identify blockages. The provider can then evaluate the suitability of vessels for interventions such as angioplasty, atherectomy, stent placement, or creation and maintenance of vascular access for dialysis. After a needle or catheter is inserted, contrast dye is injected, and images are generated to facilitate clinical decision-making.⁹

Medical Necessity Criteria

Indications

Catheter-based angiogram is considered appropriate if **ANY** of the following is **TRUE**:

- The patient is experiencing chronic limb-threatening ischemia (CTLI) with **ANY** of the following^{9,10}:
 - Gangrene; **OR**
 - Ischemic rest pain; **OR**
 - Non-healing wounds; **OR**
- The patient is experiencing symptomatic (effort-related) peripheral artery disease (PAD) including **ALL** of the following¹¹:
 - Intermittent claudication characterized by exertional muscle pain which is relieved by rest; **AND**
 - Physical exam findings indicating reduced blood flow (e.g., decreased or absent pulses); **AND**
 - Ankle-brachial index (ABI) greater than or equal to 0.90 or toe-brachial index (TBI) greater than or equal to 0.70; **OR**
- Lower extremity (LE) (popliteal, femoral) aneurysm¹¹; **OR**
- Pre-procedure (e.g., TAVR) that requires arterial access and the patient has confirmed or suspected arterial blockage or other arterial disease¹¹; **OR**
- The patient is experiencing non-limb-threatening peripheral artery disease (PAD) with lifestyle-limiting symptoms and **ALL** of the following:
 - The patient has failed optimal medical therapy^{9,10,12}; **AND**
 - **ALL** of the following:
 - Revascularization is being considered; **AND**
 - **ANY** of the following is **TRUE**:
 - MRA, CTA, or Doppler testing is abnormal (suggesting greater than 75% stenosis) or has not achieved diagnostic results; **OR**
 - An invasive angiogram has been considered an appropriate initial test; **OR**
 - Noninvasive studies for anatomic assessment (e.g., CTA and/or MRA) are perceived to be a greater risk to the patient than invasive angiography; **OR**
- The patient requires an evaluation for dialysis access maintenance of an arteriovenous (AV) fistula, including **ANY** of the following¹:
 - Compromised flow with threatened occlusion; **OR**

- Recent thrombosis of AV dialysis access; **OR**
- Management of structural abnormalities such as pseudoaneurysms/aneurysms; **OR**
- Clinical findings including **ANY** of the following:
 - Venous outflow impediment clinical findings including **ANY** of the following:
 - Elevated venous pressure in the AV dialysis access; **OR**
 - Elevated venous/arterial ratio (static venous pressure ratio above 40%); **OR**
 - Prolonged bleeding following needle removal; **OR**
 - Inefficient dialysis; **OR**
 - Recirculation percentage greater than 10–15%; **OR**
 - Development of pseudoaneurysm(s); **OR**
 - Swelling of the extremity, face, or neck; **OR**
 - Development of large superficial collateral venous channels; **OR**
 - Loss of "machine-like" bruit (i.e., short sharp bruit); **OR**
 - Abnormal physical findings, specifically pulsatile graft/fistula or loss of thrill; **OR**
 - Arterial inflow impediment clinical findings including **ANY** of the following:
 - Low pressure in graft even when outflow is manually occluded; **OR**
 - Ischemic changes of the extremity (steal syndrome); **OR**
 - Diminished intra-access flow; **OR**
- The patient requires percutaneous transluminal angioplasty (PTA) and **ALL** of the following:
 - Documentation supporting the presence of residual, hemodynamically significant stenosis, generally greater than 50% of the vessel diameter; **AND**
 - Clear documentation of the site and extent of any hemodynamically significant stenosis; **OR**
- The patient requires venous PTA to treat stenoses anywhere from the arterial inflow through the vena cava (most commonly at the level of the venous anastomosis for synthetic graft accesses); **OR**
- The procedure is an abdominal aortography or abdominal angiography as indicated by **ANY** of the following^{5,7}:
 - Acute traumatic abdominal injury; **OR**
 - Aneurysm and other primary vascular abnormalities; **OR**

- Occlusive disease, including evaluation for acute or chronic intestinal ischemia; **OR**
- Acute GI hemorrhage; **OR**
- Congenital anomaly; **OR**
- Prior to arterial interventional procedures or open surgical procedures; **OR**
- The procedure is a stand-alone renal angiography as indicated by **ANY** of the following:
 - Severe or difficult-to-control renal hypertension (e.g., progressive renal insufficiency, hypertension not controlled by 3 medications)⁵; **OR**
 - Renal neoplasm⁵; **OR**
 - Hematuria of unknown cause⁵; **OR**
 - Abnormal kidney imaging involving radioisotopes⁵; **OR**
 - Renal artery stenosis, aneurysm, trauma, or other intrinsic defects prior to renal arterial intervention⁵; **OR**
 - Renovascular occlusive disease (e.g., renal artery stenosis, severe or difficult to control renal hypertension, hypertension not controlled by 3 medications, or progressive renal insufficiency)⁷; **OR**
 - Renal aneurysm⁷; **OR**
 - Renovascular trauma⁷; **OR**
 - Primary vascular abnormalities, including aneurysms, vascular malformations, and vasculitis⁷; **OR**
 - Renal neoplasm⁷; **OR**
 - Hematuria of unknown cause⁷; **OR**
 - Pre- and postoperative evaluations for renal transplantation⁷; **OR**
 - Other intrinsic defects prior to interventional procedures on the renal arteries⁷; **OR**
 - Abnormal kidney imaging involving radioisotopes⁷; **OR**
 - Prior to interventional procedures on the renal arteries⁷; **OR**
- The procedure is a non-selective renal angiography performed at the time of cardiac catheterization and **ALL** of the following⁷:
 - The clinical index of suspicion for atherosclerotic renal artery stenosis (RAS) is high as indicated by **ANY** of the following:
 - Onset of severe hypertension before age 30 or severe hypertension after age 55; **OR**
 - Exacerbation of previously well-controlled hypertension; **OR**

- Resistant hypertension (i.e., failure to achieve goal blood pressure in patients who are adhering to full doses of an appropriate 3-drug regimen that includes a diuretic); **OR**
- Malignant hypertension (hypertension with coexistent evidence of acute end-organ damage; i.e., acute renal failure, acutely decompensated congestive heart failure, new visual or neurological disturbance, and/or advanced [grade III to IV] retinopathy); **OR**
- New azotemia or worsening renal function after the administration of an ACE inhibitor or an angiotensin receptor-blocking agent; **OR**
- Unexplained atrophic kidney (7 to 8 cm) or a discrepancy in size between the two kidneys of greater than 1.5 cm. The atrophy should be otherwise unexplained by, for example, a prior history of chronic pyelonephritis, reflux nephropathy, or trauma; **OR**
- Sudden, unexplained pulmonary edema (especially in azotemic patients); **OR**
- Unexplained renal failure, including patients starting renal replacement therapy (dialysis or renal transplantation); **AND**
- There are reasonable anticipated therapeutic implications for which the results of this angiogram will be used; **AND**
- The results of noninvasive imaging studies cannot be obtained or are inconclusive; **OR**
- The procedure is a renal angiography or lower extremity angiography performed at the time of an interventional procedure and **ALL** of the following⁵⁷:
 - At least one indication for medical necessity for a stand-alone lower extremity or renal angiography is met; **AND**
 - **ANY** of the following:
 - **ALL** of the following:
 - No prior catheter-based angiographic study is available; **AND**
 - A full diagnostic study is performed; **AND**
 - The decision to intervene is based on the diagnostic study; **OR**
 - A prior study is available with **ANY** of the following:
 - The patient's condition with respect to the clinical indication has changed since the prior study; **OR**
 - There is inadequate visualization of the anatomy or pathology; **OR**
 - There is a clinical change during the interventional procedure that requires new evaluation outside the target area of intervention; **OR**

- The procedure is a stand-alone lower extremity angiography as indicated by a pre-procedure clinical assessment that includes documentation of **ALL** of the following^{5,7}:
 - An invasive intervention is planned; **AND**
 - A prior non-invasive study was completed and indicates further study is needed by angiography for the planned intervention; **AND**
 - The patient has **ANY** of the following conditions
 - Arterial embolism; **OR**
 - Acute or chronic ischemia^{5,7}; **OR**
 - Peripheral vascular disease (including claudication)^{5,7}; **OR**
 - Aneurysm^{5,7}; **OR**
- The procedure is a thoracic aortography or carotid, vertebral, or angiography and **ANY** of the following^{3,7}:
 - Documented symptoms of ischemic cerebral disease; **OR**
 - Documented results from previous noninvasive test(s) indicating severely stenotic carotid disease or severely ulcerated carotid disease; **OR**
 - Medical history consistent with known or suspected trauma, tumor, or other intracranial anomalies; **OR**
 - Medical history consistent with upper extremity claudication, acute or chronic arterial trauma, thoracic outlet obstruction disease, certain vasculitis, and subclavian steal; **OR**
 - Surgical or percutaneous correction of the occlusive disease must be beneficial to the candidate's clinical status.

Non-Indications

Catheter-based angiogram is not considered appropriate if **ANY** of the following is **TRUE**:

- The procedure is an evaluation for dialysis access maintenance of an arteriovenous (AV) fistula, and **ANY** of the following¹:
 - In the absence of clinical findings suggesting the need to re-establish appropriate flow in a dialysis fistula, it is seldom reasonable and necessary to perform diagnostic angiography or sonographic confirmatory studies as part of the decision to treat; **OR**
 - Percutaneous interventions to treat total occlusion of graft due to thrombus of more than one year in duration; **OR**
 - Angioplasty of vessels not documented to be stenosed significantly by angiography or ultrasound; **OR**

- Dilation of the graft anastomotic site will be considered either arterial or venous, but not both; **OR**
- Revision procedures that are not for repair and/or maintenance of an existing fistula, but are performed as part of a planned staged procedure to create a new fistula; **OR**
- The procedure is a catheter-based renal angiography for renal artery stenosis (RAS) and there is no prior non-invasive renal artery study that is either inconclusive or unavailable, except in patients with fibromuscular dysplasia or renal artery aneurysms where there may be branch involvement²; **OR**
- The procedure is a routine non-selective renal arteriography performed at the time of cardiac catheterization in the absence of accepted clinical indications that support medical necessity²; **OR**
- The procedure is a repeat angiography and **ANY** of the following^{3,5,7}:
 - Appropriate non-invasive tests have not been performed; **OR**
 - There has been no trial of or change in medical management unless the patient is deemed unstable and in need of some type of surgical intervention; **OR**
- The procedure is a second diagnostic angiogram (fluoroscopic or computer tomographic) in the absence of documentation to support the medical necessity of repeating the study.³

Catheter-based angiography may not be considered appropriate if **ANY** of the following is true:

- The procedure is a diagnostic aortography/angiography and **ANY** of the following^{3,5,7}:
 - Uncorrectable coagulopathy or thrombocytopenia; **OR**
 - Clinically significant sensitivity to iodinated contrast material; **OR**
 - Renal insufficiency based on the estimated glomerular filtration rate (eGFR).

Definitions

- **Ischemic Rest Pain:** Typically described as affecting the forefoot and is often made worse with recumbency while being relieved by dependency. It should be present for greater than 2 weeks and be associated with one or more abnormal hemodynamic parameters. These parameters include an ankle-brachial index (ABI) less than 0.4 (using higher of the dorsalis pedis [DP] and posterior tibial [PT] arteries), absolute highest AP less than 50

mm Hg, absolute TP less than 30 mm Hg, transcutaneous partial pressure of oxygen (TcPO₂) less than 30 mm Hg, and flat or minimally pulsatile pulse volume recording (PVR) waveforms (equivalent to Wiffl ischemia grade 3).⁵

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
36245	Insertion of catheter into first order abdominal branch of artery, within a vascular family
36246	Insertion of catheter into initial second order abdominal branch of artery, within a vascular family
36247	Insertion of catheter into initial third order abdominal branch of artery, within a vascular family
37252	Radiologic supervision and interpretation with the IVUS procedure and are used for procedures involving both arteries and/or veins. Reported once per procedure for the first vessel studied with IVUS.
37253	Radiologic supervision and interpretation with the IVUS procedure and are used for procedures involving both arteries and/or veins. Each initial vessel.
75710	Angiography, extremity, unilateral, radiological
75716	Angiography, extremity, bilateral, radiological

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 catheter-based angiogram may include:

- Adverse effects from delayed or denied treatment, such as increased symptoms, complications, and adverse outcomes, especially in undiagnosed or incorrectly diagnosed patients. The 2024 European Society of Cardiology guidelines note that peripheral arterial and aortic diseases (PAAD) are highly prevalent and increase mortality and morbidity from cardiovascular disease.¹¹ Moreover, PAAD is often underdiagnosed and undertreated, while early diagnosis improves outcomes.
- Risks from inappropriate procedures include exposure to ionizing radiation and iodinated contrast. The 2024 American College of Cardiology guidelines note that patients undergoing invasive angiography risk contrast nephropathy, adverse outcomes related to radiation exposure, procedural discomfort, and access site complications, including bleeding events.¹⁰

The clinical benefits of using these criteria for catheter-based angiogram may include:

- Improved patient selection, resulting in better long-term outcomes. Catheter-based non-cardiac angiogram is recommended for patients expected to undergo revascularization procedures. Moreover, catheter-based angiogram is also recommended when noninvasive imaging has not been definitive.^{10,11}

- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Allen et al. (2022) compared outcomes (restenosis) in 150 patients with severe lifestyle-limiting claudication or critical limb ischemia undergoing femoropopliteal revascularization who received catheter-based angiography alone or in combination with intravascular ultrasound (IVUS). Blockage recurrence (restenosis) rates were higher 12 months after revascularization in patients who received angiography alone compared to patients who received angiography and IVUS; restenosis was seen in 72.4% and 55.4% of patients treated with angiography alone and angiography with IVUS, respectively. The authors suggested that IVUS may provide more accurate artery diameter and lesion length measurements, leading to selection of more appropriately sized devices, including drug-coated balloons.¹³

In the 2024 American College of Cardiology/American Heart Association joint committee on clinical practice guideline for the management of lower extremity peripheral artery disease, Gornik et al. recommended catheter angiography after initial non-invasive diagnostic testing when further definition of vascular structure is required, for example in planning revascularization or when peripheral arterial disease (PAD) is suspected and the ankle-brachial index (ABI) test is inconclusive. They note that catheter angiography carries several risks, including exposure to potentially carcinogenic radiation and contrast agents, as well as catheter-specific risks including arterial injury and bleeding. They recommend restriction of this procedure to patients with severe PAD and when revascularization is being considered. Specific recommendations for catheter-based angiography include for patients with functionally limiting claudication who are not responsive to disease management and who are being considered for revascularization, in order to assess anatomy and disease severity and to plan revascularization, and in patients with chronic limb-threatening ischemia. Catheter angiography is not recommended for PAD patients when revascularization is not being considered.¹⁰ The European Society of Cardiology 2024 guidelines for the management of peripheral arterial and aortic diseases similarly recommend restriction of catheter-based angiography to chronic limb-threatening ischemia patients and only PAD patients undergoing revascularization.¹¹

Gerhard-Herman et al. (2017) developed the 2016 AHA/ACC guideline for the management of patients with lower extremity peripheral artery disease. Invasive angiography is recommended in a patient with critical limb ischemia in whom revascularization is considered. The use of noninvasive imaging can create a delay in crucial treatment for the patient. A Class IIa (Moderate Strength of Recommendation) Level of Evidence Expert Opinion rating was given to invasive angiography in patients with lifestyle-limiting claudication with an inadequate response to guideline-directed medical treatment (GDMT) when revascularization is considered. The risk of invasive angiography can be less than in noninvasive studies, particularly in advanced chronic kidney disease, as the contrast dose is lower.¹²

Woo et al. (2022) published the Society of Vascular Surgery's appropriate use criteria for the management of intermittent claudication. 2280 unique intermittent claudication treatment scenarios were rated. Invasive treatment recommendations were made for patients who have completed exercise therapy, are nonsmokers, and are on optimal medical therapy with severe lifestyle limitations. The group stated unclear benefits and possible harms related to invasive intervention in the infrapopliteal segment for intermittent claudication.¹⁴

Conte et al. (2019) developed global vascular guidelines for the management of chronic limb-threatening ischemia. The group proposed a new anatomic scheme for threatened limbs, the Global Limb Anatomic Staging System (GLASS). This integrated, limb-based approach is based on a set of clinical assumptions and simplified approaches to stratification. The group concluded that there is a strong recommendation for revascularization to all average-risk patients with advanced limb-threatening conditions and significant perfusion deficits.⁹

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Clinical Guideline Revision History/Information

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Review History		
Version 2	06/11/2024	422.101 Disclaimer Added
Version 2.1	03/18/2025	Updated policy per CMS revisions for 2/6/2025 Updated Effective date Updated Links and Bookmarks
Version 3	06/26/2025	Annual Review. Changed title of policy (from "Catheter-Based Angiogram, Lower Extremity Arteries" to "Catheter-Based Angiogram") Revised indications and non-indications to better align with LCDs. Added note detailing ischemic rest pain. Updated references, Evaluation of Clinical Harms and Benefits, and Medical Evidence sections.



Cohere Medicare Advantage Policy – Coronary Intravascular Lithotripsy (IVL)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: December 19, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medicare Advantage Policy – Coronary Intravascular Lithotripsy

Date of last literature review: 12/10/2024

Document last updated: 12/19/2024

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

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Medical Necessity Criteria

Service: *Coronary Intravascular Lithotripsy (IVL)*

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 NCDs and/or LCDs for coronary intravascular lithotripsy.

Recommended Clinical Approach

This service is clinically unproven and not medically necessary. The current coronary lithotripsy device received premarket approval from the US Food and Drug Administration (FDA) on February 12th, 2021 for use on severely calcified, stenotic de novo coronary artery lesions. Coronary lithotripsy is intended to disrupt calcified coronary plaques with sonic pressure waves in order to facilitate coronary stenting. Because IVL does not yet have long-term efficacy results, nor a diverse range of randomized, controlled, double-blinded trials of statistical rigor, it is premature to presume clinical outcomes and benefits.

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 coronary intravascular lithotripsy. 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:

- No long-term data is available regarding the safety and efficacy of IVL.

- There is a lack of randomized controlled trials with statistical rigor to determine the superiority or inferiority of IVL relative to the current standard of care.
- Several of the existing studies included patients who underwent other plaque disruption methods, including before and after IVL. This limits the conclusions that can be drawn regarding IVL efficacy from these studies and therefore reduces generalizability.^{5,6}
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- IVL represents a possible treatment option for patients with severely calcified and/or undilatable coronary arteries that are not receptive to traditional treatment methods, such as rotational atherectomy or orbital atherectomy. Traditional tools may be insufficient to address “deep” (medial or intimal) circumferential calcification and may result in unsuccessful treatment.¹⁸
- The SCAI includes IVL in their 2024 expert consensus statement treatment algorithm for calcified coronary disease alongside specialty balloons and atherectomy.^{12,13}
- 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

→ **Coronary Intravascular Lithotripsy** 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.¹⁻¹⁶

Non-Indications

→ **Coronary Intravascular Lithotripsy** may not be 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
C1761	Catheter, transluminal intravascular lithotripsy, coronary
92972	Percutaneous transluminal coronary lithotripsy (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

As of December 6th, 2024, an Investigational Device Exemption (IDE) study is currently recruiting up to 145 patients to further evaluate the safety and efficacy of IVL (ClinicalTrials.gov identifier NCT05966662). This prospective, multicenter, single-arm study aims to quantify the rate of major adverse cardiac events among patients who undergo IVL at several intervals post-procedure up to one year. It will also evaluate procedural efficacy by capturing the number of patients with residual stenosis after undergoing IVL. The estimated study completion date is November 2025. As such, the study is ongoing and does not yet have published results.^{15,16} Because IVL does not yet have long-term efficacy results, nor a diverse range of randomized, controlled, double-blinded trials of statistical rigor, it is premature to presume clinical outcomes and benefits.

The Society for Cardiovascular Angiography Interventions (SCAI) published an expert consensus statement in February 2024 to guide the management of calcified coronary lesions. The statement discussed IVL in a number of clinical capacities and concluded that IVL is safe and effective with the explicit caveat that there is presently limited available data and no comparative studies. IVL is included in their treatment algorithm for calcified coronary disease alongside atherectomy and specialty balloons. A number of multicenter studies – including randomized controlled trials – examining the use of IVL are underway and will further illuminate the role of IVL in this high-risk patient population. Ultimately, although it appears likely that IVL will become an adjunct tool in the management of challenging calcified coronary disease, it lacks the long-term safety and efficacy data that are needed to robustly recommend its use.^{12,13}

A 2023 review of 747 IVL patients from Michigan's BMC2 registry found a procedural success rate of 91.4%, while an aggregate 1.91% of patients suffered perforation, myocardial infarction, or death.⁴

A 2020 study of 57 patients found procedural success of 98%, although the lithoplasty balloon ruptured in 13% of cases, and 2 patients experienced significant dissection. In addition, more than 75% of lesions were dilated before and after lithotripsy with the current standard technology of either

rotational atherectomy or cutting/scoring balloons, limiting the conclusions that can be drawn about the effect of IVL itself.⁵

A 2024 study examining sex differences between 454 IVL patients (75% males, 25% females) found relative parity of procedural success and adverse events. At one year post-procedure, 13% of all patients had experienced a major adverse cardiac event (cardiac death, myocardial infarction, or target vessel repeat revascularization). Again, other plaque disruption techniques were employed in 17% of all patients.⁶

Kereiakes et al. (2020) reported on the design and rationale for the Disrupt CAD III trial (ClinicalTrials.gov identifier NCT03595176). The study assessed the Shockwave Coronary IVL catheter, which is the only current FDA-approved device that is indicated to optimize coronary stent deployment in patients with de novo calcified coronary stenoses. Follow-up was to continue for two years after enrollment ended in 2020. The authors noted that limitations include a lack of a concurrent control group and a non-randomized study design.¹ The preliminary results of this study were published in 2020, which found no major adverse cardiac event in 92% of patients at 30 days following IVL. At one year post-procedure, that number decreased to 86.2%. At two years, 81.1% of patients remained free of major adverse cardiac events. Target lesion failure had occurred in 16.1% of patients at this time. In 2023, a larger post-approval study was published by the same study team involving 1,212 patients. The authors found a 0.25% mortality rate, lower than the predicted 0.31% rate, but acknowledged the study's weakness of lacking long-term data. A 2024 review of post-IVL in-hospital events, published by the same team, studied 17,681 higher-risk patients who were excluded from the prior post-approval study, with a total population of 18,893. 21.7% of patients also required atherectomy; post-procedure residual stenosis was observed at a rate of $4.0 \pm 12\%$. In-hospital mortality and major procedural complications remained low ($<1\%$), but no long-term data were presented.⁷⁻¹¹

Mhanna et al. (2022) performed a meta-analysis to evaluate the utility of adjunctive intravascular lithotripsy (IVL) for treating calcified coronary lesions. Eight single-arm observational studies with 980 patients (1011 lesions) were included. Almost half of the patients had a diagnosis of acute coronary syndrome. Severe calcification was found in 97% of all lesions. Additional studies should focus on evaluating IVL against other calcium/plaque modifying techniques.²

Sattar et al. (2022) evaluated the use of IVL for calcified lesions in 760 patients in seven studies. While positive outcomes were reported, limitations were identified. One single-arm observational study was included. The authors note the need for randomized, double-blind studies. Also, the definition of 'severe calcification' is needed to bring uniformity to the studies (e.g., imaging use, including intravascular ultrasounds and optical coherence tomography). Adjunct therapy was also not included.³

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Cohere Medicare Advantage Policy – Coronary Intravascular Lithotripsy (IVL)

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Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medicare Advantage Policy – Coronary Intravascular Lithotripsy

Date of last literature review: 12/10/2024

Document last updated: 12/19/2024

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

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Medical Necessity Criteria

Service: *Coronary Intravascular Lithotripsy (IVL)*

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 NCDs and/or LCDs for coronary intravascular lithotripsy.

Recommended Clinical Approach

This service is clinically unproven and not medically necessary. The current coronary lithotripsy device received premarket approval from the US Food and Drug Administration (FDA) on February 12th, 2021 for use on severely calcified, stenotic de novo coronary artery lesions. Coronary lithotripsy is intended to disrupt calcified coronary plaques with sonic pressure waves in order to facilitate coronary stenting. Because IVL does not yet have long-term efficacy results, nor a diverse range of randomized, controlled, double-blinded trials of statistical rigor, it is premature to presume clinical outcomes and benefits.

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 coronary intravascular lithotripsy. 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:

- No long-term data is available regarding the safety and efficacy of IVL.

- There is a lack of randomized controlled trials with statistical rigor to determine the superiority or inferiority of IVL relative to the current standard of care.
- Several of the existing studies included patients who underwent other plaque disruption methods, including before and after IVL. This limits the conclusions that can be drawn regarding IVL efficacy from these studies and therefore reduces generalizability.^{5,6}
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- IVL represents a possible treatment option for patients with severely calcified and/or undilatable coronary arteries that are not receptive to traditional treatment methods, such as rotational atherectomy or orbital atherectomy. Traditional tools may be insufficient to address “deep” (medial or intimal) circumferential calcification and may result in unsuccessful treatment.¹⁸
- The SCAI includes IVL in their 2024 expert consensus statement treatment algorithm for calcified coronary disease alongside specialty balloons and atherectomy.^{12,13}
- 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

→ **Coronary Intravascular Lithotripsy** 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.¹⁻¹⁶

Non-Indications

→ **Coronary Intravascular Lithotripsy** may not be 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
C1761	Catheter, transluminal intravascular lithotripsy, coronary
92972	Percutaneous transluminal coronary lithotripsy (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

As of December 6th, 2024, an Investigational Device Exemption (IDE) study is currently recruiting up to 145 patients to further evaluate the safety and efficacy of IVL (ClinicalTrials.gov identifier NCT05966662). This prospective, multicenter, single-arm study aims to quantify the rate of major adverse cardiac events among patients who undergo IVL at several intervals post-procedure up to one year. It will also evaluate procedural efficacy by capturing the number of patients with residual stenosis after undergoing IVL. The estimated study completion date is November 2025. As such, the study is ongoing and does not yet have published results.^{15,16} Because IVL does not yet have long-term efficacy results, nor a diverse range of randomized, controlled, double-blinded trials of statistical rigor, it is premature to presume clinical outcomes and benefits.

The Society for Cardiovascular Angiography Interventions (SCAI) published an expert consensus statement in February 2024 to guide the management of calcified coronary lesions. The statement discussed IVL in a number of clinical capacities and concluded that IVL is safe and effective with the explicit caveat that there is presently limited available data and no comparative studies. IVL is included in their treatment algorithm for calcified coronary disease alongside atherectomy and specialty balloons. A number of multicenter studies – including randomized controlled trials – examining the use of IVL are underway and will further illuminate the role of IVL in this high-risk patient population. Ultimately, although it appears likely that IVL will become an adjunct tool in the management of challenging calcified coronary disease, it lacks the long-term safety and efficacy data that are needed to robustly recommend its use.^{12,13}

A 2023 review of 747 IVL patients from Michigan's BMC2 registry found a procedural success rate of 91.4%, while an aggregate 1.91% of patients suffered perforation, myocardial infarction, or death.⁴

A 2020 study of 57 patients found procedural success of 98%, although the lithoplasty balloon ruptured in 13% of cases, and 2 patients experienced significant dissection. In addition, more than 75% of lesions were dilated before and after lithotripsy with the current standard technology of either

rotational atherectomy or cutting/scoring balloons, limiting the conclusions that can be drawn about the effect of IVL itself.⁵

A 2024 study examining sex differences between 454 IVL patients (75% males, 25% females) found relative parity of procedural success and adverse events. At one year post-procedure, 13% of all patients had experienced a major adverse cardiac event (cardiac death, myocardial infarction, or target vessel repeat revascularization). Again, other plaque disruption techniques were employed in 17% of all patients.⁶

Kereiakes et al. (2020) reported on the design and rationale for the Disrupt CAD III trial (ClinicalTrials.gov identifier NCT03595176). The study assessed the Shockwave Coronary IVL catheter, which is the only current FDA-approved device that is indicated to optimize coronary stent deployment in patients with de novo calcified coronary stenoses. Follow-up was to continue for two years after enrollment ended in 2020. The authors noted that limitations include a lack of a concurrent control group and a non-randomized study design.¹ The preliminary results of this study were published in 2020, which found no major adverse cardiac event in 92% of patients at 30 days following IVL. At one year post-procedure, that number decreased to 86.2%. At two years, 81.1% of patients remained free of major adverse cardiac events. Target lesion failure had occurred in 16.1% of patients at this time. In 2023, a larger post-approval study was published by the same study team involving 1,212 patients. The authors found a 0.25% mortality rate, lower than the predicted 0.31% rate, but acknowledged the study's weakness of lacking long-term data. A 2024 review of post-IVL in-hospital events, published by the same team, studied 17,681 higher-risk patients who were excluded from the prior post-approval study, with a total population of 18,893. 21.7% of patients also required atherectomy; post-procedure residual stenosis was observed at a rate of $4.0 \pm 12\%$. In-hospital mortality and major procedural complications remained low ($<1\%$), but no long-term data were presented.⁷⁻¹¹

Mhanna et al. (2022) performed a meta-analysis to evaluate the utility of adjunctive intravascular lithotripsy (IVL) for treating calcified coronary lesions. Eight single-arm observational studies with 980 patients (1011 lesions) were included. Almost half of the patients had a diagnosis of acute coronary syndrome. Severe calcification was found in 97% of all lesions. Additional studies should focus on evaluating IVL against other calcium/plaque modifying techniques.²

Sattar et al. (2022) evaluated the use of IVL for calcified lesions in 760 patients in seven studies. While positive outcomes were reported, limitations were identified. One single-arm observational study was included. The authors note the need for randomized, double-blind studies. Also, the definition of 'severe calcification' is needed to bring uniformity to the studies (e.g., imaging use, including intravascular ultrasounds and optical coherence tomography). Adjunct therapy was also not included.³

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Clinical Guideline Revision History/Information

Original Date: December 19, 2024		
Review History		



Cohere Medicare Advantage Policy – Descending and Abdominal Aortic Aneurysm Repair

Clinical Guidelines for Medical Necessity Review

Version: 3
Revision Date: June 26, 2025

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Guideline Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy - Descending and Abdominal Aortic Aneurysm Repair

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

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Medical Necessity Criteria

Service: Descending and Abdominal Aortic Aneurysm Repair

Related CMS Documents

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

- There are no applicable NCDs and/or LCDs for descending and abdominal aortic aneurysm repair.
 - [Billing and Coding Article: Endovascular Repair of Aortic and/or Iliac Aneurysms \(A53124\)](#).

Description

The descending and abdominal aorta are the part of the aorta that travels downward from the aortic arch, passing through the belly and bifurcating into the iliac arteries in the pelvis. An aortic aneurysm occurs when the wall of the aorta becomes weakened and expands outward. Because the aorta is the largest artery in the body and is highly pressurized, the aneurysmal portion may rupture – or dissect – and cause serious, life-threatening sequelae, such as rapid blood loss or poor perfusion of extremities and vital organs that may result in death. To mitigate this risk, aortic aneurysms are often prophylactically repaired. Depending on the type of repair, the patient may or may not be placed on mechanical cardiopulmonary bypass during the operation in order to survive an extended interruption of blood flow to the vital organs while the surgeon is working on the aorta. In an open surgical repair (OSR), the surgeon directly visualizes and repairs/excises the aneurysm. Endovascular aortic repair (EVAR) is a minimally invasive method of repairing the aorta and is known as TEVAR (thoracic EVAR) when it occurs in the thoracic region. The surgeon accesses the aorta by placing a catheter in the groin and deploying a stent graft to the affected portion of the aorta. The stent graft self-expands to support the diseased aorta, prevent dissection, and restore blood flow. Hybrid repair may also be performed, involving a combination of both open and endovascular techniques. The surgeon is best positioned to choose the most appropriate treatment (OSR, EVAR/TEVAR, or

hybrid repair) for the patient based on their individual anatomic and clinical factors.²⁻⁵

Medical Necessity Criteria

Indications

Descending thoracic and abdominal aortic repair (OSR, EVAR/TEVAR, or hybrid repair) or endovascular arterial repair is considered appropriate if **ALL** of the following is **TRUE**:

- This is an FDA-approved device; **AND**
- **ANY** of the following:
 - **ANY** of the following pathologies, provided that the treating clinician deems the patient to be an appropriate candidate for repair:
 - Symptomatic or ruptured aneurysms²⁻⁴; **OR**
 - Pseudoaneurysms²⁻⁴; **OR**
 - Intramural hematomas²⁻⁴; **OR**
 - Penetrating ulcers²⁻⁴; **OR**
 - Abdominal aortic aneurysm (AAA), including **ANY** of the following²⁻⁴:
 - Asymptomatic fusiform abdominal aortic aneurysms (greater than 5.5 cm in males or greater than 5 cm in females); **OR**
 - All saccular aneurysms in patients with a reasonable life expectancy; **OR**
 - Aneurysm that expands by more than 1.0 cm within 12 months or by more than 0.5 cm in 6 months; **OR**
 - AAA with concomitant Iliac artery aneurysm of at least 3.5 cm, even if the AAA has not reached the above size threshold²; **OR**
 - Asymptomatic fusiform descending thoracic or thoracoabdominal aneurysms with **ANY** of the following²⁻⁴:
 - A fusiform aortic diameter greater than 5.5 cm; **OR**
 - A saccular aneurysm; **OR**
 - Any surgical risk at a diameter of 5.5 cm; **OR**
 - Patients who require chemotherapy, radiation therapy, or solid organ transplant, and who are deemed to be at low to moderate perioperative risk (with a reasonable life expectancy) with **ANY** of the following:
 - A fusiform aortic aneurysm measuring between 4 and 5.4 cm; **OR**
 - A saccular aneurysm; **OR**

- Documented rapid thoracic or thoracoabdominal expansion defined as **ANY** of the following:
 - Greater than or equal to 0.5 cm in 12 months; **OR**
 - Greater than or equal to 0.3 cm in 12 months for those with heritable thoracic aortic disease (including but not limited to Marfan Syndrome, Vascular Ehlers-Danlos Syndrome [VEDS], Loeys-Dietz Syndrome, or Turner Syndrome) or bicuspid aortic valve (BAV); **OR**
- Patients with genetically mediated aortic diseases or bicuspid aortic valves may be appropriate for repair at an aortic diameter of less than 5.5 cm (the specific threshold diameter depends on the underlying medical condition); **OR**
- Iliac artery aneurysm (IAA) with **ANY** of the following²⁻⁴:
 - Rapidly expanding IAA (at least 7 mm in six months or at least 1 cm in 12 months); **OR**
 - Asymptomatic IAA of at least 3.5 cm⁶⁻⁸; **OR**
- Visceral aneurysm with **ANY** of the following⁵:
 - Hepatic artery aneurysm with **ANY** of the following:
 - Size greater than 2 cm; **OR**
 - Growth of at least 0.5/cm within 12 months; **OR**
 - All pancreaticoduodenal and gastroduodenal artery aneurysms, regardless of size; **OR**
 - All superior mesenteric artery aneurysms, regardless of size; **OR**
 - Jejunal and ileal artery aneurysms that are at least 2 cm; **OR**
 - All gastric and gastroepiploic artery aneurysms, regardless of size; **OR**
 - All colic artery aneurysms, regardless of size; **OR**
 - Renal artery aneurysms with **ANY** of the following:
 - Size greater than 3 cm; **OR**
 - Aneurysms of all sizes for **ANY** of the following:
 - Women of childbearing age; **OR**
 - Patients with refractory hypertension and renal artery stenosis; **OR**
 - Celiac artery aneurysms with **ANY** of the following:
 - All pseudoaneurysms; **OR**
 - Size greater than 2 cm; **OR**
 - Splenic artery aneurysms with **ANY** of the following:
 - All pseudoaneurysms; **OR**

- Size greater than 3 cm; **OR**
- All sizes for women of childbearing age; **OR**
- Traumatic aortic disruptions, including **ANY** of the following:
 - Grade I: small intimal defect; observation versus repair; **OR**
 - Grade II: intramural hematoma; TEVAR within 24 hours; **OR**
 - Grade III: pseudoaneurysms; immediate TEVAR; **OR**
 - Grade IV: evidence of contained or frank aortic rupture; immediate TEVAR; **OR**
- Complications from a previous aortic repair²⁻⁴; **OR**
- Infected/mycotic aneurysm²⁻⁴; **OR**
- Aneurysm associated with aortitis²⁻⁴; **OR**
- Open repair following EVAR of acute type B aortic dissection with genetically mediated aortic diseases.²⁻⁴

Non-Indications

Descending thoracic and abdominal aortic repair (OSR, EVAR/TEVAR, and hybrid repair) is NOT considered appropriate if **ANY** of the following is **TRUE**²⁻⁴:

- Aortic aneurysm size less than 3 cm (excluding saccular aneurysms), unless otherwise stated; **OR**
- Limited life expectancy; **OR**
- Prohibitive surgical risk.

Level of Care Criteria

Inpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33875	Descending thoracic aorta graft, with or without bypass
33877	Repair of thoracoabdominal aortic aneurysm with graft, with or without cardiopulmonary bypass
33880	Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin

33881	Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); not involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin
33883	Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); initial extension
33884	Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); each additional proximal extension (List separately in addition to code for primary procedure)
33886	Placement of distal extension prosthesis(s) delayed after endovascular repair of descending thoracic aorta
34701	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34702	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for rupture, including temporary aortic and/or iliac balloon occlusion, when

	performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34703	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac endograft, including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34704	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac endograft, including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34705	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-bi-iliac endograft, including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34706	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-bi-iliac endograft, including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta

	from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34830	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; tube prosthesis
34831	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; aorto-bi-iliac prosthesis
34832	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; aorto-bifemoral prosthesis
34841	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac, or renal artery)
34842	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34843	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated

	radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34844	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34845	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac, or renal artery)
34846	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34847	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation,

	including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34848	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])

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 **descending thoracic and abdominal aortic repair (OSR, EVAR/TEVAR, or hybrid repair)** may include:

- Adverse effects from delayed or denied treatment. Patients with aortic conditions require prompt risk stratification, individualized plan-of-care counseling, and treatment. This is particularly important as some aortopathies are characterized by rapid growth; aneurysmal size may become dangerously large in a relatively short period, conferring a higher risk of dissection, which may result in such complications as malperfusion syndrome and death.²
- Risks with inappropriate surgical procedures: Aortic repair is not a benign procedure and, if performed on a suboptimal patient, may confer serious complications. Risks include spinal cord ischemia, infection, bleeding, injury to neurovascular structures, death, anesthetic risk, and the need for repeat or additional procedures due to complications.²

The clinical benefits of using these criteria for **descending thoracic and abdominal aortic repair (OSR, EVAR/TEVAR, or hybrid repair)** may include:

- Improved patient selection resulting in better long-term outcomes. Patients with certain disease characteristics – including aneurysmal size and location, growth rate, disease etiology, and few comorbidities – are ideal for an endovascular approach. As a minimally invasive procedure, endovascular repair requires a shorter recovery time and is associated with fewer complications than traditional open surgery repair, which often requires substantial exposure of the abdominopelvic cavity, as well as lengthy operating times and the potential for cardiopulmonary bypass

support. Certain patients – younger patients, those with genetically driven aortic disease – are more appropriate for open surgical repair. Surgical repair of the aortic aneurysm may be definitive, effectively eliminating the long-term risk of aortic rupture and subsequent morbidity and mortality.^{2,3}

- Maintenance of rigorous patient safety standards aligned to best available evidence. Patients who undergo repair of a descending/abdominal aortic aneurysm of less than 3 centimeters have a low risk of rupture relative to the higher risk of sustaining complications during surgery (anesthetic complications, bleeding, infection, nerve damage, spinal cord injury, stroke, embolism), which does not usually outweigh the potential benefit of aortic repair. The same is true, more generally, of patients with a limited life expectancy or prohibitive surgical risk – the risk of surgery itself does not outweigh the benefit of aortic repair in these populations.^{2,3}
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Sharples et al. (2022) conducted a prospective study to evaluate the management and timing of intervention for patients with untreated thoracic aortic aneurysms. From 2014 to 2018, a prospective study was carried out on adult patients with new or existing arch or descending thoracic aortic aneurysms with a diameter of at least 4 centimeters. A total of 886 patients were enrolled and monitored until death, intervention, or withdrawal from the study. Various outcomes were evaluated, including aneurysm growth, survival, quality of life, and hospital admissions. Findings indicated that the maximum aneurysm diameter was predominantly in the descending aorta among 82% of patients, with an annual growth rate of 0.2 cm. Throughout the follow-up period, 129 patients died, with 64 deaths attributed to aneurysm-related events. After adjusting for age, sex, and New York Heart Association dyspnea index, the risk of death escalated with aneurysm size at baseline and with aneurysmal growth. Additionally, hospital admissions rose with aneurysm size. While quality of life decreased annually with age and current smoking, there was no association between aneurysm size and changes in quality of life. The study proposed that international guidelines contemplate extending monitoring intervals to 12 months for small aneurysms and raising intervention thresholds. Decisions regarding surveillance and intervention should be tailored, taking into consideration individual factors such as age, sex, size, growth, patient characteristics, and surgical risk.⁹

McCarthy et al. (2021) performed a systematic meta-analysis to assess and compare the efficacy of endovascular stent grafting (ESG) versus open surgical repair (OSR) in managing arch or descending thoracic aortic aneurysms (TAA). A comprehensive search of relevant studies compared ESG and OSR, encompassing randomized controlled trials (RCTs), quasi-randomized trials, and non-RCTs. Five comparative cohort studies were included, with a total of 3,955 ESG and 21,197 OSR patients. A comprehensive review of unadjusted short-term (30-day) all-cause mortality indicated a preference for ESG. Upon conducting sensitivity analysis on four studies focused solely on descending TAA, no statistical significance was found, although moderate heterogeneity persisted. When adjusted, the meta-analysis of short-term all-cause mortality favored ESG, with no observed heterogeneity. In longer-term follow-ups (beyond 30 days), survival

from all-cause mortality favored OSR in larger studies while favoring ESG in smaller ones. Additionally, freedom from reintervention in the longer term favored OSR. Studies reporting on short-term non-fatal complications suggested a lower incidence following ESG. The authors stressed the need for high-quality evidence alongside society guidelines, as available research is limited and increasingly outdated. They also noted the importance of individualized patient counseling, particularly for aortic disease of hereditary etiology, as these patients are recommended for OSR on current society guidelines.¹⁰

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Clinical Guideline Revision History/Information

Original Date: May 29, 2024		
Review History		
Version 2	6/11/2024	422.101 Disclaimer added
Version 3	6/26/2025	Annual policy review & restructuring. Simplified indications by removing redundant indications that were already captured elsewhere. Removed “infectious” qualifier for aortitis to allow approval for giant cell aortitis and Takayasu arteritis. Added visceral aneurysm criteria directly from professional society guidance. Added iliac artery criteria directly from professional society guidance. Literature review – description, medical evidence updated (including references).



Cohere Medicare Advantage Policy – Descending Thoracic and Abdominal Aortic Repair

Clinical Guidelines for Medical Necessity Review

Version: 3.1

Policy Number: CHP-129-3.1

Cohere Health UMC Approval Date: February 26, 2026

Last Annual Review: June 26, 2025

Revision: February 26, 2026

Next Annual Review: June 26, 2026

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy - Descending Thoracic and Abdominal Aortic Repair

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

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Medical Necessity Criteria

Service: Descending Thoracic and Abdominal Aortic Repair

Related CMS Documents

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

- There are no applicable NCDs and/or LCDs for descending and abdominal aortic aneurysm repair.
 - [Billing and Coding Article: Endovascular Repair of Aortic and/or Iliac Aneurysms \(A53124\)](#).

Description

The descending and abdominal aorta are the part of the aorta that travels downward from the aortic arch, passing through the belly and bifurcating into the iliac arteries in the pelvis. An aortic aneurysm occurs when the wall of the aorta becomes weakened and expands outward. Because the aorta is the largest artery in the body and is highly pressurized, the aneurysmal portion may rupture – or dissect – and cause serious, life-threatening sequelae, such as rapid blood loss or poor perfusion of extremities and vital organs that may result in death. To mitigate this risk, aortic aneurysms are often prophylactically repaired. Depending on the type of repair, the patient may or may not be placed on mechanical cardiopulmonary bypass during the operation in order to survive an extended interruption of blood flow to the vital organs while the surgeon is working on the aorta. In an open surgical repair (OSR), the surgeon directly visualizes and repairs/excises the aneurysm. Endovascular aortic repair (EVAR) is a minimally invasive method of repairing the aorta and is known as TEVAR (thoracic EVAR) when it occurs in the thoracic region. The surgeon accesses the aorta by placing a catheter in the groin and deploying a stent graft to the affected portion of the aorta. The stent graft self-expands to support the diseased aorta, prevent dissection, and restore blood flow. Hybrid repair may also be performed, involving a combination of both open and endovascular techniques. The surgeon is best positioned to choose the most appropriate treatment (OSR, EVAR/TEVAR, or

hybrid repair) for the patient based on their individual anatomic and clinical factors.²⁻⁵

Medical Necessity Criteria

Indications

Descending thoracic and abdominal aortic repair (OSR, EVAR/TEVAR, or hybrid repair) or endovascular arterial repair is considered appropriate if **ALL** of the following are **TRUE**:

- This is an FDA-approved device; **AND**
- **ANY** of the following:
 - **ANY** of the following pathologies, provided that the treating clinician deems the patient to be an appropriate candidate for repair:
 - Symptomatic or ruptured aneurysms²⁻⁴; **OR**
 - Pseudoaneurysms²⁻⁴; **OR**
 - Intramural hematomas²⁻⁴; **OR**
 - Penetrating ulcers²⁻⁴; **OR**
 - Abdominal aortic aneurysm (AAA), including **ANY** of the following²⁻⁴:
 - Asymptomatic fusiform abdominal aortic aneurysms (greater than 5.5 cm in males or greater than 5 cm in females); **OR**
 - All saccular aneurysms in patients with a reasonable life expectancy; **OR**
 - Aneurysm that expands by more than 1.0 cm within 12 months or by more than 0.5 cm in 6 months; **OR**
 - AAA with concomitant Iliac artery aneurysm of at least 3.5 cm, even if the AAA has not reached the above size threshold²; **OR**
 - Asymptomatic fusiform descending thoracic or thoracoabdominal aneurysms with **ANY** of the following²⁻⁴:
 - A fusiform aortic diameter greater than 5.5 cm; **OR**
 - A saccular aneurysm; **OR**
 - Any surgical risk at a diameter of 5.5 cm; **OR**
 - Patients who require chemotherapy, radiation therapy, or solid organ transplant, and who are deemed to be at low to moderate perioperative risk (with a reasonable life expectancy) with **ANY** of the following:
 - A fusiform aortic aneurysm measuring between 4 and 5.4 cm; **OR**
 - A saccular aneurysm; **OR**

- Documented rapid thoracic or thoracoabdominal expansion defined as **ANY** of the following:
 - Greater than or equal to 0.5 cm in 12 months; **OR**
 - Greater than or equal to 0.3 cm in 12 months for those with heritable thoracic aortic disease (including but not limited to Marfan Syndrome, Vascular Ehlers-Danlos Syndrome [VEDS], Loeys-Dietz Syndrome, or Turner Syndrome) or bicuspid aortic valve (BAV); **OR**
- Patients with genetically mediated aortic diseases or bicuspid aortic valves may be appropriate for repair at an aortic diameter of less than 5.5 cm (the specific threshold diameter depends on the underlying medical condition); **OR**
- Iliac artery aneurysm (IAA) with **ANY** of the following²⁻⁴:
 - Rapidly expanding IAA (at least 7 mm in six months or at least 1 cm in 12 months); **OR**
 - Asymptomatic IAA of at least 3.5 cm⁶⁻⁸; **OR**
- Visceral aneurysm with **ANY** of the following⁵:
 - Hepatic artery aneurysm with **ANY** of the following:
 - Size greater than 2 cm; **OR**
 - Growth of at least 0.5/cm within 12 months; **OR**
 - All pancreaticoduodenal and gastroduodenal artery aneurysms, regardless of size; **OR**
 - All superior mesenteric artery aneurysms, regardless of size; **OR**
 - Jejunal and ileal artery aneurysms that are at least 2 cm; **OR**
 - All gastric and gastroepiploic artery aneurysms, regardless of size; **OR**
 - All colic artery aneurysms, regardless of size; **OR**
 - Renal artery aneurysms with **ANY** of the following:
 - Size greater than 3 cm; **OR**
 - Aneurysms of all sizes for **ANY** of the following:
 - Women of childbearing age; **OR**
 - Patients with refractory hypertension and renal artery stenosis; **OR**
 - Celiac artery aneurysms with **ANY** of the following:
 - All pseudoaneurysms; **OR**
 - Size greater than 2 cm; **OR**
 - Splenic artery aneurysms with **ANY** of the following:
 - All pseudoaneurysms; **OR**

- Size greater than 3 cm; **OR**
- All sizes for women of childbearing age; **OR**
- Traumatic aortic disruptions, including **ANY** of the following:
 - Grade I: small intimal defect; observation versus repair; **OR**
 - Grade II: intramural hematoma; TEVAR within 24 hours; **OR**
 - Grade III: pseudoaneurysms; immediate TEVAR; **OR**
 - Grade IV: evidence of contained or frank aortic rupture; immediate TEVAR; **OR**
- Complications from a previous aortic repair²⁻⁴; **OR**
- Infected/mycotic aneurysm²⁻⁴; **OR**
- Aneurysm associated with aortitis²⁻⁴; **OR**
- Open repair following EVAR of acute type B aortic dissection with genetically mediated aortic diseases.²⁻⁴

Non-Indications

Descending thoracic and abdominal aortic repair (OSR, EVAR/TEVAR, and hybrid repair) is NOT considered appropriate if **ANY** of the following is **TRUE**²⁻⁴:

- Aortic aneurysm size less than 3 cm (excluding saccular aneurysms), unless otherwise stated; **OR**
- Limited life expectancy; **OR**
- Prohibitive surgical risk.

Level of Care Criteria

Inpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33875	Descending thoracic aorta graft, with or without bypass
33877	Repair of thoracoabdominal aortic aneurysm with graft, with or without cardiopulmonary bypass
33880	Endovascular repair of thoracic aorta, including pre-procedure sizing and device selection, nonselective catheterization(s), all associated radiological supervision and interpretation; by deployment of an aorto-aortic tube endograft covering the left subclavian artery and all aortic tube endograft extension(s) proximally in the aortic arch and ascending aorta and distally

	to the celiac artery, when performed
33881	Endovascular repair of thoracic aorta, including pre-procedure sizing and device selection, nonselective catheterization(s), all associated radiological supervision and interpretation; by deployment of an aorto-aortic tube endograft not involving coverage of the left subclavian artery origin and all endograft extension(s) placed from the level of the left subclavian carotid artery to the celiac artery
33882	Endovascular repair of the thoracic aorta by deployment of a branched endograft multipiece system involving an aorto-aortic tube device with a fenestration for the left subclavian artery stent graft(s) and all aortic tube endograft extension(s) placed from the level of the left common carotid artery to the celiac artery, including pre-procedure sizing and device selection, all target zone angioplasty, all nonselective catheterization(s) and left subclavian artery selective catheterization(s), and all associated radiological supervision and interpretation
33883	Delayed placement of proximal extension prosthesis(es) not involving coverage of the left subclavian artery origin, after endovascular repair of the thoracic aorta, including pre-procedure sizing and device selection, nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed
33886	Delayed placement of distal extension prosthesis(es) from the level of the left subclavian artery to the celiac artery, after endovascular repair of descending thoracic aorta, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation
34701	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the

	renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34702	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for rupture, including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34703	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac endograft, including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34704	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac endograft, including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34705	Endovascular repair of infrarenal aorta and/or iliac artery(ies)

	by deployment of an aorto-bi-iliac endograft, including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34706	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-bi-iliac endograft, including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34830	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; tube prosthesis
34831	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; aorto-bi-iliac prosthesis
34832	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; aorto-bifemoral prosthesis
34841	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac, or renal artery)

34842	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34843	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34844	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34845	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac, or renal artery)
34846	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic

	disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34847	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34848	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])

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 **descending thoracic and abdominal aortic repair (OSR, EVAR/TEVAR, or hybrid repair)** may include:

- Adverse effects from delayed or denied treatment. Patients with aortic conditions require prompt risk stratification, individualized plan-of-care counseling, and treatment. This is particularly important as some aortopathies are characterized by rapid growth; aneurysmal size may become dangerously large in a relatively short period, conferring a higher risk of dissection, which may result in such complications as malperfusion syndrome and death.²
- Risks with inappropriate surgical procedures: Aortic repair is not a benign procedure and, if performed on a suboptimal patient, may confer serious complications. Risks include spinal cord ischemia, infection, bleeding, injury to neurovascular structures, death, anesthetic risk, and the need for repeat or additional procedures due to complications.²

The clinical benefits of using these criteria for **descending thoracic and abdominal aortic repair (OSR, EVAR/TEVAR, or hybrid repair)** may include:

- Improved patient selection resulting in better long-term outcomes. Patients with certain disease characteristics – including aneurysmal size and location, growth rate, disease etiology, and few comorbidities – are ideal for an endovascular approach. As a minimally invasive procedure, endovascular repair requires a shorter recovery time and is associated with fewer complications than traditional open surgery repair, which often requires substantial exposure of the abdominopelvic cavity, as well as lengthy operating times and the potential for cardiopulmonary bypass

support. Certain patients – younger patients, those with genetically driven aortic disease – are more appropriate for open surgical repair. Surgical repair of the aortic aneurysm may be definitive, effectively eliminating the long-term risk of aortic rupture and subsequent morbidity and mortality.^{2,3}

- Maintenance of rigorous patient safety standards aligned to best available evidence. Patients who undergo repair of a descending/abdominal aortic aneurysm of less than 3 centimeters have a low risk of rupture relative to the higher risk of sustaining complications during surgery (anesthetic complications, bleeding, infection, nerve damage, spinal cord injury, stroke, embolism), which does not usually outweigh the potential benefit of aortic repair. The same is true, more generally, of patients with a limited life expectancy or prohibitive surgical risk – the risk of surgery itself does not outweigh the benefit of aortic repair in these populations.^{2,3}
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Sharples et al. (2022) conducted a prospective study to evaluate the management and timing of intervention for patients with untreated thoracic aortic aneurysms. From 2014 to 2018, a prospective study was carried out on adult patients with new or existing arch or descending thoracic aortic aneurysms with a diameter of at least 4 centimeters. A total of 886 patients were enrolled and monitored until death, intervention, or withdrawal from the study. Various outcomes were evaluated, including aneurysm growth, survival, quality of life, and hospital admissions. Findings indicated that the maximum aneurysm diameter was predominantly in the descending aorta among 82% of patients, with an annual growth rate of 0.2 cm. Throughout the follow-up period, 129 patients died, with 64 deaths attributed to aneurysm-related events. After adjusting for age, sex, and New York Heart Association dyspnea index, the risk of death escalated with aneurysm size at baseline and with aneurysmal growth. Additionally, hospital admissions rose with aneurysm size. While quality of life decreased annually with age and current smoking, there was no association between aneurysm size and changes in quality of life. The study proposed that international guidelines contemplate extending monitoring intervals to 12 months for small aneurysms and raising intervention thresholds. Decisions regarding surveillance and intervention should be tailored, taking into consideration individual factors such as age, sex, size, growth, patient characteristics, and surgical risk.⁹

McCarthy et al. (2021) performed a systematic meta-analysis to assess and compare the efficacy of endovascular stent grafting (ESG) versus open surgical repair (OSR) in managing arch or descending thoracic aortic aneurysms (TAA). A comprehensive search of relevant studies compared ESG and OSR, encompassing randomized controlled trials (RCTs), quasi-randomized trials, and non-RCTs. Five comparative cohort studies were included, with a total of 3,955 ESG and 21,197 OSR patients. A comprehensive review of unadjusted short-term (30-day) all-cause mortality indicated a preference for ESG. Upon conducting sensitivity analysis on four studies focused solely on descending TAA, no statistical significance was found, although moderate heterogeneity persisted. When adjusted, the meta-analysis of short-term all-cause mortality favored ESG, with no observed heterogeneity. In longer-term follow-ups (beyond 30 days), survival

from all-cause mortality favored OSR in larger studies while favoring ESG in smaller ones. Additionally, freedom from reintervention in the longer term favored OSR. Studies reporting on short-term non-fatal complications suggested a lower incidence following ESG. The authors stressed the need for high-quality evidence alongside society guidelines, as available research is limited and increasingly outdated. They also noted the importance of individualized patient counseling, particularly for aortic disease of hereditary etiology, as these patients are recommended for OSR on current society guidelines.¹⁰

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Clinical Guideline Revision History/Information

Original Date: May 29, 2024		
Review History		
Version 2	06/11/2024	422.101 Disclaimer added
Version 3	06/26/2025	Annual policy review & restructuring. Simplified indications by removing redundant indications that were already captured elsewhere. Removed “infectious” qualifier for aortitis to allow approval for giant cell aortitis and Takayasu arteritis. Added visceral aneurysm criteria directly from professional society guidance. Added iliac artery criteria directly from professional society guidance. Literature review – description, medical evidence updated (including references).
Version 3.1	02/26/2026	Revision. CPT code added: 33882. CPT code deleted per 1/1/2026 AMA code update: 33884. CPT code descriptions updated per 1/1/2026 AMA code update: 33880, 33881, 33883, 33886. No content changes.



Cohere Medicare Advantage Policy – Descending Thoracic and Abdominal Aortic Repair

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 - Descending Thoracic and Abdominal Aortic Repair

Date of last literature review: 6/11/2024

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

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Medical Necessity Criteria

Service: Descending Thoracic and Abdominal Aortic Repair

Benefit Category

Not applicable.

Recommended Clinical Approach

The surgeon is best positioned to choose the most appropriate treatment (OSR, EVAR/TEVAR, or hybrid repair) for the patient based on anatomic and clinical factors. EVAR/TEVAR is increasingly performed percutaneously, but there are clinical circumstances where surgical intervention is necessary to facilitate EVAR/TEVAR (e.g., a hybrid approach).

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 descending thoracic and abdominal aortic repair 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 aortic repair can lead to increased symptoms and complications, especially in patients with significant aortic aneurysms or dissections. The 2022 ACC/AHA guideline for the diagnosis and management of aortic disease highlights the importance of timely intervention to prevent adverse outcomes in patients with significant aortic conditions.³
- 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.

Swerdlow et al. highlight the importance of appropriate use criteria in managing aortic aneurysms to minimize surgical risks.²

- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. Proper use of aortic repair criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. The Society for Vascular Surgery practice guidelines underscore the importance of appropriate diagnostic and treatment procedures to prevent unnecessary healthcare utilization.⁴

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to descending thoracic and abdominal aortic repair 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. Isselbacher et al. noted the diagnostic accuracy of imaging and repair procedures in managing patients with aortic disease.³
- Enhanced diagnostic accuracy: This is crucial for complex vascular conditions where traditional diagnostic methods may pose additional risks. Advanced imaging and repair techniques offer the advantage of detailed vascular assessment, aiding in decision-making regarding interventions.¹
- Reduction in complications and adverse effects: Proper use of aortic repair criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. The ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS/SVU 2012 Appropriate Use Criteria for Peripheral Vascular Ultrasound emphasize the importance of accurate diagnostics in preventing complications.¹
- Enhanced overall patient satisfaction: Ensuring that aortic repair procedures are used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications. A 2007 Journal of Vascular Surgery article assessed the utility of comorbidity-based objective scoring systems for defining subgroups of patients who might most benefit from open or endovascular aneurysm repair.⁵

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

→ **Descending thoracic and abdominal aortic repair (OSR, EVAR/TEVAR, and hybrid repair)** is considered appropriate if **ANY** of the following is **TRUE**¹⁻³:

- ◆ All symptomatic or ruptured aortic aneurysms deemed by the treating clinician to be appropriate candidates for repair; **OR**
- ◆ Abdominal aortic aneurysm including ANY of the following:
 - Asymptomatic fusiform abdominal aortic aneurysms greater than 5.5 cm in males (or greater than 5 cm in females) and all saccular aneurysms in patients with a reasonable life expectancy⁴; **OR**
 - Aneurysm that expands by more than 1.0 cm in diameter within 12 months or by more than 0.5 cm over 6 months; **OR**
- ◆ Asymptomatic fusiform descending thoracic or thoracoabdominal aneurysms with **ANY** of the following:
 - A fusiform aortic diameter greater than 5.5 cm; **OR**
 - A saccular aneurysm; **OR**
 - Any surgical risk at a diameter of 5.5 or a saccular aneurysm⁵; **OR**
 - Patients who require chemotherapy, radiation therapy, or solid organ transplant and who are deemed to be at low to moderate perioperative risk with a reasonable life expectancy with **ANY** of the following:
 - A fusiform aortic aneurysm measuring between 4 and 5.4 cm; **OR**
 - A saccular aneurysm); **OR**
 - Documented rapid thoracic or thoraco-abdominal expansion defined as **ANY** of the following⁶⁻⁷:

- Greater than or equal to 0.5 cm in one year; **OR**
- Greater than or equal to 0.3 cm in 1 year for those with heritable thoracic aortic disease or bicuspid aortic valve (the specific growth criteria depends on the underlying medical condition); **OR**
- Patients with genetically mediated aortic diseases or bicuspid aortic valves may be appropriate for repair at an aortic diameter of less than 5.5 cm (the specific threshold diameter depends on the underlying medical condition)¹⁻²; **OR**
- ◆ All pseudoaneurysms deemed by the treating clinician to be appropriate candidates for repair; **OR**
- ◆ All penetrating ulcers or intramural hematomas deemed by the treating clinician to be appropriate candidates for repair; **OR**
- ◆ Traumatic aortic disruptions, including **ANY** of the following:
 - Grade I: small intimal defect; observation v repair; **OR**
 - Grade II: intramural hematoma; TEVAR within 24 hours; **OR**
 - Grade III: pseudoaneurysms; immediate TEVAR; **OR**
 - Grade IV: evidence of contained or frank aortic rupture; immediate TEVAR; **OR**
- ◆ Complications from a previous repair; **OR**
- ◆ Infected aneurysm (mycotic) or aneurysm associated with infectious aortitis; **OR**
- ◆ Descending thoracic aortic dissection as indicated by **ANY** of the following:
 - Rupture; **OR**
 - Branch artery occlusion; **OR**
 - Reduced perfusion causing impending organ failure; **OR**
 - Extension of dissection; **OR**
 - Progressive aortic enlargement; **OR**
 - Intractable hypertension; **OR**
 - Persistent pain despite conservative, nonoperative treatment; **OR**
 - Subacute (14 to 90 days) dissection with an aortic diameter greater than 40 mm; **OR**
 - Chronic dissection (greater than 90 days) including **ANY** of the following:
 - Aortic diameter greater than 55 mm; **OR**
 - Increase in diameter of more than 10 mm per year; **OR**
 - Open repair following TEVAR of acute type B aortic dissection with connective tissue disease.

Non-Indications

→ **Descending thoracic and abdominal aortic repair (OSR, EVAR/TEVAR, and hybrid repair)** is **NOT** considered appropriate if **ANY** of the following is **TRUE**:

- ◆ There are no published non-indications.

Level of Care Criteria

Inpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33875	Descending thoracic aorta graft, with or without bypass
33877	Repair of thoracoabdominal aortic aneurysm with graft, with or without cardiopulmonary bypass
33880	Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin
33881	Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); not involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin
33883	Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); initial extension

33884	Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); each additional proximal extension (List separately in addition to code for primary procedure)
33886	Placement of distal extension prosthesis(s) delayed after endovascular repair of descending thoracic aorta
34701	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34702	Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for rupture, including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34703	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac endograft, including pre-procedure sizing and device

	selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34704	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac endograft, including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34705	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-bi-iliac endograft, including pre-procedure sizing and device selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
34706	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-bi-iliac endograft, including pre-procedure sizing and device

	selection, all non selective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
34830	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; tube prosthesis
34831	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; aorto-bi-iliac prosthesis
34832	Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; aorto-bifemoral prosthesis
34841	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac, or renal artery)
34842	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision

	and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprotheses (superior mesenteric, celiac and/or renal artery[s])
34843	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprotheses (superior mesenteric, celiac and/or renal artery[s])
34844	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprotheses (superior mesenteric, celiac and/or renal artery[s])
34845	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac, or renal artery)
34846	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral

	aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34847	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34848	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])

Medical Evidence

Sharples et al. (2022) conducted a prospective study to evaluate the management and timing of intervention concerning patients afflicted with untreated thoracic aortic aneurysms. From 2014 to 2018, a prospective study was carried out on patients aged greater than or equal to 18 years who had either new or existing arch or descending thoracic aortic aneurysms with a diameter of greater than or equal to 4 cm. A total of 886 patients were enrolled and monitored until death, intervention, or withdrawal from the study. Various outcomes were evaluated, including aneurysm growth, survival, quality of life assessed using the EQ-5D-5L utility index, and hospital admissions. Findings indicated that the maximum aneurysm diameter was predominantly in the descending aorta among 82% of patients, with an annual growth rate of 0.2 cm. Aneurysms greater than or equal to 4 cm in the arch increased by 0.07 cm annually. Baseline diameter correlated with age and comorbidities, and no clinical growth correlates were identified. Throughout the follow-up period, 129 patients passed away, with 64 deaths attributed to aneurysm-related events. After adjusting for age, sex, and New York Heart Association dyspnea index, the risk of death escalated with aneurysm size at baseline and with growth. Additionally, hospital admissions rose with aneurysm size. While quality of life decreased annually with age and current smoking, there was no association between aneurysm size and changes in quality of life. The study proposes that international guidelines contemplate extending monitoring intervals to 12 months for small aneurysms and raising intervention thresholds. Decisions regarding surveillance and intervention should be tailored, considering factors such as age, sex, size, growth, patient characteristics, and surgical risk.⁷

McCarthy et al. (2021) performed a systematic meta-analysis to assess and compare the efficacy of endovascular stent grafting (ESG) vs open surgical repair (OSR) in managing chronic arch or descending thoracic aortic aneurysms (TAA). A comprehensive search was conducted of relevant studies comparing ESG and OSR, encompassing various study designs such as randomized controlled trials (RCTs), quasi-randomized trials, and non-RCTs. Comparative cohort studies and case-control studies that were matched based on key outcomes were also included. A total of five comparative cohort studies were included with a total of 3955 ESG and 21,197 OSR patients. A comprehensive review of unadjusted short-term (30-day) all-cause mortality indicates a preference for ESG. However, there is notable heterogeneity observed between larger and smaller studies. Upon conducting sensitivity analysis on four studies focusing solely on descending TAA, no statistical significance was found, although moderate heterogeneity persisted. When adjusted for, the meta-analysis of short-term all-cause

mortality favored ESG, with no observed heterogeneity. In longer-term follow-ups (beyond 30 days), survival from all-cause mortality favored OSR in larger studies while favoring ESG in smaller ones. Additionally, freedom from reintervention in the longer term favored OSR. Studies reporting on short-term non-fatal complications suggest a lower incidence following ESG. The authors stress the need for high-quality evidence as available research is limited and increasingly outdated that compares ESG and OSR in managing elective arch and/or aneurysms of the descending TAA.⁹

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Clinical Guideline Revision History/Information

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Review History		
Version 2	6/11/2024	422.101 Disclaimer added



Cohere Medicare Advantage Policy – Electrophysiological Study (EPS)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: March 20, 2025

Important Notices

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Guideline Information:

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

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Medical Necessity Criteria

Service: Electrophysiological Study (EPS)

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 applicable NCDs and/or LCDs for electrophysiological study (EPS).

Recommended Clinical Approach

An electrophysiology study (EPS) is a procedure used to evaluate the electrical activity within the heart. It involves inserting catheters into the heart to measure electrical signals and to diagnose and treat various cardiac arrhythmias (abnormal heart rhythms).

EPS for the evaluation of manifest high-grade atrioventricular (AV) block is recommended when conduction disease is suspected and non-invasive testing does not reveal the location of the AV block. EPS can identify infranodal conduction disease, which can determine if a patient requires permanent pacing.¹ While EPS can be used to evaluate AV nodal function, the study is typically part of a comprehensive EPS for other arrhythmias, especially when symptoms suggest ventricular arrhythmias.

There is no specific indication for EPS to evaluate sinus node dysfunction. However, EPS may be considered when conduction disease is suspected and when non-invasive testing does not reveal an AV block.¹ While there are maneuvers during an EPS that can evaluate sinus node recovery, the study is typically part of a comprehensive EPS for other arrhythmias. This includes atrial fibrillation (AF) or flutter, which can be associated with sinus node dysfunction in tachy-brady syndrome.

Catheter ablation is an acceptable first-line therapy for the treatment of supraventricular tachycardia (SVT). It can be used prior to medication due to its high success and low complication rate. Depending on location, the arrhythmia substrate can be approached using radiofrequency or cryothermal energy. Cryoablation has dramatically reduced the probability of inadvertent AV block during ablation procedures.² EPS describes the diagnostic studies performed to evaluate the cardiac electrical system, usually prior to catheter ablation during the same procedure. Occasionally, diagnostic EPS is used to assess the risk for life-threatening arrhythmias, especially in the decision-making process for an implantable cardioverter defibrillator (ICD) implant.³

EPS for the syncope evaluation depends on the presence of another cardiac disease.⁴ In the absence of known cardiac disease, the diagnostic yield of EPS was approximately 10% in patients without; the yield was 50% in patients with structural heart disease.⁵ EPS is recommended if clinical arrhythmias are detected during ambulatory monitoring and could benefit from interventions such as ICD implantation, ablation, or permanent pacemaker insertion. Furthermore, EPS may be warranted if conduction abnormalities are suspected, particularly if non-invasive testing fails to identify an AV block.¹ Particular techniques employed during an EPS can assess the recovery of the sinus node. These maneuvers are commonly integrated into a thorough EPS designed to address arrhythmias like AF or flutter, which may correlate with sinus node dysfunction in tachy-brady syndrome. EPS may be indicated when a patient presents with syncope and displays a Brugada pattern on ECG; however, the findings are controversial.

EPS is utilized for patients with congenital heart disease, including preoperative screening for an Ebstein's anomaly to determine the presence of accessory pathways and those with Tetralogy of Fallot (TOF) for inducible ventricular arrhythmias. Some procedures may lead to ablation of the arrhythmogenic substrate (or cause of the arrhythmia) or lead to a decision to implant a defibrillator, especially when hemodynamic risk factors are present that could increase the risk of sudden cardiac death.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 electrophysiological 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:

- Procedure-related complications. Horowitz et al (1987) conducted a prospective analysis of 1000 consecutive patients who underwent EPS. While a low rate overall, complications may include thrombophlebitis, arterial injury, pulmonary embolism, cardiac perforation, and systemic arterial embolism. In addition, one death was reported. Cardioversion for sustained ventricular tachycardia was also reported.⁷
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Low complication rate. Al-Khatib et al (2016) cite a low risk of complications in a registry study of 2169 patients (0.09% to 1%). This included pneumothorax and access site complications.⁸
- Risk stratification. There is the benefit of EPS for patients with asymptomatic pre-excitation. In addition, patients who are considered high-risk for future arrhythmias may benefit from accessory-pathway ablation.⁸
- To evaluate conduction disorders. EPS is beneficial for the diagnosis of a conduction order as well as for determining cardiac device implantation indications and utilization of catheter ablation procedures.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

→ An **electrophysiological study (EPS)** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Symptomatic or significant bradycardia (sinus node dysfunction, atrioventricular [AV] block, etc.) with inconclusive 30 days of non-invasive evaluation(s) (e.g., extended ECG monitoring, stress testing)¹; **OR**
- ◆ Focal atrial tachycardia, which is the likely etiology of new cardiomyopathy; **OR**
- ◆ Supraventricular tachycardia (SVT) with **ANY** of the following:
 - The patient has Ebstein anomaly (with or without pre-excitation or SVT) and no prior surgical intervention on the tricuspid valve^{6,10}; **OR**
 - The patient has symptomatic or sustained SVT¹¹; **OR**
- ◆ For risk stratification of Brugada Syndrome with spontaneous or induced type 1 ECG pattern¹²; **OR**
- ◆ Wolff-Parkinson-White (WPW) pattern with syncope and **ANY** of the following related to ventricular pre-excitation¹³:
 - The patient's employment would be impacted (e.g., pilots, military service)⁹; **OR**
 - The patient is asymptomatic and EPS is needed to determine **ANY** of the following:
 - Inducibility of atrioventricular reentrant tachycardia (AVRT); **OR**
 - The rapidity of antegrade conduction is a risk factor for sudden cardiac arrest; **OR**

- ◆ **ANY** of the following related to syncope:
 - Evaluation following myocardial infarction if 30 days of non-invasive monitoring is unrevealing; **OR**
 - Unexplained syncope with 30 days of inconclusive non-invasive evaluation(s) (e.g., extended ECG monitoring, stress testing) with **ANY** of the following¹⁴:
 - Asymptomatic sinus node dysfunction is suspected; **OR**
 - Bifascicular block suspected¹⁵; **OR**
 - Ventricular arrhythmia suspected; **OR**
- ◆ Congenital heart disease (CHD) with **ANY** of the following:
 - Complex CHD with non-sustained ventricular tachycardia³; **OR**
 - Complex CHD with unexplained syncope³; **OR**
 - **ALL** of the following:
 - All evaluations were inconclusive, including comprehensive ECG monitoring and stress testing; **AND**
 - **ANY** of the following symptoms of significant rhythm abnormalities:
 - ◆ Palpitations; **OR**
 - ◆ Shortness of breath; **OR**
 - ◆ Syncope; **OR**
- ◆ Ischemic cardiomyopathy with **ALL** of the following¹⁶:
 - Ejection fraction (EF) greater than 35% **AND**
 - Non-sustained ventricular tachycardia (NSVT) to determine inducibility of sustained VT or ventricular fibrillation.

Non-Indications

- An **electrophysiological study (EPS)** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Non-sustained, asymptomatic supraventricular tachycardia; **OR**
 - ◆ Risk assessment for an implantable cardioverter defibrillator (ICD) indication and the patient has heart failure with an ejection fraction (EF) less than or equal to 35%¹; **OR**
 - ◆ Any clinical scenario or documented arrhythmia that is a class I or class II indication for pacemaker or ICD implantation.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93600	Bundle of His recording
93602	Intra-atrial recording
93603	Right ventricular recording
93610	Intra-atrial pacing
93612	Intraventricular pacing
93618	Induction of arrhythmia by electrical pacing
93619	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, with right atrial pacing and recording, right ventricular pacing and recording, and His bundle recording
93620	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, with attempted induction of arrhythmia, with right atrial pacing and recording, right ventricular pacing and recording, and His bundle recording
93623	Programmed stimulation and pacing after intravenous drug infusion (List separately in addition to code for primary procedure)
93624	Electrophysiologic follow-up study with pacing and recording to test effectiveness of therapy with attempted induction of arrhythmia
93631	Intra-operative epicardial and endocardial pacing and mapping to localize the site of tachycardia or zone of slow conduction for surgical correction
93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode

	catheters, with attempted induction of arrhythmia, with right atrial pacing and recording, with treatment of supraventricular tachycardia by ablation
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, with attempted induction of arrhythmia, with right atrial pacing and recording, with focus of ventricular ectopy
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia
93662	Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation
93462	Left heart catheterization by transseptal puncture through intact septum or by transapical puncture

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

Medical Evidence

Waldmann et al (2023) conducted a prospective multicenter study to systematically evaluate electrophysiological studies (EPS) using programmed ventricular stimulation in tetralogy of Fallot (TOF) patients undergoing assessment for PVR between January 2020 and December 2021. A uniform stimulation protocol was implemented across all participating centers. A cohort included 120 patients (mean age of 39.2 ± 14.5 years; 53.3% males). Sustained ventricular tachycardia (SVT) was induced in 27 (22.5%) patients. The critical isthmus most frequently implicated (90.0%) was identified between the ventricular septal defect patch and pulmonary annulus. Factors independently associated with inducible ventricular tachycardia included a history of atrial arrhythmia and pulmonary annulus diameter greater than 26 mm. EPS findings prompted significant management alterations in 23 (19.2%) cases, including catheter ablation (CA) in 18 (15.0%), surgical cryoablation during pulmonary valve replacement (PVR) in 3 (2.5%), and defibrillator implantation in 9 (7.5%) cases. During a follow-up period of 13 (6.1–20.1) months, no patients experienced sustained ventricular arrhythmias. The authors conclude that the systematic performance of programmed ventricular stimulation in TOF patients undergoing evaluation for PVR reveals a notable rate of inducible ventricular tachycardia and holds the potential to influence treatment strategies. Further research is warranted to ascertain whether adopting a standardized treatment approach based on EPS outcomes will translate into improved clinical outcomes. (ClinicalTrials.gov identifier: NCT04205461).¹⁸

Oliveira et al (2023) performed a retrospective study to identify predictors associated with the lack of referral for CA as the initial treatment option in SVT patients. Various clinical and demographic factors were treated as independent variables, while non-referral for CA as the primary treatment was considered the dependent variable in a stepwise logistic regression analysis. Out of 350 patients, 20 clinical-demographic variables were examined, with 10 initially included in the logistic regression analysis: age, gender, presence of pre-excitation on ECG, palpitations, dyspnea, chest discomfort, number of antiarrhythmic drugs prior to ablation, number of concomitant symptoms, duration of symptoms, and emergency room visits due to SVT. Following multivariable-adjusted analysis, age, chest discomfort during SVT, and the number of antiarrhythmic drugs administered before

ablation emerged as independent predictors positively associated with the lack of referral for CA as the first-line treatment for SVT. Overall, the study suggests that certain independent predictors contribute to the underutilization of catheter ablation as the initial treatment option for SVT.¹⁹

Adhaduk et al (2022) conducted a meta-analysis and systematic review of 52 articles and 8 studies to evaluate the role of electrophysiology study in risk stratification of patients with cardiac sarcoidosis (CS). The studies included 298 patients – most studies did not include patients with coronary artery disease (CAD). Use of immunosuppression ranged from 35.8–88%; the mean left ventricle ejection fraction (LVEF) was 34–66.3%. Limitations of the analysis included heterogeneity due to differing diagnostic criteria for CS, including patients with VT. Also, some studies did not include patients with systolic heart failure. The authors concluded that the high sensitivity and specificity of EPS make it a valuable risk stratification tool for patients with CS.²⁰

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Review History		



Cohere Medicare Advantage Policy – External Cardiac Monitoring Devices

Clinical Policy for Medical Necessity Review

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Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy - External Cardiac Monitoring Devices

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

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Medical Necessity Criteria

Service: External Cardiac Monitoring Devices

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻¹¹

- [National Coverage Determination \(NCD\). Electrocardiographic services \(20.15\)](#)
- [Local Coverage Determination \(LCD\). Cardiac event detection \(L33952\)](#)
 - [Billing and Coding: Cardiac event detection \(A56452\)](#)
- [Local Coverage Determination \(LCD\). Cardiac event detection \(L34573\)](#)
 - [Billing and Coding: Cardiac event detection \(A56606\)](#)
- [Local Coverage Determination \(LCD\). Electrocardiographic \(EKG or ECG\) monitoring \(Holter or real-time monitoring\) \(L34636\)](#)
 - [Billing and Coding: Electrocardiographic \(EKG or ECG\) monitoring \(Holter or real-time monitoring\) \(A57476\)](#)
- [Local Coverage Determination \(LCD\). Ambulatory electrocardiograph \(AECG\) monitoring \(L39490\)](#)
 - [Billing and Coding: Ambulatory electrocardiograph \(AECG\) monitoring \(A59268\)](#)
- [Local Coverage Determination \(LCD\). Ambulatory electrocardiograph \(AECG\) monitoring \(L39492\)](#)
 - [Billing and Coding: Ambulatory electrocardiograph \(AECG\) monitoring \(A59270\)](#)

Description

An external cardiac monitoring device is a portable device that detects and records cardiac activity while the patient is engaged in ordinary daily activities outside of a medical setting.¹² These devices are used to detect and identify cardiac abnormalities that may not be detected on a standard in-clinic electrocardiogram (ECG/EKG). For example, irregular, transient, or setting-specific anomalies. Modern devices typically consist of three components: the wearable sensor or electrode that collects cardiac data, the communication interface (monitor or smartphone application), and an analytics platform that stores and analyzes the data.¹³ The first of these devices to be developed was the Holter monitor, which continuously monitors cardiac activity for up to 48 hours. Newer devices, including patch-based single-lead and multi-lead ECG systems, extended-duration continuous monitors, and mobile cardiac telemetry, can monitor cardiac activity for longer periods. Continuous monitors record continuously throughout the monitoring period, while event-triggered monitors only capture data when triggered by a cardiac event or by the patient.¹⁴

Medical Necessity Criteria

Indications

An **external cardiac monitoring device** is considered appropriate if **ALL** of the following are **TRUE**:

- **ALL** of the following^{15,16}:
 - Statement from a provider specifying the requested monitor type and explanation of its appropriateness; **AND**
 - A standard 12-lead electrocardiograph (ECG), complete cardiac history, and cardiac exam have not satisfactorily explained the patient's cardiac symptoms^{8,10}; **AND**
 - Testing will provide diagnostic information that will assist in developing or changing a treatment plan for a patient at risk for or with known cardiac arrhythmias^{8,10}; **AND**
- For **ANY** of the following device types:
 - For external 48-hour ECG recording (Holter monitor; CPT codes 93224 - 93227), **ANY** of the following⁶:
 - **ANY** of the following symptoms experienced one or more times per 48 hours^{6,12}:

- Arrhythmias; **OR**
- Chest pain; **OR**
- Syncope/presyncope (lightheadedness or fainting); **OR**
- Vertigo (dizziness); **OR**
- Palpitations; **OR**
- Transient ischemic episodes; **OR**
- Dyspnea (shortness of breath); **OR**
- Palpitations^{8,10}; **OR**
- Heart failure symptoms^{17,18}; **OR**
- Confusional state thought to be related to cerebral hypoperfusion¹⁸; **OR**
- Evaluation of the response to antiarrhythmic drug therapy⁶; **OR**
- Evaluation of myocardial infarction (MI) survivors with an ejection fraction of 40% or less⁶; **OR**
- Assessment of a patient with coronary artery disease with active symptoms, to correlate chest pain with ST-segment changes⁶; **OR**
- Other acute and subacute forms of ischemic heart disease⁶; **OR**
- To assess for silent myocardial ischemia in a patient with known or suspected coronary heart disease^{8,10}; **OR**
- To detect arrhythmias post-ablation procedures⁶; **OR**
- Pre- or post-implantable cardiac defibrillator reprogramming^{8,10}; **OR**
- To assess for asymptomatic ventricular premature beats or non-sustained ventricular tachycardia in a patient with **ANY** of the following^{8,10}:
 - Hypertrophic cardiomyopathy; **OR**
 - Long QT syndrome; **OR**
 - Dilated or restrictive cardiomyopathy; **OR**
 - Congenital heart disease; **OR**
 - Brugada syndrome; **OR**
 - Arrhythmogenic right ventricular cardiomyopathy; **OR**
- External electrocardiographic recording for greater than 48 hours and up to 15 days by continuous rhythm recording and storage to monitor for asymptomatic episodes in order to evaluate treatment response (extended-wear patch and long-term continuous monitors; CPT codes 93241 – 93248)⁶; **OR**

- External electrocardiographic event monitors for greater than 48 hours and up to 15 days that are either patient-activated or auto-activated (as an alternative to Holter monitoring; CPT codes 93268, 93270 – 93272) in a patient with **ALL** of the following⁶:
 - Infrequent symptoms (less than every 48 hours); **AND**
 - Symptoms are suggestive of cardiac arrhythmias (e.g., palpitations, dizziness, presyncope, syncope); **OR**
- Long-term (up to 30-day) monitoring with 24-hour attended surveillance (MCOT; CPT codes 93228 – 93229) with **ALL** of the following⁶:
 - Symptoms are occurring less often than every 24 to 48 hours (For a patient experiencing frequent symptoms within a 24 to 48 hour timeframe, monitors such as Holters are appropriate); **AND**
 - **ANY** of the following:
 - Arrhythmias; **OR**
 - Chest pain; **OR**
 - Syncope/presyncope (lightheadedness or fainting); **OR**
 - Vertigo (dizziness); **OR**
 - Palpitations; **OR**
 - Transient ischemic episodes; **OR**
 - Dyspnea (shortness of breath); **OR**
 - To initiate, revise, or discontinue arrhythmia drug therapy; **OR**
 - Evaluation of acute and subacute forms of ischemic heart disease; **OR**
 - Assessment of a patient with coronary artery disease with active symptoms, to correlate chest pain with ST-segment changes.

Non-Indications

An **external cardiac monitoring device** is not considered appropriate if **ANY** of the following is **TRUE**^{2,4}:

- Little or no potential for new clinical data beyond what has been obtained from a previous test (e.g., a standard ECG has already established a diagnosis); **OR**
- Other tests are better suited to obtain clinical data relevant to the patient's condition; **OR**
- Routine daily transmission of ECG rhythm strips; **OR**

- Monitoring in the absence of identified symptoms necessitating diagnosis; **OR**
- Testing beyond 30 consecutive days without a justification from the treating physician (failure to document arrhythmia during a 30-day test period is not sufficient justification for a subsequent test); **OR**
- A repeated test within a year in the absence of new or recurrent undiagnosed symptoms; **OR**
- An event recorder in a patient who is unresponsive, comatose, severely confused, or otherwise unable to recognize symptoms or activate the recorder (patient-activated devices) or unable to participate in the use of the device; **OR**
- Routine use of continued monitoring in the absence of treatable symptoms; **OR**
- The patient does not have exclusive use of a recorder for the entire service period; **OR**
- A cardiac event detection billed within 30 days of a previous test, even if the earlier test was discontinued when an arrhythmia was documented, and the patient is now reconnected for follow-up of therapy or intervention; **OR**
- An event recorder for outpatient monitoring of a recently discharged post-infarct patient; **OR**
- Cardiac event detection in **ANY** of the following facilities:
 - Hospital (including emergency room); **OR**
 - Skilled nursing facility; **OR**
 - Other specialized facility; **OR**
 - Outpatient or facility-based cardiac monitoring; **OR**
- Symptoms are suggestive of angina or clinically significant coronary artery obstruction and monitoring would delay other needed testing or intervention^{19,20}; **OR**
- The patient requires acute treatment for an arrhythmia²¹; **OR**
- The request is for mobile cardiac telemetry (MCT) and **ANY** of the following¹²:
 - Within six months of a previous MCT; **OR**
 - Symptoms of undetermined origin occurring daily (or near daily).

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93224	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional
93225	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)
93226	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report
93227	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified health care professional
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation

93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation
93268	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; includes transmission, review and interpretation by a physician or other qualified health care professional
93270	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)
93271	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis

93272	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; review and interpretation by a physician or other qualified health care professional
93228	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional
93229	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care 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.

The potential clinical harms of using these criteria for external cardiac monitoring devices may include:

- Adverse effects from delayed identification of cardiac abnormalities and delayed diagnosis. A randomized controlled trial (RCT) of 2659 patients at high-risk for atrial fibrillation compared patients monitored with a home-based wearable ECG sensor patch to non-monitored controls. After four months, atrial fibrillation was detected in 3.9% of monitored patients and only 0.9% of unmonitored patients.²² Monitored patients were also more likely to access cardiology care with more anticoagulant medication initiations, and more cardiology and primary care visits. A different study reported that in patients over the age of 75 years and at high-risk for atrial fibrillation, 5.3% were diagnosed with atrial fibrillation after monitoring.²³

The clinical benefits of using these criteria for external cardiac monitoring devices may include:

- Improved patient selection for external cardiac monitoring devices, resulting in better long-term outcomes. An ideal candidate should have a clinical concern for a cardiac electrical abnormality that cannot be adequately diagnosed or characterized with a conventional in-office ECG. In a study of patients over the age of 60 years with acute ischemic stroke but no atrial fibrillation on conventional ECG, atrial fibrillation was documented in 13.5% of patients monitored for a total of 30 days.²⁴
- Maintenance of rigorous patient safety standards aligned to best available evidence. Overdiagnosis of low-risk patients may lead to overtreatment

with anticoagulant medication that may increase bleeding risk without providing any benefit.^{[23](#)}

- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

In a scientific report, Kim et al. (2025) compared the diagnostic efficacy of a 72-hour ECG patch monitor with that of a conventional 24-hour Holter monitor in 47 patients with suspected cardiogenic vertigo. They reported no differences in the detection of arrhythmia events with the 72-hour patch monitor detecting 10 of 47 events compared to 8 of 47 events for the 24-hour Holter monitor. Patients reported a preference for the patch monitor, suggesting that patient compliance may be higher with this class of devices.^{[25](#)}

Reynolds et al. (2024) evaluated arrhythmia encounter diagnosis at 3 months, repeat ambulatory cardiac monitor testing at 6 months, all-cause 90-day emergency department and inpatient utilization, and the cost of five types of ambulatory cardiac monitoring devices using Medicare claims data from 2017–2018. Their final analysis, consisting of data from 287,789 patients, revealed that the Zio XT 14-day patch long-term continuous monitor had the highest odds of diagnosis and the lowest odds of retesting. They also reported that, across all monitor types, a new arrhythmia diagnosis was observed in approximately 40% of cases. Moreover, retesting was common, occurring in approximately 30% of cases. The authors concluded that long-term continuous monitoring may be preferable for many patients, with the exception of those experiencing symptoms frequently, for whom a Holter monitor may be sufficient. Patients with potentially high-risk conditions, including syncope or suspected conduction abnormalities, may prefer monitoring by real-time mobile cardiac telemetry (MCT).^{[26](#)}

Feuerborn et al. (2024) reported no differences in median time to ablation, median days to new cardiac implantable electronic device implantation, initiation of anticoagulation, or time to first emergency department visit or hospitalization between patients monitored with real-time event notification versus Holter devices in their cohort of 20,259 patients. The authors concluded that the widespread use of real-time notification devices may not be warranted due to the increased burdens associated with data management, analysis, and interpretation required for real-time event notification monitoring. For example, the authors stated that while there is a clear benefit

to real-time monitoring in a patient with a paroxysmal atrioventricular block, a 2- to 4-week delay may not be impactful for a patient under consideration for anticoagulation medication for atrial fibrillation.²⁷

The 2025 Japanese Heart Rhythm Society/Japanese Circulation Society consensus statement on the appropriate use of ambulatory and wearable electrocardiographs reviewed wearable ambulatory external electrocardiographs.¹⁴ The document first reviewed lead-based, patch, garment-based, and handheld devices, as well as the storage and security of the data recorded by these devices. The consensus document compared these non-invasive external devices to internal loop recorders (ILRs), which are ECG devices that are implanted subcutaneously on the anterior chest. It noted that external recording devices cannot completely replace ILRs for patients with syncope or silent cerebral infarction, citing a study that found significantly higher diagnosis of unexplained loss of consciousness in patients monitored for one year with an ILR compared to patients monitored with external recorders. However, the document also noted that external devices may have utility in patients reluctant to consent to the more invasive ILRs, suggesting a strategy of initially using an external device for these patients, pivoting to an ILR if no diagnosis is achieved within a few weeks.

In the 2024 American College of Cardiology (ACC) expert decision pathway on practical approaches for arrhythmia monitoring after stroke, Spooner et al. presented a three-step pathway for monitoring patients after a stroke. The final step involved selecting a monitoring strategy that optimizes accuracy, practicality, and minimizes barriers to care and follow-up. In adult patients with stroke of presumed cardiac origin who require anticoagulation, the consensus document recommended monitoring only when arrhythmia detection will influence treatment decisions, for example, if stopping coagulation medications is being considered. In patients with ischemic stroke presumed to be due to small- or large-vessel disease, monitoring was recommended for 2 – 4 weeks. In patients with embolic stroke of undetermined source who are candidates for long-term anticoagulation if atrial fibrillation is identified, monitoring for 2 – 4 weeks was recommended.²⁸

In the 2024 Heart Rhythm Society expert consensus statement on arrhythmias in the athlete, Lampert et al. noted that ambulatory ECG monitoring is

beneficial in athletes with unexplained syncope or when arrhythmic syncope is suspected. Specific recommendations included: wire-based Holter monitors when symptoms are frequent (daily); external loop/event monitors when symptoms are less frequent (weekly to monthly); patch continuous monitors when symptoms occur daily, near daily, or weekly; ILRs when symptoms potentially leading to syncope are very infrequent (monthly to yearly); mobile cardiac telemetry when palpitations occur weekly to monthly; and commercially available wearables including fitness trackers when palpitations last long enough to manually record.^{[29](#)}

Joglar et al. (2023) discussed the guidelines for the diagnosis and management of atrial fibrillation by the American College of Cardiology (ACC), American Heart Association (AHA), American College of Clinical Pharmacy (ACCP), and the Heart Rhythm Society (HRS). Key clinical trials were also included. The EMBRACE (30-day Event Monitoring Belt for Recording Atrial Fibrillation After a Cerebral Ischemic Event) trial included 572 randomized patients aged 55 years or older who had a recent transient ischemic attack (TIA) or cryptogenic stroke. The patients were randomized and received either a 30-day external loop recorder (ELR) or conventional 24-hour Holter monitoring. At 90-day follow-up, detection of atrial fibrillation (AF) was higher with extended monitoring.^{[30](#)}

Kusumoto et al. (2019) cited support from the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society (HRS) for the use of external wearable devices for temporary pacing scenarios. These guidelines covered short-term cardiac pacing support during surgery or in the acute setting of a cardiac event. External monitors are typically selected as the primary diagnostic tools to seek potential correlations between bradycardia and symptoms.^{[31](#)}

The 2017 International Society for Holter and Noninvasive Electrocardiology (ISHNE)-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry described the various available recording devices according to several characteristics: whether recording is continuous, event-triggered, or auto-triggered; the number of leads; the type of recording system; and the available analyses. Clinical indications for these devices

include the diagnosis of syncope, palpitations, chest pain, and coronary ischemia.^{[32](#)}

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Policy Revision History/Information

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Cohere Medicare Advantage Policy – Internal Loop Recorders

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 - Internal Loop Recorders

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

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Medical Necessity Criteria

Service: Internal Loop Recorders

Benefit Category

Not applicable.

Related CMS Documents

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

- [National Coverage Determination \(NCD\). Electrocardiographic Services \(20.15\)](#)

Recommended Clinical Approach

Noninvasive ambulatory ECG monitoring is recommended first in patients with symptoms suggestive of an arrhythmia, unexplained syncope, and/or cryptogenic stroke (i.e., stroke of unknown cause) with a concern for atrial fibrillation (AF). Poor diagnostic yield of noninvasive monitoring in the setting of continued symptoms may lead a physician to recommend an internal loop recorder (ILR, also known as an insertable cardiac monitor) for their patient.¹⁻⁶ This procedure is performed by a cardiac electrophysiologist (a specialized cardiologist) or trained cardiologist, and referral to a center that supports this service is required.

A single outpatient procedure is typical, and the implant's specific battery life determines the length of effectiveness.^{5,7} Periodic recordings are actively or passively transmitted for interpretation by a physician.⁷ Subsequent requests may be considered with documentation of device malfunction, an infection requiring removal of the initial device, or incorrect placement resulting in poor sensing, all with a documented continued need for monitoring.

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 internal loop recorders. 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:

- Though this device requires a minimally invasive procedure, the risks may include pain, swelling, or bruising at the internal loop recorder (ILR) insertion site.⁸
- As with any implanted device, there is the potential for infection or an immune response to implantation, which may require device removal or antibiotic treatment.
- Shifts in ILR placement may lead to data collection failures, which may require the device to be repositioned or replaced and may warrant further evaluation in a hospital setting.⁵
- Additional implantation procedures may be required as the battery depletes, which may occur as early as 2–3 years.^{5,7}
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- ILRs provide continuous heart rhythm monitoring, improving diagnostic accuracy and increasing the likelihood of detecting arrhythmias before they lead to severe complications, such as stroke or cardiac arrest.^{1–6}
- Wireless data transmission can guide faster treatment decisions and allow for early intervention.⁵
- The continuous functioning of ILRs provides long-term insight into cardiac health.⁵
- Accurately diagnosing or ruling out arrhythmias can reduce complications and adverse effects from unnecessary procedures, minimizing healthcare costs and patient burden.⁹
- Eliminating the need for external monitors can improve patient comfort and reduce lifestyle disruptions.
- 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

→ **Internal loop recorders (ILRs)** are considered appropriate if **ANY** of the following are **TRUE**¹⁻⁶:

◆ **ALL** of the following:

- No diagnostic conclusions were achieved after 30 days of non-invasive monitoring methods, including **ANY** of the following^{10,11}:
 - Holter monitor; **OR**
 - Extended-wear patch monitor (e.g., long-term continuous cardiac rhythm monitor); **OR**
 - External event monitor / external loop recorder; **OR**
 - Mobile cardiac outpatient telemetry (MCOT); **AND**
- The patient has no other implantable cardiac devices that can detect, record, and transmit data to a physician/cardiologist⁸; **AND**
- The patient has **ANY** positive findings from the following list:
 - **ANY** of the following¹²:
 - Cryptogenic stroke; **OR**
 - A systemic thromboembolic event; **OR**
 - Recurrent and unexplained infrequent syncope without documented orthostatic hypotension or autonomic dysfunction^{13,14}; **OR**
 - Sporadic symptoms (for greater than or equal to 30 days) reasonably suspected to be related to ventricular arrhythmias¹⁴; **OR**
 - High risk for arrhythmias due to documented structural or infiltrative heart disease (e.g., valvular

aortic stenosis, hypertrophic cardiomyopathy, cardiac sarcoidosis, complex congenital heart disease, dilated ischemic or nonischemic cardiomyopathy)¹⁵; **OR**

- ◆ ILR replacement may be appropriate for **ALL** of the following:
 - Ongoing or unresolved medical primary indication (as listed above); **AND**
 - **ANY** of the following:
 - End of battery life; **OR**
 - Device malfunction; **OR**
 - Incorrect placement of prior device leading to documented poor sensing.

Non-Indications

- **Internal loop recorders (ILRs)** may not be considered appropriate if **ANY** of the following is **TRUE**:
- ◆ ILR placement for the purpose of anticoagulation decisioning based on atrial fibrillation/atrial flutter burden, including post-ablation¹⁵; **OR**
 - ◆ The patient has an untreated active infection⁸; **OR**
 - ◆ The patient has an untreated, irreversible bleeding disorder.⁸

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
33286	Removal of subcutaneous cardiac rhythm monitor

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

Medical Evidence

According to an American College of Cardiology guideline by Al-Khatib et al (2017), in patients with sporadic symptoms, including syncope, implantable loop recorders (ILRs) can evaluate whether symptoms are related to or caused by ventricular arrhythmias. They are generally reserved for patients in whom other ambulatory monitoring is nonrevealing due to the infrequency of events.⁴

Giancaterino et al (2018) published a focused review that includes published reviews of major cardiovascular societies, including the American Heart Association (AHA), American College of Cardiology (ACC), and the European Society of Cardiology (ESC). Guidelines emphasize the need for a comprehensive evaluation of patients suspected to have an arrhythmia, including prolonged cardiac monitoring when appropriate, to identify underlying atrial fibrillation (AF) that may have gone undetected.⁹

The International Society for Holter and Noninvasive Electrocardiology (ISHNE) and Heart Rhythm Society (HRS) published a consensus statement on Ambulatory ECG (AECG) and External Cardiac Monitoring/Telemetry. ILRs may be necessary for patients remaining undiagnosed after prolonged noninvasive monitoring. The selection of appropriate technology has to take into account diagnostic power, monitoring, and risk stratification accuracy with consideration of cost-effectiveness, patient acceptance, degree of automaticity, and local availability and experience, as well as symptom frequency, the overall patient clinical condition, and the probability of life-threatening arrhythmia.¹¹

Zangiabadian and colleagues (2024) published a systematic review of the predictors of pacemaker requirement in patients with an implantable loop recorder and unexplained syncope. The group concluded that heart conduction disorders, atrial arrhythmias, and underlying medical conditions were the main predictors of the need for pacemaker implantation following loop recorder installation in patients with unexplained syncope.¹³

Diederichsen et al (2022) conducted a post hoc analysis of the LOOP randomized clinical trial (RCT) for atrial fibrillation (AF). Patients aged 70 years

or older with hypertension, diabetes, heart failure, or previous stroke but no history of AF were assigned to ILR or usual care to assess stroke characteristics. A total of 6004 individuals were included (4503 in the control group and 1501 in the ILR) group. Overall, screening for AF using ILRs did not show a significant decrease in ischemic or severe strokes compared with usual care; however, there may be a potential reduction in these outcomes among participants with no prior history of stroke.¹⁶

Sagris et al (2022) published a review on embolic stroke of undetermined source (ESUS), a subtype of ischemic stroke. Long-term continuous monitoring with cardiac implantable electronic devices, especially in selected patients with ESUS, has shown promise in improving the detection of atrial fibrillation. An extended monitoring period increases the chances of capturing infrequent or asymptomatic atrial fibrillation episodes. Unlike traditional intermittent monitoring methods, such as Holter monitoring, long-term continuous monitoring allows for a more prolonged and comprehensive assessment of the patient's cardiac rhythm. Several studies report that long-term cardiac monitoring, facilitated by implantable devices, significantly enhances the likelihood of detecting atrial fibrillation in patients with ESUS.¹⁷

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Clinical Guideline Revision History/Information

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Review History		



Cohere Medicare Advantage Policy – Left Atrial Appendage Implants

Clinical Guidelines for Medical Necessity Review

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medicare Advantage Policy - Left Atrial Appendage Implants

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

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Medical Necessity Criteria

Service: Left Atrial Appendage Implants

Benefit Category

Inpatient Hospital Services
Physicians' Services

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 \(NCD\) – Percutaneous Left Atrial Appendage Closure \(LAAC\) 20.34](#)

Recommended Clinical Approach

Left atrial appendage (LAA) implants (WATCHMAN Left Atrial Appendage device and AMPLATZER Amulet Occluder) are alternatives to chronic anticoagulant therapy for patients with nonvalvular atrial fibrillation (in the absence of moderate to severe mitral stenosis or a mechanical heart valve) at increased risk for a stroke. This procedure is a percutaneous catheter-based intervention that serves as an alternative to anticoagulation for patients who have become intolerant to anticoagulation, have poor drug adherence, have an increased risk of bleeding, or have had major bleeding events from recommended anticoagulant regimens.¹⁻² This procedure may also be considered for patients with high-risk occupations that place individuals at-risk for bleeding or comorbid conditions requiring treatments that are not compatible with oral anticoagulants. In patients with either (1) a CHA₂DS₂-VASc score of 3 or greater, (2) a hospitalization related to a bleeding event, or (3) a cardioembolic event while on oral anticoagulants, left atrial appendage closure devices were shown to be non-inferior to direct-acting oral anticoagulants (DOACs) at preventing stroke, systemic embolism, significant bleeding events, and cardiovascular death.³ There is a risk of procedural complications with these implants, including peri-device leakage, perforation, pericardial tamponade, thrombosis, stroke, and death.⁴⁻⁶ Oral

anticoagulation remains the preferred therapy for stroke prevention for most patients with atrial fibrillation (AF) and elevated stroke risk.¹ Current consensus guidelines favor a trial of oral anticoagulation therapy before considering primary LAA closure.

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 Left Atrial Appendage Implants. 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:

- Blood clot, infection, pericardial effusion, and stroke are potential complications of a left atrial appendage implant. In an incorrectly-selected patient population, these risks may outweigh the potential benefit of the device. This underscores the importance of careful, proper patient selection.¹⁻³
- Risks are associated with the transcatheter placement of the device, including pain at the catheterization site, dizziness, and swelling of the incision. The risks of anesthesia and sedation include nausea and vomiting, dizziness, and increased fall risk.¹⁻³
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The potential clinical benefits of using these criteria include:

- LAA implants do not require the same lifestyle restrictions as certain anticoagulation medications, such as frequent blood tests, avoidance of certain foods, and abstinence from high-risk sports and activities.¹⁻³
- LAA implants do not require open-heart surgery and instead are placed via catheter in the groin or arm, thereby avoiding the lengthy hospital stay, increased cost, and associated nosocomial risks of a traditional open left atrial appendage ligation.¹⁻³
- LAA implants have an excellent long-term safety profile and rate of efficacy, serving as a near-lifelong solution for stroke risk mitigation for properly selected patients.¹⁻³
- 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

→ A **left atrial appendage implant** is considered appropriate if **ALL** of the following are **TRUE**¹⁻³:

- ◆ The patient has non-valvular atrial fibrillation (NVAf); **AND**
- ◆ The left atrial appendage occlusion device has received Food and Drug Administration (FDA) Premarket Approval (PMA) for that device's FDA-approved indication, including **ALL** of the following:
 - The patient is recommended for long-term anticoagulation therapy; **AND**
 - The patient is deemed by their physician to be suitable for (short-term) warfarin or DOAC; **AND**
 - The patient has an appropriate, documented rationale (including HASBLED score) to seek a non-pharmacologic alternative to warfarin or DOA; **AND**
 - **ANY** of the following:
 - CHADS2 score of at least 2 (Congestive heart failure, Hypertension, Age of 75 or more, Diabetes, Stroke/transient ischemia attack/thromboembolism); **OR**
 - CHA2DS2-VASc score of at least 3 (Congestive heart failure, Hypertension, Age of 65 or more, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category); **AND**

- ◆ The patient is part of a Coverage with Evidence Development (CED) study, registry, or randomized-controlled trial (RCT) investigating left atrial appendage implants that is approved by the Centers for Medicare and Medicaid Services (CMS).

Non-Indications

→ A **left atrial appendage implant** is not considered appropriate if **ANY** of the following is **TRUE**¹⁻³:

- ◆ LAAC is non-covered for the treatment of NVAf when not furnished under CED according to the above-noted criteria; **OR**
- ◆ The subject requires long-term anticoagulation therapy for reasons other than AF-related stroke risk reduction; **OR**
- ◆ The subject has a contraindication for short-term anticoagulant therapy with DOAC post-implantation; **OR**
- ◆ The patient is contraindicated to aspirin and/or clopidogrel; **OR**
- ◆ Intracardiac thrombus is present; **OR**
- ◆ The LAA anatomy will not accommodate a closure device; **OR**
- ◆ The patient has a known hypersensitivity to any portion of the device material or the individual components; **OR**
- ◆ The patient has a history of atrial septal repair or has an atrial septal defect (ASD) or patent foramen ovale (PFO) closure device; **OR**
- ◆ The patient has an implanted mechanical valve prosthesis in any position; **OR**
- ◆ The patient has New York Heart Association class IV heart failure or Stage D heart failure on a mechanical assist or heart replacement device; **OR**
- ◆ Physical limitations that preclude device implantation, including small patient size such that necessary TEE probe or catheters are unable to be placed; **OR**
- ◆ Active infection; **OR**
- ◆ Leg ulcers are present; **OR**
- ◆ Bleeding disorder (e.g., hemophilia, Von Willebrand, etc.).

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description

33340	Percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation

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

Medical Evidence

The US Food and Drug Administration (FDA) granted Premarket Approval (PMA) to Boston Scientific Corporation (2015) for the WATCHMAN Left Atrial Appendage Closure Device with Delivery System in addition to subsequent generation devices, the WATCHMAN FLX and WATCHMAN FLX Pro (2020). The WATCHMAN FLX is stated to occlude a wider size range of LAAs than the first-generation device, as well as to allow for short-term postoperative use of a DOAC instead of warfarin, as was required with WATCHMAN. A similar device, known as the Amplatzer Amulet Left Atrial Appendage Occluder, received PMA in 2021.¹⁻³

Makkar et al. (2024) reviewed the post-approval study of the Amulet occluder following failure of LAA occlusion. The two FDA-approved devices for LAA occlusion at the time of this publication were Amulet and WATCHMAN, with the Amulet consisting of a dual occlusive mechanism versus the WATCHMAN device's single mechanism. The authors state that in complex LAA anatomies, failures may occur, particularly with single-mechanism devices. This post-approval study consisted of 8591 patients who underwent Amulet implantation, of which 244 patients failed prior LAA occlusion. 88.9% of study participants with prior failed LAA occlusion had success with the Amulet implantation. There was a low rate of adverse events, and the Amulet device was found to facilitate successful closure in challenging LAA anatomies.⁹

The Journal of Cardiology published an overview of current indications for left atrial appendage closure in 2025. The authors note the utility of nonpharmacologic stroke risk mitigation among certain groups, including patients with end-stage renal disease on hemodialysis and patients with hereditary bleeding disorders (e.g., hemophilia). Importantly, they highlight that, amid the acceptable safety profile and efficacy of LAAC devices, the most concerning complication is device-associated thrombi – although a number of potentially modifiable predictive risk factors are identified (e.g., large volume of remaining uncovered appendage, inappropriate device size selection, deep device implantation). The authors also emphasize the optimal selection of patients who are able to tolerate the required short-term oral anticoagulants following implantation.¹⁵

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Cohere Medicare Advantage Policy – Leadless Cardiac Pacemakers

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: Leadless Cardiac Pacemakers

Benefit Category

Inpatient Hospital Services
Physicians' Services
Prosthetic Devices

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

Recommended Clinical Approach

Leadless cardiac pacemakers eliminate the need for a device pocket and insertion of a pacing lead, which is integral to traditional pacing systems. The elimination of these elements minimizes complications while providing similar benefits. A leadless pacemaker is delivered percutaneously via a catheter through the femoral vein to the heart; the device(s) is/are implanted directly in the right atrium and/or ventricle walls. Dual-chamber devices are now available. Leadless pacemakers function similarly to other transvenous pacemakers.¹⁻²

Medical Necessity Criteria

Indications

→ **Leadless cardiac pacemakers** are appropriate if **ALL** of the following are **TRUE**¹:

- ◆ Is covered through Coverage with Evidence Development (CED);
AND
- ◆ **ANY** of the following:
 - The study is FDA-approved; **OR**
 - The study is used in accordance with the FDA-approved label for a device that has **ANY** of the following:
 - An associated ongoing FDA-approved post-approval study; **OR**
 - Completed an FDA post-approval study; **AND**
- ◆ The study is CMS-approved and as a fully-described, written part of its protocol, addresses **ALL** of the following:

- Peri-procedural and post-procedural complications of leadless pacemakers; **AND**
- Long-term outcomes of leadless pacemakers; **AND**
- Effects of patient characteristics (e.g., age, gender, comorbidities) on the use and health effects of leadless pacemakers.

Non-Indications

→ **Leadless cardiac pacemakers** are not considered appropriate when **ANY** of the following is **TRUE**:

- ◆ Leadless cardiac pacemakers are non-covered when furnished outside of a CMS-approved CED study.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (HCPCS/CPT)

HCPCS/CPT Code	Code Description
0795T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; complete system (i.e., right atrial and right ventricular pacemaker components)
0796T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)
0797T	Transcatheter insertion of permanent

	dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0798T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system(i.e., right atrial and right ventricular pacemaker components)
0799T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right atrial pacemaker component
0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0801T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; dual-chamber system (i.e., right atrial and right ventricular pacemaker components)
0802T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right

	ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right atrial pacemaker component
0803T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual chamber leadless pacemaker system)
0804T	Programming device evaluation (in person) with iterative adjustment of implantable device to test the function of device and to select optimal permanent programmed values, with analysis, review, and report, by a physician or other qualified health care professional, leadless pacemaker system in dual cardiac chambers
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed

Medical Evidence

Ngo et al. (2021) performed a systematic review and meta-analysis on the safety and efficacy of leadless pacemakers placed in the right ventricle. Thirty-six observational studies were reviewed that included Nanostim (30%) and Micra (70%) leadless pacemakers. Fewer complications were found with Micra; at one-year follow-up, complications were 51% less when compared with transvenous pacemakers. At one-year follow-up, capture thresholds with Micra pacemakers were reported among 98.96% of patients. Among patients with a Nanostim pacemaker, complications were reported in 6.06% to 23.54% at 90-day follow-up and 5.33% to 6.67% at one-year follow-up. Good pacing capture was reported in 90% to 100% of patients at one-year follow-up.⁹

Reynolds et al. (2016) report on the Micra Transcatheter Pacing Study (ClinicalTrials.gov ID NCT02004873). A multicenter study without controls included 719 patients who had a successful procedure. At the six-month follow-up, performance goals were met. The pacing capture threshold was adequate in 98.3% of patients, higher than the performance goal of 80%. Complications were reported in 4% including invasive revision, termination of therapy, hospitalization or extension of hospitalization, and death.¹⁰

Glikson et al. (2021) discuss guidelines published by the European Society of Cardiology (ESC) titled *Cardiac Pacing and Cardiac Resynchronization Therapy*. Two recommendations are included. First, leadless pacemakers should be considered an alternative to transvenous pacemakers when no upper extremity venous access exists or when the risk of device pocket infection is particularly high, such as previous infection and patients on hemodialysis. Leadless pacemakers may also be considered as an alternative to standard single lead ventricular pacing, taking into consideration life expectancy and using shared decision-making.²

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Cohere Medicare Advantage Policy – Left and Right Heart Catheterization

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Medical Necessity Criteria

Service: Left and Right Heart Catheterization

Benefit Category

Inpatient Hospital Services

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹⁻²

Recommended Clinical Approach

A left and right catheterization is invasive, with more risks than other tests (e.g., cardiac computed tomography angiography [CCTA], or stress echo). It is appropriate when there is a high likelihood of coronary artery disease (CAD) with the additional need for a hemodynamic assessment. Unless the clinical situation is emergent or progressive, non-invasive testing (e.g., cardiac CCTA or stress testing with or without accompanying echo or isotope imagery) should precede a direct catheterization if the primary assessment is for CAD.³⁻⁴ The addition of a right cardiac catheterization to a left cardiac catheterization is needed for a hemodynamic assessment when evaluating valvular heart disease, cardiomyopathies, or pericardial 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 left and right heart catheterization 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 left and right heart catheterization can lead to increased symptoms and complications, especially in patients with a high likelihood of coronary artery disease (CAD) or those requiring hemodynamic assessment for conditions like valvular heart disease. Otto et al. emphasized the importance of cardiac catheterization in providing valuable information, particularly in assessing transvalvular pressure gradients and cardiac output, especially when noninvasive test results are inconclusive.⁵ The CMS Local Coverage Determination (LCD) for Cardiac Catheterization and Coronary Angiography (L33557) also highlights the necessity of timely procedures to avoid adverse outcomes in patients with significant cardiovascular 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. Cochran et al. highlight the importance of right heart catheterization in diagnosing and managing advanced heart failure and evaluating eligibility for heart replacement therapies.¹³
- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. Proper use of left and right heart catheterization criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health.

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to left and right heart catheterization 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. Choi et al. noted the diagnostic accuracy of invasive hemodynamic measurement in predicting heart failure with preserved ejection fraction (HFpEF) and its strong correlation with the 10-year risk of all-cause death or HF readmission.¹⁰ The information obtained from a coronary angiogram can lead to appropriate coronary artery revascularization, which can improve survival in certain clinical scenarios.¹¹
- Enhanced diagnostic accuracy: This is crucial for complex cardiovascular conditions where traditional diagnostic methods may pose additional risks. Cardiac catheterization offers the advantage of measuring intracardiac pressures and pulmonary vascular resistance, aiding in decision-making regarding valve intervention, as well as defining coronary anatomy.⁶
- Reduction in complications and adverse effects: Proper use of left and right heart catheterization criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. Cochran et al. highlighted the importance of right heart catheterization in reducing complications by providing crucial diagnostic information in advanced heart failure management.¹²
- Enhanced overall patient satisfaction: Ensuring that left and right heart catheterizations are used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications.

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

→ **Left and right heart catheterization** is considered appropriate if **ALL** of the following are **TRUE**¹⁻⁹:

◆ **ANY** of the following indications for coronary or bypass angiography:

- Anginal syndrome with **ALL** of the following characteristics³:
 - **ANY** of the following:
 - ◆ Substernal location of chest discomfort (burning, dull, heaviness, pressure, squeezing, tightness); **OR**
 - ◆ Anginal equivalent (discomfort in the shoulders, arms, neck, back, upper abdomen, or jaw, as well as shortness of breath and fatigue); **AND**
 - Precipitated by exertion or emotional stress; **AND**

- Prompt relief with rest or sublingual nitroglycerin (time span ranging from approximately 30 seconds to 10 minutes); **OR**
- Atypical chest pain syndrome suggesting ischemia defined by **2 of 3** of the following characteristics³:
 - **ANY** of the following:
 - ◆ Substernal location of chest discomfort (burning, dull, heaviness, pressure, squeezing, tightness); **OR**
 - ◆ Anginal equivalent (discomfort in the shoulders, arms, neck, back, upper abdomen, or jaw, as well as shortness of breath and fatigue); **OR**
 - Precipitated by exertion or emotional stress; **OR**
 - Prompt relief with rest or sublingual nitroglycerin (time span ranging from approximately 30 seconds to 10 minutes); **OR**
- Congenital heart disease; **OR**
- Following cardiac arrest suspected to be due to ischemia or infarction; **OR**
- Myocardial infarction; **OR**
- Known atherosclerotic or other coronary disease (history of documented myocardial infarction, known coronary artery revascularization, documented coronary artery disease or coronary anomaly by coronary angiogram or CCTA); **OR**
- Suspected graft or stent/percutaneous transluminal coronary angioplasty closure; **OR**
- Prinzmetal's angina; **OR**

- Coronary shunt or fistula; **OR**
- Cardiac trauma; **OR**
- The patient is undergoing non-coronary cardiac surgical procedure (e.g., aortic or mitral valve surgery not requiring left heart catheterization); **OR**
- The patient is high-risk with evidence of ischemic heart disease (history of documented myocardial infarction, known coronary artery revascularization, documented coronary artery disease by coronary angiogram or CCTA) undergoing a high-risk non-cardiac surgical procedure (arterial or aortic surgery, or surgery with large fluid shift);

AND

◆ **ANY** of the following indications for right heart catheterization¹⁻¹³:

- Valvular heart disease; **OR**
- CHF; **OR**
- Congenital heart disease; **OR**
- Cor pulmonale; **OR**
- Pulmonary hypertension; **OR**
- Intracardiac shunts (including septal rupture) and extracardiac vascular shunts; **OR**
- Suspected cardiomyopathy or myocarditis; **OR**
- Endocarditis requiring valvular surgery; **OR**
- Suspected rejection of a transplanted heart; **OR**
- The patient is being considered for or has received a heart transplant; **OR**
- Suspected pericardial tamponade or constriction.

Non-Indications

→ **Left and right heart catheterization** may not be considered appropriate if **ANY** of the following is **TRUE**¹:

- ◆ Inpatient or observation stay following routine outpatient cardiac catheterization; **OR**
- ◆ Right heart catheterization billed for "bedside placement" of flow-directed (Swan-Ganz type) catheter; **OR**
- ◆ Right heart catheterization for atherosclerotic heart disease without heart failure; **OR**
- ◆ Right heart catheterization for angioplasty, electrophysiologic studies, or other interventional procedures; **OR**
- ◆ Aortography for atherosclerotic heart disease; **OR**
- ◆ Aortography performed for a diagnosis of "rule out (valvular lesion)"; **OR**
- ◆ When the service is performed by a resident alone, without a teaching physician present with the resident throughout the entire procedure; **OR**
- ◆ Separate reimbursement for vascular closure of puncture site (with or without implantable device or other mechanical intervention); **OR**
- ◆ Separate reimbursement for dye injection during catheterization or angiographic procedures for the purpose of guiding catheter placement; **OR**
- ◆ Assistant at the surgery while catheterization is performed; **OR**
- ◆ Right heart catheterization solely for the purpose of inserting a temporary pacemaker, performing endomyocardial biopsy, or performing electrophysiologic studies; **OR**
- ◆ Standby anesthesia or surgeon during angioplasty.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93453	Combined right and left heart catheterization with intraprocedural injection for left ventriculography

93456	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with right heart catheterization
93457	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with catheter placement in bypass graft, with intraprocedural injection for bypass graft angiography and right heart catheterization
93460	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with right and left heart catheterization
93461	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with right and left heart catheterization, catheter placement in bypass graft, with bypass graft angiography
93596	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); normal native connections
93597	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); abnormal native connections

Medical Evidence

Gulati et al. (2021)⁴ provided guidelines for the evaluation and diagnosis of chest pain and Lawton et al. (2021)¹³ provided guidelines for coronary revascularization. Both served to assist with the care of patients with suspected or known CAD.

Otto et al. (2021) reviewed published guidelines from the American College of Cardiology (ACC) and the American Heart Association (AHA) on the management of patients with valvular heart disease. When noninvasive testing results are inconclusive, especially in symptomatic patients, or when there's a discrepancy between noninvasive tests and clinical findings, cardiac catheterization with direct intracardiac measurements becomes crucial. Catheterization provides valuable information, particularly in assessing transvalvular pressure gradients and cardiac output. Imaging difficulties or misalignment of the Doppler beam can lead to underestimation of stenosis severity, while suboptimal image or Doppler data quality can cause overestimation or underestimation of valve regurgitation severity. In such cases, contrast angiography may be helpful for semiquantitative assessment, especially when noninvasive results conflict with physical examination findings. Cardiac catheterization offers the advantage of measuring intracardiac pressures and pulmonary vascular resistance, aiding in decision-making regarding valve intervention.⁶

Choi et al. (2023) conducted a retrospective, single-center, observational study to evaluate the discriminatory and prognostic significance of invasively measured left ventricular end-diastolic pressure in patients suspected of having heart failure with preserved ejection fraction (HFpEF). The authors focus on patients with intermediate scores on the Heart Failure Association Pre-test Assessment, Echocardiography and Natriuretic Peptide, Functional Testing, Final Etiology (HFA-PEFF) scale. A total of 404 patients were included – all patients exhibited symptoms of heart failure and preserved left ventricular ejection fraction (greater than or equal to 50%) who underwent left heart catheterization (LHC). Exclusion criteria included patients who presented without definitive HF symptoms or with acute coronary syndrome (ACS),

primary cardiomyopathies, significant valvular heart disease (beyond mild stenosis or moderate left-sided regurgitation), pulmonary arterial hypertension, heart transplantation, constrictive pericarditis, or stress-induced cardiomyopathy. The authors note that the diagnostic accuracy of the HFA-PEFF score in predicting HFpEF, confirmed through invasive hemodynamic measurement, is moderate, with an optimal cutoff value of 4.5. Also, a strong correlation was identified between the HFA-PEFF score and the 10-year risk of all-cause death or HF readmission. Finally, elevated left ventricular end-diastolic pressure (LVEDP) is linked to a significantly higher 10-year risk of all-cause death or HF readmission in patients suspected of having HFpEF, especially among those with intermediate HFA-PEFF scores. This association remains even after adjusting for multiple variables, including the HFA-PEFF score. (Clinicaltrial.gov, NCT04505449).¹¹

Cochran et al. (2022) performed a review on the role of right heart catheterization in patients (RHC) with heart failure. The procedure is a fundamental diagnostic tool for patients experiencing refractory heart failure or cardiogenic shock. The procedure is also crucial for evaluating eligibility for heart replacement therapies and for managing patients post-implantation of mechanical circulatory assist devices and heart transplantation. Guidelines published by the American College of Cardiology Foundation (ACCF), American Heart Association (AHA), and European Society of Cardiology (ESC) specify situations when RHC may be indicated. While RHC is not typically suggested for patients with decompensated heart failure, it may benefit those whose condition does not improve with initial therapy as well as those with uncertain volume status and persistent hypoperfusion, or those being evaluated for advanced treatments.¹²

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in the assessment of cardiac structure and function in nonvalvular heart disease: A report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and the Society of Thoracic Surgeons. *J Thorac Cardiovasc Surg*. 2019 Apr;157(4):e153–e182. doi: 10.1016/j.jtcvs.2018.12.061. PMID: 30635178.

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Clinical Guideline Revision History/Information

Original Date: May 29, 2024		
Review History		
Version 2	6/11/2024	422.101 Disclaimer Added
Version 2.1	3/19/2025	Updated policy per CMS revisions for 11/07/2024 • Updated Effective date • Updated Links and Bookmarks



**Cohere Medicare Advantage Policy –
Left Heart Catheterization, Coronary Angiography
and/or Bypass Angiography**
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 - Left Heart Catheterization, Coronary Angiography and/or Bypass Angiography

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: Left Heart Catheterization, Coronary Angiography and/or Bypass Angiography

Benefit Category

Inpatient Hospital Services

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

Recommended Clinical Approach

A left heart catheterization is invasive, with more risks than other tests (e.g., cardiac computed tomography angiogram [CCTA], stress echo). It is appropriate when there is a high likelihood of coronary artery disease (CAD). Unless the clinical situation is emergent or progressive, non-invasive testing (e.g., CCTA, stress testing with or without accompanying echo, or isotope imagery) should precede a direct catheterization.²⁻³

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 left heart catheterization with coronary angiography 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 left heart catheterization with coronary angiography can lead to increased symptoms and complications, especially in patients with a high likelihood of coronary artery disease (CAD)³ or those requiring hemodynamic assessment for conditions like valvular heart disease. Otto et al. emphasized the importance of cardiac catheterization in providing valuable information, particularly in assessing transvalvular

pressure gradients and cardiac output, especially when noninvasive test results are inconclusive.¹⁰ Additionally, the CMS Local Coverage Determination (LCD) for Cardiac Catheterization and Coronary Angiography (L33557) highlights the necessity of timely procedures to avoid adverse outcomes in patients with significant cardiovascular conditions.¹

- Risks with inappropriate procedures: This includes infection, bleeding, injury to neurovascular structures, anesthetic risk, and the need for repeat or additional procedures due to complications. Sorajja et al. highlight the importance of invasive hemodynamics in diagnosing and managing cardiovascular disease.⁹ Gulati et al. review the appropriate use of non-invasive technology in patients with a lower likelihood of obstructive CAD.³
- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. Proper use of left heart catheterization with coronary angiography criteria defines the need for coronary intervention and thus helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. The CMS LCD (L33557) also supports the necessity of appropriate use criteria to minimize healthcare costs and prevent complications.¹

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to left heart catheterization with coronary angiography 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. Choi et al. noted the diagnostic accuracy of invasive hemodynamic measurement in predicting heart failure with preserved ejection fraction (HFpEF) and its strong correlation with the 10-year risk of all-cause death or HF readmission.¹⁴ The information obtained from a coronary angiogram can lead to appropriate coronary artery revascularization, which can improve survival in certain clinical scenarios.¹⁶
- Enhanced diagnostic accuracy: This is crucial for complex cardiovascular conditions where traditional diagnostic methods may pose additional risks. Cardiac catheterization offers the advantage of

measuring intracardiac pressures and pulmonary vascular resistance, aiding in decision-making regarding valve intervention as well as defining coronary anatomy.¹⁰

- Reduction in complications and adverse effects: Proper use of left heart catheterization with coronary angiography criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. Sorajja et al. highlighted the importance of invasive hemodynamics in reducing complications by providing crucial diagnostic information in cardiovascular disease management.⁶
- Enhanced overall patient satisfaction: Ensuring that left heart catheterizations with coronary angiography are used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications.

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

→ **Left heart catheterization, coronary angiography and/or bypass angiography** is considered appropriate if **ANY** of the following is **TRUE**¹⁻¹²:

◆ Anginal syndrome with **ALL** of the following characteristics^{3,13}:

- **ANY** of the following:
 - Substernal location of chest discomfort (burning, dull, heaviness, pressure, squeezing, tightness); **OR**

- Anginal equivalent (discomfort in the shoulders, arms, neck, back, upper abdomen, or jaw, as well as shortness of breath and fatigue); **AND**
 - Precipitated by exertion or emotional stress; **AND**
 - Prompt relief with rest or sublingual nitroglycerin (time span ranging from approximately 30 seconds to 10 minutes); **OR**
- ◆ Atypical chest pain syndrome suggesting ischemia defined by **2 of 3** of the following characteristics^{3.13}:
 - **ANY** of the following:
 - Substernal location of chest discomfort (burning, dull, heaviness, pressure, squeezing, tightness); **OR**
 - Anginal equivalent (discomfort in the shoulders, arms, neck, back, upper abdomen, or jaw, as well as shortness of breath and fatigue); **OR**
 - Precipitated by exertion or emotional stress; **OR**
 - Prompt relief with rest or sublingual nitroglycerin (time span ranging from approximately 30 seconds to 10 minutes); **OR**
- ◆ Congenital heart disease; **OR**
- ◆ Following cardiac arrest suspected to be due to ischemia or infarction; **OR**
- ◆ Myocardial infarction; **OR**
- ◆ Known atherosclerotic or other coronary disease (history of documented myocardial infarction, known coronary artery revascularization, documented coronary artery disease or coronary anomaly by coronary angiogram or CCTA); **OR**
- ◆ Suspected graft or stent/percutaneous transluminal coronary angioplasty closure; **OR**
- ◆ Prinzmetal's angina; **OR**
- ◆ Coronary shunt or fistula; **OR**
- ◆ Cardiac trauma; **OR**
- ◆ The patient is undergoing non-coronary cardiac surgical procedure (e.g., aortic or mitral valve surgery not requiring left heart catheterization); **OR**

- ◆ The patient is high-risk with evidence of ischemic heart disease (history of documented myocardial infarction, known coronary artery revascularization, documented coronary artery disease by coronary angiogram or CCTA) undergoing a high-risk non-cardiac surgical procedure (arterial or aortic surgery, or surgery with large fluid shift).

Non-Indications

→ **Left heart catheterization, coronary angiography and/or bypass angiography** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Inpatient or observation stay following routine outpatient cardiac catheterization; **OR**
- ◆ Right heart catheterization billed for "bedside placement" of flow-directed (Swan-Ganz type) catheter; **OR**
- ◆ Right heart catheterization for atherosclerotic heart disease without heart failure; **OR**
- ◆ Right heart catheterization for angioplasty, electrophysiologic studies, or other interventional procedures; **OR**
- ◆ Aortography for atherosclerotic heart disease; **OR**
- ◆ Aortography performed for a diagnosis of "rule out (valvular lesion)"; **OR**
- ◆ When the service is performed by a resident alone, without a teaching physician present with the resident throughout the entire procedure; **OR**
- ◆ Separate reimbursement for vascular closure of puncture site (with or without implantable device or other mechanical intervention); **OR**
- ◆ Separate reimbursement for dye injection during catheterization or angiographic procedures for the purpose of guiding catheter placement; **OR**
- ◆ Assistant at the surgery while catheterization is performed; **OR**
- ◆ Right heart catheterization solely for the purpose of inserting a temporary pacemaker, performing endomyocardial biopsy, or performing electrophysiologic studies; **OR**
- ◆ Standby anesthesia or surgeon during angioplasty.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93454	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation
93455	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with catheter placement in bypass graft, with intraprocedural injections for bypass graft angiography
93458	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with left heart catheterization, with intraprocedural injection for left ventriculography
93459	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision and interpretation, with left heart catheterization, catheter placement in bypass graft, with bypass graft angiography
93595	Left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone, normal or abnormal native connections

Medical Evidence

Gulati et al. (2021)³ provided guidelines for the evaluation and diagnosis of chest pain and Lawton et al. (2021)¹⁶ provided guidelines for coronary revascularization. Both served to assist with the care of patients with suspected or known CAD.

Choi et al. (2023) conducted a retrospective, single-center, observational study to evaluate the discriminatory and prognostic significance of invasively measured left ventricular end-diastolic pressure in patients suspected of having heart failure with preserved ejection fraction (HFpEF). The authors focus on patients with intermediate scores on the Heart Failure Association Pre-test Assessment, Echocardiography and Natriuretic Peptide, Functional Testing, Final Etiology (HFA-PEFF) scale. A total of 404 patients were included – all patients exhibited symptoms of heart failure and preserved left ventricular ejection fraction (greater than or equal to 50%) who underwent left heart catheterization (LHC). Exclusion criteria included patients who presented without definitive HF symptoms or with acute coronary syndrome (ACS), primary cardiomyopathies, significant valvular heart disease (beyond mild stenosis or moderate left-sided regurgitation), pulmonary arterial hypertension, heart transplantation, constrictive pericarditis, or stress-induced cardiomyopathy. The authors note that the diagnostic accuracy of the HFA-PEFF score in predicting HFpEF, confirmed through invasive hemodynamic measurement, is moderate, with an optimal cutoff value of 4.5. Also, a strong correlation was identified between the HFA-PEFF score and the 10-year risk of all-cause death or HF readmission. Finally, elevated left ventricular end-diastolic pressure (LVEDP) is linked to a significantly higher 10-year risk of all-cause death or HF readmission in patients suspected of having HFpEF, especially among those with intermediate HFA-PEFF scores. This association remains even after adjusting for multiple variables, including the HFA-PEFF score. (Clinicaltrial.gov, NCT04505449).¹⁴

Otto et al. (2021) reviewed published guidelines from the American College of Cardiology (ACC) and the American Heart Association (AHA) on the management of patients with valvular heart disease. When noninvasive testing results are inconclusive, especially in symptomatic patients, or when there's a discrepancy between noninvasive tests and clinical findings, cardiac catheterization with direct intracardiac measurements becomes crucial. Catheterization provides valuable information, particularly in assessing transvalvular pressure gradients and cardiac output. Imaging difficulties or misalignment of the Doppler beam can lead

to underestimation of stenosis severity, while suboptimal image or Doppler data quality can cause overestimation or underestimation of valve regurgitation severity. In such cases, contrast angiography may be helpful for semiquantitative assessment, especially when noninvasive results conflict with physical examination findings. Cardiac catheterization offers the advantage of measuring intracardiac pressures and pulmonary vascular resistance, aiding in decision-making regarding valve intervention.¹⁰

Ruiz-Rodriguez et al. (2016) performed a systematic review and meta-analysis to compare radial artery (RA) access versus femoral artery (FA) access during LHC. Percutaneous coronary interventions (PCIs) were also analyzed. The authors included 15 randomized controlled trials (RCTs) and 17 cohort studies with a total of 44,854 patients with ACS. Complications related to bleeding (odds ratio [OR] 0.45, 95% confidence interval [CI] 0.33–0.61; P less than 0.001), access to the artery (OR 0.27, 95% CI 0.18–0.39; P less than 0.001), mortality (OR 0.64, 95% CI 0.54–0.75; P less than 0.001), and major adverse cardiac events (OR 0.70, 95% CI 0.57–0.85; P less than 0.001) were reduced with RA versus FA during LHC.¹⁵

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Cohere Medicare Advantage Policy – Lower Extremity Arterial Revascularization

Clinical Guidelines for Medical Necessity Review

Version: 1.2

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Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy - Lower Extremity Arterial Revascularization

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Medical Necessity Criteria

Service: Lower Extremity Arterial Revascularization

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 Lower Extremity Arterial Revascularization.

Description

Lower extremity peripheral artery disease (PAD) is a condition where blood flow is restricted in the arteries of the legs due to narrowing or blockage caused by plaque build-up. Pain, numbness, and tissue damage to the legs and feet may result from a lack of blood flow, and surgical intervention may be required. Lower extremity arterial revascularization is a surgical procedure that can be performed in patients to restore blood flow to the legs and feet, improving pain and quality of life.¹⁻²

Medical Necessity Criteria

Indications

Lower extremity arterial revascularization (percutaneous) is considered appropriate if **ANY** of the following is **TRUE**¹⁻⁹:

- The patient has chronic limb-threatening arterial occlusive disease (CLTI), and **ALL** of the following are **TRUE**:
 - The disease is classified as Rutherford stage 4-6 or Fontaine stage III to I (see Table 1)⁹⁻¹¹; **AND**
 - The clinician determines that the patient is an appropriate candidate for intervention and provides appropriate clinical documentation supporting the clinical decision-making process, including **ANY** of the following:
 - Angiographic (CTA, MRA, invasive angiogram) lesion greater than or equal to 75%²; **OR**
 - A stenosis of 50% to 75% by angiography may not be hemodynamically significant (i.e., the cause of limited perfusion).

- Resting (greater than 10 mmHg) or provoked (greater than or equal to 10 mmHg) intravascular pressure measurements may be needed to determine whether lesions are hemodynamically significant⁷; **OR**
- Lower extremity duplex Doppler with peak systolic velocity (PSV) greater than 3 m/s or velocity ratio 4:1⁷; **AND**
 - **ANY** of the following:
 - Percutaneous transluminal angioplasty (PTA) and/or stent for aortoiliac disease arterial occlusive disease¹; **OR**
 - PTA and/or stent for femoral-popliteal arterial occlusive disease¹; **OR**
 - Atherectomy for femoral-popliteal arterial occlusive disease with documentation of **ANY** of the following⁹:
 - In-stent restenosis (ISR)(only laser atherectomy is Class IIa and should documented in the medical record); **OR**
 - Documented moderate to severe calcification (arc of calcification extends circumferentially to greater than or equal to 180 degrees in a vessel that has failed PTA or, in the opinion of the provider, is not dilatable¹²); **OR**
 - PTA in an infrapopliteal (tibial or peroneal) vessel⁹; **OR**
 - Atherectomy and/or stent for infrapopliteal occlusive disease with documentation of **ANY** of the following^{*9}:
 - Documented moderate to severe calcification (arc of calcification extends circumferentially to greater than or equal to 180 degrees in a vessel that has failed PTA or, in the opinion of the provider, is not dilatable¹²); **OR**
 - Aneurysm (stent); **OR**
 - Flow-limiting dissection after intervention (stent); **OR**
 - The patient has non-limb threatening/intermittent claudication arterial occlusive disease, and **ALL** of the following are **TRUE**¹⁻⁴:
 - The disease is classified as Rutherford stage 0-3 or Fontaine stage I to IIb (see Table 1)⁹⁻¹¹; **AND**
 - The patient fails to show significant clinical improvement despite documented compliance with optimal medical care (OMC)(smoking cessation, weight management, glycemic control, statin therapy, blood pressure management, supervised exercise program, pharmacotherapy [e.g., anti-platelet, cilostazol]); **AND**
 - The patient reports their symptoms to be negatively affecting activities of daily living (ADLs); **AND**

- The clinician determines that the patient is an appropriate candidate for intervention and provides appropriate clinical documentation supporting the clinical decision-making process, including **ANY** of the following:
 - Angiographic (computed tomography angiography [CTA], magnetic resonance angiography [MRA], invasive angiogram lesion greater than or equal to 75%)⁷; **OR**
 - A stenosis of 50% to 75% by angiography with documented resting (greater than 10 mmHg) or provoked (greater than or equal to 10 mmHg) intravascular pressure measurements⁷; **OR**
 - Lower extremity duplex Doppler with peak systolic velocity (PSV) greater than 3 m/sec or a velocity ratio greater than 4:1⁷; **AND**
- **ANY** of the following^{**}:
 - PTA and/or stent for aortoiliac disease arterial occlusive disease⁹; **OR**
 - PTA and/or stent for femoral-popliteal arterial occlusive disease⁹; **OR**
 - Atherectomy for femoral-popliteal arterial occlusive disease with documentation of **ANY** of the following⁹:
 - In-stent restenosis (ISR)(only laser atherectomy is Class IIa and should documented in the medical record); **OR**
 - Documented moderate to severe calcification (arc of calcification extends circumferentially to greater than or equal to 180 degrees in a vessel that has failed PTA or, in the opinion of the provider, is not dilatable¹²); **OR**
- The procedure is considered appropriate in the presence or absence of symptoms, and **ANY** of the following is **TRUE**:
 - Bail-out stenting for flow-limiting dissection after procedure¹; **OR**
 - Stenting for aneurysm or pseudoaneurysm¹; **OR**
 - Threatened bypass graft for PTA/stenting and **ANY** of the following:
 - Drop in ABI of 0.15 or greater⁷; **OR**
 - Stenosis in graft/inflow or outflow of greater than 50% by lower extremity arterial Doppler (LEAD) or CTA/MRA.⁷

*NOTE: Infrapopliteal interventions besides a balloon angioplasty (PTA) in the setting of limb-threatening arterial occlusive disease of the extremities may be subject to prospective and/or retrospective review. Inframalleolar revascularization should be extremely rare. Multilevel arterial revascularization procedures may be indicated in the setting of

limb-threatening ischemia (e.g., suprainguinal, infrainguinal, and/or infrapopliteal) with appropriate documentation.

****NOTE:** Infrapopliteal interventions (endovascular or surgical) are rarely indicated in the treatment of non-limb-threatening arterial occlusive disease of the extremities. All infrapopliteal interventions in the setting of non-limb-threatening arterial occlusive disease of the extremities will be subject to review.

Non-Indications

Lower extremity arterial revascularization is not considered appropriate if **ANY** of the following is **TRUE**^{1-3,7-9}:

- Revascularization performed in a patient with peripheral artery disease solely to prevent progression to CLTI; **OR**
- **ANY** of the following conditions¹³⁻¹⁵:
 - Pure venous ulcers; **OR**
 - Pure traumatic wounds; **OR**
 - Embolic disease; **OR**
 - Nonatherosclerotic chronic vascular conditions of the lower extremity (e.g., vasculitis, Buerger disease, radiation arteritis); **OR**
- A successful arterial intervention could increase the risk of the patient developing a limb-threatening condition or would not extend the quality or length of life, such as **ANY** of the following:
 - The patient's age or existing co-morbid conditions indicate the risk of a complication; **OR**
 - The patient is permanently non-ambulatory or the patient's activity level is severely limited; **OR**
- Evidence of occlusion without accompanying clinical symptoms (i.e., claudication); **OR**
- Isolated tibial artery occlusive disease for claudication; **OR**
- The patient is not considered a suitable candidate for percutaneous intervention based on documentation from the most recent physician encounter and TASC criteria (i.e., TASC D; see Tables 3 and 4).¹⁶⁻¹⁸

Tables

Table 1.

Rutherford/Fontaine Peripheral Arterial Disease Classification System²⁻¹¹		
Rutherford Stage	Fontaine Stage	Description/Definition
0	I	Asymptomatic
1	IIa	Mild claudication
2	IIb	Moderate claudication
3	IIb	Severe claudication
4	III	Rest pain
5	IV	Ischemic ulcers of the digits of the foot (minor tissue loss)
6	IV	Severe ischemic ulcers or gangrene (major tissue loss)

Table 2.
**WiFi Classification System:
Risk stratification based on wound, ischemia, and foot infection¹²**

Wound (W)	Grade	Description
	0	No ulcer or gangrene (ischemic pain at rest)
	1	Small or superficial ulcer on leg or foot, without gangrene (SDA or SC)
	2	Deep ulcer with exposed bone, joint or tendon with or without gangrene limited to digits
	3	Deep, extensive ulcer involving forefoot and/or midfoot with or without calcaneal involvement with or without extensive gangrene (CR of the foot or nontraditional TMA)
Ischemia (I)	Grade	ABI/SBP of the ankle/TP, TcPO2
	0	Greater than or equal to 0.80/Greater than 100 mmHg/Greater than or equal to 60 mmHg
	1	0.6-0.79/70-100 mmHg/40-59 mmHg
	2	0.4-0.59/50-70 mmHg/30-39 mmHg
	3	Less than or equal to 0.39/Less than or equal to 50 mm/Hg/Less than 30 mmHg
Foot Infection (fi)	Grade	Description
	0	Uninfected
	1	Mild local infection, involving only the skin and subcutaneous tissue, erythema greater than 0.5 to less than or equal to 2 cm
	2	Moderate local infection, with erythema greater than 2 cm or involving deeper structures
	3	Severe local infection with signs of SIRS

Wifi = Wound, Ischemia, and foot Infection; SDA = simple digital amputation; SC = skin coverage; MDA = multiple digital amputations; TMA = transmetatarsal amputation; CR = complex reconstruction; ABI = ankle-brachial index; SBP = systolic blood pressure; TP = toe pressure (SBP of toe); TCPO2 = transcutaneous oxygen pressure; SIRS = systemic inflammatory response syndrome.

Table 3.

TASC Classification of Femoral Popliteal Lesions¹⁸	
TASC A Lesions	Single stenosis ≤ 10 cm in length Single occlusions less than ≤ 5 cm in length
TASC B Lesions	Multiple stenoses or occlusions each ≤ 5 cm Single stenosis ≤ 15 cm Heavily calcified occlusions ≤ 5 cm Single popliteal stenosis
TASC C Lesions	Multiple stenoses or occlusions totaling ≥ 15 cm Recurrent stenoses or occlusions after failing treatment (Two endovascular interventions).
TASC D Lesions	Chronic total occlusion of common femoral artery or superficial femoral artery (> 20 cm) Chronic total occlusion of popliteal artery and proximal trifurcation vessels.

Table 4.

TASC Classification of Aortoiliac Lesions¹⁸	
TASC A Lesions	Unilateral or bilateral common iliac artery stenoses Unilateral or bilateral short (≤ 3 cm) external iliac artery stenosis
TASC B Lesions	Short (3 cm) stenosis of infrarenal aorta Unilateral common iliac artery occlusion External iliac artery stenosis/stenoses totaling 3–10 cm Unilateral external iliac artery occlusion
TASC C Lesions	Bilateral common iliac artery (CIA) occlusions Bilateral external iliac artery (EIA) stenoses 3–10cm long not extending into the common femoral artery (CFA) Unilateral external iliac artery (EIA) stenosis extending into the common femoral artery (CFA) Heavily calcified unilateral external iliac artery (EIA) occlusion
TASC D Lesions	Diffuse disease involving the aorta and both iliac arteries Diffuse multiple stenoses Unilateral occlusion of both external iliac artery (EIA) and common iliac artery (CIA) Bilateral occlusion of external iliac artery (EIA)

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
37254	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel
37256	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel
37258	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37260	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with

	transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel
37262	Intravascular lithotripsy(ies), iliac vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)
37263	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel
37265	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel
37267	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including

	all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37269	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel
37271	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37273	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary

	to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel
37275	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37277	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel
37280	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel
37282	Revascularization, endovascular, open or

	percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel
37284	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37286	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel
37288	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and

	radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37290	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel
37292	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37294	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent

	placement, atherectomy, and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel
37296	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel
37298	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel
0238T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion

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

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 lower extremity arterial revascularization. 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:

- Complications associated with lower extremity arterial revascularization include arterial perforation, distal embolism, or myocardial infarction.¹
- Although rare, adverse reactions to anesthesia or contrast agents used during the procedure may occur. As with any surgical procedure, there is a risk of infection at the surgical site.¹
- Restenosis, or re-narrowing of the artery, can occur and may require additional procedures.¹
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- This procedure improves blood flow and restores adequate blood circulation to the affected limb.¹
- Restoring blood flow can reduce or eliminate pain and cramping.¹
- Improved limb function can allow patients to resume activities of daily living (ADLs).¹
- Reduction in complications and adverse effects from unnecessary procedures.²
- Improved patient outcomes through timely and appropriate access to the procedure. In patients with critical limb ischemia, this procedure decreases the likelihood of amputation.²
- 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 Evidence

Conte et al (2019) developed global vascular guidelines for the management of chronic limb-threatening ischemia. The group proposed a new anatomic scheme for threatened limbs, the Global Limb Anatomic Staging System (GLASS). This integrated, limb-based approach is based on a set of clinical assumptions and simplified approaches to stratification. They make a strong recommendation for revascularization to all average-risk patients with advanced limb-threatening conditions and significant perfusion deficits. There was a weak recommendation for revascularization in average-risk patients with intermediate limb threat (based on a scoring tool such as Wlfi). It is stated that a more in-depth study is required regarding the relationship between regional ischemia and patterns of infrapopliteal and pedal disease.²

Woo et al (2022) published the Society of Vascular Surgery appropriate use criteria for the management of intermittent claudication. Twenty-two hundred and eighty unique intermittent claudication treatment scenarios were rated. Invasive treatment recommendations were made for patients who have completed exercise therapy, are nonsmokers, and are on optimal medical therapy with severe lifestyle limitations. The group stated that there is an unclear benefit and possible harm related to invasive intervention in the infrapopliteal segment for intermittent claudication.⁴

Gerhard-Herman et al (2017) developed the 2016 AHA/ACC guideline for the management of patients with lower extremity peripheral artery disease. Strong evidence-based recommendations were made for revascularization in the setting of CLTI to minimize tissue loss. Interdisciplinary team evaluation is strongly recommended prior to intervention. The BASIL (bypass versus angioplasty in severe ischemia of the leg) randomized controlled trial (RCT) revealed that endovascular revascularization is an effective option for those patients with chronic limb-threatening ischemia as compared with open surgery. The group stated that multiple RCTs are ongoing that compare surgical and endovascular treatment.⁷

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Cohere Medicare Advantage Policy – Multiple Gated Acquisition (MUGA) Scan and Infarct Avid Scintigraphy

Clinical Policy for Medical Necessity Review

Version: 2.2

Policy Number: CHP-247-2.2

Cohere Health UMC Approval Date: October 16, 2025

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medicare Advantage Policy - Multiple Gated Acquisition (MUGA) Scan and Infarct Avid Scintigraphy

Policy Number: CHP-247-2.2

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

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Medical Necessity Criteria

Service: Multiple Gated Acquisition (MUGA) Scan and Infarct Avid Scintigraphy

Related CMS Documents

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

- [National Coverage Determination \(NCD\) 220.12. Single Photon Emission Computed Tomography \(SPECT\)](#)
- [Local Coverage Determination \(LCD\) L33457. Cardiac Radionuclide Imaging](#)
 - [Billing and Coding: Cardiac Blood Pool Imaging \(A54768\)](#)
 - [Billing and Coding: Cardiac Radionuclide Imaging \(A56476\)](#)
- [Local Coverage Determination \(LCD\) L33560. Cardiovascular Nuclear Medicine](#)
 - [Billing and Coding: Cardiovascular Nuclear Medicine \(A56743\)](#)
- [Local Coverage Determination \(LCD\) L33960. Cardiovascular Nuclear Medicine](#)
 - [Billing and Coding: Cardiovascular Nuclear Medicine \(A56494\)](#)

Description

A multiple gated acquisition scan (MUGA scan) is a noninvasive nuclear medicine test used to evaluate the heart's structural and dynamic properties. Other names include radionuclide angiography (RNA), radionuclide ventriculography (RVG), gated equilibrium radionuclide angiography (ERNA), and blood pool imaging. It uses a radioactive tracer to create a computerized image of the heart as it beats. The primary contemporary use of a MUGA scan is to evaluate the overall ability of the heart to pump blood by calculating a left and right ventricular ejection fraction and assessing regional wall motion abnormalities. However, there are many other possible uses for a MUGA scan, including assessing the orientation of the heart and great vessels in the chest, determining diastolic dysfunction, and evaluating valve motion.⁹⁻¹²

An equilibrium MUGA scan most commonly utilizes technetium-99m (Tc-99m) pertechnetate bound to red blood cells. The technetium remains within the blood pool, and serial imaging studies to assess function can be acquired over several hours. A “first-pass” study utilizes rapidly acquired image frames to observe a bolus of technetium-99m or other suitable radionuclide as it moves through the venous system into the right atrium, right ventricle, pulmonary artery, lungs, left atrium, left ventricle and aorta.¹⁰ The procedure can give a separate evaluation of right ventricular function, as well as assess for an intracardiac shunt.¹⁰

Other cardiac radionuclide imaging includes myocardial infarct avid scintigraphy, which is used when it is not possible to make a definitive diagnosis of myocardial infarction by electrocardiogram (ECG) or enzyme testing.^{10,12} Technetium-99m (stannous) pyrophosphate localizes in recently infarcted myocardium with the most intense visualization, usually 48–72 hours after infarction.

Medical Necessity Criteria

Indications

A **MUGA scan** is considered appropriate if **ANY** of the following is **TRUE**:

- **An equilibrium MUGA scan** is considered appropriate for evaluation of ventricular size, wall motion, stroke volume, and ejection fraction when this information is medically necessary to direct further evaluation and management for **ALL** of the following¹⁻⁴:
 - **ANY** of the following clinical scenarios⁹⁻¹²:
 - Assessment of ventricular function when required for management, and transthoracic echocardiography (TTE) or other imaging have proven inadequate¹²; **OR**
 - When there are conflicting results between other testing in the measurement of ejection fraction (EF), and the results of the MUGA will help in the management of the patient; **AND**
 - **ANY** of the following:
 - Evaluation of ventricular function in a patient with myocardial disease¹⁰; **OR**
 - Determination of accurate left ventricular ejection fraction (LVEF) in patients with ongoing heart failure despite guideline-directed medical therapy; **OR**
 - Evaluation of patient in whom accurate measure of ejection fraction is needed to make a determination of whether to implant defibrillator or biventricular pacemaker; **OR**
 - Post-transplant cardiac disease, for **ANY** of the following:
 - Assessment of coronary arteriopathy; **OR**
 - Evaluation for ventricular dysfunction with post-transplant rejection; **OR**
 - Assessment of cardiac function for cardiotoxic chemotherapy, as indicated by **ANY** of the following:
 - Initial baseline study prior to initiation of cardiotoxic chemotherapy (see list below), and **ANY** of the following:
 - No echocardiogram is planned or performed; **OR**
 - Prior echocardiogram is uninterpretable due to poor visualization window; **OR**

- Given the widespread use of echocardiography, serial MUGA imaging should be limited. It can be used for cardiac function monitoring during or at the completion of cardiotoxic chemotherapy, as indicated by **ANY** of the following^{2,13-15}:
 - **ALL** of the following:
 - Anthracycline drug use, including **ANY** of the following:
 - Daunorubicin (Cerubidine); **OR**
 - Doxorubicin (Adriamycin); **OR**
 - Epirubicin (Ellence); **OR**
 - Idarubicin (Idamycin, Zavedos); **OR**
 - Mitoxantrone (Novantrone); **OR**
 - Valrubicin (Valstar); **AND**
 - **ANY** of the following:
 - Every 3 months during therapy; **OR**
 - Six and twelve months post-therapy; **OR**
 - For patients getting very high-dose treatment (e.g., equivalent dose of doxorubicin 250 mg/m² and every additional 50–100 mg/m² during therapy); **OR**
 - **ALL** of the following:
 - HER2-targeted therapy, including **ANY** of the following:
 - Trastuzumab (Herceptin and others); **OR**
 - Lapatibin [Tykerb]; **OR**
 - Pertuzumab (Perjeta); **OR**
 - Margetuximab (Margetenza); **AND**
 - **ANY** of the following intervals:
 - Every 3 months during therapy; **OR**
 - Every 6 months up to 2 years post therapy; **OR**
 - Other cardiotoxic treatments including **ANY** of the following:
 - Tyrosine kinase inhibitors; **OR**
 - Proteasome inhibitors; **OR**
 - V-raf murine sarcoma viral oncogene homolog B1 (BRAF) inhibitors; **OR**
 - Mitogen-activated extracellular signal-regulated kinase (MEK) inhibitors; **OR**
 - Immune checkpoint inhibitors; **OR**
 - Antimetabolites; **OR**
 - 5-FU (5 fluorouracil); **OR**

- Bevacizumab (Avastin); **OR**
 - Clofarabine (Clolar); **OR**
 - Cyclophosphamide (Cytoxan); **OR**
 - Imatinib (Gleevec); **OR**
 - Ifosfamide (Ifex); **OR**
 - Mitomycin (Mutamycin); **OR**
 - Sorafenib (Nexavar); **OR**
 - Sunitinib (Sutent); **OR**
 - Paclitaxel (Taxol); **OR**
 - Docetaxel (Taxotere); **OR**
 - Capecitabine (Xeloda); **OR**
- Cardiomyopathy for **ANY** of the following:
 - Diagnosis of hypertrophic cardiomyopathy and/or myocardial ischemia²; **OR**
 - Differentiation of ischemic from non-ischemic cardiomyopathy²; **OR**
 - In rare cases, MUGA can be used to reassess patients with heart failure reduced ejection fraction if an echocardiogram is technically difficult¹⁶; **OR**
- A **first-pass MUGA study** is considered appropriate for **ANY** of the following:^{4,10}
 - Need for assessment of RV function or identification of shunt (e.g., suspected congenital abnormality)¹⁰; **OR**
 - Information has not been previously obtained or is likely to be obtained from other planned tests such as echocardiography or equilibrium gated blood pool studies; **OR**
 - Assessment of right ventricular ejection fraction (RVEF) when transthoracic echocardiography (TTE) or other imaging have proven inadequate¹²; **OR**
- **Infarct avid scintigraphy** (typically with tracers such as technetium-99m tetracycline or technetium-99m pyrophosphate) when it is not possible to make a definitive diagnosis of recent myocardial infarction by ECG or enzyme testing^{3,4}; **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 a change in symptoms, there is an established need for monitoring that would influence management.

Non-Indications

MUGA scan/cardiac radionuclide imaging is not considered appropriate for **ANY** of the following:

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms¹⁷.

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.^{[18,19](#)}

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.^{[18,19](#)}

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.^{[18,19](#)}

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.^{[18,19](#)}

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
78472	Cardiac blood pool imaging, gated equilibrium; planar, single study at rest or stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without additional quantitative processing
78473	Cardiac blood pool imaging, gated equilibrium; multiple studies, wall motion study plus ejection fraction, at rest and stress (exercise and/or pharmacologic), with or without additional quantification
78481	Cardiac blood pool imaging (planar), first pass technique; single study, at rest or with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification
78483	Cardiac blood pool imaging (planar), first pass technique; multiple studies, at rest and with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification
78494	Cardiac blood pool imaging, gated equilibrium, spect, at rest, wall motion study plus ejection fraction, with or without quantitative processing
78496	Cardiac blood pool imaging, gated equilibrium, single study, at rest, with right ventricular ejection fraction by first pass technique (list separately in addition to code for primary procedure)

78466	Myocardial imaging, infarct avid, planar; qualitative or quantitative
78468	Myocardial imaging, infarct avid, planar; with ejection fraction by first pass technique
78469	Myocardial imaging, infarct avid, planar; tomographic spect with or without quantification

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 MUGA scans may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, allergic reaction, and contrast extravasation into the surrounding tissues.^{18,20-22}
- Potential danger to pregnancy: MUGA scan 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.²³
- Increased healthcare costs and complications from the inappropriate use of additional interventions.

The clinical benefits of using these criteria for MUGA scans include:

- Non-invasive: MUGA scans are less invasive and have lower radiation burdens than procedures like the coronary angiogram (A MUGA scan imparts a relatively low radiation dose (0.3-0.52 rem equivalent in a standard study).⁹ The non-invasive nature of MUGA scans allows for the collection of diagnostic and prognostic information before invasive cardiac evaluations are necessary.²⁴
- Cost-effective and time-efficient: MUGA scans are widely available and inexpensive compared to alternative procedures. Furthermore, a MUGA

study may maybe be performed in an hour, taking half the time of a myocardial perfusion study.^{[24](#)}

- Ease of administration: MUGA scans have excellent reproducibility in determining left ventricular ejection fraction (LVEF), as the imaging tests produce low rates of intra- and inter-observer variability and operator-dependent variation.^{[9,25](#)}

Medical Evidence

Mitra et al. (2012) describe two important uses of MUGA scans in day-to-day clinical practice, such as serial assessment of LVEF in patients who are receiving cardiotoxic chemotherapy and assessment of patients with intractable heart failure (HF) to determine an accurate LVEF. Additionally, in heart failure patients, uses include identifying diastolic dysfunction in HF with preserved LVEF and evaluation of dyssynchrony with MUGA single photon emission tomography prior to cardiac resynchronization therapy.⁹

Printezi et al. (2022) performed a systematic review examining the relative concordance between MUGA, TTE, and cardiac magnetic resonance imaging (CMR) for the monitoring of LVEF in patients with cancer therapy-related cardiac dysfunction. Twenty-two studies were included in the review, reporting on 1017 total patients. Overall, TTE and MUGA showed greater concordance, while the agreement between CMR and MUGA was less strong. The authors conclude that a multimodal approach to diagnostic imaging may be possible when monitoring LVEF in patients receiving treatment for cancer.¹²

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Version 2.2	03/16/2026	Revision. Updated links and references for A56743, L33960, and A56494.



Cohere Medicare Advantage Policy – Multiple Gated Acquisition (MUGA) Scan

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 - Multiple Gated Acquisition (MUGA) Scan

Date of last literature review: 10/22/2024

Document last updated: 10/24/2024

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

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Medical Necessity Criteria

Service: Multiple Gated Acquisition (MUGA) Scan

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 [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁴

- [National Coverage Determination \(NCD\) 220.12. Single Photon Emission Computed Tomography \(SPECT\)](#)
- [Local Coverage Determination \(LCD\) L33457. Cardiac Radionuclide Imaging](#)
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- [Billing and Coding: Cardiac Radionuclide Imaging \(A56476\)](#)
- [Billing and Coding: Cardiovascular Nuclear Medicine \(A56743\)](#)
- [Billing and Coding: Cardiovascular Nuclear Medicine \(A56494\)](#)

Recommended Clinical Approach

A multiple-gated acquisition scan (MUGA scan) is a noninvasive, nuclear medicine test used to evaluate the heart's structural and dynamic properties. Other names include radionuclide angiography (RNA), radionuclide ventriculography (RVG), gated equilibrium radionuclide angiography (ERNA), and blood pool imaging. It uses a radioactive tracer to create a computerized image of the heart as it beats. The primary contemporary use of a MUGA scan is for evaluating the overall ability of the heart to pump blood

by calculating a left and right ventricular ejection fraction and assessing regional wall motion abnormalities. However, there are multiple other possible uses for a MUGA scan, such as the assessment of the orientation of the heart and great vessels in the chest, determination of diastolic dysfunction, evaluation of valve motion, and assessment of intracardiac shunts.^{5,6}

There are a number of protocols that can be utilized. An equilibrium MUGA scan most commonly utilizes technetium-99m (Tc-99m) pertechnetate bound to red blood cells. Accordingly, the technetium remains within the blood pool, and serial imaging studies to assess function can be acquired over several hours. A “first-pass” study radionuclide angiography utilizes rapidly acquired image frames to observe a bolus of technetium-99m or another suitable radionuclide as it moves through the venous system into the right atrium, right ventricle, pulmonary artery, lungs, left atrium, left ventricle and aorta.¹⁵ The procedure can give a separate evaluation of right ventricular function as well as assess for an intracardiac shunt.¹⁵

Other Cardiac radionuclide imaging includes myocardial infarct avid scintigraphy, which is used in patients in whom it is not possible to make a definitive diagnosis of myocardial infarction by ECG or enzyme testing if the duration from onset of the infarction is greater than 24 hours and less than 7 days.^{6,15} Technetium-99m (stannous) pyrophosphate localizes in recently infarcted myocardium with the most intense visualization, usually 48–72 hours after infarction.¹⁵

Evaluation of Potential Harms and Clinical Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of a Multiple Gated Acquisition (MUGA) scan. 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, allergic reaction, and contrast extravasation into the surrounding

tissues.⁷⁻¹⁰

- Potential danger to pregnancy: MUGA scan 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.

The clinical benefits of using these criteria include:

- Non-invasive: MUGA scans are less invasive and have lower radiation burdens than procedures like the coronary angiogram (A MUGA scan imparts a relatively low radiation dose (0.3–0.52 rem equivalent in a standard study).⁵ The non-invasive nature of MUGA scans allows for the collection of diagnostic and prognostic information before invasive cardiac evaluations are necessary.⁶
- Cost Effective and Time Efficient: MUGA scans are widely available and inexpensive compared to alternative procedures. Furthermore, a MUGA study may maybe be performed in an hour, taking half the time of a myocardial perfusion study.⁶
- Ease of Administration: MUGA scans have excellent reproducibility in determining left ventricular ejection fraction (LVEF), as the imaging tests produce low rates of intra- and inter-observer variability and operator-dependent variation.^{5,12}

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

→ **MUGA scan** is considered appropriate if **ANY** of the following is **TRUE**:

◆ **A MUGA scan** (not first pass) is considered appropriate for evaluation of ventricular size, wall motion, stroke volume, and ejection fraction when this information is medically necessary to direct further evaluation and management for **ANY** of the following¹⁻⁴:

- Post-transplant cardiac disease, for **ANY** of the following:
 - Assessment of coronary arteriopathy; **OR**
 - Evaluation for ventricular dysfunction with post-transplant rejection; **OR**
- Assessment of cardiac function for cardiotoxic chemotherapy, as indicated by **ANY** of the following:
 - Initial baseline study prior to initiation of cardiotoxic chemotherapy (see list below), and **ANY** of the following:
 - ◆ No echocardiogram is planned or performed; **OR**
 - ◆ Prior echocardiogram is uninterpretable due to poor visualization window; **OR**
 - Given the widespread use of echocardiography, serial MUGA imaging should be limited. It can be used for cardiac function monitoring during or at the completion of cardiotoxic chemotherapy, as indicated by **ANY** of the following^{21,22,23}:
 - ◆ Anthracycline drug use [Daunorubicin (Cerubidine), Doxorubicin (Adriamycin), Epirubicin (Ellence), Idarubicin (Idamycin), Mitoxantrone (Novantrone), Valrubicin (Valstar)] and **ANY** of the following:

- Every 3 months during therapy; **OR**
- Six and twelve months post-therapy; **OR**
- For patients getting very high-dose treatment (e.g., equivalent dose of doxorubicin 250 mg/m² and every additional 50-100 mg/m² during therapy);

OR

- ◆ HER2-targeted therapy [trastuzumab (Herceptin and others),, Pertuzumab (Perjeta), and margetuximab(Margenza)] at **ANY** of the following intervals:
 - Every 3 months during therapy; **OR**
 - Every 6 months up to 2 years post therapy; **OR**
- ◆ Other cardiotoxic treatments including tyrosine kinase inhibitors, proteasome inhibitors, BRAF (v-raf murine sarcoma viral oncogene homolog B1) inhibitors, MEK (mitogen-activated extracellular signal-regulated kinase) inhibitors, immune checkpoint inhibitors, antimetabolites, 5-FU (5 fluorouracil), Bevacizumab (Avastin), Clofarabine (Clolar), Cyclophosphamide (Cytoxan), Imatinib (Gleevec), Ifosfamide (Ifex), Mitomycin (Mutamycin), Sorafenib (Nexavar), Sunitinib (Sutent), Paclitaxel (Taxol), Docetaxel (Taxotere), Capecitabine (Xeloda) periodically (but no more than every 3 months) in high-risk patients, including **ANY** of the following:
 - High-risk female patient greater than or equal to 50 years old; **OR**
 - Presence of traditional cardiovascular risk factors (hypertension, smoking, obesity, dyslipidemia, insulin resistance); **OR**

- Past medical history with **ANY** of the following:
 - Reduced or low-normal LVEF (50% to 54%) pre-treatment; **OR**
 - Presence of pre-existing cardiovascular disease (e.g., CAD, PAD, cardiomyopathy, severe valvular heart disease, heart failure, or diabetes); **OR**
 - Chronic kidney disease stage 2 (eGFR less than 78 ml/min/1.73 m²); **OR**
 - Abnormal Biomarkers including **ANY** of the following:
 - ◆ Elevated baseline troponin and/or NT-proBNP; **OR**
 - ◆ Elevated cardiac troponin or NT-proBNP during cancer therapy; **OR**
- Cardiomyopathy for **ANY** of the following:
 - Diagnosis of hypertrophic cardiomyopathy and/or myocardial ischemia; **OR**
 - Differentiation of ischemic from non-ischemic cardiomyopathy; **OR**
 - In rare cases, MUGA can be used to reassess patients with heart failure reduced ejection fraction if an echocardiogram is technically difficult²⁰; **OR**
- Evaluation of patient in whom an accurate measure of ejection fraction is needed to make a determination of whether to implant defibrillator or biventricular pacemaker; **OR**
- ◆ A **first-pass study** (for calculation of RV ejection fraction and shunting) is considered appropriate for **ANY** of the following:^{4,15}

- Need for assessment of RV function or identification of shunt (e.g., suspected congenital abnormality); **OR**
- Information has not been previously obtained or is likely to be obtained from other planned tests such as echocardiography; **OR**
- Assessment of right ventricular ejection fraction when transthoracic echocardiography (TTE) or other imaging have proven inadequate; **OR**
- ◆ **Infarct avid scintigraphy** (typically with tracers such as technetium-99m tetracycline or technetium-99m pyrophosphate) is considered appropriate for **ALL** of the following:^{4,15}
 - A clinical scenario where it is not possible to make a definitive diagnosis of recent myocardial infarction by ECG or enzyme testing; **AND**
 - The duration from the onset of the infarction is greater than 24 hours and less than 7 days.
- ◆ 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

→ **MUGA scans/cardiac radionuclide imaging** are **NOT** considered appropriate for **ANY** of the following:

- ◆ Pregnant or lactating patients; **OR**
- ◆ Known allergy or sensitivity to the radioactive or other materials used during the procedure.

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 or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
78472	Cardiac blood pool imaging, gated equilibrium; planar, single study at rest or stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without additional quantitative processing
78473	Cardiac blood pool imaging, gated equilibrium; multiple studies, wall motion study plus ejection fraction, at rest and stress (exercise and/or pharmacologic), with or without additional quantification
78481	Cardiac blood pool imaging (planar), first pass technique; single study, at rest or with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification
78483	Cardiac blood pool imaging (planar), first pass technique; multiple studies, at rest and with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification
78494	Cardiac blood pool imaging, gated equilibrium, spect, at rest, wall motion study plus ejection fraction, with or without quantitative processing
78496	Cardiac blood pool imaging, gated equilibrium, single study, at rest, with right ventricular ejection fraction by first pass technique (list separately in addition to code for primary procedure)
78466	Myocardial imaging, infarct avid, planar; qualitative or quantitative

78468	Myocardial imaging, infarct avid, planar; with ejection fraction by first pass technique
78469	Myocardial imaging, infarct avid, planar; tomographic spect with or without quantification

Medical Evidence

Mitra et al. (2012) describe two important uses of MUGA scans in day-to-day clinical practice: serial assessment of LVEF in patients who are receiving cardiotoxic chemotherapy as well as with intractable heart failure (HF) patients to determine an accurate LVEF. Additionally, in heart failure patients, identifying diastolic dysfunction in HF with preserved LVEF and evaluation of dyssynchrony with MUGA single photon emission tomography prior to cardiac resynchronization therapy.⁵

A 1995 American College of Cardiology guideline from the Committee on Radionuclide Imaging. Gated equilibrium blood pool radionuclide angiography under rest and stress is recommended in chronic ischemic heart disease to determine accurate left and right ventricular ejection fraction values and the ability to assess regional wall motion. Rest and exercise or pharmacological stress may be appropriate.¹⁵

For decades, Multi Gated Acquisition (MUGA) scans were used to detect left ventricular dysfunction.¹⁶ However, due to concerns surrounding serial radiation exposure, echocardiography has largely superseded MUGA scans to become the primary method of medical imaging used to monitor and manage chemotherapy-induced cardiomyopathy.¹⁷ Patients living with breast cancer and patients receiving trastuzumab were found to be particularly vulnerable to radiation exposure and secondary cancer risk associated with repeated MUGA scans.¹⁸ However, the imaging test is still used to monitor left ventricular ejection fraction (LVEF) in clinical settings due to its high reproducibility and ease of administration.¹⁹

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Clinical Guideline Revision History/Information

Original Date: October 24, 2024		
Review History		



Cohere Medicare Advantage Policy – Multiple Gated Acquisition (MUGA) Scan

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 24, 2024

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by calculating a left and right ventricular ejection fraction and assessing regional wall motion abnormalities. However, there are multiple other possible uses for a MUGA scan, such as the assessment of the orientation of the heart and great vessels in the chest, determination of diastolic dysfunction, evaluation of valve motion, and assessment of intracardiac shunts.^{5,6}

There are a number of protocols that can be utilized. An equilibrium MUGA scan most commonly utilizes technetium-99m (Tc-99m) pertechnetate bound to red blood cells. Accordingly, the technetium remains within the blood pool, and serial imaging studies to assess function can be acquired over several hours. A “first-pass” study radionuclide angiography utilizes rapidly acquired image frames to observe a bolus of technetium-99m or another suitable radionuclide as it moves through the venous system into the right atrium, right ventricle, pulmonary artery, lungs, left atrium, left ventricle and aorta.¹⁵ The procedure can give a separate evaluation of right ventricular function as well as assess for an intracardiac shunt.¹⁵

Other Cardiac radionuclide imaging includes myocardial infarct avid scintigraphy, which is used in patients in whom it is not possible to make a definitive diagnosis of myocardial infarction by ECG or enzyme testing if the duration from onset of the infarction is greater than 24 hours and less than 7 days.^{6,15} Technetium-99m (stannous) pyrophosphate localizes in recently infarcted myocardium with the most intense visualization, usually 48–72 hours after infarction.¹⁵

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The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, allergic reaction, and contrast extravasation into the surrounding

tissues.⁷⁻¹⁰

- Potential danger to pregnancy: MUGA scan 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.

The clinical benefits of using these criteria include:

- Non-invasive: MUGA scans are less invasive and have lower radiation burdens than procedures like the coronary angiogram (A MUGA scan imparts a relatively low radiation dose (0.3–0.52 rem equivalent in a standard study).⁵ The non-invasive nature of MUGA scans allows for the collection of diagnostic and prognostic information before invasive cardiac evaluations are necessary.⁶
- Cost Effective and Time Efficient: MUGA scans are widely available and inexpensive compared to alternative procedures. Furthermore, a MUGA study may maybe be performed in an hour, taking half the time of a myocardial perfusion study.⁶
- Ease of Administration: MUGA scans have excellent reproducibility in determining left ventricular ejection fraction (LVEF), as the imaging tests produce low rates of intra- and inter-observer variability and operator-dependent variation.^{5,12}

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

→ **MUGA scan** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ **A MUGA scan** (not first pass) is considered appropriate for evaluation of ventricular size, wall motion, stroke volume, and ejection fraction when this information is medically necessary to direct further evaluation and management for **ANY** of the following¹⁻⁴:

- Post-transplant cardiac disease, for **ANY** of the following:
 - Assessment of coronary arteriopathy; **OR**
 - Evaluation for ventricular dysfunction with post-transplant rejection; **OR**
- Assessment of cardiac function for cardiotoxic chemotherapy, as indicated by **ANY** of the following:
 - Initial baseline study prior to initiation of cardiotoxic chemotherapy (see list below), and **ANY** of the following:
 - ◆ No echocardiogram is planned or performed; **OR**
 - ◆ Prior echocardiogram is uninterpretable due to poor visualization window; **OR**
 - Given the widespread use of echocardiography, serial MUGA imaging should be limited. It can be used for cardiac function monitoring during or at the completion of cardiotoxic chemotherapy, as indicated by **ANY** of the following^{21,22,23}:
 - ◆ Anthracycline drug use [Daunorubicin (Cerubidine), Doxorubicin (Adriamycin), Epirubicin (Ellence), Idarubicin (Idamycin), Mitoxantrone (Novantrone), Valrubicin (Valstar)] and **ANY** of the following:

- Every 3 months during therapy; **OR**
- Six and twelve months post-therapy; **OR**
- For patients getting very high-dose treatment (e.g., equivalent dose of doxorubicin 250 mg/m² and every additional 50-100 mg/m² during therapy); **OR**

◆ HER2-targeted therapy [trastuzumab (Herceptin and others),, Pertuzumab (Perjeta), and margetuximab(Margenza)] at **ANY** of the following intervals:

- Every 3 months during therapy; **OR**
- Every 6 months up to 2 years post therapy; **OR**

◆ Other cardiotoxic treatments including tyrosine kinase inhibitors, proteasome inhibitors, BRAF (v-raf murine sarcoma viral oncogene homolog B1) inhibitors, MEK (mitogen-activated extracellular signal-regulated kinase) inhibitors, immune checkpoint inhibitors, antimetabolites, 5-FU (5 fluorouracil), Bevacizumab (Avastin), Clofarabine (Clolar), Cyclophosphamide (Cytoxan), Imatinib (Gleevec), Ifosfamide (Ifex), Mitomycin (Mutamycin), Sorafenib (Nexavar), Sunitinib (Sutent), Paclitaxel (Taxol), Docetaxel (Taxotere), Capecitabine (Xeloda) periodically (but no more than every 3 months) in high-risk patients, including **ANY** of the following:

- High-risk female patient greater than or equal to 50 years old; **OR**
- Presence of traditional cardiovascular risk factors (hypertension, smoking, obesity, dyslipidemia, insulin resistance); **OR**

- Past medical history with **ANY** of the following:
 - Reduced or low-normal LVEF (50% to 54%) pre-treatment; **OR**
 - Presence of pre-existing cardiovascular disease (e.g., CAD, PAD, cardiomyopathy, severe valvular heart disease, heart failure, or diabetes); **OR**
 - Chronic kidney disease stage 2 (eGFR less than 78 ml/min/1.73 m²); **OR**
 - Abnormal Biomarkers including **ANY** of the following:
 - ◆ Elevated baseline troponin and/or NT-proBNP; **OR**
 - ◆ Elevated cardiac troponin or NT-proBNP during cancer therapy; **OR**
- Cardiomyopathy for **ANY** of the following:
 - Diagnosis of hypertrophic cardiomyopathy and/or myocardial ischemia; **OR**
 - Differentiation of ischemic from non-ischemic cardiomyopathy; **OR**
 - In rare cases, MUGA can be used to reassess patients with heart failure reduced ejection fraction if an echocardiogram is technically difficult²⁰; **OR**
- Evaluation of patient in whom an accurate measure of ejection fraction is needed to make a determination of whether to implant defibrillator or biventricular pacemaker; **OR**
- ◆ A **first-pass study** (for calculation of RV ejection fraction and shunting) is considered appropriate for **ANY** of the following:^{4,15}

- Need for assessment of RV function or identification of shunt (e.g., suspected congenital abnormality); **OR**
- Information has not been previously obtained or is likely to be obtained from other planned tests such as echocardiography; **OR**
- Assessment of right ventricular ejection fraction when transthoracic echocardiography (TTE) or other imaging have proven inadequate; **OR**
- ◆ **Infarct avid scintigraphy** (typically with tracers such as technetium-99m tetracycline or technetium-99m pyrophosphate) is considered appropriate for **ALL** of the following:^{4,15}
 - A clinical scenario where it is not possible to make a definitive diagnosis of recent myocardial infarction by ECG or enzyme testing; **AND**
 - The duration from the onset of the infarction is greater than 24 hours and less than 7 days.
- ◆ 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

→ **MUGA scans/cardiac radionuclide imaging** are **NOT** considered appropriate for **ANY** of the following:

- ◆ Pregnant or lactating patients; **OR**
- ◆ Known allergy or sensitivity to the radioactive or other materials used during the procedure.

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 or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
78472	Cardiac blood pool imaging, gated equilibrium; planar, single study at rest or stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without additional quantitative processing
78473	Cardiac blood pool imaging, gated equilibrium; multiple studies, wall motion study plus ejection fraction, at rest and stress (exercise and/or pharmacologic), with or without additional quantification
78481	Cardiac blood pool imaging (planar), first pass technique; single study, at rest or with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification
78483	Cardiac blood pool imaging (planar), first pass technique; multiple studies, at rest and with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification
78494	Cardiac blood pool imaging, gated equilibrium, spect, at rest, wall motion study plus ejection fraction, with or without quantitative processing
78496	Cardiac blood pool imaging, gated equilibrium, single study, at rest, with right ventricular ejection fraction by first pass technique (list separately in addition to code for primary procedure)
78466	Myocardial imaging, infarct avid, planar; qualitative or quantitative

78468	Myocardial imaging, infarct avid, planar; with ejection fraction by first pass technique
78469	Myocardial imaging, infarct avid, planar; tomographic spect with or without quantification

Medical Evidence

Mitra et al. (2012) describe two important uses of MUGA scans in day-to-day clinical practice: serial assessment of LVEF in patients who are receiving cardiotoxic chemotherapy as well as with intractable heart failure (HF) patients to determine an accurate LVEF. Additionally, in heart failure patients, identifying diastolic dysfunction in HF with preserved LVEF and evaluation of dyssynchrony with MUGA single photon emission tomography prior to cardiac resynchronization therapy.⁵

A 1995 American College of Cardiology guideline from the Committee on Radionuclide Imaging. Gated equilibrium blood pool radionuclide angiography under rest and stress is recommended in chronic ischemic heart disease to determine accurate left and right ventricular ejection fraction values and the ability to assess regional wall motion. Rest and exercise or pharmacological stress may be appropriate.¹⁵

For decades, Multi Gated Acquisition (MUGA) scans were used to detect left ventricular dysfunction.¹⁶ However, due to concerns surrounding serial radiation exposure, echocardiography has largely superseded MUGA scans to become the primary method of medical imaging used to monitor and manage chemotherapy-induced cardiomyopathy.¹⁷ Patients living with breast cancer and patients receiving trastuzumab were found to be particularly vulnerable to radiation exposure and secondary cancer risk associated with repeated MUGA scans.¹⁸ However, the imaging test is still used to monitor left ventricular ejection fraction (LVEF) in clinical settings due to its high reproducibility and ease of administration.¹⁹

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Clinical Guideline Revision History/Information

Original Date: October 24, 2024		
Review History		



Cohere Medicare Advantage Policy – Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

Clinical Guidelines for Medical Necessity Review

Version: 1.2
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 - Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

Date of last literature review: 10/28/2024

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

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Medical Necessity Criteria

Service: Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

Benefit Category

Diagnostics tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.^{1,24-27,30-35}

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.^{1,24-27,30-35}

- [National Coverage Determination \(NCD\). Single Photon Emission Computed Tomography \(SPECT\) \(220.12\)](#)
- [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 \(A56952\)](#)
- [Local Coverage Determination \(LCD\). Cardiac Radionuclide Imaging \(L33457\)](#)
- [Billing and Coding: Cardiac Radionuclide Imaging \(A56476\)](#)
- [Local Coverage Determination \(LCD\). Cardiovascular Nuclear Medicine \(L33560\)](#)
- [Billing and Coding: Cardiovascular Nuclear Medicine \(A56743\)](#)
- [Local Coverage Determination \(LCD\). Cardiovascular Nuclear Medicine \(L33960\)](#)
- [Billing and Coding: Cardiovascular Nuclear Medicine \(A56494\)](#)

Recommended Clinical Approach

Myocardial perfusion imaging – single photon emission computed tomography (MPI-SPECT) is typically appropriate for patients with chest pain (or an ischemic equivalent) and an intermediate (16 to 50%) or high (greater than 50%) pretest probability (PTP) of obstructive (greater than or equal to 50% stenosis) coronary artery disease (CAD). (See the [Pre-Test Probability of CAD](#) published by the CAD Consortium). An exercise stress test is appropriate if the patient can exercise to a satisfactory workload.¹⁷ If the patient cannot exercise or has echocardiographic (ECG) abnormalities that interfere with the ECG interpretation during exercise, a pharmacologic MPI-SPECT or cost-effective alternatives such as stress echocardiography or coronary computed tomographic angiography (CCTA) should be considered. Limitations of MPI-SPECT include cost and radiation. Interpretation of MPI-SPECT can be affected by attenuation artifacts related to soft tissue overlying the heart or extracardiac radioisotope (e.g., liver or gastrointestinal uptake adjacent to the heart).²⁻³ In patients with known CAD, guideline-directed medical therapy (GDMT) for angina includes beta blockers, calcium channel blockers, long-acting nitrates, and ranolazine.¹³

Evaluation of Potential Harms and Clinical Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT). 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, and contrast extravasation into surrounding tissues.⁴⁻⁷
- **Potential danger to pregnancy:** MPI-SPECT 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.⁴ Fetal risk

includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁴

- Enhanced Increased healthcare costs and complications from the inappropriate use of emergency services and additional interventions.⁵

The clinical benefits of using these criteria include:

- Diagnostic accuracy: Vasodilator stress perfusion cardiac magnetic resonance (CMR), as performed with gadobutrol 0.1 mmol/kg body weight, is superior for the diagnosis and exclusion of coronary artery disease (CAD) versus gated SPECT. Positron emission tomography (PET) MPI is more effective than MPI-SPECT in predicting major adverse cardiovascular events (MACEs) in patients following kidney transplant. SPECT, however, appears to be superior to stress echocardiography (ECHO) in the diagnosis of isolated circumflex stenosis, as well as for the correct identification of multivessel CAD.⁶⁻⁷
- Screening at-risk patients for CVD: While the accuracy of MPI-SPECT is not high for the diagnosis of CAD, it is recommended to screen patients at-risk.⁸
- Utilization of MPI-SPECT decreases the utilization of coronary angiography and revascularization.⁹
- Assessment of infection-associated cardiac complications: Individuals with a history of COVID-19 have been shown to be more prone to having MPIs that demonstrate abnormalities, such as ischemia.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.

Medical Necessity Criteria

Indications

→ **Myocardial perfusion imaging single-photon emission computed tomography (MPI-SPECT)** is considered appropriate if **ANY** of the following is **TRUE**^{11-12,16,36}:

- ◆ Patient with new, recurrent, or worsening cardiac or anginal equivalent symptoms and **ANY** of the following:
 - Physical inability to reach maximum exercise workload; **OR**
 - Uninterpretable ECG with **ANY** of the following:
 - Complete Left Bundle Branch Block (LBBB); **OR**
 - Ventricular paced rhythm; **OR**
 - Pre-excitation pattern (e.g., Wolff-Parkinson-White); **OR**
 - Greater than 1 mm ST segment depression; **OR**
 - Left ventricular hypertrophy (LVH) with repolarization abnormalities; **OR**
 - Patient on digoxin therapy; **OR**
 - History of CAD based on prior anatomic evaluation of the coronary arteries or a history of coronary artery bypass graft surgery (CABG)/percutaneous coronary intervention (PCI); **OR**
 - Syncope (abrupt, transient, complete loss of consciousness) with an intermediate (ASCVD risk 7.5% to 20%) or high CHD risk (greater than 20%) ([ATP III risk criteria](#)), or an intermediate or high CAD risk (greater than or equal to 16%) on the [Pre-test probability of CAD \(CAD consortium\)](#) AND cardiac etiology is suspected based on initial evaluation, including history, physical examination, or ECG¹¹; **OR**
 - Known or suspected ventricular arrhythmia [frequent PVCs (greater than 30 PVCs per hour), non-sustained ventricular tachycardia, sustained ventricular tachycardia, ventricular fibrillation]; **OR**
 - Prior normal or submaximal exercise stress test with suspicion of a false negative result; **OR**

- Prior equivocal or borderline testing where ischemia remains a concern; **OR**
- Taking beta blocker, calcium channel blocker, and/or antiarrhythmic medication and documentation supports that adequate workload may not be attainable to enable 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 in patients with **ANY** of the following:
 - Intermediate to high pre-test probability for CAD based on the [Pre-test probability of CAD \(CAD consortium\)](#) calculator; **OR**
 - Prior revascularization; **OR**
 - Elevated cardiac troponins, Non-ST segment elevation MI [NSTEMI]; **OR**
- Patients with hypertrophic cardiomyopathy (HCM); **OR**
- ◆ New-onset atrial fibrillation with no prior cardiac evaluation; **OR**
- ◆ Patients with established CAD who experienced an acute coronary syndrome (ACS) event (STEMI, NSTEMI, 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 and able to exercise; **OR**
- ◆ Disease condition(s) associated with CAD (e.g., atherosclerotic abdominal aortic aneurysm, peripheral vascular disease, carotid artery disease, chronic renal failure) and **ALL** of the following:
 - No stress imaging evaluation performed within the preceding 2 years; **OR**
- ◆ Patients without cardiac symptoms and **ANY** of the following:
 - Elevated cardiac troponin; **OR**
 - Underwent a PCI (with stent) procedure more than 2 years prior with no evaluation for CAD in the past 2 years; **OR**
 - Underwent a CABG more than 5 years prior with no evaluation for CAD in the past 2 years; **OR**
- ◆ New, recurrent, or worsening left ventricular dysfunction/congestive heart failure; **OR**

- ◆ Preoperative testing before intermediate or high-risk surgery^{(Table 1),[14,29](#)} and **ANY** of the following:
 - Planned solid organ transplant (renal, pancreas, combined renal pancreas, liver, lung, or intestinal); **OR**
 - No known or suspected heart disease^{A,[29](#)} and **ALL** of the following:
 - 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 nonvascular 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 heart disease^{B,[29](#)} and **ANY** of the following:
 - 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 metabolic equivalents of tasks (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); **OR**
- Prior cardiac stress testing within 3 to 8 months and **ANY** of the following:
 - High-risk vascular surgery^(Table 1) with risk factors that the physician feels warrant repeat testing; **OR**
 - New findings on transthoracic echocardiography (TTE) such as new wall motion abnormalities, new significant valvular disease, or significant drop in ejection fraction; **OR**
 - New or worsening possible cardiovascular symptoms; **OR**
- ◆ Coronary calcium Agatston score greater than 400; **OR**
- ◆ Planned solid-organ transplant when no cardiac evaluation has been performed within the past year; **OR**
- ◆ Evaluation for transplant coronary artery disease (TCAD) or cardiac allograft vasculopathy (CAV) after organ transplantation; **OR**
- ◆ Coronary stenosis, as documented by **ANY** of the following:
 - Coronary angiography with stenosis greater than 50%; **OR**
 - CCTA with stenosis greater than 40%; **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.

^A**No Known or Suspected Heart Disease by History, Exam, or Electrocardiogram (ECG)**²⁹: Heart disease is not suspected based on history of no prior cardiac event, lack of cardiac risk factors, or prior cardiac testing indicating no ischemic heart disease, VHD, or HF. Exam does not suggest underlying heart disease by lack of murmurs, other than functional, and no signs of cardiac decompensation (i.e., 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.

^B**Known or Suspected Heart Disease by History, Exam, or Electrocardiogram**²⁹: PCI, 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 3x the upper limit of normal.

Table 1. Definitions of Low, Intermediate, and High-Risk Surgery^{28,29}

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	1. Total abdominal hysterectomy	-

	2. Diagnostic gynecologic procedures (laparoscopy)	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

Non-Indications

→ **Myocardial perfusion imaging single-photon emission computed tomography (MPI-SPECT)** is not considered appropriate if **ANY** of the following is **TRUE**^{1,11-12,21,24-27,30-35,36-41}:

- ◆ Routine screening in asymptomatic patients with **ANY** of the following, unless under specific conditions as outlined above:
 - Diabetes mellitus; **OR**
 - Preoperative evaluation for low-risk nonvascular surgery; **OR**
- ◆ Routine screening of patients beyond the first cardiac stress test in the absence of a documented change in condition (i.e. new symptoms or progression of existing symptoms); **OR**
- ◆ **ALL** of the following:
 - Low pretest probability (PTP) of CAD; **AND**
 - Interpretable ECG; **AND**
 - Ability to exercise; **OR**
- ◆ **ANY** of the following:
 - Recent (2-4 days) acute myocardial infarction (MI); **OR**
 - High-risk unstable angina; **OR**
 - Uncontrolled arrhythmia causing symptoms or hemodynamic compromise; **OR**
 - Critical aortic stenosis; **OR**
 - Decompensated or uncontrolled congestive heart failure; **OR**
 - Systolic blood pressure (BP) at rest greater than 200 mmHG or diastolic BP at rest greater than 110 mmHg; **OR**
 - Acute pulmonary embolus or pulmonary infarction; **OR**
 - Acute myocarditis or pericarditis; **OR**
 - Acute aortic dissection.

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.^{[18-19](#)}

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.^{[18-19](#)}

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.^{[18-19](#)}

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.^{[18-19](#)}

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
78451	Single-photon emission computed tomography (SPECT) myocardial perfusion imaging study with stress
78452	Multiple single-photon emission computed tomography (SPECT) myocardial perfusion imaging studies with stress
78453	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)
78454	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection

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

Definitions

Symptomatic/Ischemic Equivalent: Chest pain syndrome, anginal equivalent, or ischemic electrocardiogram (ECG) abnormalities are any constellation of clinical findings 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 CAD may also be considered an ischemic equivalent.²⁰

Pretest Probability (of Obstructive CAD): Pretest probability of CAD is the likelihood that the patient has obstructive CAD, calculated before the test result is known. These guidelines reference the 2019 European Society of Cardiology (ESC) Guidelines for the diagnosis and management of chronic coronary syndromes model to calculate the pretest probability based on age, sex, and type of chest pain.^{12,15,21-23,25-27} Additional information such as a coronary artery calcium (CAC) score or risk factors for CAD (such as diabetes mellitus, smoking, family history of premature CAD [first degree relative: male less than 55 years old or female less than 65 years old, hypertension, or dyslipidemia) can be used to improve the identification of obstructive CAD. (Use the [CAD Consortium Calculator](#)).

Medical Evidence

Huck et al. (2024) conducted a retrospective study to evaluate patients post-kidney transplant due to the risk of major adverse cardiovascular events (MACEs). The population is also at higher risk of developing cardiovascular disease. Single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI) and pretransplant positron emission tomography (PET) were utilized in the study of 393 patients. Results were taken from a follow-up period of 5.9 years. Overall PET MPI was more effective than SPECT-MPI to predict MACEs in patients post-kidney transplant. Future research should include the effectiveness of normal PET vs SPECT when evaluating low-risk patients.⁷

Kelderman et al. (2022) performed a systematic review on using MPI SPECT to diagnose cardiovascular disease in patients assessed for kidney transplantation. Thirteen studies that focused on MPI-SPECT were identified and included in the meta-analysis of 1245 MPI SPECT scans. The pooled sensitivity was 0.66 (95% CI 0.53 to 0.77), pooled specificity was 0.75 (95% CI 0.63 to 0.84) and the area under the curve (AUC) was 0.76. The authors note that while the accuracy is not high with MPI-SPECT for the diagnosis of CAD, it is recommended to screen patients at-risk.⁸

Patel et al. (2019) conducted a single-center randomized control trial (RCT) to determine the clinical efficacy of pharmacological MPI-SPECT and PET MPI in patients with coronary artery disease (CAD) and ischemia. A total of 322 symptomatic patients were included. The following pharmacologic agents were given to patients: aspirin therapy (88.8%), beta-blockers (76.7%), and statin therapy (77.3%). Seven patients (2.2%) had a diagnostic failure at 60 days; however, no major differences in diagnostic failure rates were observed overall. Decreased utilization of coronary angiography or revascularization was noted. (ClinicalTrials.gov Identifier NCT00976053).⁹

A number of recent articles provided recommendations for several common clinical scenarios. Gulati et al. (2021)¹² provided insights into the evaluation and diagnosis of chest pain, Winchester et al. (2023)¹¹ provided appropriate use criteria (AUC) for the detection and risk assessment of chronic coronary

disease, and Doherty et al. (2024)²⁹ updated a previous AUC document for the cardiovascular evaluation for nonemergency, noncardiac surgery, focusing more on ischemic heart disease, valvular heart disease, and heart failure (rather than cardiovascular disease in general) and their relation to the risks associated with various types of surgery (solid organ transplant, vascular, non-vascular).

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Cohere Medicare Advantage Policy – Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

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 - Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

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Medical Necessity Criteria

Service: Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

Benefit Category

Diagnostics tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.^{1,24-27,30-35}

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.^{1,24-27,30-35}

- [National Coverage Determination \(NCD\). Single Photon Emission Computed Tomography \(SPECT\) \(220.12\)](#)
- [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 \(A56952\)](#)
- [Local Coverage Determination \(LCD\). Cardiac Radionuclide Imaging \(L33457\)](#)
- [Billing and Coding: Cardiac Radionuclide Imaging \(A56476\)](#)
- [Local Coverage Determination \(LCD\). Cardiovascular Nuclear Medicine \(L33560\)](#)
- [Billing and Coding: Cardiovascular Nuclear Medicine \(A56743\)](#)
- [Local Coverage Determination \(LCD\). Cardiovascular Nuclear Medicine \(L33960\)](#)
- [Billing and Coding: Cardiovascular Nuclear Medicine \(A56494\)](#)

Recommended Clinical Approach

Myocardial perfusion imaging – single photon emission computed tomography (MPI-SPECT) is typically appropriate for patients with chest pain (or an ischemic equivalent) and an intermediate (16 to 50%) or high (greater than 50%) pretest probability (PTP) of obstructive (greater than or equal to 50% stenosis) coronary artery disease (CAD). (See the [Pre-Test Probability of CAD](#) published by the CAD Consortium). An exercise stress test is appropriate if the patient can exercise to a satisfactory workload.¹⁷ If the patient cannot exercise or has echocardiographic (ECG) abnormalities that interfere with the ECG interpretation during exercise, a pharmacologic MPI-SPECT or cost-effective alternatives such as stress echocardiography or coronary computed tomographic angiography (CCTA) should be considered. Limitations of MPI-SPECT include cost and radiation. Interpretation of MPI-SPECT can be affected by attenuation artifacts related to soft tissue overlying the heart or extracardiac radioisotope (e.g., liver or gastrointestinal uptake adjacent to the heart).²⁻³ In patients with known CAD, guideline-directed medical therapy (GDMT) for angina includes beta blockers, calcium channel blockers, long-acting nitrates, and ranolazine.¹³

Evaluation of Potential Harms and Clinical Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT). 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, and contrast extravasation into surrounding tissues.⁴⁻⁷
- **Potential danger to pregnancy:** MPI-SPECT 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.⁴ Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly,

delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁴

- Enhanced Increased healthcare costs and complications from the inappropriate use of emergency services and additional interventions.⁵

The clinical benefits of using these criteria include:

- Diagnostic accuracy: Vasodilator stress perfusion cardiac magnetic resonance (CMR), as performed with gadobutrol 0.1 mmol/kg body weight, is superior for the diagnosis and exclusion of coronary artery disease (CAD) versus gated SPECT. Positron emission tomography (PET) MPI is more effective than MPI-SPECT in predicting major adverse cardiovascular events (MACEs) in patients following kidney transplant. SPECT, however, appears to be superior to stress echocardiography (ECHO) in the diagnosis of isolated circumflex stenosis, as well as for the correct identification of multivessel CAD.⁶⁻⁷
- Screening at-risk patients for CVD: While the accuracy of MPI-SPECT is not high for the diagnosis of CAD, it is recommended to screen patients at-risk.⁸
- Utilization of MPI-SPECT decreases the utilization of coronary angiography and revascularization.⁹
- Assessment of infection-associated cardiac complications: Individuals with a history of COVID-19 have been shown to be more prone to having MPIs that demonstrate abnormalities, such as ischemia.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.

Medical Necessity Criteria

Indications

→ **Myocardial perfusion imaging single-photon emission computed tomography (MPI-SPECT)** is considered appropriate if **ANY** of the following is **TRUE**^{11-12,16,36}:

- ◆ Patient with new, recurrent, or worsening cardiac or anginal equivalent symptoms and **ANY** of the following:
 - Physical inability to reach maximum exercise workload; **OR**
 - Uninterpretable ECG with **ANY** of the following:
 - Complete Left Bundle Branch Block (LBBB); **OR**
 - Ventricular paced rhythm; **OR**
 - Pre-excitation pattern (e.g., Wolff-Parkinson-White); **OR**
 - Greater than 1 mm ST segment depression; **OR**
 - Left ventricular hypertrophy (LVH) with repolarization abnormalities; **OR**
 - Patient on digoxin therapy; **OR**
 - History of CAD based on prior anatomic evaluation of the coronary arteries or a history of coronary artery bypass graft surgery (CABG)/percutaneous coronary intervention (PCI); **OR**
 - Syncope (abrupt, transient, complete loss of consciousness) with an intermediate (ASCVD risk 7.5% to 20%) or high CHD risk (greater than 20%) ([ATP III risk criteria](#)), or an intermediate or high CAD risk (greater than or equal to 16%) on the [Pre-test probability of CAD \(CAD consortium\)](#) AND cardiac etiology is suspected based on initial evaluation, including history, physical examination, or ECG¹¹; **OR**
 - Known or suspected ventricular arrhythmia [frequent PVCs (greater than 30 PVCs per hour), non-sustained ventricular tachycardia, sustained ventricular tachycardia, ventricular fibrillation]; **OR**
 - Prior normal or submaximal exercise stress test with suspicion of a false negative result; **OR**
 - Prior equivocal or borderline testing where ischemia remains a concern; **OR**

- Taking beta blocker, calcium channel blocker, and/or antiarrhythmic medication and documentation supports that adequate workload may not be attainable to enable 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 in patients with **ANY** of the following:
 - Intermediate to high pre-test probability for CAD based on the [Pre-test probability of CAD \(CAD consortium\)](#) calculator; **OR**
 - Prior revascularization; **OR**
 - Elevated cardiac troponins, Non-ST segment elevation MI [NSTEMI]; **OR**
- Patients with hypertrophic cardiomyopathy (HCM); **OR**
- ◆ New-onset atrial fibrillation with no prior cardiac evaluation; **OR**
- ◆ Patients with established CAD who experienced an acute coronary syndrome (ACS) event (STEMI, NSTEMI, 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 and able to exercise; **OR**
- ◆ Disease condition(s) associated with CAD (e.g., atherosclerotic abdominal aortic aneurysm, peripheral vascular disease, carotid artery disease, chronic renal failure) and **ALL** of the following:
 - No stress imaging evaluation performed within the preceding 2 years; **OR**
- ◆ Patients without cardiac symptoms and **ANY** of the following:
 - Elevated cardiac troponin; **OR**
 - Underwent a PCI (with stent) procedure more than 2 years prior with no evaluation for CAD in the past 2 years; **OR**
 - Underwent a CABG more than 5 years prior with no evaluation for CAD in the past 2 years; **OR**
- ◆ New, recurrent, or worsening left ventricular dysfunction/congestive heart failure; **OR**
- ◆ Preoperative testing before intermediate or high-risk surgery^{(Table 1),[14,29](#)} and **ANY** of the following:

- Planned solid organ transplant (renal, pancreas, combined renal pancreas, liver, lung, or intestinal); **OR**
- No known or suspected heart disease^{A,29} and **ALL** of the following:
 - 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 nonvascular 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 heart disease^{B,29} and **ANY** of the following:
 - 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 metabolic equivalents of tasks (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); **OR**
- Prior cardiac stress testing within 3 to 8 months and **ANY** of the following:
 - High-risk vascular surgery^(Table 1) with risk factors that the physician feels warrant repeat testing; **OR**
 - New findings on transthoracic echocardiography (TTE) such as new wall motion abnormalities, new significant valvular disease, or significant drop in ejection fraction; **OR**
 - New or worsening possible cardiovascular symptoms; **OR**
- ◆ Coronary calcium Agatston score greater than 400; **OR**
- ◆ Planned solid-organ transplant when no cardiac evaluation has been performed within the past year; **OR**
- ◆ Evaluation for transplant coronary artery disease (TCAD) or cardiac allograft vasculopathy (CAV) after organ transplantation; **OR**
- ◆ Coronary stenosis, as documented by **ANY** of the following:
 - Coronary angiography with stenosis greater than 50%; **OR**
 - CCTA with stenosis greater than 40%; **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.

^ANo Known or Suspected Heart Disease by History, Exam, or Electrocardiogram (ECG)²⁹: Heart disease is not suspected based on history of no prior cardiac event, lack of cardiac risk factors, or prior cardiac testing indicating no ischemic heart disease, VHD, or HF. Exam does not suggest underlying heart disease by lack of murmurs, other than functional, and no signs of cardiac decompensation (i.e., 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.

^BKnown or Suspected Heart Disease by History, Exam, or Electrocardiogram²⁹: PCI, 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 3x the upper limit of normal.

Table 1. Definitions of Low, Intermediate, and High-Risk Surgery^{28,29}

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	1. Abdominal aortic aneurysm repair 2. Aorto-femoral bypass graft 3. Thoracic aortic aneurysm repair 4. Infra-inguinal open peripheral revascularization

		4. Above or below knee amputation	
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

Non-Indications

→ **Myocardial perfusion imaging single-photon emission computed tomography (MPI-SPECT)** is not considered appropriate if **ANY** of the following is **TRUE** [11-12,21,24-27,30-35,36-41](#).

- ◆ Routine screening in asymptomatic patients with **ANY** of the following, unless under specific conditions as outlined above:
 - Diabetes mellitus; **OR**
 - Preoperative evaluation for low-risk nonvascular surgery; **OR**
- ◆ Routine screening of patients beyond the first cardiac stress test in the absence of a documented change in condition (i.e. new symptoms or progression of existing symptoms); **OR**
- ◆ **ALL** of the following:
 - Low pretest probability (PTP) of CAD; **AND**
 - Interpretable ECG; **AND**
 - Ability to exercise; **OR**
- ◆ **ANY** of the following:
 - Recent (2-4 days) acute myocardial infarction (MI); **OR**
 - High-risk unstable angina; **OR**
 - Uncontrolled arrhythmia causing symptoms or hemodynamic compromise; **OR**

- Critical aortic stenosis; **OR**
- Decompensated or uncontrolled congestive heart failure; **OR**
- Systolic blood pressure (BP) at rest greater than 200 mmHG or diastolic BP at rest greater than 110 mmHg; **OR**
- Acute pulmonary embolus or pulmonary infarction; **OR**
- Acute myocarditis or pericarditis; **OR**
- Acute aortic dissection.

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.^{[18-19](#)}

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.^{[18-19](#)}

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.^{[18-19](#)}

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.^{[18-19](#)}

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
78451	Single-photon emission computed tomography (SPECT) myocardial perfusion imaging study with stress
78452	Multiple single-photon emission computed tomography (SPECT) myocardial perfusion imaging studies with stress
78453	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)
78454	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection

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

Definitions

Symptomatic/Ischemic Equivalent: Chest pain syndrome, anginal equivalent, or ischemic electrocardiogram (ECG) abnormalities are any constellation of clinical findings 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 CAD may also be considered an ischemic equivalent.²⁰

Pretest Probability (of Obstructive CAD): Pretest probability of CAD is the likelihood that the patient has obstructive CAD, calculated before the test result is known. These guidelines reference the 2019 European Society of Cardiology (ESC) Guidelines for the diagnosis and management of chronic coronary syndromes model to calculate the pretest probability based on age, sex, and type of chest pain.^{12,15,21-23,25-27} Additional information such as a coronary artery calcium (CAC) score or risk factors for CAD (such as diabetes mellitus, smoking, family history of premature CAD [first degree relative: male less than 55 years old or female less than 65 years old, hypertension, or dyslipidemia) can be used to improve the identification of obstructive CAD. (Use the [CAD Consortium Calculator](#)).

Medical Evidence

Huck et al. (2024) conducted a retrospective study to evaluate patients post-kidney transplant due to the risk of major adverse cardiovascular events (MACEs). The population is also at higher risk of developing cardiovascular disease. Single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI) and pretransplant positron emission tomography (PET) were utilized in the study of 393 patients. Results were taken from a follow-up period of 5.9 years. Overall PET MPI was more effective than SPECT-MPI to predict MACEs in patients post-kidney transplant. Future research should include the effectiveness of normal PET vs SPECT when evaluating low-risk patients.⁷

Kelderman et al. (2022) performed a systematic review on using MPI SPECT to diagnose cardiovascular disease in patients assessed for kidney transplantation. Thirteen studies that focused on MPI-SPECT were identified and included in the meta-analysis of 1245 MPI SPECT scans. The pooled sensitivity was 0.66 (95% CI 0.53 to 0.77), pooled specificity was 0.75 (95% CI 0.63 to 0.84) and the area under the curve (AUC) was 0.76. The authors note that while the accuracy is not high with MPI-SPECT for the diagnosis of CAD, it is recommended to screen patients at-risk.⁸

Patel et al. (2019) conducted a single-center randomized control trial (RCT) to determine the clinical efficacy of pharmacological MPI-SPECT and PET MPI in patients with coronary artery disease (CAD) and ischemia. A total of 322 symptomatic patients were included. The following pharmacologic agents were given to patients: aspirin therapy (88.8%), beta-blockers (76.7%), and statin therapy (77.3%). Seven patients (2.2%) had a diagnostic failure at 60 days; however, no major differences in diagnostic failure rates were observed overall. Decreased utilization of coronary angiography or revascularization was noted. (ClinicalTrials.gov Identifier NCT00976053).⁹

A number of recent articles provided recommendations for several common clinical scenarios. Gulati et al. (2021)¹² provided insights into the evaluation and diagnosis of chest pain, Winchester et al. (2023)¹¹ provided appropriate use criteria (AUC) for the detection and risk assessment of chronic coronary disease, and Doherty et al. (2024)²⁹ updated a previous AUC document for the cardiovascular evaluation for nonemergency, noncardiac surgery, focusing more on ischemic heart disease, valvular heart disease, and heart failure (rather than cardiovascular disease in general) and their relation to the risks

associated with various types of surgery (solid organ transplant, vascular, non-vascular).

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Clinical Guideline Revision History/Information

Original Date: October 29, 2024		
Review History		



Cohere Medicare Advantage Policy – Patent Foramen Ovale (PFO) and Atrial Septal Defect (ASD) Closure

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: May 24, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medicare Advantage Policy - Patent Foramen Ovale (PFO) and Atrial Septal Defect (ASD) Closure

Date of last literature review: 5/24/2024

Document last updated: 5/24/2024

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

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Medical Necessity Criteria

Service: Patent Foramen Ovale (PFO) and Atrial Septal Defect (ASD) Closure

Benefit Category

Not applicable.

Recommended Clinical Approach

Patent foramen ovale (PFO) refers to the nonclosure between the septum primum and secundum located at the superior and inferior margin of the foramen ovale. Closure can prevent stroke in appropriate patients.¹⁻³ Patients with reduced functional capacity caused by hemodynamically important isolated secundum atrial septal defect (ASD) benefit from surgical or transcatheter closure of the secundum ASD. Patients who do not undergo ASD closure may experience atrial arrhythmias, reduced functional capacity, and greater degrees of pulmonary arterial hypertension (PAH).⁴ While secundum ASDs can be closed percutaneously, anatomy permitting, the primum, sinus venosus, and coronary sinus ASDs require surgical treatment.

Medical Necessity Criteria

Indications

→ **PFO closure** is considered appropriate if **ANY** of the following is **TRUE**^{1,5-8}:

- ◆ The patient is 18 to 65 years of age with PFO with a right-to-left shunt and non-lacunar embolic appearing ischemic stroke with no other evident source of stroke despite a comprehensive evaluation; **OR**
- ◆ Systemic embolism without a prior PFO-associated stroke, in whom other embolic etiologies have been excluded⁹; **OR**
- ◆ The patient has PFO with unexplained recurrent embolic stroke despite medical therapy (without another identified cause); **OR**
- ◆ The patient has orthodeoxia/platypnea syndromes after other causes of hypoxia have been excluded; **OR**

→ **ASD closure** is considered appropriate if the patient has **ANY** of the following^{1,5-6,10-11}:

- ◆ Isolated secundum ASD and **ALL** of the following:
 - Impaired functional capacity; **AND**

- RA or RV enlargement; **AND**
- Hemodynamically significant net left-to-right shunt (Qp:Qs greater than or equal to 1.5:1); **OR**
- ◆ Asymptomatic and **ALL** of the following:
 - Isolated atrial septal defect (ASD); **AND**
 - RA and RV enlargement; **AND**
 - Net left-to-right shunt sufficiently large to cause physiological sequelae (e.g., Qp:Qs 1.5:1 or greater); **OR**
- ◆ Percutaneous or surgical closure may be considered for adults with **ANY** of the following:
 - ASD when net left-to-right shunt (Qp:Qs) is 1.5:1 or greater; **OR**
 - PA systolic pressure is 50% or more of systemic arterial systolic pressure; **OR**
 - Pulmonary vascular resistance is greater than one-third of the systemic resistance; **OR**
- ◆ Worsening hypoxia in a patient with a fenestrated Fontan circuit; **OR**
- ◆ The patient can be considered for documented recurrent paradoxical embolization event on treatment (without another identified cause)⁶; **OR**
- ◆ Orthodeoxia/platypnea syndrome; **OR**
- ◆ Unrepaired Ebstein anomaly with moderate-severe tricuspid regurgitation and impaired exercise tolerance.

Non-Indications

- **PFO closure** is not considered appropriate if the patient has **ANY** of the following^{4,8}:
- ◆ Irreversible severe pulmonary hypertension (e.g., Eisenmenger physiology (net right-to-left shunt), pulmonary artery pressure or pulmonary vascular resistance greater than $\frac{2}{3}$ systemic)^{4,10-11}; **OR**
 - ◆ Active endocarditis, sepsis, or other untreated infections⁸; **OR**
 - ◆ Intracardiac mass, vegetation, tumor, or thrombus at the intended site of implant⁸; **OR**
 - ◆ PFO was discovered incidentally without associated symptoms; **OR**
 - ◆ Alternative cause of stroke identified (e.g., atherosclerotic lesions, atrial fibrillation); **OR**
 - ◆ Bleeding disorder or other contraindication to antiplatelet therapy¹⁰⁻¹¹; **OR**
- **ASD closure** is not considered appropriate if the patient has **ANY** of the following:

- ◆ Irreversible severe pulmonary hypertension (pulmonary artery pressure or pulmonary vascular resistance greater than $\frac{2}{3}$ systemic)^{4,10-11}; **OR**
- ◆ Eisenmenger physiology, net right to left shunt; **OR**
- ◆ Bleeding disorder or other contraindication to antiplatelet therapy¹⁰⁻¹¹; **OR**
- ◆ Active endocarditis, sepsis, or other untreated infections¹⁰⁻¹¹; **OR**
- ◆ Known intracardiac thrombi.¹⁰⁻¹¹

Level of Care Criteria

Inpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93580	Percutaneous transcatheter closure of congenital interatrial communication (i.e., fontan fenestration, atrial septal defect) with implant.

Medical Evidence

Collado et al. (2018) conducted a systematic review of patent foramen ovale closure for stroke prevention and other disorders. The evidence showed that while approximately 25% of the adult population has a PFO, the condition itself has not been proven to increase the risk of ischemic stroke. However, up to 40% of ischemic cryptogenic strokes are in patients with PFOs, suggesting that paradoxical embolism through a PFO may be the cause of a significant percentage of cryptogenic strokes. A study was reviewed regarding procedural complications including transient ST elevations, transient ischemic attack, device dislodgement, and large residual shunt in 3% of the 307 patients evaluated. Vascular injury at the access site was found to occur in as many as 30% of cases, with only 2.4% requiring surgical intervention. In a study of 1355 cases, major complications occurred in 1.5% of patients and 7.9 experienced minor complications. Device embolization was a very rare complication at 0.7% overall.¹

In the 2018 AHA/ACC guideline for the management of adults with congenital heart disease, Stout and colleagues discuss PFO in relation to Ebstein anomaly, in that an otherwise normal-appearing PFO may have a significant impact on Ebstein anomaly. Surgery for PFO or ASD as well as tricuspid valve repair and arrhythmia surgery may be beneficial to the patient. The committee stated that patients who do not undergo ASD closure have worse long-term outcomes, including atrial arrhythmias, eventual greater degrees of pulmonary arterial hypertension (PAH), and significantly reduced functional capacity. They stated that data suggests that ASD closure improves functional capacity, but in patients with preoperatively normal functional capacity, the benefit is less clear. Until further studies are completed, it is stated to be reasonable to close a hemodynamically important ASD if significant PAH is not present.⁴

Kernan et al. (2014) developed guidelines for the prevention of stroke in patients with stroke and transient ischemic attack (TIA). In patients with a cryptogenic ischemic stroke or TIA and a PFO in which there is no deep vein thrombosis, it was stated that the available data do not support the benefits of PFO closure. Transcatheter PFO closure may be considered in the event of PFO with DVT, based on the risk of the DVT reoccurring.⁵ However, Kavinsky CJ et al. (2022) recommended PFO closure in patients aged 18–60 with a PFO-associated stroke but not for TIA. Also, the same guideline recommended against PFO closure in persons with a history of deep vein thrombosis (DVT) and without a prior PFO-associated stroke.⁶

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Clinical Guideline Revision History/Information

Original Date: May 24, 2024		
Review History		

Cohere Medicare Advantage Policy – Patent Foramen Ovale (PFO)/Atrial Septal Defect (ASD) Closure

Clinical Policy for Medical Necessity Review

CHP-098-4 Version 4

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Specialty: Cardiovascular Disease

Population Type: Adult (18+ years old), Pediatric (0-17 years old)

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Procedure Codes (CPT/HCPCS)

Service: Patent Foramen Ovale (PFO) and Atrial Septal Defect (ASD) Closure	
Code	Description
93580	Percutaneous transcatheter closure of congenital interatrial communication (ie, Fontan fenestration, atrial septal defect) with implant

Important Notices

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Service: Patent Foramen Ovale (PFO) and Atrial Septal Defect (ASD) Closure - Description

Closure of a patent foramen ovale (PFO) and atrial septal defect (ASD) - congenital openings between the heart's upper chambers - is performed via endovascular, minimally invasive means. During closure of a PFO, a device (often a mesh disc) is implanted in the atrial septum to seal an abnormal opening between the atria that is suspected of contributing to stroke. The procedure requires transcatheter access to a large vein, typically the femoral vein in the groin.²⁻⁴ ASD closure similarly involves transcatheter insertion and implantation of occluder devices to seal an abnormal opening in the atrial septum. However, because ASDs are typically larger, the occluder devices are often larger, and their insertion is more complex, requiring more extensive imaging, balloon sizing of the defect, and a larger device delivery system.¹⁷

Service: Patent Foramen Ovale (PFO) and Atrial Septal Defect (ASD) Closure - 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 - Patent Foramen Ovale (PFO) and Atrial Septal Defect (ASD) Closure* 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	N/A
LCD	No LCD Available for Jurisdiction	N/A	N/A	Use Cohere Medicare Advantage internal coverage criteria

Indications

- **Patent foramen ovale (PFO) or atrial septal defect (ASD) closure** is considered appropriate if **ANY** of the following is **TRUE**:
 - **PFO closure** with **ANY** of the following^{2,5-8}:
 - **ALL** of the following:
 - ☐ 18 to 60 years of age with PFO with a right-to-left shunt⁹; **AND**
 - ☐ Non-lacunar embolic stroke determined after comprehensive evaluation by a qualified radiologist or neurologist; **AND**
 - ☐ No other evident source of stroke¹⁰⁻¹⁵; **OR**
 - Systemic embolism without a prior PFO-associated stroke, in whom other embolic etiologies have been excluded^{10,11,14,16}; **OR**
 - PFO with unexplained recurrent embolic stroke despite medical therapy (without another identified cause)^{10,14}; **OR**

- **ASD closure** with **ANY** of the following^{2,8,17-19}:
 - Symptomatic (e.g., shortness of breath, fatigue, heart palpitations, swelling, tachycardia); **OR**
 - Right ventricle(RV)/right atrium (RA) enlargement; **OR**
 - Qp:Qs greater than or equal to 1.5:1; **OR**
 - Evidence of elevated RV/pulmonary artery (PA) systolic pressure; **OR**
 - Fenestrated Fontan circuit²⁰⁻²²; **OR**
 - Documented recurrent paradoxical embolization event on treatment (without another identified cause)¹⁷; **OR**
 - Unrepaired Ebstein anomaly with moderate-severe tricuspid regurgitation and impaired exercise tolerance.²³

Non-Indications

- **Patent foramen ovale (PFO) or atrial septal defect (ASD) closure** is not considered appropriate if **ANY** of the following is **TRUE**:
 - **PFO closure** with **ANY** of the following²⁴:
 - Irreversible severe pulmonary hypertension (e.g., Eisenmenger physiology [net right-to-left shunt], pulmonary artery pressure or pulmonary vascular resistance greater than $\frac{2}{3}$ systemic)^{5,16}; **OR**
 - Active endocarditis, sepsis, or other untreated infection; **OR**
 - Intracardiac mass, vegetation, tumor, or thrombus at the intended site of implant; **OR**
 - PFO was discovered incidentally without associated symptoms; **OR**
 - Alternative cause of stroke identified (e.g., atherosclerotic lesions, atrial fibrillation)^{12,14}; **OR**
 - Bleeding disorder or other contraindication to antiplatelet therapy^{5,16}; **OR**
 - **ASD closure** with **ANY** of the following^{16,17}:
 - Irreversible severe pulmonary hypertension (pulmonary artery pressure or pulmonary vascular resistance greater than $\frac{2}{3}$ systemic); **OR**
 - Eisenmenger physiology, net right-to-left shunt; **OR**
 - Bleeding disorder or other contraindication to antiplatelet therapy; **OR**
 - Active endocarditis, sepsis, or other untreated infection; **OR**
 - Known intracardiac thrombi.

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

The potential clinical harms of using the internal coverage criteria in *Cohere Medicare Advantage Policy - Patent Foramen Ovale (PFO) and Atrial Septal Defect (ASD) Closure* include:

- Adverse effects from delayed or denied treatment, which may include increased risk of stroke and other embolic events which may increase all-cause mortality.^{14,25-27} Additionally, significant ASD shunts, left untreated, may increase pulmonary blood flow which may then increase the risk of developing pulmonary hypertension, atrial arrhythmias, right ventricular dilation, and right heart failure.^{28,29}
- Risks associated with inappropriate care, which may confer serious complications. Risks may include device embolization requiring additional surgery, cerebrovascular events, and device thrombosis.³⁰ PFO closure is also noted to increase the risk of atrial fibrillation in the period immediately after the procedure.³¹ Recurrent stroke may persist after device closure, particularly in older patients and in those with diabetes or hypertension.³²
- Increased healthcare costs and complications from the avoidable use of emergency services and additional treatments.

The potential clinical benefits of using *Cohere Medicare Advantage Policy - Patent Foramen Ovale (PFO) and Atrial Septal Defect (ASD)* include:

- Improved patient selection for PFO/ASD closure, supporting better health outcomes such as lower rates of recurrent stroke (93% of patients).³²
- Mitigation of the risk of morbidity and mortality. Patients with cryptogenic ischemic stroke and a PFO had a 64% lower risk of stroke recurrence if they underwent PFO closure compared to those patients taking antithrombotic medications.²⁵
- Care aligned to recommendations of society guidelines including recently published guidelines for both adult and pediatric patients by the American College of Cardiology (ACC), American Heart Association (AHA), and the American Academy of Neurology.^{15,17,19}
- Appropriate allocation of healthcare resources. Appropriate patient selection can result in very low rates of stroke and other embolic event recurrence with freedom from stroke for 5 and 10 years following closure in 97.5% and 96.2% of patients respectively.³³

Medical Evidence

Amini (2025) reviewed findings on PFO and cryptogenic stroke, noting that while it may not be possible to definitively conclude whether a PFO was causally involved in a stroke, a high risk of paradoxical embolism (RoPE) score increases the likelihood that PFO was involved in the stroke. The RoPE score considers history of hypertension, diabetes, stroke, smoking, cortical infarct, and age. Similarly, the PFO-associated stroke causal likelihood (PASCAL) classification considers anatomical features of the PFO, including size of the defect and shunt type, to determine the likelihood that PFO was causally involved in a stroke. The author then reviewed studies showing that, in patients with high-risk PFOs, PFO closure decreased the recurrent stroke rate by up to 41%.¹¹

In 2020, Messe et al. updated the 2016 American Academy of Neurology's practice advisory guidelines on the treatment of patients with PFO and stroke. They recommended thorough patient evaluation prior to PFO closure. Specific recommendations included the elimination of any other cause of stroke, exercising particular caution when alternative stroke mechanisms are identified, and the importance of advising patients that PFO is common and that it is not possible to definitively determine whether the PFO was causally involved in their stroke.¹⁴ In 2019, a panel of neurologists and cardiologists published recommendations on PFO closure as a treatment for cryptogenic stroke. Their recommendations included age between 16-60, ischemic stroke within the last 6 months attributable to the PFO after examination with a stroke specialist, and specific PFO characteristics - including atrial septal aneurysm, a right-to-left shunt greater than 20 microbubbles, or a diameter at least 2 mm.¹⁴

Collado et al. (2018) systematically reviewed PFO closure for stroke prevention and other disorders. The evidence showed that, while approximately 25% of the adult population has a PFO, the condition itself has not been proven to increase the risk of ischemic stroke. However, up to 40% of ischemic cryptogenic strokes occur in patients with PFOs, suggesting that paradoxical embolism through a PFO may be the cause of a significant percentage of cryptogenic strokes. The authors reviewed procedural complications, including transient ST elevations, transient ischemic attack, device dislodgement, and large residual shunt, occurring in 3% of the 307 patients evaluated. Vascular injury at the access site was found to occur in as many as 30% of cases, though only 2.4% required surgical intervention. In a study of 1355 cases, major complications occurred in 1.5% of patients, and 7.9% experienced minor complications. Device embolization was a very rare complication at 0.7% overall.²

In 2026, the American College of Cardiology (ACC) published a concise clinical guidance on the outpatient management of isolated left-to-right shunts in pediatric patients. These guidelines cover the most prevalent left-to-right shunt lesions, including ASD, ventricular septal defect (VSD), patent ductus arteriosus (PDA), and atrioventricular septal defect (AVSD). The guidelines note that PFO is generally considered benign in childhood and rarely requires intervention in childhood. For ASD, the guidelines specify that ASD closure is not indicated for small ASDs when the atrial-level shunting is not hemodynamically significant, noting high rates of spontaneous closure for these small ASDs. The guidelines recommend risk counseling and regular surveillance by transthoracic echocardiography for these patients. Moderate or large ASDs that result in volume overload and right ventricular dilation are recommended for closure. Specifically, the guidelines state that ASD closure is indicated for patients with a hemodynamically significant shunt (Qp:Qs greater than or equal to 1.5:1), right ventricular dilation, or both. Notably, closure is recommended in asymptomatic patients to prevent later complications, including pulmonary hypertension, atrial arrhythmias, right ventricular dysfunction, paradoxical embolism, and hemodynamically significant tricuspid regurgitation.¹⁹

In 2025, the ACC and American Heart Association (AHA), in collaboration with the Heart Rhythm Society (HRS), International Society for Adult Congenital Heart Disease (ISACHD), and the Society for Cardiovascular Angiography and Interventions (SCAI) published a guideline for the management of adults with congenital heart disease, updating the earlier 2018 guideline. These guidelines also cover several lesion types, including shunt lesions such as ASD, as well as left-sided lesions, right-sided lesions, complex lesions, and coronary artery anomalies. Diagnostic recommendations for ASD include advanced imaging to define lesion size, morphology, rim anatomy, and pulmonary venous connections, consultation with pulmonary hypertension specialists, and assessment for the presence of pulmonary artery hypertension (PAH). Therapeutic recommendations include closure for patients with unrepaired closure who also have a significant left-to-right shunt and right ventricular (RV) dilation.¹⁷

Kernan et al. (2014) developed guidelines for the prevention of stroke in patients with stroke and transient ischemic attack (TIA). In patients with a cryptogenic ischemic stroke or TIA who also have a PFO and no deep vein thrombosis, the available data do not support the benefits of PFO closure. Transcatheter PFO closure may be considered in the event of PFO with deep vein thrombosis (DVT), based on the risk of the DVT reoccurring.⁸ However, Kavinsky et al. (2022) recommended PFO closure in patients aged 18-60 with a PFO-associated stroke but not for TIA. Also, the same guideline recommended against PFO closure in persons with a history of DVT and without a prior PFO-associated stroke.⁵

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Policy Revision History/Information

Clinical Policy Version	Date	Review History
Version 1	05/24/2024	Original Date.
Version 2	06/10/2024	422.101 Disclaimer added.
Version 3	05/22/2025	Annual review. Change to medical necessity criteria: non-lacunar embolic stroke must be determined by a qualified radiologist or neurologist. No changes to procedure codes. Updated medical evidence and harms/benefits (including references).
Version 4	05/07/2026	Annual review. No changes to procedure code. Updated template, including addition of "Table 1 - Related CMS Policies". Cohere MA criteria updated for internal alignment across policies. Simplified criteria for ASD closure including removal of specific requirements for isolated secundum ASD and for asymptomatic patients. Removed "or surgical closure" from ASD indication. Removed qualifier of "worsening hypoxia" for patients with HLHS/Fontan palliation in adherence to society guidelines. Removal of indication: orthodeoxia/platypnea syndrome. Expanded the Medical Evidence section (8 new references).



Cohere Medicare Advantage Policy – Percutaneous Coronary Intervention (PCI)

Clinical Policy for Medical Necessity Review

Version: 4

Policy Number: CHP-094-4

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Last Annual Review: May 7, 2026

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Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy - Percutaneous Coronary Intervention (PCI)

Policy Number: CHP-094-4

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

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Medical Necessity Criteria

Service: Percutaneous Coronary Intervention (PCI)

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 - Percutaneous Coronary Intervention (PCI)* 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	Percutaneous Transluminal Angioplasty	20.7	Not fully established	Detailed Percutaneous Coronary Intervention criteria for consistent and appropriate decision making ^A
LCD	Percutaneous Coronary Interventions	L34761	Not fully established	Detailed Percutaneous Coronary Intervention criteria for consistent and appropriate decision making ^B
LCD	Percutaneous Coronary Intervention	L33623	Not fully established	Detailed Percutaneous Coronary Intervention criteria for consistent and appropriate decision making ^B
LCD	No LCD Available for Jurisdiction	N/A	N/A	Use NCD 20.7 and Cohere Medicare Advantage internal coverage criteria

Description

Coronary artery revascularization is the process of re-establishing blood flow through the coronary arteries that vascularize the cardiac muscle. This is accomplished through a traditional, open approach (coronary artery bypass graft surgery [CABG]) or a minimally invasive approach (percutaneous coronary intervention [PCI]). In patients with stable ischemic heart disease (SIHD), a PCI is typically performed during a heart catheterization for symptomatic, significant stenosis or blockage that is refractory to optimal medical therapy, or to improve survival.

Coronary atherectomy is a PCI technique used to remove atheromatous (fatty) plaque from the coronary arteries. Atherectomy devices—such as rotational, orbital, or excimer laser systems—mechanically or thermally ablate plaque to improve vessel wall compliance and luminal patency. Coronary atherectomy is typically used as an adjunct to balloon angioplasty when fibrotic or moderate to severely calcified lesions are unlikely to be crossed or adequately expanded with balloon angioplasty alone.⁵

Medical Necessity Criteria

Indications

Percutaneous coronary intervention (PCI) (e.g., percutaneous transluminal angioplasty [PTA] with or without stenting, coronary atherectomy) is considered appropriate if **ALL** of the following are **TRUE**⁵⁻¹³:

- Significant coronary artery disease (CAD) defined by **ANY** of the following:
 - Significant anatomic stenosis greater than or equal to 50% left main CAD^{5,6,12}; **OR**
 - Minimal luminal area (MLA) less than 6 mm² on intravascular ultrasound (IVUS)^{6,12}; **OR**
 - Significant anatomic stenosis greater than or equal to 70% non-left main CAD⁵; **OR**
 - Significant physiological stenosis: fractional flow reserve (FFR) less than or equal to 0.80 or instantaneous wave-free ratio (iFR) less than or equal to 0.89^{5,6,8,12}; **AND**
- **ANY** of the following:
 - Ventricular fibrillation (VF)⁵; **OR**
 - Polymorphic ventricular tachycardia (VT)⁵; **OR**
 - Prior cardiac arrest⁵; **OR**
 - Severe left ventricle dysfunction (ejection fraction less than or equal to 35%)⁶; **OR**
 - Prior to structural heart interventions or high-risk vascular procedures (such as transcatheter aortic valve replacement [TAVR])^{5,14}; **OR**
 - Prior to renal transplantation^{5,15}; **OR**
 - Prior to liver transplantation¹⁶⁻¹⁸; **OR**
 - Silent ischemia associated with high-risk findings (e.g., significant defects on myocardial perfusion imaging [MPI]); **OR**
 - Acute ST-elevation myocardial infarction (STEMI)^{5,19,20}; **OR**
 - Non-ST-elevation acute coronary syndrome (NSTEMI/ACS)^{5,7,9,19,20}; **OR**
 - Unstable angina^C; **OR**
 - Refractory angina (or ischemic equivalent^D) with symptoms despite optimal medical therapy (guideline-based medical therapy [GDMT], including two anti-anginal drugs or documented intolerance)⁸; **OR**
 - Stable ischemic heart disease (SIHD) and **ANY** of the following:
 - Multivessel CAD with significant stenoses in the three major coronary arteries that are suitable for PCI^{5,10}; **OR**

- **ALL** of the following^{5,6}:
 - Significant left main stenosis (greater than or equal to 50%); **AND**
 - PCI is expected to provide equivalent revascularization to coronary artery bypass graft surgery (CABG); **OR**
- In patients with STEMI or non-ST-elevation myocardial infarction (NSTEMI) after PCI of the culprit lesion, staged PCI for significant non-culprit stenosis, typically within 90 days^{5,10,21}; **OR**
- Prior heart transplant and severe cardiac allograft vasculopathy (as diagnosed by coronary angiography/IVUS) with proximal, discrete lesion(s)^{6,8,22,23}; **OR**
- **ANY** of the following (92930):
 - Two or more distinct noncontiguous lesions; **OR**
 - Bifurcation lesion; **OR**
- Chronic total occlusion with combined antegrade and retrograde approaches (92945).

Non-Indications

Percutaneous coronary intervention is not considered appropriate if **ANY** of the following is **TRUE**^{5-9,12,13,20,24}:

- Acute presentation with STEMI and **ALL** of the following:
 - Totally occluded infarct-related artery greater than 72 hours after symptoms onset²⁵; **AND**
 - No evidence of ongoing ischemia, acute severe heart failure, or life-threatening arrhythmia²⁰; **OR**
- Significant left main CAD with high-complexity CAD^{6,8,9}; **OR**
- Multivessel CAD with complex or diffuse CAD (e.g., SYNTAX score greater than 33)^{5,6,8,12}; **OR**
- Diabetes mellitus and multivessel CAD with the involvement of the left anterior descending artery (LAD), and an appropriate candidate for CABG.^{5-8,12}

Definitions and Notes

^ANCD 20.7 is considered not fully established because, while it addresses coronary angioplasty, it does not define what qualifies as an atherosclerotic obstructive lesion, and Cohere's criteria are necessary to define medical necessity for these gaps.

^BLCD 34761 and LCD 33623 are considered not fully established. While they address coronary angioplasty and stenting, they do not describe what qualifies as an atherosclerotic obstructive lesion or when stents are required for patients who are asymptomatic. Cohere's criteria are necessary to define medical necessity for these gaps.

^C**Unstable angina:** Defined as at least one of the following in patients whose cardiac biomarker levels do not meet criteria for acute myocardial infarction²⁶:

- Prolonged rest angina (typically greater than 20 minutes)
- New onset angina of at least Canadian Cardiovascular Society (CCS) class III or higher
- Increasing angina (e.g., previously diagnosed angina that has become more frequent or severe, longer in duration, or lower in threshold)

^D**Ischemic equivalent:** Examples 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 CAD may also be considered an ischemic equivalent.²⁷

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
92920	Percutaneous transluminal coronary angioplasty, single major coronary artery and/or its branch(es)
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed, single major coronary artery and/or its branch(es)
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); 1 lesion involving 1 or more coronary segments

92930	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); 2 or more distinct coronary lesions with 2 or more coronary stents deployed in 2 or more coronary segments, or a bifurcation lesion requiring angioplasty and/or stenting in both the main artery and the side branch
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed, single major coronary artery and/or its branch(es)
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed, single major coronary artery and/or its branches
92941	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single major coronary artery and/or its branches or single bypass graft and/or its subtended branches
92943	Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery branches of the bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; antegrade approach
92945	Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery

	branches of the bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; combined antegrade and retrograde approaches
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
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 (list separately in addition to code for primary procedure)
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)

C1724	Catheter, transluminal atherectomy, rotational

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

The potential clinical harms of using these criteria for *Cohere Medicare Advantage Policy – Percutaneous Coronary Intervention (PCI)* may include:

- Adverse effects from delayed or denied treatment, which may include increased symptoms.
- Risks associated with inappropriate procedures, which may confer serious complications. Risks may include increased risk of bleeding complications and stroke after PCI, particularly in patients greater than or equal to 75 years.⁵
- Increased healthcare costs and complications from the avoidable use of emergency services and additional treatments.

The potential clinical benefits of using *Cohere Medicare Advantage Policy – Percutaneous Coronary Intervention (PCI)* may include:

- Improved patient selection for PCI, supporting better health outcomes.⁵
- Care aligned to recommendations of society guidelines, including the American College of Cardiology, the American Heart Association, and the Society for Cardiovascular Angiography and Interventions.^{5,11,20}
- Appropriate allocation of healthcare resources at the individual and population levels.

Medical Evidence

Abusnina et al. (2022) conducted a systematic review to evaluate the clinical outcomes of atherectomy in treating coronary artery calcification (CAC) in patients with reduced left ventricular ejection fraction (LVEF). The review includes 7 studies involving 2,238 unique patients with a median follow-up duration of 22.4 months. Comparing patients with severely reduced LVEF compared to those with moderately reduced or preserved LVEF, the authors found the risk ratio (RR) of in-hospital all-cause mortality using atherectomy was 5.28 (95% CI 1.65–16.84; P equal to 0.005) and RR for long-term all-cause mortality was 2.84 (95% CI 1.16–6.95; P equal to 0.02). The results indicate that treating severe CAC with atherectomy in patients with severely reduced LVEF had significantly higher in-hospital and long-term all-cause mortality risks compared to patients with moderate or preserved LVEF. While there was no significant difference in in-hospital cardiac mortality between the two groups, long-term cardiac mortality was significantly higher in patients with severe CAC and severely reduced LVEF who underwent atherectomy.²⁸

Schwarz et al. (2022) conducted a systematic review and meta-analysis to compare periprocedural characteristics and outcomes of planned atherectomy (PA), bailout atherectomy (BA), and RA. PA is defined as RA performed immediately prior to balloon pre-dilation, while BA is defined as RA after failure to expand a pre-dilating balloon. Pooling 2120 patients from 5 studies, the authors found no difference in procedural success (PA vs BA risk ratio [RR] 1.03; 95% confidence interval [95% CI] 0.99–1.07), major adverse cardiovascular events on follow-up (RR 1.04, 95% CI 0.62–1.74), death (RR 0.98, 95% CI 0.59–1.64), myocardial infarction (MI) (RR 1.16, 95% CI 0.62–2.18), target vessel re-vascularization (RR 1.40, 95% CI 0.83 to 2.36), stroke (RR 1.50, 95% CI 0.46–4.86), or stent thrombosis (RR 0.82, 95% CI 0.06–10.74). However, compared to BA, PA was associated with shorter procedural times (mean difference [MD] -25.88 min, 95% CI -35.55 to -16.22), fewer coronary dissections (RR 0.50, 95% CI 0.26–0.99), fewer stents (MD -0.20, 95% CI -0.29 to -0.11), and a trend toward less periprocedural MI (RR 0.77, 95% CI 0.54–1.11).²⁹

Khan et al. (2019) conducted a meta-analysis to compare the safety and efficacy of rotational atherectomy (RA) performed using trans-radial (TR)

and transfemoral (TF) access to evaluate the widespread reluctance to use TR access for complex percutaneous coronary intervention (PCI), including RA, for heavily calcified coronary lesions. The meta-analysis includes 5 retrospective studies with 3315 patients undergoing RA via TR access and 5838 patients undergoing RA via TF access. TR access was associated with lower major access site bleeding (OR: 0.45, 95% CI: 0.31–0.67, P less than 0.001) and radiation exposure (MD: -16.1, 95% CI: -25.4--6.7 Gy cm², P equal to 0.0007). No significant differences were observed in all-cause in-hospital mortality, major adverse cardiac events (MACE), stent thrombosis, myocardial infarction, hospital stay, procedure time, or procedure success between the two groups.³⁰

The 2025 American College of Cardiology (ACC)/American Heart Association (AHA) guideline for the management of patients with acute coronary syndrome (ACS) contains several recommendations on the use of PCI in both emergent and non-emergent settings in addition to several important recommendations on appropriate medical management of patients undergoing PCI. In non-emergent settings, the guidelines recommend PCI in patients with ST-segment elevation myocardial infarction or non-ST-segment elevation ACS. The guidelines also note that the choice of revascularization method (e.g., surgical bypass vs. percutaneous) should be determined by disease complexity and any patient comorbidities.²⁰

Similarly, the 2024 Japanese Association of Cardiovascular Interventional and Therapeutics (CVIT) expert consensus statement also recommends complete revascularization in some patients, including STEMI or non-ST-elevation myocardial infarction (NSTEMI) patients with multivessel disease.¹⁹

In 2024, the Society for Cardiovascular Angiography and Interventions (SCAI) issued an expert consensus statement on treating patients with ST-elevation myocardial infarction (STEMI) through PCI. The authors acknowledge the complexity of managing multivessel disease, present in about half of patients with STEMI, and therefore recommend complete revascularization with treatment of the non-infarct stenosis. At the time of authorship of the statement, the existing guidelines recommended staged PCI among stable patients—although research in this area is ongoing with respect to the optimal timing of resolution of non-culprit lesions.¹¹

Virani et al. (2023) developed a clinical practice guideline for managing patients with chronic coronary disease for the American Heart Association and the American College of Cardiology. Revascularization has a strong recommendation in patients with lifestyle-limiting angina who are currently on guideline-based medical therapy (GDMT) and who have significant coronary artery stenoses. Due to higher survival rates, coronary artery bypass grafting (CABG) is recommended over PCI in patients with chronic coronary disease with significant left main artery involvement associated with high-complexity CAD.⁸

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 to describe the best practices of coronary artery revascularization. It is recommended that, in patients with significant left main disease, traditional surgical revascularization be undertaken. Percutaneous revascularization (PCI) is a reasonable option to improve survival as 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.⁵

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Policy Revision History/Information

Original Date: June 03, 2024		
Review History		
Version 2	06/11/2024	422.101 Disclaimer Added
Version 3	05/22/2025	Annual review. Added indication for “acute ST-elevation myocardial infarction (STEMI).” Added indication for “prior heart transplant with severe cardiac allograft vasculopathy.” Revised Harms & Benefits section. Added non-indications as specified by CMS 2023, 2019; Lawton et al., 2021. Literature review – Medical Evidence section updated (Tamis-Holland, 2024).
Version 4	05/07/2026	Annual review. Merged with previously titled “Cohere Medicare Advantage Policy – Coronary Atherectomy”. Renamed policy from “Cohere Medicare Advantage Policy – Percutaneous Coronary Intervention (PCI)/Angioplasty/Stent” to “Cohere Medicare Advantage Policy – Percutaneous Coronary Intervention”. Updated template, including addition of “Table 1 – Related CMS Policies” that

		describes Cohere definition of which LCDs/NCDs are not fully established. Added NCD 20.7 – Percutaneous Transluminal Angioplasty (PTA). Cohere MA criteria updated for internal alignment across policies. Added notes for NCD 20.7, L34761, and L33623. Updated Harms and Benefits section. Expanded the Medical Evidence section. New codes added: 92930, 92945. Codes deleted per AMA code update effective 01/01/2026: 92921, 92925, 92929, 92934, 92944. References reviewed and updated.



Cohere Medicare Advantage Policy – Percutaneous Coronary Intervention (PCI)/Angioplasty/Stent

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 - Percutaneous Coronary Intervention/Angioplasty/Stent

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: Percutaneous Coronary Intervention (PCI)/Angioplasty/Stent

Benefit Category

Not applicable.

Recommended Clinical Approach

Coronary artery revascularization (percutaneous coronary intervention [PCI] versus coronary artery bypass graft surgery [CABG]) can occur in a number of clinical settings, including medical emergencies such as an acute myocardial infarction or an acute coronary syndrome, in contrast to less urgent environments, such as in stable ischemic heart disease (SIHD). In the latter scenario, a PCI is typically done during a heart catheterization for a symptomatic, significant stenosis or blockage that is refractory to optimal medical therapy or to improve survival as described in the 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization.¹

In patients being considered for coronary revascularization for whom the optimal treatment strategy is unclear, a multidisciplinary Heart Team (which involves the cardiologist, cardiac surgeon, and other specialists) approach is recommended. Treatment decisions should be patient-centered, incorporate patient preferences and goals, and include shared decision-making.¹

Coronary angiography remains the default method to define coronary anatomy and characterize the severity of coronary arterial stenoses. A visually estimated diameter stenosis severity of greater than or equal to 70% for non-left main disease and greater than or equal to 50% for left main disease has been used to define significant stenosis and to guide revascularization strategy. An angiographically intermediate coronary stenosis is defined as a diameter stenosis severity of 40% to 69%, and generally warrants additional investigation to assess physiological significance.¹ Coronary computed tomography angiography (CCTA) is gaining acceptance as an alternative to coronary angiography to define coronary anatomy.

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 percutaneous coronary intervention (PCI), angioplasty, and stent 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 PCI, angioplasty, and stent procedures can lead to increased symptoms and complications, especially in patients with severe coronary artery disease. The 2021 ACC/AHA/SCAI 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 local coverage determinations by CMS highlight the importance of appropriate patient selection to minimize surgical risks and enhance the benefits of PCI and related procedures.²⁻³
- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. Proper use of PCI 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.^{1,4}

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to PCI 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 chronic coronary disease

emphasize the diagnostic accuracy of imaging and monitoring procedures in managing patients with heart conditions.⁹

- 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.⁶
- Reduction in complications and adverse effects: Proper use of PCI criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. The guidelines on the use of PCI procedures emphasize the importance of accurate diagnostics in preventing complications.⁷
- Enhanced overall patient satisfaction: Ensuring that PCI procedures are used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications.⁸

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

→ **Percutaneous coronary interventions (PCI)/angioplasty/stents/IVUS/FFR** may be covered for **ANY** of the following²⁻³:

- ◆ Percutaneous coronary intervention to be used in management of **ANY** of the following:

- Acute coronary syndrome (eg, acute MI, unstable angina);

OR

- History of significant obstructive atherosclerotic disease as defined by **ANY** of the following^{1,4}:
 - Non-left main artery stenosis greater than or equal to 70% by invasive angiography; **OR**
 - Intermediate non-left main artery stenosis (40–69% by invasive angiography) with FFR less than 0.80 or iFR less than 0.89; **OR**
 - Left main artery stenosis with **ANY** of the following:
 - ◆ Stenosis greater than or equal to 50% by invasive angiography; **OR**
 - ◆ A minimum lumen area of < 6 mm squared by intravascular ultrasound (IVUS); **OR**⁴
 - ◆ A minimum lumen diameter of < 2.8 mm by IVUS⁴; **OR**
- Restenosis of coronary artery previously treated with intracoronary stent or another revascularization procedure (50% or greater restenosis); **OR**
- Chronic angina with **ALL** of the following characteristics^{5–6}:
 - **ANY** of the following:
 - ◆ Substernal location of chest discomfort, (burning, dull, heaviness, pressure, squeezing, tightness [not an all-inclusive list]); **OR**
 - ◆ Anginal equivalent (discomfort in the shoulders, arms, neck, back, upper abdomen, or jaw, as well as shortness of breath and fatigue [not an all-inclusive list]); **AND**
 - Precipitated by exertion or emotional stress; **AND**
 - Prompt relief with rest or sublingual nitroglycerin (time span ranging from approximately 30 seconds to 10 minutes); **OR**
- Silent ischemia defined by objective evidence of ischemia with **ANY** of the following⁴:
 - ST segment changes consistent with ischemia seen during exercise treadmill testing or ambulatory monitoring; **OR**
 - Reversible myocardial perfusion defects noted during radionuclide myocardial perfusion imaging; **OR**

- Reversible regional wall motion abnormalities noted during exercise or dobutamine echocardiography; **OR**
- ◆ Intracoronary ultrasound, as indicated by **ANY** of the following:
 - Need to assess extent of coronary stenosis if equivocal on angiography; **OR**
 - Need to assess patency and integrity of coronary artery post-intervention: **OR**
- ◆ Intravascular Doppler velocity and/or pressure-derived coronary flow reserve measurement, and need to assess the degree of stenosis within a vessel.

Non-Indications

None

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
92920	Percutaneous transluminal coronary angioplasty into single major coronary artery
92928	Percutaneous transcatheter insertion of stent into single major coronary artery
92937	Percutaneous transluminal revascularization of a single coronary artery bypass graft with angioplasty
92943	Percutaneous transluminal revascularization of chronic total occlusion of a single coronary artery branch with atherectomy, angioplasty, and insertion of stent
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
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

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

A 2018 European Society of Cardiology and European Association for Cardio-Thoracic Surgery guideline for myocardial revascularization (Neumann et al.) includes the following Class I recommendations (not an all-inclusive list):

- FFR or iFR are recommended to assess hemodynamic relevance of intermediate-grade stenosis
- In patients with left main or multivessel disease, the SYNTAX score should be calculated to assess the anatomical complexity of coronary artery disease (CAD) and long term risk after percutaneous coronary intervention
- The indications for revascularization in patients with stable coronary artery disease (SCAD) who receive guideline-recommended medical treatment are the persistence of symptoms despite medical treatment and/or the improvement of prognosis. The indications for improved prognosis include: Left main disease with stenosis >50%*, Proximal LAD stenosis >50%*, Two- or three-vessel disease with stenosis >50% with impaired LV function (LVEF less than or equal to 35%)*, Single remaining patent coronary artery with stenosis >50%*, and/or Large area of ischemia detected by functional testing (>10% LV) or abnormal invasive FFR (defined as <0.75). Percutaneous coronary intervention (PCI) had a Class I indication (that was better than or equal to CABG) for patients with a low predicted procedural/surgical mortality for one-vessel CAD

with or without proximal LAD stenosis, two-vessel CAD with or without proximal LAD stenosis, left main CAD with low SYNTAX scores (0-22), and three-vessel disease without diabetes mellitus with a low SYNTAX score.⁷

*With documented ischemia or a hemodynamically relevant lesion defined by FFR less than or equal to 0.80 or iFR less than or equal to 0.89, or >90% stenosis in a major coronary vessel.

Roffi et al. (2016) published guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation on behalf of the European Society of Cardiology. It was noted during the discussion of percutaneous coronary intervention that in acute coronary syndrome patients who underwent PCI revascularization procedures represent the most frequent, most costly and earliest cause for rehospitalization.⁸

Virani et al. (2023) developed a clinical practice guideline for the management of patients with chronic coronary disease for the American Heart Association and the American College of Cardiology. Revascularization has a strong recommendation in patients with life-limiting angina who are currently on guideline-based medical therapy (GDMT) and with significant coronary artery stenoses. Due to higher survival rates, coronary artery bypass grafting (CABG) is recommended over PCI in patients with chronic coronary disease with significant left main artery involvement associated with high-complexity CAD.⁹

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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 – Percutaneous Coronary Intervention (PCI)/ Angioplasty/Stent

Clinical Guidelines for Medical Necessity Review

Version: 3
Revision Date: May 22, 2025

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy - Percutaneous Coronary Intervention (PCI)/Angioplasty/Stent

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

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Medical Necessity Criteria

Service: Percutaneous Coronary Intervention (PCI)/Angioplasty/Stent

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁴

- [Local Coverage Determination \(LCD\): Percutaneous coronary intervention \(L33623\)](#)
 - [Billing and coding: Percutaneous coronary intervention \(A56823\)](#)
- [Local coverage determination \(LCD\): Percutaneous coronary interventions \(L34761\)](#)
 - [Billing and Coding: Percutaneous coronary intervention \(A57479\)](#)

Description

Coronary artery revascularization (percutaneous coronary intervention [PCI] versus coronary artery bypass graft surgery [CABG]) can occur in a number of clinical settings, including medical emergencies such as an acute myocardial infarction or an acute coronary syndrome, in contrast to less urgent environments, such as in stable ischemic heart disease. In the latter scenario, a PCI is typically performed during a heart catheterization for a symptomatic, significant stenosis or blockage that is refractory to optimal medical therapy or to improve survival.⁵

Coronary angiography remains the default method to define coronary anatomy and characterize the severity of coronary arterial stenoses. A visually estimated diameter stenosis severity of greater than or equal to 70% for non-left main disease and greater than or equal to 50% for left main disease has been used to define significant stenosis and to guide revascularization strategy. An angiographically intermediate coronary stenosis is defined as a diameter stenosis severity of 40–69% and generally warrants additional investigation to assess physiological significance.⁵

Coronary computed tomography angiography (CCTA) is gaining acceptance as an alternative to coronary angiography to define coronary anatomy.

Medical Necessity Criteria

Indications

A **percutaneous coronary intervention (PCI), angioplasty, or stent** is considered appropriate if **ANY** of the following is **TRUE**:

- For the management of **ANY** of the following:
 - Coronary artery disease (CAD) with **ANY** of the following:
 - Acute coronary syndrome (e.g., acute MI, unstable angina)^{1,2}; **OR**
 - Polymorphic ventricular tachycardia (VT); **OR**
 - Ventricular fibrillation (VF); **OR**
 - Recent cardiac arrest; **OR**
 - New onset severe left ventricle dysfunction (ejection fraction less than or equal to 35%)⁶; **OR**
 - Prior to transcatheter aortic valve replacement (TAVR)^{5,6}; **OR**
 - History of significant obstructive atherosclerotic disease as defined by **ANY** of the following^{1,2,5}:
 - Left main artery stenosis with **ANY** of the following⁷:
 - Stenosis greater than or equal to 50% by invasive angiography; **OR**
 - Minimum lumen area of less than 6 mm squared by intravascular ultrasound (IVUS); **OR**
 - Minimum lumen diameter of less than 2.8 mm by IVUS; **OR**
 - Non-left main artery stenosis greater than or equal to 70% by invasive angiography; **OR**
 - Intermediate non-left main artery stenosis (40–69% by invasive angiography) with fractional flow reserve (FFR) less than 0.80 or iFR less than 0.89; **OR**
 - Restenosis of a coronary artery previously treated with an intra-coronary stent or another revascularization procedure (50% or greater restenosis)^{1,2}; **OR**
 - Acute ST-elevation myocardial infarction (STEMI)⁸; **OR**
 - The patient has had a prior heart transplant and now has severe cardiac allograft vasculopathy (as diagnosed by coronary angiography/intravascular ultrasound) with proximal, discrete lesion(s)^{6,9}; **OR**

- Intravascular ultrasound (IVUS) or intracoronary ultrasound (ICUS), as indicated by **ANY** of the following^{1,2}:
 - Need to assess the extent of coronary stenosis if equivocal on angiography; **OR**
 - Need to evaluate patency and integrity of the coronary artery post-intervention; **OR**
- Intravascular Doppler velocity and/or pressure-derived coronary flow reserve measurement is needed, and the degree of stenosis within a vessel must be assessed.^{1,2}

*NOTE: Ischemic equivalent: Examples 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 CAD may also be considered an ischemic equivalent.¹⁰

Non-Indications

A **percutaneous coronary intervention (PCI), angioplasty, or stent** is not considered appropriate if **ANY** of the following is **TRUE**:

- Repeat diagnostic catheterization service without **ANY** of the following¹:
 - New clinical event; **OR**
 - Change in symptomatology; **OR**
 - Results from an examination or other test; **OR**
 - Before completion of the staged intervention; **OR**
- Right heart catheterization and insertion of a Swan-Ganz catheter (unless medically necessary) when performed incident to a diagnostic catheterization before the intervention, as this is not generally medically necessary for a PCI^{1,2}; **OR**
- Standby services of a surgeon or anesthesiologist^{1,2}; **OR**
- The patient can be managed medically²; **OR**
- Stable ischemic heart disease with **ALL** of the following:
 - The patient has an unprotected left main CAD with unfavorable anatomy for PCI; **AND**
 - The patient is a good candidate for coronary artery bypass graft surgery (CABG); **OR**
- The patient has diabetes and multivessel CAD with the involvement of the LAD, and is an appropriate candidate for CABG (CABG with LIMA to LAD is

recommended over PCI to reduce mortality and repeat revascularizations).¹⁵

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
92920	Percutaneous transluminal coronary angioplasty into single major coronary artery
92928	Percutaneous transcatheter insertion of stent into single major coronary artery
92937	Percutaneous transluminal revascularization of a single coronary artery bypass graft with angioplasty
92943	Percutaneous transluminal revascularization of chronic total occlusion of a single coronary artery branch with atherectomy, angioplasty, and insertion of stent
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
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

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' 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 the **management of conditions stemming from narrowed or blocked coronary arteries or for heart transplant recipients with severe cardiac allograft vasculopathy** may include:

- Adverse effects from delayed or denied treatment, such as delays or denials in the use of percutaneous coronary interventions (PCI), angioplasty, and stent procedures, can lead to increased symptoms and complications, especially in patients with severe coronary artery disease (CAD). The guideline published in 2021 by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Society for Cardiovascular Angiography and Interventions (SCAI) emphasized the importance of timely intervention to prevent adverse outcomes in patients with significant heart conditions.⁵ The use of PCI for obstructive coronary stenoses in asymptomatic patients has been debated as the efficacy is unknown. Wakabayashi et al. (2010) performed a comparative study (n=1944) of outcomes at 1-year following elective PCI in patients with stable CAD. The authors noted a correlation between asymptomatic patients and an increased risk of mortality at 1-year following PCI.¹¹

The clinical benefits of using these criteria for the **management of conditions stemming from narrowed or blocked coronary arteries or for heart transplant recipients with severe cardiac allograft vasculopathy** may include:

- Improved patient selection, resulting in better long-term outcomes. Ensuring timely and appropriate access to PCI procedures for the patients selected for the 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 disease emphasize the diagnostic accuracy of imaging and monitoring procedures in managing patients with heart conditions.^{6.12}

The potential clinical harms of using these criteria for **revascularization** may include:

- Adverse effects from delayed or denied treatment include increased healthcare costs and complications stemming from inappropriate use of emergency services and additional treatments.^{5.7}

The clinical benefits of using these criteria for **revascularization or for candidates for coronary artery bypass surgery with diabetes and multivessel CAD with the involvement of the left anterior descending artery (LAD)** may include:

- Improved patient selection, resulting in better long-term outcomes. Proper use of PCI criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. Guidelines support the necessity of appropriate diagnostic and treatment procedures to prevent unnecessary healthcare utilization.^{5.7.13}

Medical Evidence

In 2024, the Society for Cardiovascular Angiography and Interventions (SCAI) issued an expert consensus on treating patients with ST-elevation myocardial infarction (STEMI) through percutaneous coronary intervention (PCI). The authors acknowledge the complexity of managing multivessel disease, present in about half of patients with STEMI, and therefore recommend complete revascularization with treatment of the non-infarct stenosis. At the time of authorship of the statement, the existing guidelines recommend staged PCI among stable patients, although research in this area is ongoing with respect to the optimal timing of resolution of non-culprit lesions.⁸

Virani et al. (2023) developed a clinical practice guideline for the management of patients with chronic coronary artery disease (CAD) for the American Heart Association (AHA) and the American College of Cardiology (ACC). Revascularization is a strong recommendation in patients with life-limiting angina who are currently on guideline-based medical therapy (GDMT) and with significant coronary artery stenoses. Due to higher survival rates, coronary artery bypass grafting (CABG) is recommended over PCI in patients with CAD with significant left main artery involvement associated with high-complexity CAD.⁶

In 2021, the ACC, AHA, and SCAI published a clinical practice guideline for coronary artery revascularization. Surgical revascularization is indicated for patients with significant left main disease. Percutaneous revascularization is a reasonable option to improve survival compared with medical therapy in selected patients with low to medium anatomic complexity of CAD and left main disease that is suitable for revascularization. In patients with stable ischemic heart disease, normal left ventricular ejection fraction, and triple vessel CAD, surgical revascularization may be reasonable, and the percutaneous revascularization survival benefit is uncertain.⁵

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Clinical Guideline Revision History/Information

Original Date: June 3, 2024		
Review History		
Version 2	06/11/2024	422.101 Disclaimer Added
Version 3	05/22/2025	Annual review. Added indication for “acute ST-elevation myocardial infarction (STEMI).” Added indication for “prior heart transplant with severe cardiac allograft vasculopathy.” Revised Harms & Benefits section. Added non-indications as specified by CMS 2023, 2019; Lawton et al., 2021. Literature review – Medical Evidence section updated (Tamis-Holland, 2024).



Cohere Medicare Advantage Policy – Percutaneous Ventricular Assist Devices

Clinical Guidelines for Medical Necessity Review

Version: 2
Revision Date: March 27, 2025

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medicare Advantage Policy – Percutaneous Ventricular Assist Devices

Date of last literature review: 3/19/2025

Document last updated: 3/26/2025

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

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Medical Necessity Criteria

Service: Percutaneous Ventricular Assist Devices

Benefit Category

Inpatient Hospital Services
Prosthetic Devices

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 \(NCD\) 20.9.1 Ventricular Assist Devices](#)
- [Billing and Coding: Artificial Hearts and Percutaneous Endovascular Cardiac Assist Procedures and Devices \(A59657\)](#)
- [Billing and Coding: Artificial Hearts and Percutaneous Endovascular Cardiac Assist Procedures and Devices \(A59658\)](#)
- [Billing and Coding: Percutaneous Ventricular Assist Device \(A53986\)](#)
- [Billing and Coding: Percutaneous Ventricular Assist Device \(A53988\)](#)

Recommended Clinical Approach

A percutaneous ventricular assist device (pVAD) is utilized for temporary, short-term mechanical circulatory support (MCS). This minimally invasive technology may be used during cardiac or cardiovascular compromise, such as during high-risk cardiac procedures (elective use), in patients with cardiogenic shock, or with acute heart failure (emergent uses).²⁻⁴ Current examples of FDA-approved pVADs include Impella and TandemHeart. pVADs have been frequently utilized instead of the more invasive intra-aortic balloon pumps (IABP).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 percutaneous ventricular assist devices

(pVADs). 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:

- Adverse effects from delayed or denied treatment: Delays or denials in the use of pVADs can lead to increased symptoms and complications, especially in patients with advanced heart failure. The 2022 AHA/ACC/HFSA guideline for the management of heart failure highlights the importance of timely intervention to prevent adverse outcomes in patients with significant heart failure.³
- Risks with inappropriate surgical procedures: This includes infection, ischemic complications, hemolysis, device failure, worsening aortic regurgitation, severe bleeding, injury to neurovascular structures, anesthetic risk, and the need for repeat or additional procedures due to complications. The American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation guidelines on selected topics in mechanical circulatory support emphasize the importance of appropriate use criteria in managing mechanical circulatory support devices to minimize surgical risks.²
- Increased healthcare costs and complications: Specific risks may include sepsis and renal complications.⁶ Complications may also include inappropriate use of emergency services and additional treatments. Proper use of pVAD criteria helps avoid unnecessary interventions and their associated risks, thus safeguarding patient health. The SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the use of percutaneous mechanical circulatory support devices in cardiovascular care supports the necessity of appropriate diagnostic and treatment procedures to prevent unnecessary healthcare utilization, while the ACC/AHA/ACEP/NAEMSP/SCAI guideline for the management of patients with coronary syndromes urges careful patient selection when considering pVADs.⁷⁻⁸

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to pVADs for patients. The goal is to provide accurate diagnostics and

effective treatment planning, reducing the risk of complications and improving overall patient health. Møller et al noted that, in appropriately selected patients, use of pVAD significantly increased 180-day survival rates.⁹

- Reduction in complications and adverse effects: Proper use of pVAD criteria helps avoid unnecessary interventions and their associated risks, thus safeguarding patient health.
- Enhanced overall patient satisfaction: Ensuring that pVAD procedures are used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications. The ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure support the necessity of appropriate use criteria to minimize healthcare costs and prevent complications.¹⁰
- Percutaneous ventricular assist devices, unlike traditional ventricular assist devices, are implanted via cardiac catheterization, avoiding open-chest surgery with its associated potential risks.¹¹

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

- **A percutaneous ventricular assist device (pVAD)** is considered appropriate for **ANY** of the following:
- ◆ As an adjunct for high-risk percutaneous coronary interventions if **ALL** of the following are **TRUE**^{10,12-14}:
 - Severe left ventricular (LV) dysfunction (EF less than 30%);
- AND**

- Complex coronary artery disease exists (sole-remaining vessel, left main, or three-vessel disease)^{3,7,15}; **OR**
- ◆ As a short-term therapy (e.g., bridge to transplant, recovery, or surgery) if **ALL** of the following are **TRUE**^{8,16,17}:
 - A patient requires circulatory support due to **ANY** of the following^{2,8,9,16,17}:
 - Cardiogenic shock; **OR**
 - Severe decompensated heart failure; **OR**
 - Postoperative/intraoperative circulatory system complications; **AND**
 - IABP is not expected to be sufficiently beneficial.¹⁸

NOTE: The percutaneous ventricular assist device must be used according to FDA-approved indications.

Non-Indications

- **A percutaneous ventricular assist device (pVAD)** may not be appropriate if **ANY** of the following is **TRUE**^{2,14,15,19-21}:
- ◆ Bleeding diathesis; **OR**
 - ◆ Severe peripheral artery disease (PAD); **OR**
 - ◆ Unrepaired aneurysm of the ascending aorta or aortic arch; **OR**
 - ◆ Mechanical aortic valve is present; **OR**
 - ◆ Aortic valve stenosis/calcification; **OR**
 - ◆ Atrial or ventricular septal defect.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33990	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only
33991	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture

33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only

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

Medical Evidence

In January 2025, Rao et al. presented the joint American College of Cardiology/American Heart Association guideline for the management of patients with acute coronary syndromes (ACS).⁸ Based on findings from clinical trials and meta-analyses, these guidelines recommend percutaneous Ventricular Assist Devices (pVADs) for select patients with ST-elevation myocardial infarction (STEMI) and severe or refractory cardiogenic shock, and for patients with mechanical complications of ACS as a bridge to surgery. Best practices for use and insertion of MCS devices included careful patient selection and use of fluoroscopy and ultrasound for femoral access.

Møller et al. (2024) reported the results of a clinical trial comparing pVAD to standard medical care in 355 patients with STEMI and cardiogenic shock.⁹ Compared to the standard care group, patients treated with a pVAD (Impella CP) had significantly lower all-cause mortality at 180 days (45.8% vs 58.5%), despite worse performance on safety measures, including severe bleeding, limb ischemia, hemolysis, device failure, and worsening aortic regulation. However, other studies have reported no differences in survival outcomes between pVAD and other treatment options, such as IABP.^{22,23} Moreover, Watanabe et al. (2024) compared outcomes after nonacute myocardial infarction with cardiogenic shock in 704 and 2140 Medicare fee-for-service patients treated with pVAD and IABP, respectively, and found higher 30-day mortality in pVAD patients.²⁴ Møller et al. (2024) suggested that the positive outcomes after pVAD seen in their study may have been partly due to careful patient selection and very early use of pVAD; devices were inserted 14 minutes after study arm assignment.⁹ In the clinical guidelines for the management of acute coronary syndromes, Rao et al. (2025) recommend pVAD use for patients with STEMI with SCAI shock stages C, D, or E, who are not comatose, and who have peripheral vasculature able to accommodate large-bore access.⁸

Kirklin et al. (2020) published guidelines for mechanical circulatory support (MCS) on behalf of the American Association for Thoracic Surgery and the International Society for Heart and Lung Transplantation. Regardless of the specific MCS device, recommendations included complete preoperative evaluation of cardiac and non-cardiac physical function, organ systems, and

psychosocial issues. Biventricular support should be considered for patients who remain in refractory biventricular failure or who are experiencing persistent destabilizing ventricular dysrhythmias.²

Bjarnason and colleagues (2022) conducted a retrospective review of 79,176 Medicare patients who underwent percutaneous coronary intervention (PCI) assisted by either an intra-aortic balloon pump (IABP; 60% of study participants) or pVAD (40% of study participants) between 2013 and 2019. It was noted that the incidence of use of mechanical circulatory devices of either kind increased significantly over the study period (8514 in 2013 to 14,459 in 2019). The study outcome revealed no difference in mortality between groups and a higher cost for the pVAD cohort. Additionally, the most critically ill patients were less likely to receive pVAD.⁵ Two meta-analyses comparing pVADs and IABPs in patients undergoing PCI were similarly inconclusive, with similar outcomes across devices and no statistical differences between groups.^{25,26}

Rihal et al. (2015) developed a multi-society expert consensus document for the use of percutaneous mechanical circulatory support devices in cardiovascular care. A limited number of randomized clinical trials existed at the time of publication. The PROTECT II trial, with 452 patients, was the largest single randomized trial comparing pVAD (Impella) and IABP at the time. Impella was found to provide superior hemodynamic support.⁷ However, this clinical trial was terminated prior to completion due to futility and lack of difference in primary endpoints. Later analyses of outcomes suggested that, in patients who underwent extensive revascularization, use of pVAD may have led to fewer major adverse events, including death and myocardial infarction.²⁷

Lawton and colleagues (2022) published a clinical practice guideline on coronary artery revascularization for the American College of Cardiology, the American Heart Association, and the Society for Cardiovascular Angiography and Interventions. Recommendations included appropriate hemodynamic support devices for elective complex PCI to prevent hemodynamic compromise during the procedure. The BCIS-1 study is cited, which reported no difference in the primary composite outcome when hemodynamic support devices were used routinely during PCI. The study found fewer major procedural complications with IABP use. Despite mixed findings in studies, the

authors concluded that hemodynamic support devices such as pVAD can benefit select patients during complex PCI.¹⁵

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Clinical Guideline Revision History/Information

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Version 2	03/27/2025	• Annual review. • Added references to CMS documents (NCD and Billing and Coding articles). • Added indications for short-term use. • Refined indications for use as an adjunct to PCI. • Updated language in CPT Codes. • Expanded Medical Evidence section. • Updated references.



Cohere Medicare Advantage Policy – Percutaneous Ventricular Assist Devices

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: May 24, 2024

Important Notices

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Guideline Information:

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Medical Necessity Criteria

Service: Percutaneous Ventricular Assist Devices

Benefit Category

Inpatient Hospital Services
Prosthetic Devices

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

Recommended Clinical Approach

Mechanical circulatory support (MCS) may be appropriate for patients with advanced heart failure with reduced ejection fraction (HFrEF). Technology has progressed to allow MCS to be used in a variety of clinical situations involving critically ill patients or high-risk procedures.² MCS is characterized in a variety of ways, including the expected use length (i.e., short-term (temporary, non-implanted, usually placed percutaneously), intermediate to long-term (destination, implanted)), ventricle assisted (left, right, both), and the physical location of the pumping device (intracorporeal vs extracorporeal). Short-term devices include the intra-aortic balloon pump (IABP), other percutaneous devices (Impella or TandemHeart), extracorporeal mechanical oxygenation (ECMO), and centrifugal pumps used for coronary artery bypass surgery (CABG).³⁻⁴ Contraindications to short-term MCS vary between devices.⁵

Medical Necessity Criteria

Indications

→ **Percutaneous ventricular assist devices** (short-term or temporary devices) are considered appropriate if **ANY** of the following is **TRUE**.^{1,4-7}

◆ The patient has New York Heart Association (NYHA) Class IV heart failure and **ANY** of the following:

- **ALL** of the following:
 - Left ventricular ejection fraction (LVEF) less than or equal to 25%; **AND**
 - Inotrope dependent; **OR**
- Adjunct for high-risk percutaneous coronary interventions (severe LV dysfunction [EF less than 20% to 30%] and complex coronary artery disease (CAD) involving a large

territory [sole-remaining vessel, left main, or three-vessel disease])³⁻⁴; **OR**

- Cardiogenic shock (LV, RV, or both); **OR**
- Ischemic mitral regurgitation; **OR**
- Acute reversible cardiomyopathies (myocarditis, stress cardiomyopathy, peripartum cardiomyopathy); **OR**
- Primary cardiac transplant allograft failure due to rejection; **OR**
- Post-transplant RV failure; **OR**
- Patients slow to wean from cardiopulmonary bypass following heart surgery; **OR**
- Refractory arrhythmias.

Non-Indications

→ **Percutaneous ventricular assist devices** are not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ There are no published non-indications.

Level of Care Criteria

Inpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33990	Insertion of percutaneous arterial ventricular assist device by arterial access only
33991	Insertion of percutaneous arterial ventricular assist device by arterial and venous access, with transseptal puncture, with radiological supervision and interpretation
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only

Medical Evidence

Kirklin et al. (2020) published guidelines for mechanical circulatory support on behalf of the American Association for Thoracic Surgery and the International Society for Heart and Lung Transplantation. It was recommended to fully evaluate both cardiac and non-cardiac physical function and organ systems pre-operatively. Psychosocial issues should be identified and addressed. Biventricular support should be considered for patients who remain in refractory biventricular failure or who are experiencing persistent destabilizing ventricular dysrhythmias.²

In a 2022 clinical practice guideline on the management of heart failure for the American Heart Association and The American College of Cardiology, Heidenreich et al. make a strong recommendation for mechanical circulatory support. Select patients with heart failure with reduced ejection fraction with New York Heart Association class IV symptoms who are dependent upon continuous intravenous inotropes or temporary mechanical circulatory support may be appropriate for durable left ventricular assist device implantation.³

Rihal et al. (2015) developed a multi-society expert consensus document for the use of percutaneous mechanical circulatory support devices in cardiovascular care. At the time of publication, a limited number of randomized clinical trials existed. The PROTECT 2 trial was discussed, which at the time was the largest single randomized trial ever performed using percutaneous mechanical circulatory support, consisting of 452 symptomatic patients. The Impella device was studied in comparison with the intra-aortic balloon pump. Impella was found to provide superior hemodynamic support. It was noted that the most ill patients with the most significant hemodynamic compromise are not readily involved in large clinical trials.⁴

The Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Determination (NCD 20.9.1) for ventricular assist devices (2020) with coverage for the following indications:

- Post cardiectomy (following open-heart surgery)
- Left ventricular assist devices (LVADs), which are approved for short-term (bridge-to-recovery or bridge-to-transplant).¹

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Cohere Medicare Advantage Policy – Percutaneous Ventricular Assist Devices

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Medical Necessity Criteria

Service: Percutaneous Ventricular Assist Devices

Benefit Category

Inpatient Hospital Services
Prosthetic Devices

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 \(NCD\) 20.9.1 Ventricular Assist Devices](#)
- [Billing and Coding: Artificial Hearts and Percutaneous Endovascular Cardiac Assist Procedures and Devices \(A59657\)](#)
- [Billing and Coding: Artificial Hearts and Percutaneous Endovascular Cardiac Assist Procedures and Devices \(A59658\)](#)
- [Billing and Coding: Percutaneous Ventricular Assist Device \(A53986\)](#)
- [Billing and Coding: Percutaneous Ventricular Assist Device \(A53988\)](#)

Recommended Clinical Approach

A percutaneous ventricular assist device (pVAD) is utilized for temporary, short-term mechanical circulatory support (MCS). This minimally invasive technology may be used during cardiac or cardiovascular compromise, such as during high-risk cardiac procedures (elective use), in patients with cardiogenic shock, or with acute heart failure (emergent uses).²⁻⁴ Current examples of FDA-approved pVADs include Impella and TandemHeart. pVADs have been frequently utilized instead of the more invasive intra-aortic balloon pumps (IABP).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 percutaneous ventricular assist devices

(pVADs). 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:

- Adverse effects from delayed or denied treatment: Delays or denials in the use of pVADs can lead to increased symptoms and complications, especially in patients with advanced heart failure. The 2022 AHA/ACC/HFSA guideline for the management of heart failure highlights the importance of timely intervention to prevent adverse outcomes in patients with significant heart failure.³
- Risks with inappropriate surgical procedures: This includes infection, ischemic complications, hemolysis, device failure, worsening aortic regurgitation, severe bleeding, injury to neurovascular structures, anesthetic risk, and the need for repeat or additional procedures due to complications. The American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation guidelines on selected topics in mechanical circulatory support emphasize the importance of appropriate use criteria in managing mechanical circulatory support devices to minimize surgical risks.²
- Increased healthcare costs and complications: Specific risks may include sepsis and renal complications.⁶ Complications may also include inappropriate use of emergency services and additional treatments. Proper use of pVAD criteria helps avoid unnecessary interventions and their associated risks, thus safeguarding patient health. The SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the use of percutaneous mechanical circulatory support devices in cardiovascular care supports the necessity of appropriate diagnostic and treatment procedures to prevent unnecessary healthcare utilization, while the ACC/AHA/ACEP/NAEMSP/SCAI guideline for the management of patients with coronary syndromes urges careful patient selection when considering pVADs.⁷⁻⁸

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to pVADs for patients. The goal is to provide accurate diagnostics and

effective treatment planning, reducing the risk of complications and improving overall patient health. Møller et al noted that, in appropriately selected patients, use of pVAD significantly increased 180-day survival rates.⁹

- Reduction in complications and adverse effects: Proper use of pVAD criteria helps avoid unnecessary interventions and their associated risks, thus safeguarding patient health.
- Enhanced overall patient satisfaction: Ensuring that pVAD procedures are used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications. The ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure support the necessity of appropriate use criteria to minimize healthcare costs and prevent complications.¹⁰
- Percutaneous ventricular assist devices, unlike traditional ventricular assist devices, are implanted via cardiac catheterization, avoiding open-chest surgery with its associated potential risks.¹¹

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

- **A percutaneous ventricular assist device (pVAD)** is considered appropriate for **ANY** of the following:
- ◆ As an adjunct for high-risk percutaneous coronary interventions if **ALL** of the following are **TRUE**^{10,12-14}:
 - Severe left ventricular (LV) dysfunction (EF less than 30%);
- AND**

- Complex coronary artery disease exists (sole-remaining vessel, left main, or three-vessel disease)^{3,7,15}; **OR**
- ◆ As a short-term therapy (e.g., bridge to transplant, recovery, or surgery) if **ALL** of the following are **TRUE**^{8,16,17}:
 - A patient requires circulatory support due to **ANY** of the following^{2,8,9,16,17}:
 - Cardiogenic shock; **OR**
 - Severe decompensated heart failure; **OR**
 - Postoperative/intraoperative circulatory system complications; **AND**
 - IABP is not expected to be sufficiently beneficial.¹⁸

NOTE: The percutaneous ventricular assist device must be used according to FDA-approved indications.

Non-Indications

- **A percutaneous ventricular assist device (pVAD)** may not be appropriate if **ANY** of the following is **TRUE**^{2,14,15,19-21}:
- ◆ Bleeding diathesis; **OR**
 - ◆ Severe peripheral artery disease (PAD); **OR**
 - ◆ Unrepaired aneurysm of the ascending aorta or aortic arch; **OR**
 - ◆ Mechanical aortic valve is present; **OR**
 - ◆ Aortic valve stenosis/calcification; **OR**
 - ◆ Atrial or ventricular septal defect.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33990	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only
33991	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture

33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only

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

Medical Evidence

In January 2025, Rao et al. presented the joint American College of Cardiology/American Heart Association guideline for the management of patients with acute coronary syndromes (ACS).⁸ Based on findings from clinical trials and meta-analyses, these guidelines recommend percutaneous Ventricular Assist Devices (pVADs) for select patients with ST-elevation myocardial infarction (STEMI) and severe or refractory cardiogenic shock, and for patients with mechanical complications of ACS as a bridge to surgery. Best practices for use and insertion of MCS devices included careful patient selection and use of fluoroscopy and ultrasound for femoral access.

Møller et al. (2024) reported the results of a clinical trial comparing pVAD to standard medical care in 355 patients with STEMI and cardiogenic shock.⁹ Compared to the standard care group, patients treated with a pVAD (Impella CP) had significantly lower all-cause mortality at 180 days (45.8% vs 58.5%), despite worse performance on safety measures, including severe bleeding, limb ischemia, hemolysis, device failure, and worsening aortic regulation. However, other studies have reported no differences in survival outcomes between pVAD and other treatment options, such as IABP.^{22,23} Moreover, Watanabe et al. (2024) compared outcomes after nonacute myocardial infarction with cardiogenic shock in 704 and 2140 Medicare fee-for-service patients treated with pVAD and IABP, respectively, and found higher 30-day mortality in pVAD patients.²⁴ Møller et al. (2024) suggested that the positive outcomes after pVAD seen in their study may have been partly due to careful patient selection and very early use of pVAD; devices were inserted 14 minutes after study arm assignment.⁹ In the clinical guidelines for the management of acute coronary syndromes, Rao et al. (2025) recommend pVAD use for patients with STEMI with SCAI shock stages C, D, or E, who are not comatose, and who have peripheral vasculature able to accommodate large-bore access.⁸

Kirklin et al. (2020) published guidelines for mechanical circulatory support (MCS) on behalf of the American Association for Thoracic Surgery and the International Society for Heart and Lung Transplantation. Regardless of the specific MCS device, recommendations included complete preoperative evaluation of cardiac and non-cardiac physical function, organ systems, and

psychosocial issues. Biventricular support should be considered for patients who remain in refractory biventricular failure or who are experiencing persistent destabilizing ventricular dysrhythmias.²

Bjarnason and colleagues (2022) conducted a retrospective review of 79,176 Medicare patients who underwent percutaneous coronary intervention (PCI) assisted by either an intra-aortic balloon pump (IABP; 60% of study participants) or pVAD (40% of study participants) between 2013 and 2019. It was noted that the incidence of use of mechanical circulatory devices of either kind increased significantly over the study period (8514 in 2013 to 14,459 in 2019). The study outcome revealed no difference in mortality between groups and a higher cost for the pVAD cohort. Additionally, the most critically ill patients were less likely to receive pVAD.⁵ Two meta-analyses comparing pVADs and IABPs in patients undergoing PCI were similarly inconclusive, with similar outcomes across devices and no statistical differences between groups.^{25,26}

Rihal et al. (2015) developed a multi-society expert consensus document for the use of percutaneous mechanical circulatory support devices in cardiovascular care. A limited number of randomized clinical trials existed at the time of publication. The PROTECT II trial, with 452 patients, was the largest single randomized trial comparing pVAD (Impella) and IABP at the time. Impella was found to provide superior hemodynamic support.⁷ However, this clinical trial was terminated prior to completion due to futility and lack of difference in primary endpoints. Later analyses of outcomes suggested that, in patients who underwent extensive revascularization, use of pVAD may have led to fewer major adverse events, including death and myocardial infarction.²⁷

Lawton and colleagues (2022) published a clinical practice guideline on coronary artery revascularization for the American College of Cardiology, the American Heart Association, and the Society for Cardiovascular Angiography and Interventions. Recommendations included appropriate hemodynamic support devices for elective complex PCI to prevent hemodynamic compromise during the procedure. The BCIS-1 study is cited, which reported no difference in the primary composite outcome when hemodynamic support devices were used routinely during PCI. The study found fewer major procedural complications with IABP use. Despite mixed findings in studies, the

authors concluded that hemodynamic support devices such as pVAD can benefit select patients during complex PCI.¹⁵

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Clinical Guideline Revision History/Information

Original Date: May 24, 2024		
Review History		
Version 2	03/27/2025	• Annual review. • Added references to CMS documents (NCD and Billing and Coding articles). • Added indications for short-term use. • Refined indications for use as an adjunct to PCI. • Updated language in CPT Codes. • Expanded Medical Evidence section. • Updated references.



Cohere Medicare Advantage Policy – Peripheral Atherectomy, Non-Lower Extremity

Clinical Policy for Medical Necessity Review

Version: 1

Policy Number: CHP-318-1

Cohere Health UMC Approval Date: February 26, 2026

Last Annual Review: February 26, 2026

Revision: Not Applicable

Next Annual Review: February 26, 2027

Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy - Peripheral Atherectomy, Non-Lower Extremity

Policy Number: CHP-318-1

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

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Medical Necessity Criteria

Service: Peripheral Atherectomy, Non-Lower Extremity

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 - Peripheral Atherectomy, Non-Lower Extremity* 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	N/A
LCD	No LCD available	N/A	N/A	N/A
LCD	Not Applicable – No LCD Available for Jurisdiction	N/A	N/A	• Use Cohere Medicare Advantage internal coverage criteria

Description

Atherectomy is a minimally invasive procedure that removes blockages in blood vessels to re-establish normal blood flow. The procedure generally involves the removal of atheromatous plaque from within a blood vessel and uses a catheter fitted with a cutting blade, laser, or grinding burr.²⁻⁶

Medical Necessity Criteria

Indications

Peripheral atherectomy, non-lower extremity 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

Peripheral atherectomy, non-lower extremity is not considered appropriate if **ANY** of the following is **TRUE**:

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

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0234T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; renal artery
0235T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; visceral artery (except renal), each vessel
0236T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation of the abdominal aorta
0237T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; brachiocephalic trunk and branches, each vessel

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 peripheral atherectomy, non-lower extremity may include:

- Adverse effects from delayed or denied treatment, such as leg ulcerations, pain, or further narrowing or blocking of the arteries of the non-lower extremities.⁷
- Increased healthcare costs and complications from the inappropriate use of peripheral atherectomy-related services and additional treatments.

The clinical benefits of using these criteria for peripheral atherectomy, non-lower extremity may include:

- Improved patient selection for peripheral atherectomy of a non-lower extremity, resulting in better long-term outcomes. While the use of atherectomy for peripheral vascular interventions has increased in the United States, there is a dearth of prospective studies comparing the various atherectomy approaches (directional, rotational, orbital, and laser). Furthermore, there is insufficient high-quality evidence to support the superiority of peripheral atherectomy over endovascular approaches.⁸
- Potential to mitigate the risk of morbidity from challenging calcified coronary disease.⁴⁻⁶
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Huber et al. (2021) provided practice guidelines for diagnosing and treating patients with chronic mesenteric ischemia (CMI) caused by atherosclerosis. The authors, including a committee of vascular surgeons, conducted a systematic review to identify the optimal technique for revascularization. The committee recommended that patients with symptoms consistent with CMI should undergo an expedited workup, including a computed tomography arteriogram to exclude other potential causes of CMI. Significant arterial occlusive disease in the mesenteric vessels, particularly the superior mesenteric artery, is consistent with a diagnosis of CMI. Revascularization should primarily target the superior mesenteric artery. Endovascular revascularization with a balloon-expandable covered intraluminal stent is recommended as the initial treatment, with open repair in select younger patients and patients who are not endovascular candidates. Long-term surveillance is recommended following revascularization and in asymptomatic patients with severe mesenteric occlusion. An endovascular-first approach is recommended if symptoms recur following revascularization due to stenoses.⁶

Usai et al. (2020) conducted a retrospective review on patients at two institutions to evaluate the performance of less invasive endovascular stent therapy versus open surgical revascularization in patients with subclavian artery atherosclerotic disease (SAAD). Reintervention-free survival (RFS) was the primary endpoint of the study, while the secondary endpoints included primary patency (PPR) and secondary patency (SPR) rates, overall survival (OS) times, and time to reintervention. The median time to follow-up was 87 months in the surgical group versus 27 months in the endovascular group. At 98 months, RFS was significantly higher in the surgical group, although OS did not differ significantly between the two groups. Open surgical repair was also associated with a reduced reintervention rate. At 98 months, PPR was 96% in the surgery group and 65% in the endovascular group, but SPR did not differ significantly. The authors concluded that surgical treatment was associated with higher patency and lower reintervention than endovascular treatment.⁷

Diaz et al. (2020) presented a case report on laser atherectomy to treat in-stent restenosis of the superior mesenteric artery in a 53-year-old male with chronic mesenteric ischemia caused by severe in-stent restenosis who experienced abdominal pain and weight loss. The authors used a 0.9 mm laser catheter with low energy and pulse rate, together with balloon therapy. Based on the patient's improved symptoms following revascularization, the authors conclude that treating severe in-stent restenosis of the superior mesenteric artery using laser atherectomy is safe and can result in a favorable outcome when conventional percutaneous therapies fail.⁹

Aboyans et al. (2018) documented diagnostic methods and therapeutic recommendations for atherosclerotic disease in several anatomic regions, including mesenteric, renal, and upper extremity arteries. For acute or chronic mesenteric artery disease (MAD), characterized by high mortality and underdiagnosis, the authors recommend endovascular surgery in most cases because a less invasive option is preferred in patients who are often frail. In chronic MAD, open surgery provides the advantage of durability. In acute embolic occlusion, open and endovascular surgery have comparable success rates. The authors recommend first-line endovascular therapy for revascularization in patients with acute thrombotic occlusion of the superior mesenteric artery. In patients with acute embolic occlusion of the superior mesenteric artery, they recommend both endovascular therapy and open surgery. The authors note that in patients with atherosclerotic renal artery disease (RAD), defined by greater than 60% renal arterial stenosis, renal revascularization generally does not improve blood pressure or renal or cardiovascular outcomes. Upper extremity artery disease (UEAD) due to atherosclerosis is most common at the level of the brachiocephalic trunk and the subclavian and axillary arteries. Aboyans et al. note that revascularization can be proposed for severe or disabling symptoms, bilateral stenosis or stenosis with ipsilateral arteriovenous fistula for dialysis, or in patients with upcoming coronary artery bypass grafting, or patients who have already undergone such surgery with evidence of myocardial ischemia. When revascularization surgery is considered, both endovascular and open options can be proposed based on the characteristics of the lesion and the patient's risk.²

Valle et al. (2017) described the use of orbital atherectomy in a renal artery in a 55-year-old male with severe renal artery stenosis and drug-refractory hypertension. The patient presented with severe calcification of the right renal artery. The authors initially used orbital atherectomy to modify the renal plaque, followed by stenting of the renal artery. Based on favorable follow-up angiography and clinical results, the authors conclude that using orbital atherectomy in the renal vasculature is safe and effective and warrants further evaluation.¹⁰

Parikh et al. (2014) report renal artery stenting has emerged as the predominant revascularization strategy in most patients with hemodynamically significant atherosclerotic renal arterial stenosis, despite considerable debate regarding the role of medical therapy versus revascularization in patients with renovascular hypertension. In the consensus statement from the Society for Cardiovascular Angiography and Interventions (SCAI), experts note that systolic and diastolic blood pressure show improvement with high safety profiles in patients with renal artery stenosis, according to prospective multicenter registries. The authors also note that although randomized controlled clinical trials comparing the efficacy of optimal medical therapy and renal stenting show limited benefit in preserving renal function following stenting, such trials often exclude patients who may benefit from renal artery stenting.⁶

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Policy Revision History/Information

Original Date: February 26, 2026		
Review History		



Cohere Medicare Advantage Policy – Pulmonary Artery Denervation (PADN)

Clinical Policy for Medical Necessity Review

Version: 2

Policy Number: CHP-069-2

Cohere Health UMC Approval Date: March 26, 2026

Last Annual Review: March 26, 2026

Revision: Not Applicable

Next Annual Review: March 26, 2027

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy - Pulmonary Artery Denervation (PADN)

Policy Number: CHP-069-2

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

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Medical Necessity Criteria

Service: Pulmonary Artery Denervation (PADN)

Related Centers for Medicare & Medicaid Services (CMS) Documents

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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 - Pulmonary Artery Denervation (PADN)* 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	N/A
LCD	No LCD Available for Jurisdiction	N/A	N/A	Use Cohere Medicare Advantage internal coverage criteria

Description

Pulmonary artery denervation (PADN) is a minimally invasive, catheter-based procedure to reduce pulmonary artery pressure in patients with pulmonary arterial hypertension (PAH).² In PADN a catheter is advanced into the pulmonary artery where energy is used to ablate nerve fibers surrounding the artery. This denervation is intended to reduce vasoconstriction and lower pulmonary artery pressures. The most common technique uses catheter-directed thermal ablation, though ablation can also be achieved via ultrasonic energy.

Medical Necessity Criteria**Indications**

Pulmonary artery denervation (PADN) is considered appropriate if **ANY** of the following is **TRUE**^{3,4}:

- This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

Pulmonary artery denervation (PADN) is not considered appropriate if **ANY** of the following is **TRUE**^{3,4}:

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

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0793T	Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance
0632T	Percutaneous transcatheter ultrasound ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance

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 pulmonary artery denervation (PADN) may include:

- Adverse effects from delayed or denied treatment, such as ongoing hemodynamic compromise and worsening cardiac function.^{4,5}

The clinical benefits of using these criteria for pulmonary artery denervation (PADN) may include:

- Avoidance of unnecessary and unproven procedures that carry procedural risks and potential for iatrogenic injury.⁶

- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Pulmonary arterial hypertension (PAH) is a disease with a poor prognosis and high mortality that leads to right ventricular failure and sudden cardiac death. Abouzid et al. (2025) conducted a meta-analysis to evaluate patients with pulmonary hypertension and the hemodynamic parameters of pulmonary artery denervation PADN (e.g., mean right atrial pressure [mRAP], mean pulmonary artery pressure [mPAP], and pulmonary vascular resistance [PVR]). The authors stated that while PADN may be effective, additional research is needed. Specifically, long-term results are required to understand the impact on hemodynamic parameters, safety, and efficacy. Patient selection criteria also warrant further research to ensure proper treatment.¹⁰

Wu et al. (2024) reported a meta-analysis of 44 studies involving 7356 patients that compared PADN with other treatments for PAH. Their primary endpoint was change in the 6-minute walking distance (6MWD) from baseline. They reported that patients treated with PADN showed greater improvement in 6MWD than those treated with placebo or 9 pharmacological treatments. However, there were no differences in clinical worsening, hospitalization, mortality, or serious adverse effects between patients treated with PADN compared to any other treatment.⁷

Chin et al. (2024) outlined the current treatment algorithm for PAH, with maximal medical therapy now involving four drugs.³ Current therapy, consisting of a combination of pharmacological treatments, yields mixed results.⁸ PADN is a relatively new, minimally invasive endovascular catheter-based interventional procedure for treating patients with PAH.² The authors reported that most clinical studies and reviews agree that larger clinical trials are needed to define and confirm the efficacy of PADN.^{2,3,9}

Salazar et al. (2023) and Constatine et al. (2021) also stated that additional randomized controlled trials (RCTs) are needed to establish a recommendation for the use of PADN.^{11,12} Vorla et al. (2023) published an abstract outlining the results of a meta-analysis of 8 studies (including 7

RCTs) and 577 patients. The authors noted the small sample sizes in the trials.¹³

Zhang et al. (2022) conducted an RCT evaluating the effect of PADN in 128 patients with stable group 1 PAH. While results were positive, larger RCTs that include patients who do not respond optimally to combination pharmacotherapy are needed. Future studies should also include patients with various etiologies of PAH (e.g., idiopathic, hereditary, connective tissue disease, congenital heart disease, portal hypertension). (ClinicalTrials.gov NCT03282266).⁵

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Policy Revision History/Information

Original Date: April 03, 2025		
Review History		
Version 2	03/26/2026	Annual review. No changes to medical necessity criteria or procedure codes. 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 1 new reference.



Cohere Medicare Advantage Policy – Pulmonary Artery Denervation

Clinical Guidelines for Medical Necessity Review

Version: 1
Revision Date: April 3, 2025

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Pulmonary Artery Denervation

Date of last literature review: 03/22/2025

Document last updated: 04/01/2025

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

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Medical Necessity Criteria

Service: Pulmonary Artery Denervation (PADN)

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 pulmonary artery denervation (PADN).

Recommended Clinical Approach

This service is clinically unproven and not medically necessary. Pulmonary arterial hypertension (PAH) is a disease with a poor prognosis and high mortality that leads to right ventricular failure and sudden cardiac death. Current therapy consists of combination pharmacological treatments, which yield mixed results.¹

Pulmonary artery denervation (PADN) is a minimally invasive, catheter based procedure to reduce pulmonary artery pressure in patients with pulmonary arterial hypertension (PAH).² The most common method of PADN is catheter-directed thermal ablation.

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 pulmonary artery denervation. 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:

- Although PADN is a minimally invasive procedure with reasonable pathophysiology, it is subject to procedural risk and iatrogenic injury.³
- Disproportionate increased costs.³
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- PADN can significantly increase the 6-minute walk distance in patients with PAH.^{4, 5}
- Significant Improvements in hemodynamic parameters.⁵
- Improvement in cardiac function.⁵
- 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

→ **Pulmonary artery denervation (PADN)** is considered appropriate if **ANY** of the following is **TRUE**^{6,7}:

- ◆ This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

→ **Pulmonary artery denervation (PADN)** is not considered appropriate if **ANY** of the following is **TRUE**^{6,7}:

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

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0793T	Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance.
0632T	Percutaneous transcatheter ultrasound ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance.

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

Medical Evidence

Pulmonary arterial hypertension (PAH) is a disease with a poor prognosis and high mortality that leads to right ventricular failure and sudden cardiac death. Chin et al (2024) recently outlined the current treatment algorithm for PAH, with maximal medical therapy now involving four drugs.⁶ Current therapy consisting of combination pharmacological treatments yields mixed results.¹

Pulmonary artery denervation (PADN) is a relatively new, minimally invasive endovascular catheter-based interventional procedure for the treatment of patients with PAH.² In a prospective, randomized, sham-controlled trial (the PADN-5 trial), Zhang et al (2019) studied the benefits of PADN in combined pre- and post-capillary pulmonary hypertension (CpcPH) patients. This was the first randomized, sham-controlled trial to determine the benefits of PADN treatment in these patients. The results showed that patients treated with PADN had significant improvements in hemodynamic and clinical outcomes.⁴

In another randomized, sham-controlled trial (the PADN-CFDA trial), Zhang et al (2023) studied 128 treatment-naïve patients with PAH. Patients received either PADN along with drug monotherapy or a sham procedure with drug monotherapy. They found that the patients treated with PADN and drug monotherapy improved exercise capacity and hemodynamic outcomes at 6 months compared to the sham group.⁵ This trial was done in China, and the response to PADN treatment could differ in other populations.

Davies et al (2022) and Xie et al (2022) also note the potential of PADN as a treatment for patients with PAH; however, additional research is needed.^{2,9}

A recent review guideline for the treatment of PAH does not mention PADN.⁶ Most clinical studies and reviews agree that larger clinical trials are needed to define and confirm the efficacy of PADN.

The European Society of Cardiology (ESC) and the European Respiratory Society (ERS) published guidelines in 2022 for the Diagnosis and Treatment of Pulmonary Hypertension (PH). The guidelines mention that although potentially promising, PADN should be considered experimental.⁷

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Clinical Guideline Revision History/Information

Original Date: April 3, 2025		
Review History		



Cohere Medicare Advantage Policy – Right Heart Catheterization and/or Left Ventriculogram

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: May 26, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medicare Advantage Policy - Right Heart Catheterization and/or Left Ventriculogram

Date of last literature review: 5/26/2024

Document last updated: 5/26/2024

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

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Medical Necessity Criteria

Service: Right Heart Catheterization and/or Left Ventriculogram

Benefit Category

Inpatient Hospital Services

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

Recommended Clinical Approach

Cardiac catheterization is invasive, with more risks than other tests. Thus, it should be used to provide important information that may change the treatment plan. In some clinical situations, the performance of a right cardiac catheterization (hemodynamics and cardiac output) or a left heart catheterization/left ventricular angiogram alone may be needed.

Medical Necessity Criteria

Indications

→ **Other cardiac catheterization** is considered appropriate if **ANY** of the following is **TRUE**¹⁻¹⁸:

- ◆ The procedure is a **right cardiac catheterization**, and **ANY** of the following is **TRUE**:
 - Valvular heart disease; **OR**
 - CHF; **OR**
 - Congenital heart disease; **OR**
 - Cor pulmonale; **OR**
 - Pulmonary hypertension; **OR**
 - Intracardiac shunts (including septal rupture) and extracardiac vascular shunts; **OR**
 - Suspected cardiomyopathy or myocarditis; **OR**
 - Endocarditis requiring valvular surgery; **OR**
 - Suspected rejection of a transplanted heart; **OR**
 - The patient is being considered for or has received a heart transplant; **OR**
 - Suspected pericardial tamponade or constriction; **OR**
- ◆ The procedure is a **left heart catheterization/left ventricular angiogram**, and **ANY** of the following is **TRUE**¹⁻²:
 - Assessment of left ventricular systolic function; **OR**

- Assessment of the degree of mitral regurgitation; **OR**
- Assessment for a ventricular septal defect, other intracardiac shunts, or other congenital heart abnormalities; **OR**
- Pericardial tamponade; **OR**
- Hemodynamic assessment of the aortic valve; **OR**
- Measurement of the left ventricular end-diastolic pressure.

Non-Indications

→ **Other cardiac catheterization** is not considered appropriate if **ANY** of the following is **TRUE**¹:

- ◆ Inpatient or observation stay following routine outpatient cardiac catheterization; **OR**
- ◆ Right heart catheterization billed for "bedside placement" of flow directed (Swan-Ganz type) catheter; **OR**
- ◆ Right heart catheterization for atherosclerotic heart disease without heart failure; **OR**
- ◆ Right heart catheterization for angioplasty, electrophysiologic studies, or other interventional procedures; **OR**
- ◆ Aortography for atherosclerotic heart disease; **OR**
- ◆ Aortography performed for a diagnosis of "rule out (valvular lesion)"; **OR**
- ◆ When the service is performed by a resident alone, without a teaching physician present with the resident throughout entire procedure; **OR**
- ◆ Separate reimbursement for vascular closure of puncture site (with or without implantable device or other mechanical intervention); **OR**
- ◆ Separate reimbursement for dye injection during catheterization or angiographic procedures for the purpose of guiding catheter placement; **OR**
- ◆ Assistant at the surgery while catheterization is performed; **OR**
- ◆ Right heart catheterization solely for the purpose of inserting a temporary pacemaker, performing endomyocardial biopsy, or performing electrophysiologic studies; **OR**
- ◆ Standby anesthesia or surgeon during angioplasty.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Codes	Code Description
93451	Right heart catheterization

93452	Left heart catheterization with intraprocedural injection for left ventriculography
93593	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; normal native connections
93594	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; abnormal native connections

Medical Evidence

Cochran et al. (2022) performed a review on the role of right heart catheterization in patients (RHC) with heart failure. The procedure is a fundamental diagnostic tool for patients experiencing refractory heart failure or cardiogenic shock. The procedure is also crucial for evaluating eligibility for heart replacement therapies and for managing patients post-implantation of mechanical circulatory assist devices and heart transplantation. Guidelines published by the American College of Cardiology Foundation (ACCF), American Heart Association (AHA), and European Society of Cardiology (ESC) specify situations when RHC may be indicated. While RHC is not typically suggested for patients with decompensated heart failure, it may benefit those whose condition does not improve with initial therapy as well as those with uncertain volume status and persistent hypoperfusion, or those being evaluated for advanced treatments.¹⁹

Otto et al. (2021) reviewed published guidelines from the American College of Cardiology (ACC) and the American Heart Association (AHA) on the management of patients with valvular heart disease. When noninvasive testing results are inconclusive, especially in symptomatic patients, or when there's a discrepancy between noninvasive tests and clinical findings, cardiac catheterization with direct intracardiac measurements becomes crucial. Catheterization provides valuable information, particularly in assessing transvalvular pressure gradients and cardiac output. Imaging difficulties or misalignment of the Doppler beam can lead to underestimation of stenosis severity, while suboptimal image or Doppler data quality can cause overestimation or underestimation of valve regurgitation severity. In such cases, contrast angiography may be helpful for semiquantitative assessment, especially when noninvasive results conflict with physical examination findings. Cardiac catheterization offers the advantage of measuring intracardiac pressures and pulmonary vascular resistance, aiding in decision-making regarding valve intervention.²⁰

Shellenberger et al. (2021) conducted a systematic review on the role of physical examination and RHC in the diagnosis of pulmonary hypertension (PH). Data from four studies (including calculated pooled diagnostic odds ratios [DOR]) were analyzed for several indicators, including right ventricular heave, a loud pulmonic component of the second heart sound (P2), jugular venous pressure (JVP) greater than 3 cm above sternal angle, and a palpable P2. Of these, three findings supported the diagnosis of PH: JVP greater than 3 cm above the sternal angle (DOR 5.90, 95% CI 2.57,

13.57), a loud P2 (DOR 2.91, 95% CI 1.38, 6.10), and a right ventricular heave (DOR 2.78, 95% CI 1.12, 6.89). Limitations of the review include a small sample size and a lack of control groups. Also, the studies were unable to correlate patient physical examination results with the NYHA functional class or stage of PH. Larger cohort studies employing a combination of tests may provide further insights into the role of physical examination in PH diagnosis and early detection.²¹

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Cohere Medicare Advantage Policy – Stress Echocardiogram

Clinical Policy for Medical Necessity Review

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Important Notices

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Medical Necessity Criteria

Service: Stress Echocardiogram

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻¹⁵

- [National Coverage Determination. Ultrasound Diagnostic Procedures \(220.5\).](#)
- [Local Coverage Determination \(LCD\). Transthoracic Echocardiography \(TTE\). \(L33577\).](#)
 - [Billing and Coding: Transthoracic Echocardiography \(TTE\) \(A56781\).](#)
- [Local Coverage Determination \(LCD\). Cardiovascular Stress Testing, Including Exercise and/or Pharmacological Stress and Stress Echocardiography \(L34324\).](#)
 - [Billing and Coding: Cardiovascular Stress Testing, Including Exercise and/or Pharmacological Stress and Stress Echocardiography \(A57183\).](#)
- [Local Coverage Determination \(LCD\). Transthoracic Echocardiography \(L34338\).](#)
 - [Billing and Coding: Transthoracic Echocardiography \(TTE\) \(A57306\).](#)
- [Local Coverage Determination \(LCD\). Cardiology Non-Emergent Outpatient Stress Testing \(L35083\).](#)
 - [Billing and Coding: Cardiology Non-Emergent Outpatient Stress Testing \(A56423\).](#)
- [Local Coverage Determination \(LCD\). Echocardiography \(L37379\).](#)
 - [Billing and Coding: Echocardiography \(A56625\).](#)
- [Local Coverage Determination \(LCD\). Cardiology Non-Emergent Outpatient Stress Testing \(L38396\).](#)
 - [Billing and Coding: Cardiology Non-Emergent Outpatient Stress Testing \(A56952\).](#)
- [Local Coverage Determination \(LCD\). Echocardiography for Myocardial Perfusion \(L38786\).](#)
 - [Billing and Coding: Echocardiography for Myocardial Perfusion \(A58503\).](#)

Description

Stress echocardiography is a noninvasive diagnostic tool that uses ultrasound to provide an overview of cardiac structure and function at rest and under stress. It is used to evaluate a variety of clinical presentations, including chest pain (or ischemic equivalent) and intermediate (16%–50%) or high (>50%) pretest probability of coronary artery disease (CAD).^{16–20} During stress echocardiography, the patient is first fitted with a transducer and baseline images at rest are generated. The patient is then put under stress, either physical exercise (treadmill or stationary bicycle), pharmacologic agents (e.g., dobutamine), or stress pacing in a patient with a permanent pacemaker and images are generated when the patient's heart rate is increased. These images are used to determine cardiac function under stress including coronary heart disease and valvular defects.²¹ Stress echo results in no radiation exposure, is typically lower cost, requires a shorter patient time commitment, and provides additional information on cardiac structures (e.g., valves, ascending aorta, pericardial space) compared to myocardial perfusion imaging (MPI-SPECT). Stress echocardiography has lower diagnostic accuracy in patients with limited acoustic windows.^{19,22–23}

In patients with valvular heart disease, stress echocardiography is a useful modality to assess a patient's functional capacity, ventricular function, and severity of valve dysfunction during exercise. This information may help determine the need for, and timing of, surgical or interventional treatments. Stress echocardiography is well-tolerated in the pediatric population and is often a preferred modality, as it requires no sedation, needle sticks, or radiation exposure and has been completed in children as young as 6 years.²⁴ The absence of radiation is of particular importance among groups that require serial screening, including transplant recipients, patients with a history of radiation to the chest, and patients with a history of Kawasaki disease.²⁴

Medical Necessity Criteria

Indications

Stress echocardiogram is considered appropriate if **ANY** of the following is **TRUE**^{1,4,25}:

- The echocardiogram is conducted in addition to an electrical stress test and **ALL** of the following:
 - **ANY** of the following;
 - The patient has signs or symptoms consistent with coronary artery disease (CAD), including **ANY** of the following^{24,26-27}:
 - Angina pectoris or anginal equivalent symptoms; **OR**
 - Cardiac rhythm disturbances; **OR**
 - Unexplained syncope; **OR**
 - Heart failure; **OR**
 - Significant atherosclerotic vascular disease elsewhere in the body (e.g., carotid obstructive disease, peripheral vascular disease involving the lower extremities, abdominal aortic aneurysm); **OR**
 - The patient has a metabolic disorder known to cause CAD, including **ANY** of the following:
 - Diabetes mellitus; **OR**
 - Syndrome X; **OR**
 - Atherogenic hypercholesterolemia; **OR**
 - Abnormal electrocardiogram (ECG) consistent with CAD, including **ANY** of the following:
 - The patient needs an evaluation for progression of CAD with the potential for a change in treatment; **OR**
 - Following coronary artery bypass graft (CABG) surgery; **OR**
 - Following a myocardial infarction (MI); **OR**
 - Following a coronary revascularization procedure (e.g., percutaneous transluminal coronary angioplasty, PTCA); atherectomy; intracoronary thrombolysis); **OR**
 - Following medical treatment to reverse or stabilize CAD; **OR**
 - A history of coronary artery ischemic event(s) without symptoms (e.g., silent MI); **OR**
 - As part of a preoperative assessment when intermediate or high risk for CAD is present and surgery is likely to induce significant stress²⁸⁻²⁹; **OR**

- Information from the clinical assessment does not adequately assess functional capacity and such information is needed to manage the patient; **AND**
- **ANY** of the following:
 - Electrical stress test alone is not useful or effective due to **ANY** of the following circumstances^{24,30}:
 - Abnormal resting ECG due to **ANY** of the following:
 - Digitalis; **OR**
 - Left ventricular hypertrophy; **OR**
 - Bundle branch block; **OR**
 - Preexcitation syndrome (Wolff-Parkinson-White); **OR**
 - Electronically paced ventricular rhythm; **OR**
 - Greater than 1 mm of resting ST depression; **OR**
 - Prior equivocal stress ECG; **OR**
 - A history of wall MI; **OR**
 - The patient has significant valvular heart disease and measuring the physiologic changes with exercise is necessary to determine the need for a valve intervention; **OR**
 - To determine the significance or extent of myocardial ischemia (or scar); **OR**
 - To assess myocardial viability (e.g., risk stratification following acute myocardial infarction); **OR**
 - When information from the clinical assessment and electrical stress test does not adequately assess functional capacity and such information is needed to manage the patient; **OR**
 - To aid in diagnosis of hypertrophic or dilated cardiomyopathy; **OR**
 - To differentiate ischemic from non-ischemic cardiomyopathy; **OR**
 - As part of pre-operative evaluation in a patient at intermediate or high risk of CAD when the surgery is likely to induce significant cardiac stress²⁸⁻²⁹; **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:
 - 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

Stress echocardiogram is not considered appropriate if **ANY** of the following is **TRUE**^{1,4,26,30-36}:

- The incremental information obtained from the addition of an echocardiogram to an electrical stress test is of no clinical relevance; **OR**
- The results of the test have no potential to affect the treatment of the patient (e.g., the patient has a severe comorbidity likely to limit life expectancy and/or likely to limit candidacy for revascularization); **OR**
- Secondary conditions will potentially decrease both the sensitivity and specificity of testing (e.g., immediate postoperative period, anemia, or infection); **OR**
- A stress test is performed too frequently; **OR**
- For screening CAD (e.g., in a patient without signs or symptoms of CAD) such as for the presence of risk factors (e.g., smoking, obesity, family history of CAD) but no personal history of vascular disease or related metabolic disorder; **OR**
- When used solely to motivate changes in lifestyle; **OR**
- To qualify a patient for a non-covered service (e.g., fitness training, weight loss program, occupational fitness evaluation); **OR**
- For preoperative assessment prior to either a non-covered surgery or a covered surgery if the reasonable and necessary criteria for the testing are not documented; **OR**
- A stress echocardiogram is not reasonable or necessary if performed simultaneously with **ANY** of the following additional tests:
 - Radionuclide ventriculography; **OR**
 - A myocardial perfusion imaging stress test with or without pharmacological stress; **OR**
 - A stress nuclear test for the same clinical problem.

Level of Care Criteria

Outpatient

Table 1. Definitions of Low, Intermediate, and High-Risk Surgery²⁷

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	1. Total abdominal hysterectomy	-

	2. Diagnostic gynecologic procedures (laparoscopy)	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

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93350	Real time transthoracic echocardiography with 2-dimensional (2D) image documentation during rest and cardiovascular stress test using treadmill and pharmacologically induced stress, with interpretation and report
93351	Real time transthoracic echocardiography with 2-dimensional (2D) image documentation during rest and cardiovascular stress test using treadmill, bicycle exercise and pharmacologically induced stress, with interpretation and report, including performance of continuous electrocardiographic monitoring, with physician supervision
C8928	TTE w or w/o fol w/con, stress
C8930	TTE w or w/o contr, cont ecg

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 stress echocardiogram 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

Woodward et al. (2025) investigated long-term outcomes in over 5,000 patients who had received a stress echocardiogram at community hospitals.⁴³ Over a mean follow-up period of over 800 days, the authors found that patients with positive stress echocardiograms had a higher risk of myocardial infarction, all-cause mortality, and cardiac-related mortality. Furthermore, the authors reported that patients with no previous history of coronary artery disease who had a negative stress echocardiogram had a five-year event-free warranty period, during which they reported no major adverse cardiac events. These findings demonstrate the long-term utility of stress echocardiography in identifying patients at-risk for major cardiac events.

Ihekwaba et al. (2024) conducted a systematic review and meta-analysis of long-term outcomes in patients with suspected or known CAD who underwent stress echocardiography. Their final analysis included over 16,000 patients across 6 trials who underwent either treadmill or pharmacological stress testing and had followup between 21-101 months. They reported that patients with positive stress echocardiography results (test results showing evidence of ischemia) had higher rates of major adverse cardiovascular events (MACE) and all-cause mortality compared to patients with negative stress echocardiography results (test results showing no evidence of ischemia). They concluded that stress echocardiography results can be used to guide treatment, with positive results informing the need for interventions in patients with suspected coronary artery disease.³⁷

Lee et al. (2023) reviewed the literature on the risks and contraindications of exercise and pharmacological stress echocardiography.⁴⁴ Across 3 exercise stress studies, including a total of over 50,000 patients, the probability of a patient experiencing a life-threatening event was extremely rare, between 0.015 - 0.04 across studies. Reported complications included arrhythmias, acute myocardial infarction (AMI), and cardiac and ventricular ruptures. The probability of a life-threatening event during a pharmacological stress test was somewhat higher, though still low overall, at 0.2 for dobutamine and 0.08 for vasodilatory agents. Reported life-threatening risks included AMI and

ventricular tachyarrhythmias for dobutamine, and AMI, asystole, and hypotension for vasodilators. The authors concluded that the overall risk of life-threatening adverse events as a result of stress testing is very low. However, they also caution that certain patients, notably those with valvular dysfunction, may be at higher risk for adverse events. These patients, along with pediatric patients, pregnant patients, and patients not able to communicate easily with medical personnel, may require increased monitoring during the procedure.

Moscattelli et al. (2023) reviewed the use of stress cardiovascular imaging in pediatric patients.⁴⁵ They note that while coronary artery disease (CAD), the most common indication for stress testing in adult patients, is rare in pediatric patients, pediatric patients may still experience chest pain and ischemia due to several causes, including Kawasaki disease, cardiac transplantation, or coronary artery reimplantation. Stress testing may also be used in the evaluation and assessment of valvular heart diseases, cardiomyopathies, and several congenital diseases. Specific conditions that may benefit from stress echocardiography in pediatric patients include post-transplant coronary vasculopathy, anomalous origin of coronary arteries, and after cardiotoxic chemotherapy. The authors note that children younger than 8 years old may be unable to cooperate with provider instructions during exercise stress testing and may therefore need to undergo pharmacological stress testing, with the further potential need for sedation.

Pellikka et al. (2020) and the American Society of Echocardiography published echocardiography guidelines for detection and risk assessment of stable ischemic heart disease, per the 2015 American College of Cardiology/American Heart Association clinical practice guidelines.²⁴ Stress echocardiography was rated as appropriate as a noninvasive diagnostic and surveillance modality for several pediatric and adult cardiac conditions. In follow-up testing for new or worsening symptoms, stress echocardiography testing was appropriate for patients with suspected stable CAD. Stress echocardiography is also the preferred imaging modality for unexplained dyspnea on exertion. Stress echocardiography is appropriate following revascularization with new cardiac symptoms, especially if refractory to guideline-directed medical therapy (GDMT). Stress echocardiography is less recommended for preoperative evaluation before noncardiac surgery and

before an exercise prescription for cardiac rehabilitation. The authors noted that the absence of radiation makes this imaging modality particularly attractive for pediatric patients, women with indications for noninvasive imaging, serial imaging scenarios, and patients with a history of radiation to the chest. Additionally, stress echocardiography is preferred to studies such as cardiovascular magnetic resonance, which involves gadolinium administration, for certain patient subsets (e.g., those with kidney disease).²⁴

In 2021, Gulati and colleagues developed a multi-society guideline for the evaluation and diagnosis of chest pain. Stress echocardiography was recommended for determining the etiology of chest pain including pericardial effusion, stress cardiomyopathy, and hypertrophic cardiomyopathy. Stress echocardiography may also be used to define ischemia severity and for risk stratification after acute coronary syndrome has been ruled out.²⁰

Stout et al. (2019), on behalf of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, developed the 2018 AHA/ACC guideline for the management of adults with congenital heart disease (ACHD). Based on clinical evidence, a strong recommendation was made to limit and monitor radiation exposure during imaging of patients with ACHD due to the potential for multiple exposures in these patients. Exercise stress testing is considered reasonable for patients with subaortic stenosis to measure exercise capacity, stress-induced arrhythmias, and ischemia. Patients with transposition of the great arteries with arterial switch are recommended to have baseline serial imaging, and if the patient is symptomatic following arterial switch.³⁸

In the 2020 ACC/AHA guideline for the management of patients with valvular heart disease, Otto et al. state that it is reasonable to use low-dose dobutamine stress echocardiography in patients with suspected low-flow, low gradient severe aortic stenosis with normal left ventricular ejection fraction (stage D3). Stress echocardiography is also recommended in the diagnosis of chronic secondary mitral regurgitation, as well as before and during pregnancy evaluation in women with native valvular heart disease.³⁹

The 2024 European Society of Cardiology (ESC) guidelines for the management of chronic coronary syndromes (CCS) updated and expanded the guidelines initially issued five years prior.⁴⁶ The authors defined CCS as a range of clinical presentations of coronary artery disease (CAD) which can produce transient, reversible ischemia during exertion, emotion, or stress. Physical symptoms may include angina, other chest pain, or dyspnoea, or patients may be asymptomatic. The updated 2024 guidelines included a new recommendation for stress echocardiography to estimate the risk of MACEs or to diagnose myocardial ischemia in patients with suspected CCS and a moderate or high pre-test probability of obstructive coronary artery disease. The updated guidelines also recommended the use of ultrasound contrast agents to improve image quality and increase diagnostic accuracy, especially in obese patients and in patients with chronic obstructive pulmonary disease.

A number of recent articles provided recommendations for several common clinical scenarios. Gulati et al. (2021) provided insights into the evaluation and diagnosis of chest pain.²⁰ Winchester et al (2023) provided appropriate use criteria (AUC) for the detection and risk assessment of chronic coronary disease.³⁰ Doherty et al. (2024) updated a previous AUC document on cardiovascular evaluation for nonemergency, noncardiac surgery, focusing on ischemic heart disease, valvular heart disease and heart failure (rather than cardiovascular disease in general) and their relation to the risks associated with various types of surgery (solid organ transplant, vascular, non-vascular).^{28,40-42}

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Version 2	10/23/2025	Annual review. Adjusted criteria to mirror LCD L34324. Updated links to LCDs and Billing and Coding Articles. Removed L36889- Retired by CMS 10/16/2025 Added link to NCD 220.5. Updated Medical Evidence (9 studies)
Version 2.1	11/14/2025	Updated link and reference for A57306 per CMS
Version 2.2	03/17/2026	Updated links and references for L38786/A58503



Cohere Medicare Advantage Policy – Transesophageal Echocardiography (TEE)

Clinical Guidelines for Medical Necessity Review

Version: 1.1

Revision Date: March 18, 2025

Important Notices

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Guideline Name: Cohere Medicare Advantage Policy - Transesophageal Echocardiography (TEE)

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Medical Necessity Criteria

Service: Transesophageal Echocardiography (TEE)

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.¹⁻⁵

- [Local Coverage Determination \(LCD\). Transesophageal Echocardiography \(TEE\) L34337](#)
- [Local Coverage Determination \(LCD\). Transesophageal Echocardiography \(TEE\) L33579](#)
- [Local Coverage Determination \(LCD\). Transesophageal Echocardiography \(TEE\) L35016](#)
- [Local Coverage Determination \(LCD\). Transesophageal Echocardiogram \(L33756\)](#)
- [Local Coverage Determination \(LCD\). Echocardiography \(37379\)](#)
- [Billing and Coding: Transesophageal Echocardiography \(TEE\) \(A52868\)](#)
- [Billing and Coding: Transesophageal Echocardiography \(TEE\) \(A56505\)](#)
- [Billing and Coding: Transesophageal Echocardiography \(A56625\)](#)
- [Billing and Coding: Transesophageal Echocardiogram \(A57179\)](#)

Recommended Clinical Approach

Transesophageal echocardiography (TEE) provides a more comprehensive evaluation of the presence of intracardiac thrombus in the setting of prolonged episodes of atrial fibrillation or episodes of indefinite duration. Compared to transthoracic echo imaging, its superior visualization of the left atrial appendage can assess the safety of both outpatient elective cardioversions and acute inpatient cardioversions. TEE is also valuable for evaluating other heart structures, including better imaging of mitral valve

function and the atrial septum, both of which can have clinical significance for a patient with atrial fibrillation.

Transesophageal echocardiography (TEE) can be useful for valvular disease patients when transthoracic echocardiography results are inconclusive or discordant with history and physical exam. TEE is particularly useful in patients with mitral regurgitation to assess mitral leaflet anatomy when considering the mitral leaflet repair or MitraClip procedure feasibility. TEE is also useful in assessing the presence of infective endocarditis and/or left atrial thrombus. TEE is an integral part of minimally invasive valve interventions, including TAVR and MitraClip procedures.

Transesophageal echocardiography (TEE) can identify the cause of stroke by detecting potential intrathoracic sources of embolism. TEE is more expensive, more invasive, and takes longer to perform than TTE, but it is more sensitive, especially for patent foramen ovale and left atrial appendage.

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 Transesophageal Echocardiography (TEE). 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:

- Esophageal injury or gastric trauma, as a result of the insertion and manipulation of the ultrasound probe.^{6,7}
- Laryngeal injuries such as vocal cord trauma, compression of airway structure, and inadvertent tracheal intubation.^{6,7}
- Individuals with esophageal abnormalities, or massive cardiomegaly, may be at higher risk of TEE-related complications, as these are predisposing factors for esophageal injury.⁸
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Transesophageal echocardiograms are not limited by the challenges inherent in transthoracic ultrasound techniques, including patient positioning, limited acoustic windows, and the need to perform other interventions such as chest compressions in critically ill patients.⁹
- Compared to transthoracic echocardiogram (TTE), TEE offers improved image quality, and may permit better visualization of the interatrial septum, mitral valve, left atrium, and pulmonary veins.¹⁰ This higher resolution facilitates the definitive detection of vegetations, thrombi, masses, and intracardiac shunts. The superior imaging afforded by TEE also allows for the precise localization of valvular and paravalvular defects.¹¹
- Intraoperative TEE imaging can provide valuable real-time feedback to surgical teams during procedures.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

→ **Transesophageal echocardiography (TEE)** is considered appropriate if **ANY** of the following is **TRUE**:

◆ The patient has mitral valve disease, and **ANY** of the following is **TRUE**:

- An assessment of the cause of mitral regurgitation is necessary; **OR**
- TEE is necessary to decide between mitral valve repair or replacement; **OR**

- ◆ To evaluate known or suspected valvular heart disease when transthoracic echocardiogram (TTE) provides insufficient or discordant information; **OR**
- ◆ The patient has known or suspected endocarditis, and a TTE does not document endocarditis¹³; **OR**
- ◆ Re-evaluation of complex endocarditis; **OR**
- ◆ Evaluation of bacteremia without a known source; **OR**
- ◆ Evaluation of known or suspected prosthetic valve endocarditis otherwise obscured because of reverberations and other image artifacts related to mechanical or other non-native valves during TTE; **OR**
- ◆ Evaluation of suspected prosthetic valve dysfunction when therapeutic decisions are critical and TTE is inconclusive or when the left atrium must be well-visualized; **OR**
- ◆ Suspected thrombi or emboli and **ANY** of the following:
 - Evaluation of the left atrium and atrial appendage for clot, when clot is not visualized on TTE; **OR**
 - Evaluation for an atrial septal defect, patent foramen ovale or atrial septal aneurysm with clot; **OR**
 - Evaluation of the mitral valve in patients with a history of emboli; **OR**
- ◆ Visualization of left atrial masses when needed to provide therapeutic direction; **OR**
- ◆ When cardiac mass lesions are suspected and cannot be visualized on TTE and TEE is needed to determine a management strategy; **OR**
- ◆ To assess pericardial effusion when surface studies do not provide adequate information; **OR**
- ◆ Known or suspected aortic pathological conditions and diseases of the great vessels and **ANY** of the following¹⁴:
 - Adequate visualization of the aortic root is insufficient with TTE; **OR**
 - Identification of aortic dissection, aortic ulceration, atherosclerotic plaque, and mural thrombotic material¹⁵; **OR**
 - Visualization of **ANY** of the following¹³:
 - Descending thoracic aortic aneurysms; **OR**
 - Superior vena cava and diagnosing various congenital and acquired abnormalities, including, but not limited, to vena caval thrombosis; **OR**
 - The proximal inferior vena cava, vena caval dilation and detection of thrombosis or extension of tumors from the inferior vena cava to the right-heart chambers; **OR**
 - All four pulmonary veins; **OR**

- The heart and great vessels following blunt trauma to the chest, including, but not limited to, rupture or transection of the aorta, acute dissection, hematoma; **OR**
- When needed to assist in the decision-making prior to aortic valve operative intervention; **OR**
- ◆ To assess complications of congenital heart surgery, visualization of shunt flow across atrial-septal defects, guidance of clamshell device to close atrial-septal defects, diagnosis of cor triatriatum, and detection of pulmonary valve abnormalities¹⁴; **OR**
- ◆ For **ANY** of the following patient populations:
 - Patients with congenital heart disease postoperatively where fibrosis, echo opaque patches and prostheses, inadequate penetration, and acoustical shadowing can result in incomplete TTE data; **OR**
 - Patients in which TTE is technically inadequate or anatomic definition is incomplete; **OR**
 - Patients in whom a more precise definition of atrial, outflow tract, and proximal pulmonary vascular anomalies by TEE can be critical to management strategies; **OR**
 - Critically ill patient for whom TTE is otherwise contraindicated or inadequate; **OR**
 - Patients with persistent hypoxemia having suspected right-to-left shunt; **OR**
 - Patients with complications of myocardial infarction including, but not limited to, ruptured septum, papillary muscle, or free wall; **OR**
 - Hemodynamically unstable patients in whom TTE images are suboptimal; **OR**
 - Brain-dead patients being considered as cardiac donors;
 - Patients with persistent unexplained fever when endocarditis or myocardial abscess is suspected and TTE is non-diagnostic¹⁶; **OR**
- ◆ Guidance during percutaneous cardiac interventions, including, but not limited to, **ANY** of the following¹³:
 - Creation of shunts; **OR**
 - Placement of septation devices; **OR**
 - Valvuloplasty procedures; **OR**
 - Endomyocardial biopsy; **OR**
 - Electrophysiologic studies/procedures; **OR**
 - Placement of septal or atrial appendage occluders; **OR**
 - Percutaneous valve replacement; **OR**
- ◆ Intraoperative evaluation to assess prosthetic, repaired, or reconstructed valve function, or the integrity and function of complex congenital heart repairs; **OR**

- ◆ Intraoperative evaluation to assess the integrity of the cardiopulmonary circulation in patients during lung or heart-lung transplants; **OR**
- ◆ Intraoperative assessment for the presence of an outflow tract obstruction or the presence or repair of an intracardiac shunt; **OR**
- ◆ Intraoperative assessment of wall motion abnormalities in the case of acute deterioration in the patient's status, once the chest has been closed; **OR**
- ◆ For patients in cardioversion for whom **ANY** of the following apply;
 - They require urgent cardioversion and for whom extended pre-cardioversion anticoagulation is not desirable; **OR**
 - Who have had prior cardioembolic events thought to be related to intra-atrial thrombus; **OR**
 - For whom anticoagulation is contraindicated and for whom a decision about cardioversion will be influenced by TEE results; **OR**
 - Patients with an intra-atrial thrombus that has been demonstrated in previous TEE; **OR**
- ◆ Doppler color flow velocity mapping in addition to echocardiogram when examination could contribute significant information to patient's condition or treatment plan; **OR**
- ◆ 3-dimensional echo when billed with TEE for **ANY** of the following:
 - Possible valve surgical repair is necessary to assess the mechanism and severity of a disease prior to a required surgery; **OR**
 - The pre-operative planning of valve repair for multiple etiologies of mitral regurgitation¹⁰; **OR**
 - In the assessment of mitral stenosis and the accurate calculation of mitral valve area¹⁰; **OR**
 - Pre-operative planning for diagnosis and treatment of atrial septal defects; **OR**
 - Pre-operative and intraoperative planning for interventional cardiac procedures (eg, transcatheter placement of occluders for atrial septal defects or patent foramen ovals, or paravalvular dehiscence or leaks); **OR**
 - Intraoperative mapping for atrial ablation procedures; **OR**
 - Evaluation of tricuspid valve 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

→ **Transesophageal Echocardiography (TEE)** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Another imaging modality (e.g., CT, MRI) is requested simultaneously to evaluate for intracardiac thrombus; **OR**
- ◆ The patient has a history of esophageal pathology (e.g., stricture, malignancy, fistula, diverticulum), recent surgery of the esophagus, active GI bleeding, esophageal varices (relative), or prior surgery (relative); **OR**
- ◆ The patient has suspected atrioesophageal fistula following atrial fibrillation ablation; **OR**
- ◆ The patient has a history of undiagnosed dysphagia; **OR**
- ◆ Routine TEE for a patient with a prosthetic valve; **OR**
- ◆ The purpose is to screen for structural cardiac abnormalities in the absence of an established diagnosis, sign, or symptom; **OR**
- ◆ Routine reassessment of global and regional left ventricular function, especially if TTE is technically adequate.

Level of Service

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description/Definition
93312	Real time transesophageal echocardiography with 2-dimensional (2D) image documentation, M-mode recording, probe placement, image acquisition, interpretation, and report
93313	Real time transesophageal echocardiography with 2-dimensional (2D) image documentation and placement of transesophageal probe only
93314	Interpretation and report only of real time transesophageal echocardiography with 2-dimensional (2D) image documentation and image acquisition
93315	Transesophageal echocardiography (TEE) with probe placement, image acquisition, interpretation, and report

93316	Transesophageal echocardiography (TEE) for placement of transesophageal probe only
93317	Interpretation and report only of transesophageal echocardiography (TEE) with image acquisition
93318	Real time transesophageal echocardiography (TEE) with probe placement, 2-dimensional (2D) image acquisition and interpretation
93355	Transesophageal echocardiography (TEE) for guidance of transcatheter closure of left atrial appendage, with quantitative measurements, probe manipulation, interpretation and report
C8925	Transesophageal echocardiography (tee) with contrast, or without contrast followed by with contrast, real time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report
C8926	Transesophageal echocardiography (tee) with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report
C8927	Transesophageal echocardiography (tee) with contrast, or without contrast followed by with contrast, for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis

Medical Evidence

Garg et al. (2016) reviewed 1581 direct current cardioversion cases at the Cleveland Clinic between January 1996 and December 2012, to assess the risk of thromboembolism in patients within 48 hours of atrial fibrillation onset without prior therapeutic anticoagulation. This risk was compared to patients being treated with anticoagulants. In Group 1, TEE was performed before 33 cardioversions, with six reporting mild to moderate smoke (spontaneous echocardiographic contrast suggesting low blood flow velocities that may lead to thromboembolic events) and no thrombus or severe smoke noted. Group 2 patients received 11 TEEs before cardioversions with three revealing mild to moderate smoke. Two neurological events were experienced within 30 days of cardioversion in Group 3 patients, in which 140 of the cardioversions were preceded by TEE reporting mild to moderate smoke and five with severe smoke, with no patients having left atrial thrombus. The study concluded that there exists a significantly greater risk of thromboembolic events in patients undergoing electrical cardioversion within 48 hours of becoming symptomatic and no therapeutic anticoagulation.¹⁷

Joglar and colleagues (2024) developed the 2023 guideline for the diagnosis and management of atrial fibrillation for the American College of Cardiology and the American Heart Association. Evaluated studies recommended TEE to assess for successful closure of the left atrial appendage (LAA), most notably presence of thrombus or leakage around the area of closure. Based upon the ACUTE trial (Assessment of Cardioversion Using Transesophageal Echocardiography), precardioversion anticoagulation for at least 3 weeks is recommended.¹⁸

In the 2017 appropriate use criteria for multimodality imaging in valvular heart disease, Doherty et al. state that TEE is rarely appropriate for initial evaluation of an asymptomatic patient, and in symptomatic patients, may be appropriate in the setting of suspected acute mitral or aortic regurgitation as well as respiratory failure or hypoxemia of uncertain etiology. TEE is stated to be appropriate for suspected infectious endocarditis of native or prosthetic valves, endocardial leads, positive blood cultures or new murmur. The committee stated that TEE is also appropriate for suspected cardiac mass, tumor or embolus, in certain cases of mitral and aortic regurgitation, and further evaluation of valvular masses. A number of other evidence-based appropriateness recommendations may be found in the guideline.¹⁹

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Cohere Medicare Advantage Policy – Transthoracic Echocardiogram (TTE)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 24, 2024

Important Notices

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Guideline Name: Cohere Medicare Advantage Policy – Transthoracic Echocardiogram (TTE)

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Medical Necessity Criteria

Service: Transthoracic Echocardiogram (TTE)

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹⁻⁴

Related CMS Documents

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

- [Local coverage determination, LCD. Echocardiography \(L37379\)](#)
- [Local coverage determination, LCD. Transthoracic Echocardiography \(TTE\) \(CGS\) \(L34338\)](#)
- [Local coverage determination, LCD. Transthoracic Echocardiography \(TTE\) \(NGS\) \(L33577\)](#)
- [Billing and Coding: Transthoracic Echocardiography \(TTE\) \(A56781\)](#)

Recommended Clinical Approach

Transthoracic echocardiography (TTE) can be useful for patients with possible cardiac etiology for chest pain or shortness of breath, heart failure, palpitations, arrhythmias, lightheadedness, dizziness, syncope, TIA, stroke, or peripheral embolic event.^{5,6} It can also be used for the evaluation of suspected valvular heart disease, pericardial disease, or pulmonary hypertension. Appropriate use criteria for repeat echocardiograms are more stringent than first-time studies.

Evaluation of Potential Harms and Clinical Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of transthoracic echocardiography (TTE). 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:

In comparison with other diagnostic modalities, TEE is relatively safe and noninvasive. However, the insertion and manipulation of the ultrasound probe can cause oropharyngeal, esophageal, or gastric trauma.

- Soreness and pain at the injection site or infection: Venous access can be challenging, particularly in patients with small or collapsed veins. Complications of IV injections also include phlebitis, infiltration, extravasation, and infections.⁷
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Evaluation of structure and function of the heart, valves, and proximal aorta without radiation
- TTE allows detailed insight into cardiac structure and function, including the configuration and changing dimensions of the chambers, cyclic variations in myocardial thickness, and valve motions throughout the cardiac cycle. The proximal great vessels and the pericardium can also be directly visualized, although transesophageal echocardiography (TEE) often permits better visualization of the thoracic aorta and great veins than TTE.⁸
- TTE allows the serial evaluation of pericardial effusion and evaluation of left ventricular function during antineoplastic chemotherapy following cardiac surgery.²
- TTE allows estimation of pulmonary artery systolic pressure or sequential evaluation of the transmitral velocity profile in patients with mitral stenosis, to evaluate changes in gradient or valve area.²
- 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

→ **Transthoracic echocardiogram (TTE)** is considered appropriate if **ANY** of the following is **TRUE**^{5-6, 9}:

- ◆ The patient has chest pain (or ischemic equivalent) and clinical evidence of valvular, pericardial, primary myocardial disease, or congenital heart disease; **OR**
- ◆ The patient has chest pain (or ischemic equivalent) and an additional sign or symptom, including shortness of breath, abnormal electrocardiogram (ECG), palpitations, transient ischemic attack (TIA), stroke, or a peripheral embolism; **OR**
- ◆ The patient has syncope or pre-syncope⁵; **OR**
- ◆ Prior testing (e.g., chest X-ray, ECG, cardiac biomarkers) suggested heart disease or structural heart abnormality; **OR**
- ◆ There is a suspicion of hypertensive heart disease; **OR**
- ◆ The patient requires evaluation of right ventricular function with suspected pulmonary hypertension or pulmonary embolism; **OR**
- ◆ The patient has known or suspected infective endocarditis¹⁰; **OR**
- ◆ The patient has an embolic event that is unexplained; **OR**
- ◆ Evaluation of infiltrative and ventricular tumors and masses, including quantification of their extent and hemodynamic consequences; **OR**
- ◆ CAMZYOS™ (mavacamten) treatment: Patients with symptomatic obstructive hypertrophic cardiomyopathy New York Heart Association (NYHA) Class II-III may be prescribed mavacamten by a certified and enrolled provider and pharmacy through a restricted program called the CAMZYOS Risk Evaluation and Mitigation Strategy (REMS) program.¹⁷⁻¹⁸ This requirement is due to serious risk of heart failure due to systolic dysfunction associated with this agent in this population; however, there are few options for treatment and improvement in the health status on this agent

in select patients leading to the REMS program to provide treatment while furthering understanding of the risk: benefit ratio.^{17,19-20} This program requires echocardiograms if **ANY** of the following is **TRUE**:

- Baseline study; **OR**
 - 4, 8, and 12 weeks after treatment initiation, then every 12 weeks thereafter; **OR**
 - 4 weeks after interruption of treatment; **OR**
 - 4 and 12 weeks after any dose change (including restart of treatment); **OR**
 - 4 and 12 weeks after initiating a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor; **OR**
- ◆ The patient has **ALL** of the following²³:
- **ANY** of the following indications:
 - Prior procedure/surgery for correction of atrial septal defect (ASD); **OR**
 - Partial anomalous pulmonary venous connection repair; **AND**
 - **ANY** of the following indications²³:
 - Worsening symptoms; **OR**
 - Change on exam suggestive of repair failure; **OR**
 - Surveillance (with no worsening symptoms) and **ANY** of the following:
 - ◆ Post-device closure can be done at 1 week, 1 month, 3–6 months, 1 year and then every 2–5 years; **OR**
 - ◆ Post-surgical closure can be done at 30 days, then one year, and afterwards every 2–5 years; **OR**
 - ◆ Every 3–12 months in patients with significant residual shunt, valvular or ventricular dysfunction, arrhythmias and/or pulmonary hypertension; **OR**
- ◆ The patient has prior ventricular septal defect (VSD) repair and **ANY** of the following²³:
- Worsening symptoms; **OR** or
 - Change on exam suggestive of repair failure; **OR**
 - Surveillance (with no worsening symptoms) and **ANY** of the following:
 - Post-procedure/surgery at 1 month, then 1 year and afterward every 2–3 years; **OR**
 - Every 3–12 months in patients with significant residual shunt, valvular or ventricular dysfunction, arrhythmias and/or pulmonary hypertension; **OR**

- ◆ The patient has complex congenital heart repair (not ASD/VSD) and **ANY** of the following:
 - Worsening symptoms; **OR**
 - Change on exam suggestive of repair failure; **OR**
 - Surveillance (with no worsening of symptoms) every 3 to 12 months, especially if shunting, left ventricular (LV) dysfunction, or pulmonary hypertension persists; **OR**
- ◆ The patient requires re-evaluation for asymptomatic valvular heart disease with normal left ventricular (LV) function, including **ANY** of the following:
 - Aortic or mitral regurgitation with **ANY** of the following frequency limitations:
 - The patient has mild disease: no more than one echo every 3-5 years; **OR**
 - The patient has moderate disease: no more than one echo every 1-2 years; **OR**
 - The patient has severe disease: no more than one echo every 6 months to 1 year; **OR**
 - Aortic stenosis with **ANY** of the following frequency limitations:
 - The patient has mild disease (maximum aortic velocity or V_{max} is equal to 2.0-2.9 m/s): no more than one echo every 3-5 years; **OR**
 - The patient has moderate disease (V_{max} is equal to 3.0-3.9 m/s): no more than one echo every 1-2 years; **OR**
 - The patient has severe disease (V_{max} is greater than or equal to 4 m/s): no more than one echo every 6 months to 1 year; **OR**
 - Mitral stenosis with **ANY** of the following frequency limitations:
 - The patient has mild disease (mitral valve or MV area is greater than 1.5 cm²): no more than one echo every 3-5 years; **OR**
 - The patient has moderate disease (MV area is 1.0 to 1.5 cm²): no more than one echo every 1-2 years; **OR**
 - The patient has severe disease (MV area is less than 1 cm²): no more than one echo every 1 year; **OR**
- ◆ In patients with either systolic or diastolic heart failure (HF) who have **ANY** of the following¹:
 - A significant clinical change; **OR**
 - Patients who have received guideline-directed medical therapy (GDMT) and are being considered for invasive procedures or device therapy; **OR**

- Evaluation of treatment changes (e.g., following cardiac resynchronization therapy [CRT]); **OR**
- ◆ The patient has newly diagnosed left bundle branch block (LBBB); **OR**
- ◆ The patient has frequent ventricular premature complexes (VPCs) without other evidence of heart disease; **OR**
- ◆ The patient has nonsustained ventricular tachycardia (VT); **OR**
- ◆ The patient has sustained VT, ventricular fibrillation (VF), or cardiac arrest; **OR**
- ◆ The patient has a new onset of atrial fibrillation or atrial flutter; **OR**
- ◆ The patient has **ANY** of the following:
 - The patient has any form or degree of conduction disease and clinical evidence of valvular, pericardial, or primary myocardial disease; **OR**
 - The patient has atrioventricular (AV) block with suspicion of reduced ventricular function at an initial or follow-up evaluation; **OR**
 - The patient has AV block with abnormal findings (including chest X-ray, ECG, or physical exam) suggesting structural heart disease; **OR**
 - The patient has AV block and a history of congenital heart disease; **OR**
 - The patient has any form of conduction disease and an additional sign or symptom, including chest pain, shortness of breath, palpitations, TIA, stroke, or peripheral embolic event; **OR**
- ◆ In patients with mechanical or bioprosthetic valves with either symptoms or physical exam findings indicative of prosthetic valve dysfunction¹²; **OR**
- ◆ The patient requires surveillance for transcatheter aortic valve replacement (TAVR) or transcatheter edge-to-edge repair (TEER) at 6 weeks to 3 months post-implantation and annually¹¹; **OR**
- ◆ The patient requires surveillance for **ANY** of the following:
 - In patients with a bioprosthetic¹² and mechanical valve, initial TTE at 6 weeks to 3 months post-implantation⁵; **OR**
 - In patients with mechanical valves, surveillance TTE every 5 years is reasonable⁵; **OR**
 - In patients with a bioprosthetic surgical valve¹², TTE at 5 and 10 years and then annually after implantation is reasonable, even in the absence of a change in clinical status¹²; **OR**
 - After valve replacement, female patient planning pregnancy and no TTE within the past year¹²; **OR**
 - Surveillance of known thoracic aortic dilation every 6–12 months depending on the rate of enlargement and

underlying conditions (e.g., bicuspid aortic valve [BAV], Turner's syndrome, Ehlers-Danlos, etc.)^{21-22,24}; **OR**

- Cardiac function monitoring during or at the completion of cardiotoxic chemotherapy, as indicated by **ANY** of the following¹³⁻¹⁵:

- Anthracycline drug use [Daunorubicin (Cerubidine), Doxorubicin (Adriamycin), Epirubicin (Ellence), Idarubicin (Idamycin), Mitoxantrone (Novantrone), Valrubicin (Valstar)] and **ANY** of the following:
 - ◆ Every 3 months during therapy; **OR**
 - ◆ Six and twelve months post-therapy; **OR**
 - ◆ For patients getting very high-dose treatment (e.g., equivalent dose of doxorubicin 250 mg/m² and every additional 50-100 mg/m² during therapy); **OR**
- HER2-targeted therapy [trastuzumab (Herceptin and others), Pertuzumab (Perjeta), and margetuximab (Margenza)] at **ANY** of the following intervals:
 - ◆ Every 3 months during therapy; **OR**
 - ◆ Every 6 months up to 2 years post therapy; **OR**
- Other cardiotoxic treatments including tyrosine kinase inhibitors, proteasome inhibitors, BRAF (v-raf murine sarcoma viral oncogene homolog B1) inhibitors, MEK (mitogen-activated extracellular signal-regulated kinase) inhibitors, immune checkpoint inhibitors, antimetabolites, 5-FU (5 fluorouracil), Bevacizumab (Avastin), Clofarabine (Clolar), Cyclophosphamide (Cytosan), Imatinib (Gleevec), Ifosfamide (Ifex), Mitomycin (Mutamycin), Sorafenib (Nexavar), Sunitinib (Sutent), Paclitaxel (Taxol), Docetaxel (Taxotere), Capecitabine (Xeloda) at **ANY** of the following intervals:
 - ◆ Periodically (but no more than every 3 months) in high risk patients, including **ANY** of the following:
 - High risk female patient greater than or equal to 50 years old; **OR**
 - Presence of traditional cardiovascular risk factors: Hypertension, smoking, obesity, dyslipidemia, insulin resistance; **OR**
 - Past medical history with **ANY** of the following:

- Reduced or low-normal LVEF (50% to 54%) pre-treatment; **OR**
- Presence of pre-existing cardiovascular disease (e.g., CAD, PAD, cardiomyopathy, severe valvular heart disease, heart failure, or diabetes); **OR**
- Chronic kidney disease stage 2 (eGFR less than 78 ml/min/1.73 m²); **OR**
- Abnormal Biomarkers including **ANY** of the following:
 - ◆ Elevated baseline troponin and/or NT-proBNP; **OR**
 - ◆ Elevated cardiac troponin or NT-proBNP during cancer therapy; **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

- **TTE** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Routine echocardiogram in a patient without known cardiovascular disease with no clinical changes; **OR**
 - ◆ Routine echocardiogram for known, asymptomatic valvular heart disease more frequently than listed above; **OR**
 - ◆ Routine echocardiogram in a known heart failure patient without any significant clinical changes, treatment changes that may affect cardiac function, or plans for invasive procedures/device therapy; **OR**
 - ◆ Repeat TTE for hypertensive heart disease and no symptoms and prior TTE less than a year ago.¹⁶

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
93303	Complete transthoracic echocardiography for congenital cardiac anomalies
93304	Follow-up transthoracic echocardiography for congenital cardiac anomalies
93306	Real time transthoracic echocardiography with 2-dimensional (2D) image documentation, M-mode recording with spectral Doppler echocardiography, and color flow Doppler echocardiography
93307	Complete real time transthoracic echocardiography with 2-dimensional (2D) image documentation
93308	Follow-up real time transthoracic echocardiography with 2-dimensional (2D) image documentation
C8921	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; complete
C8922	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; follow-up or limited study
C8923	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, complete, without spectral or color doppler echocardiography
C8924	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, follow-up or limited study
C8929	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image

	documentation (2d), includes m-mode recording, when performed, complete, with spectral doppler echocardiography, and with color flow doppler echocardiography

Medical Evidence

Doherty and colleagues (2017) developed a multi-society appropriate use criteria document for multimodality imaging in valvular heart disease. TTE is considered the examination of choice (appropriate) for initial evaluation of asymptomatic patients with any of the following: unexplained murmur, history of rheumatic heart disease, first-degree family history of a bicuspid aortic valve, etc. In the examination of patients with clinical signs and/or symptoms, TTE may be appropriate for arrhythmias and presyncope as well as assessment of volume status in a critically ill patient and established cause of respiratory failure. It was found to be appropriate in other instances such as syncope, hemodynamic instability, heart failure, endocarditis with positive blood cultures, and respiratory failure. TTE was rated as appropriate for evaluation of valvular mass, stage A valvular heart disease (VHD), mild or moderate VHD, some forms of severe VHD, and valve replacement or repair evaluations. In pre-transcatheter aortic valve replacement (TAVR) evaluation, TTE is deemed appropriate only for assessment and number of valve cusps and degree of calcification and appropriate during intra and post-procedural evaluations. In mitral valve repair, TTE is deemed appropriate to determine patient eligibility, post procedurally and may be appropriate for certain intraprocedural evaluation situations.⁵

In the 2011 appropriate use criteria for echocardiography document (American College of Cardiology, American Society of Echocardiography, American Heart Association, et al.) Douglas et al. address the appropriate use of TTE, transesophageal echocardiography (TEE), and stress echocardiography. The application of the 2007 appropriate use criteria was stated to have been evaluated in academic medical centers, Veterans Affairs hospitals, and community settings. It was found that only 11-16% of TTE applications were unclassified, meaning that most TTEs ordered were captured by acceptable use criteria (AUC) indications (87-91%). It was found that the most commonly reported appropriate indications for TTE included initial evaluation of symptoms potentially caused by suspected cardiac etiology.⁶

In a 2011 study, McDermott and colleagues concluded that TTE was a sufficiently sensitive screening test for native valve infective endocarditis for patients with normal heart valves. Additionally, in those patients with abnormal heart valves, a transesophageal echocardiogram (TEE) did not increase the diagnostic yield in 12 out of 15 patients evaluated. TEEs were reviewed (N=2218), with 87 having a preceding TTE. Infectious endocarditis was defined as high-grade continuous bacteremia with heart valve

vegetation. Patients with pacemakers, defibrillators, and prosthetic heart valves were excluded.¹⁰

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Clinical Guideline Revision History/Information

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Cohere Medicare Advantage Policy – Transthoracic Echocardiogram (TTE)

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 - Transthoracic Echocardiogram (TTE)

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

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Medical Necessity Criteria

Service: Transthoracic Echocardiogram (TTE)

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁶

- [Local Coverage Determination \(LCD\). Transthoracic echocardiography \(TTE\) \(NGS\) \(L33577\)](#)
 - [Billing and Coding: Transthoracic echocardiography \(TTE\) \(A56781\)](#)
- [Local Coverage Determination \(LCD\). Transthoracic echocardiography \(TTE\) \(L34338\)](#)
 - [Billing and Coding: Echocardiography \(A57306\)](#)
- [Local Coverage Determination \(LCD\). Echocardiography \(L37379\)](#)
 - [Billing and Coding: Echocardiography \(A56625\)](#)

Description

A transthoracic echocardiogram (TTE) is a noninvasive diagnostic test that uses ultrasound to generate images of the heart.⁷ A small probe is placed on the outside of the patient's chest, and sound waves are emitted, generating live, moving images of the heart and providing information on the health and functioning of heart structures, including the myocardium, valves, pericardium, coronary arteries, and great vessels.⁸ Following the test, a detailed report is generated that is used to guide clinical decision-making.

Medical Necessity Criteria

Indications

Transthoracic echocardiogram (TTE) is considered appropriate if **ANY** of the following is **TRUE**:

- Ventricular function, cardiomyopathy, or heart failure with **ANY** of the following^{1,3,9,10}:
 - To rule out common cardiac causes of pulmonary congestion (e.g., left-sided valvular disease, depressed systolic or diastolic function, cardiomyopathy) when history, physical examination, and routine laboratory tests suggest or cannot eliminate cardiac disease; **OR**
 - The patient presents with edema and clinical signs of elevated central venous pressure when a potential cardiac etiology is suspected or central venous pressure cannot be estimated with confidence, and clinical suspicion of heart disease is high; **OR**
 - The patient is experiencing dyspnea with clinical signs of heart disease; **OR**
- Hypertensive cardiovascular disease with **ANY** of the following:
 - Evaluation of the cardiac effects of systemic hypertension^{1,3,9}; **OR**
 - Left ventricular hypertrophy (LVH) correlates with prognosis in hypertensive cardiovascular disease³; **OR**
- Acute myocardial infarction and coronary insufficiency for **ANY** of the following:
 - Evaluation of regional motion, systolic thickening perturbations, and mural thinning^{1,3}; **OR**
 - Evaluation of right ventricular ischemia and/or infarction^{1,3}; **OR**
 - Diagnosis or evaluation of complications of acute infarction (e.g., mural thrombi, papillary muscle dysfunction and rupture, septal defects, true or false aneurysm, and myocardial rupture)^{1,3}; **OR**
 - Following an initial TTE in the setting of acute infarction, with frequency dictated by the acute clinical course^{1,3}; **OR**
 - Evaluation of chest pain with suspected acute myocardial ischemia, when baseline electrocardiogram (ECG) and other laboratory markers are nondiagnostic and a study can be obtained during pain or within minutes after its abatement^{1,3,9}; **OR**
 - Diagnosis of acute myocardial infarction when the clinical history and ECG findings are nondiagnostic^{1,3,9}; **OR**

- Evaluation of exposure to a cardiotoxic agent for **ANY** of the following:
 - Initial complete TTE prior to first administration of chemotherapeutic agents (e.g., degenerative cardiomyopathy produced by doxorubicin therapy) to monitor cardiac toxicity*^{1,3,5,11,12}; **OR**
 - Surveillance during the titration of a therapeutic agent**⁵; **OR**
- Monitoring for rejection in a cardiac transplant patient and **ANY** of the following^{1,3,5}:
 - Cardiac donor-selection and donor-recipient matching process to evaluate ventricular function and valvular integrity; **OR**
 - Management of allograft recipients (typically weekly for the first four to eight [4-8] weeks following transplant, with reduced frequency over time); **OR**
 - Annually, when acute rejection episodes are absent in a chronic transplant recipient (approximately two [2] TTE examinations are typically performed yearly); **OR**
- Evaluation of valvular pathology and the effect upon the overall mechanical performance and contractility of the heart muscle^{1,3,5,9,10}; **OR**
- After prosthetic valve implant to establish a baseline structural and hemodynamic profile with reassessment following convalescence (3-6 months)^{1,3,5,13}; **OR**
- Known or suspected infective endocarditis or complications or sequelae of acute infective endocarditis^{1,3,5,14}; **OR**
- Pericardial disease and TTE for **ANY** of the following^{1,3,5}:
 - Detection and quantitation of the amount of pericardial effusion; **OR**
 - Characterization of the hemodynamic consequences of pericardial fluid accumulation; **OR**
 - As an adjunct during the removal of pericardial fluid and creation of pericardial windows; **OR**
 - Diagnosis of pericardial constriction and differentiating it from restrictive myocardial disease (may require Doppler); **OR**
 - Repeat examination and the patient has evolving pericardial pathology (limited focused TTE exam may be appropriate); **OR**
- **ANY** of the following for abnormalities of the great vessels^{1,3,10}:
 - Evaluation of acute or chronic aortic pathology; **OR**
 - Annual evaluation for severe aortic stenosis or regurgitation; **OR**
 - A focused, limited follow-up exam to serially measure ascending aortic diameters for ascending aortic dilatation or aneurysms; **OR**

- Evaluation of the main pulmonary artery segment and the proximal right and left pulmonary arteries; **OR**
- Evaluation of the vena cavae and diagnosing congenital and acquired abnormalities (e.g., vena caval thrombosis, vena caval dilation, and thrombosis or extension of tumors from the inferior vena cava to the right-heart chambers); **OR**
- Congenital heart disease and **ANY** of the following^{1,3,5,10}:
 - TTE with Doppler hemodynamic measurements for diagnosis and noninvasive serial assessment; **OR**
 - When the disease process and therapy are stable, assessment more often than annually requires medical necessity documentation; **OR**
 - The patient is asymptomatic following repair of atrial septal defect (ASD), patent foramen ovale (PFO), ventricular septal defect (VSD), or patent ductus arteriosus (PDA), and follow-up examination is only indicated within the first year after correction; **OR**
- Suspected cardiac thrombi and embolic sources, and **ANY** of the following:
 - Evaluation for cardiovascular source of embolic events (ASD/PFO, atrial or ventricular thrombus, intracardiac tumor) in a patient with abrupt occlusion of a major peripheral or visceral artery^{1,3}; **OR**
 - Cardiac pathology associated with a high incidence of thromboemboli (e.g., valvular heart disease, arrhythmias – especially atrial fibrillation, cardiomyopathies, and ventricular dysfunction) and TTE is expected to provide adequate supplemental data for therapeutic decision making⁵; **OR**
- Diagnosis, assessment, and surveillance of cardiac tumors^{1,3,5,10}; **OR**
- Critically ill and trauma patients for **ANY** of the following:
 - Diagnosis of suspected aortic or central pulmonary pathology, cardiac contusion, or pericardial effusion^{1,3,5}; **OR**
 - Assessment of volume status in a patient who is critically ill or has identified trauma; **OR**
- Management of cardiac arrhythmias (e.g., atrial fibrillation, atrial flutter) and palpitations with evidence of heart disease^{1,3,5}; **OR**
- Syncope or pre-syncope when other findings are suggestive of valvular heart disease or obstructive cardiomyopathy^{3,5,10,13}; **OR**
- Pulmonary heart disease for evaluation of **ANY** of the following³:
 - Unexplained pulmonary hypertension; **OR**
 - Pulmonary emboli with suspected right atrial or right ventricular sources of emboli^{3,5}; **OR**

- Contrast echocardiography for **ANY** of the following:
 - Evaluate myocardial ischemia⁵; **OR**
 - Quantify myocardial perfusion during stress⁵; **OR**
 - Identify the “area at risk” during acute myocardial infarction (AMI)⁵; **OR**
 - Determine the success of reperfusion interventions⁵; **OR**
 - Assess myocardial viability⁵; **OR**
 - Conventional studies have failed to provide adequate and critically needed information on left ventricular function³; **OR**
 - To improve the delineation of the left ventricular endocardial borders in a patient whose non-contrast study is inadequate or suboptimal, and for whom the left ventricular function information is essential to the management of the patient (contrast is indicated when more than two [2] contiguous segments of the left ventricular border are not visualized)³; **OR**
- CAMZYOS™ (mavacamten) treatment for symptomatic obstructive hypertrophic cardiomyopathy New York Heart Association (NYHA) Class II–III for **ANY** of the following^{3,15–17}:
 - Baseline study before enrollment; **OR**
 - 4, 8, and 12 weeks after treatment initiation, then every 12 weeks thereafter; **OR**
 - 4 weeks after interruption of treatment; **OR**
 - 4 and 12 weeks after any dose change (including restart of treatment); **OR**
 - 4 and 12 weeks after initiating a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor; **OR**
- Evaluation using Doppler spectral or color flow velocity mapping in addition to TTE for evaluation of conditions such as syncope and dyspnea, some heart murmurs, valvular problems, suspected congenital heart disease, cardiomyopathy, shunts, or complications of myocardial infarction^{3,5,9}; **OR**
- The patient is considered pediatric or has documented congenital heart disease and **ANY** of the following¹⁸:
 - The patient is undergoing initial imaging and **ANY** of the following:
 - Abnormal fetal echocardiogram; **OR**
 - Concerning maternal history during pregnancy; **OR**
 - Signs, symptoms, physical findings, or abnormal test results suggestive of congenital heart disease; **OR**
 - Systemic or genetic disorders associated with heart disease; **OR**

- Family history of heritable heart disease; **OR**
- The procedure is to establish a baseline before receiving a therapy that affects cardiac function; **OR**
- The patient is undergoing a follow-up study and **ANY** of the following:
 - Established congenital heart disease (CHD) before and after therapeutic intervention; **OR**
 - Established CHD with potential for change in chamber size, hemodynamics, ventricular function, or valvar function; **OR**
 - Established acquired heart disease; **OR**
 - Systemic or genetic disorders with associated heart disease; **OR**
 - Familial cardiomyopathy; **OR**
 - Pulmonary hypertension; **OR**
 - The patient is receiving therapy with known potential adverse effects on cardiac structure or function; **OR**
- Repeat imaging (defined as 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

Transthoracic echocardiogram (TTE) 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; **OR**
- The patient is not enrolled in the FDA CAMZYOS REMS program, and echocardiograms used outside of the protocol will not be covered³; **OR**
- Doppler color flow-velocity mapping when performed routinely with all ECHO exams (i.e., without a clinical indication)⁵; **OR**
- Edema when the jugular venous pressure does not appear to be elevated¹; **OR**
- Palpitations without evidence of arrhythmias, or minor arrhythmias (e.g., isolated atrial premature complex [APC], also known as premature atrial contraction [PAC], or ventricular premature complexes [VPCs] without evidence of heart disease)^{1,3,5,15}; **OR**
- Isolated APCs/PACs or VPCs/premature ventricular contraction (PVCs) without other evidence of heart disease^{3,15}; **OR**
- Echocardiography performed for screening purposes (e.g., the patient who presents with risk factors, including the risk factor as having a positive family history [e.g., familial history of Marfan's disease])^{3,5}; **OR**
- Routine (annual) evaluation or re-evaluation of **ANY** of the following³:
 - Asymptomatic patient with corrected atrial septal defect (ASD), ventricular septal defect (VSD), and patent ductus arteriosus (PDA) more than one year after successful correction; **OR**
 - Mitral valve prolapse in a patient with no or mild mitral regurgitation and no change in clinical status¹⁵; **OR**
 - Asymptomatic patient with mild native aortic stenosis or mild to moderate native mitral stenosis and no change in clinical status¹⁵; **OR**
 - Native valvular regurgitation in an asymptomatic patient with mild regurgitation, no change in clinical status, and normal left ventricular size¹⁵; **OR**
 - Prosthetic valve with no suspicion of valvular dysfunction and no change in clinical status¹⁵; **OR**
 - Heart failure (systolic or diastolic) with no change in clinical status; **OR**
 - Hypertrophic cardiomyopathy with no change in clinical status¹⁵; **OR**

- Systemic hypertension without suspected hypertensive heart disease^{3,15}; **OR**
- Evaluation for **ANY** of the following:
 - Left ventricular function with prior ventricular function within the past year, with normal findings (e.g., prior echocardiogram, left ventriculogram, SPECT, cardiac MRI) in patients in whom there has been no change in clinical status^{3,15}; **OR**
 - Native and/or prosthetic valves in patients with transient fever but without evidence of bacteremia or new murmur^{3,15}; **OR**
 - Atrial fibrillation/flutter for left atrial thrombus or spontaneous contrast when a decision has been made to anticoagulate and not perform cardioversion^{3,15}; **OR**
 - Initial evaluation of a patient with suspected pulmonary embolism to establish a diagnosis^{3,15}; **OR**
 - Re-evaluation of a patient with known hypertensive heart disease without a change in clinical status.^{3,15}

*NOTE: Frequency of repeat studies to be determined by the patient's clinical course and the toxicity profile of the agent being administered, although tests performed bimonthly during chemotherapy and at six (6) months following therapy are generally considered medically appropriate.^{1,3,5}

**NOTE: Baseline assessment, bimonthly during and at 6 months following therapy, is generally considered medically appropriate for exposure to many cardiotoxic agents.^{1,3,5}

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93303	Complete transthoracic echocardiography for congenital cardiac anomalies
93304	Follow-up transthoracic echocardiography for congenital cardiac anomalies
93306	Real-time transthoracic echocardiography with 2-dimensional (2D) image documentation, M-mode recording with spectral Doppler echocardiography, and color flow Doppler echocardiography
93307	Complete real-time transthoracic echocardiography with 2-dimensional (2D) image documentation
93308	Follow-up real-time transthoracic echocardiography with 2-dimensional (2D) image documentation

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 transthoracic echocardiogram (TTE) may include:

- Adverse effects from delayed or denied treatment may delay the diagnosis or management of serious conditions (e.g., heart failure, heart attack, stroke).
- Soreness and pain may occur at the injection site, or infection may develop. Venous access can be challenging, particularly if the patient has small or collapsed veins. Complications of IV injections also include phlebitis, infiltration, extravasation, and infections.¹⁹
- In comparison with other diagnostic modalities, TEE is relatively safe and noninvasive. However, the insertion and manipulation of the ultrasound probe can cause oropharyngeal, esophageal, or gastric trauma.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria for TTE may include:

- Improved patient selection may result in better long-term outcomes. This includes evaluation of the structure and function of the heart, valves, and proximal aorta without radiation. TTE allows detailed insight into cardiac structure and function, including the configuration and changing dimensions of the chambers, cyclic variations in myocardial thickness, and valve motions throughout the cardiac cycle. The proximal great vessels and the pericardium can also be directly visualized, although

transesophageal echocardiography (TEE) often permits better visualization of the thoracic aorta and great veins than TTE.⁹

- TTE allows the serial evaluation of pericardial effusion and evaluation of left ventricular function during antineoplastic chemotherapy following cardiac surgery.³
- TTE allows estimation of pulmonary artery systolic pressure or sequential evaluation of the transmitral velocity profile in patients with mitral stenosis, to evaluate changes in gradient or valve area.³
- Enhanced overall patient satisfaction and healthcare experience.

Medical Evidence

Lopez et al. (2024) published guidelines for performing a comprehensive pediatric transthoracic echocardiogram for the American Society of Echocardiography (ASE). These guidelines contained technical information on the optimal performance of TTE in children, including views, z-score calculation, contrast use, segmental protocols, and the calculation of several 2- and 3-dimensional measurements. The guidelines also contained recommendations for clinical scenarios that warrant TTE in pediatric patients. These recommendations include TTE for children with suspected heart disease, congenital heart disease, genetic disorders with a known cardiac component, and a significant family history of cardiovascular disease.¹⁸

Doherty et al. (2017) developed a multi-society appropriate use criteria document for multimodality imaging in valvular heart disease. TTE is considered the examination of choice (appropriate) for initial evaluation of asymptomatic patients with any of the following: unexplained murmur, history of rheumatic heart disease, first-degree family history of a bicuspid aortic valve, etc. In the examination of patients with clinical signs and/or symptoms, TTE may be appropriate for arrhythmias and presyncope, as well as assessment of volume status in a critically ill patient with an established cause of respiratory failure. It was found to be appropriate in other instances, such as syncope, hemodynamic instability, heart failure, endocarditis with positive blood cultures, and respiratory failure. TTE was rated as appropriate for evaluation of valvular mass, stage A valvular heart disease, mild or moderate valvular heart disease, some forms of severe valvular heart disease, and valve replacement or repair evaluations. In pre-transcatheter aortic valve replacement (TAVR) evaluation, TTE is deemed appropriate only for assessing the number of valve cusps and degree of calcification, and appropriate during intra- and post-procedural evaluations. In mitral valve repair, TTE is deemed appropriate to determine patient eligibility post-procedurally, and may be appropriate for certain intraprocedural evaluation situations.¹³

Douglas et al. (2011) reported on the appropriate use criteria for echocardiography document published by multiple cardiology medical societies. Appropriate use of TTE, transesophageal echocardiogram (TEE), and stress echocardiography is discussed. The application of the 2007 appropriate use criteria was stated to have been evaluated in academic medical centers, Veterans Affairs hospitals, and community settings. It was found that only 11-16% of TTE applications were unclassified, meaning that most TTEs ordered were captured by acceptable use criteria (AUC) indications (87-91%). It was found that the most commonly reported appropriate indications for TTE included initial evaluation of symptoms potentially caused by suspected cardiac etiology.²⁰

McDermott et al. (2011) concluded that TTE was a sufficiently sensitive screening test for native valve infective endocarditis for patients with normal heart valves. Additionally, in those patients with abnormal heart valves, a TEE did not increase the diagnostic yield in 12 out of 15 patients evaluated. A total of 2218 TEEs were reviewed, with 87 having a preceding TTE. Infectious endocarditis was defined as high-grade continuous bacteremia with heart valve vegetation. Patients with pacemakers, defibrillators, and prosthetic heart valves were excluded.¹⁴

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Policy Revision History/Information

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Review History		
Version 1.1	03/19/2025	Updated policy per CMS revisions for 10/03/2024 (effective date, links, and bookmarks).
Version 2	10/16/2025	Annual review. Rewrote indication and non-indication language throughout policy to align with CMS LCDs L33577, L34338, and L37379. Added criteria for pediatric patients with congenital heart disease. Clarified indications for repeat imaging to improve usability and organization. Removed codes C8921, C8922, C8923, C8924, and C8929. Expanded the Medical Evidence section; added one citation.



Cohere Medicare Advantage Policy – Venous Stents

Clinical Policy for Medical Necessity Review

Version: 1

Policy Number: CHP-320-1

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Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy - Venous Stents

Policy Number: CHP-320-1

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

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Medical Necessity Criteria

Service: Venous Stents

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 – Venous Stents* 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	No NCD available	N/A	N/A	N/A
LCD	Endovenous Stenting	L37893	Fully established	• Not applicable
LCD	Endovenous Stenting	L38231	Fully established	• Not applicable
LCD	Non-Coronary Vascular Stents	L35998	Fully established	• Not applicable
LCD	No LCD Available for Jurisdiction	N/A	N/A	Use Cohere Medicare Advantage internal coverage criteria

Description

Venous stent placement is a minimally invasive surgery in which small mesh tubes are used to open narrowed or blocked sections of veins or treat venous conditions, including venous aneurysms, arteriovenous fistulae, and venous perforations. Venous stents can be placed percutaneously or using a combination of open and percutaneous techniques. The stent is inserted into the vein, typically at the mid-thigh, often under ultrasound guidance.¹

Medical Necessity Criteria

Indications

Venous stenting is considered appropriate if **ANY** of the following is **TRUE**:

- Symptomatic abdominopelvic venous disease as indicated by **ANY** of the following:
 - Compression or obstruction of the hepatic veins⁶⁻⁸; **OR**
 - Portal venous hypertension⁹⁻¹⁴; **OR**
 - Iliac vein compression with **ALL** of the following^{15,16}:
 - **ANY** of the following:
 - Greater than 50% diameter reduction of the affected vein; **OR**
 - 75% cross-sectional area stenosis; **AND**
 - Skin or subcutaneous changes (healed or active ulcers [CEAP {clinical, etiology, anatomy, and pathophysiology} classes 4-6]); **AND**
 - An absence of superficial venous reflux; **OR**
 - Iliocaval or iliofemoral venous obstruction confirmed by Doppler ultrasound, computed tomography (CT), or magnetic resonance venography (MRV)¹⁷⁻¹⁹; **OR**
 - Iliocaval or iliofemoral venous stenosis, as indicated by **ANY** of the following:
 - Greater than 50% diameter reduction of the affected vein; **OR**
 - 75% reduction in cross-sectional area stenosis; **OR**
 - Residual stenosis of greater than 30% following angioplasty; **OR**
 - Renal vein compression with **ANY** of the following^{20,21}:
 - Nonsurgical management has been attempted for at least 6 months; **OR**
 - Prior left renal vein (LRV) transposition has failed, with recurrent/unimproved symptoms and evidence of persistent stenosis on imaging; **OR**
- Symptomatic thoracic venous disease, including **ANY** of the following:
 - Pulmonary vein stenosis with **ALL** of the following:
 - Diagnostic imaging confirmation; **AND**
 - Pulmonary vein stenosis is the result of **ANY** of the following:
 - Congenital malformation; **OR**
 - Extrinsic compression; **OR**
 - Lung transplantation; **OR**

- Repair of total anomalous pulmonary vein return (TAPVR); **OR**
 - Sequelae of radiofrequency ablation (RFA); **OR**
- Superior or inferior vena cava obstruction, confirmed by diagnostic imaging²²; **OR**
- Symptomatic venous complications relating to a procedure or treatment, including **ANY** of the following:
 - Complications of arteriovenous dialysis access²³; **OR**
 - Post-procedure venous complications²⁴⁻²⁶; **OR**
 - Post-radiation venous stenosis confirmed by diagnostic imaging²⁷; **OR**
 - Postoperative venous stenosis after repair of congenital cardiac disease, confirmed by diagnostic imaging; **OR**
- Arteriovenous malformation (AVM) confirmed by diagnostic imaging⁵; **OR**
- Failed or suboptimal angioplasty and **ANY** of the following:
 - Abrupt occlusion at the angioplasty site; **OR**
 - Elastic recoil or refractory spasm; **OR**
 - Greater than 50% diameter reduction or greater than 75% cross sectional area; **OR**
 - Intractable symptoms¹; **OR**
 - Perforation; **OR**
 - Residual stenosis of greater than 30%; **OR**
- Idiopathic intracranial hypertension (IIH) and **ALL** of the following^{28,29}:
 - **ANY** of the following:
 - Bilateral venous sinus stenosis; **OR**
 - Unilateral stenosis and contralateral hypoplasia; **AND**
 - Documented vision loss and papilledema; **AND**
 - Failed medical treatment³⁰; **AND**
 - Refractory or unremitting IIH; **OR**
- Repeat stenting of any of the preceding indications is appropriate for **ANY** of the following:
 - Prevention of variceal rebleeding for more than 72 hours beyond the index bleed¹²; **OR**
 - Stent fracture in association with restenosis or occlusion; **OR**
 - Stent recoil; **OR**
 - Suboptimal or failed stenting; **OR**
 - Symptomatic restenosis.

Non-Indications

Venous stenting is not considered appropriate if **ANY** of the following are **TRUE**:

- Stenting for asymptomatic venous stenosis or compression.³¹

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
37182	Insertion of a TIPS (Transjugular Intrahepatic Portosystemic Shunt), which includes venous access, catheterization of the hepatic and portal veins, portography, intrahepatic tract formation, stent placement, and imaging guidance
37183	Revision of a TIPS (Transjugular Intrahepatic Portosystemic Shunt), which includes venous access, catheterization of the hepatic and portal veins, portography, intrahepatic tract recanalization, stent placement, and imaging guidance
37238	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein
37239	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein (List separately in addition to code for primary procedure)
37248	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein
37249	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the

	same vein; each additional vein (List separately in addition to code for primary procedure)

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 venous stents may include:

- Adverse effects from delayed or denied treatment of idiopathic intracranial hypertension, which may include chronic headaches, cognitive issues, vision loss, and a reduced quality of life.³²
- Increased healthcare costs and complications from potentially serious complications, including infection, iatrogenic arteriovenous fistula access site bleeds, and arrhythmias resulting from stent migration.³³
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria for venous stents may include:

- Improved patient selection for venous stents, resulting in better long-term outcomes, including an improved quality of life.¹⁶
- Earlier resolution or improvement of chronic venous disease, resulting in symptom relief, including reductions in ulcerations, swelling, and pain.³⁴
- Reduction in complications and adverse effects from unnecessary procedures, including the use of arterial devices not indicated or optimized for venous pathologies.³⁵
- Enhanced overall patient satisfaction and healthcare experience.^{34,35}
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Morris et al. (2023) performed a systematic review of the benefits of inferior vena cava (IVC) stenting. The review included 33 studies with 1575 patients. The indications for stenting included IVC syndrome, thrombotic disease, Budd–Chiari syndrome, and IVC stenosis following liver transplant. IVC stenting was deemed safe, with clinical outcomes including improved symptoms and quality of life, although the authors encouraged future randomized controlled trials to refine the evidence supporting these recommendations.¹⁶

Hoshino et al. (2022) reported on the mid-term outcomes for venous stenting in patients with post-thrombotic syndrome (PTS). The authors performed venous stenting in 30 patients with moderate and severe PTS and monitored outcomes for 40 months. Overall, the patients showed a decrease in Villalta score from a preoperative median of 16 to a postoperative median of 7. Similarly, the primary and secondary patency at 40 months were 93% and 96%, respectively. The authors conclude that the results demonstrate the promise of venous stenting as a treatment for severe PTS, while acknowledging the need for additional studies.¹⁷

Wei et al. (2020) conducted a retrospective cohort study looking at patients with sinistral portal hypertension who received either splenic arterial embolization (SAE) or splenic vein stenting. Thirty-seven total patients were included in the review, of which 11 underwent SAE alone, 12 underwent SAE following splenic vein stenting failure, and 14 underwent splenic vein stenting alone. The outcome of interest was the rate of rebleeding after intervention. Overall, splenic vein stenting was found to be safe and effective, with lower rates of rebleeding compared to SAE.¹⁴

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Review History		



Cohere Medicare Advantage Policy – Wearable Defibrillators

Clinical Policy for Medical Necessity Review

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Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy - Wearable Defibrillators

Policy Number: CHP-315-1

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

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Medical Necessity Criteria

Service: Wearable Defibrillators

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 – wearable defibrillators 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	No NCD available	N/A	N/A	N/A
LCD	Automatic External Defibrillators	L33690	Not fully established	Continued use beyond the initially approved period.
LCD	Cardiac Rhythm Device Evaluation	L34833	Fully established	Not applicable
LCD	Surveillance of Implantable or Wearable Cardioverter Defibrillators (ICDs): Office, Hospital, Web, or Non-Web Based	L34087	Not fully established	Continued use beyond the initially approved period.
LCD	Not Applicable – No LCD Available for Jurisdiction	N/A	N/A	Use Cohere Medicare Advantage internal coverage criteria.

Description

A wearable defibrillator or wearable cardioverter-defibrillator (WCD) is an external defibrillator device worn as a garment that monitors a patient's heart rhythm. It is capable of automatically detecting and treating ventricular tachycardia (VT) and ventricular fibrillation (VF). WCDs are intended to be worn as temporary, short-term devices for 3 months or less.⁵ Since the first WCD was approved by the U.S. Food and Drug Administration (FDA) over two decades ago, other WCDs have obtained FDA approval.⁶⁻¹⁰

Medical Necessity Criteria

Indications

Continued use of **wearable defibrillators** beyond the initially approved 90-day monitoring period (CPT K0606, 93292, 93745) and **ALL** of the following^{10,11}:

- Provider has documented why extended use is requested; **AND**
- **ANY** of the following:
 - Awaiting planned heart transplant; **OR**
 - Systemic infection or other correctable condition that has temporarily delayed implant of a permanent defibrillator.

Replacement of battery (CPT K0607) and **ALL** of the following are **TRUE**:

- When damaged or lost; **AND**
- Continued use of the wearable defibrillator is medically reasonable and necessary.

Replacement of garment (CPT K0608) and **ALL** of the following are **TRUE**:

- When damaged or lost; **AND**
- Continued use of the wearable defibrillator is medically reasonable and necessary.

Replacement of electrodes (CPT K0609) and **ALL** of the following are **TRUE**:

- When damaged or lost; **AND**
- Continued use of the wearable defibrillator is medically reasonable and necessary.

Non-Indications

Wearable defibrillators are not considered appropriate if **ANY** of the following is **TRUE**:

- When an active implantable defibrillator is in place⁶; **OR**
- In a patient who is a candidate for an implantable cardioverter-defibrillator (ICD)⁶; **OR**
- VT that is amenable to catheter ablation; **OR**
- Terminal disease with a life expectancy of less than 6 months⁹.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93292	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified healthcare professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system
93745	Initial set-up and programming by a physician or other qualified healthcare professional of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
K0607	Replacement battery for automated external defibrillator, garment type only, each
K0608	Replacement garment for use with automated external defibrillator, each
K0609	Replacement electrodes for use with automated external defibrillator, garment type only, each

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 wearable defibrillators may include:

- Adverse effects from delayed or denied continuation of WCD therapy. These may include implantation of an ICD in a patient who would have further improved EF beyond the standard 90-day period. One study reported that one-third of patients with extended WCD use continued to show EF improvements beyond 90 days and did not require ICD implantation.¹² Delayed or denied continuation therapy may also place patients at risk of untreated ventricular arrhythmia events. Several patients in this study remained at risk for ventricular arrhythmia events beyond 90 days.¹²
- Adverse effects from inappropriate continuation of WBC therapy. These may include inappropriate shocks, death due to asystole events, and death while not wearing the device.¹³

The clinical benefits of using these criteria for wearable defibrillators may include:

- Improved patient selection for continuation of wearable defibrillators, resulting in better long-term outcomes. Ideal candidates should be awaiting a planned heart transplant or have a systemic infection or other correctable condition that temporarily delays the implantation of a permanent defibrillator. The American College of Cardiology (ACC) notes that WCDs are reasonable as a bridge to definitive therapy, including cardiac transplantation and for patients with a transiently high risk of sudden cardiac death.⁹ Similarly, the National Congress of the Italian

Association of Hospital Cardiologists (ANMCO) has noted that wearable defibrillators are recommended as a bridge to an implantable device when an ICD cannot be immediately implanted.¹⁴ In a 2017 study, 102 patients had their ICDs explanted for extended periods due to infection or mechanical failure of the device. The authors reported a one-year survival rate of 89% and that only 38% of patients underwent ICD reimplantation. Reported reasons for delay of reimplantation included ongoing infection, cancer diagnosis, and being listed for a cardiac transplant.¹³

- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

In 2025, a patch-WCD received FDA premarket approval. The Jewel patch-WCD was designed to overcome the limitations of traditional garment-based WCDs in two areas: poor patient compliance and inappropriate detections and false alarms. First, the device is water-resistant and can be worn almost all the time, even in the shower, which could improve patient compliance. Second, the software has a machine learning detection algorithm designed to improve detection and protection against sudden cardiac arrest.⁸

Hummel et al. (2024) published the results of the Jewel investigational device exemption (IDE) study, which assessed the safety and effectiveness of the patch-WCD for monitoring, detecting, and terminating sustained VT/VF. The multicenter, prospective, single-arm study enrolled 305 patients who were typically indicated for WCDs and were not candidates for, or had refused, an implantable defibrillator. Of all patients studied for the safety endpoint of <15% (to be in line with the incidence of skin-related adverse events for other commercially available WCDs), only 2.30% experienced a clinically significant cutaneous adverse event, and all clinically significant cutaneous adverse events were moderate in severity. In the current study, false alarms and inappropriate shock rates were low, which is important because Dang et al. (2024) showed that false alarms lead to sleep interruption, patient noncompliance, and generate anxiety.¹⁵ Also, they showed the effective detection and conversion of shockable events. No false alarms were experienced in 61.7% of patients, compared to only 28.3% with the LifeVest WCD. This IDE study met the primary and secondary effectiveness and safety endpoints, and no patient deaths or device-missed episodes requiring external rescue occurred. The high median wear time compliance of 23.5 hours/day exceeded the secondary endpoint of >14.1 hours/day, resulting in a high number of successful lifesaving conversions.¹⁶

Olgin et al. (2018) conducted a trial to determine the efficacy of WCDs in preventing arrhythmic and all-cause mortality. The VEST trial (Vest Prevention of Early Sudden Death Trial) was a multicenter, randomized, controlled trial that evaluated 2,302 patients with an acute myocardial infarction and

ejection fraction <35% during the period before ICDs were indicated. Two-thirds of the patients received a WCD plus guideline-directed therapy (the device group), while the remaining one-third received only guideline-directed therapy (the control group). They found that treatment with a WCD did not result in a significantly lower rate of arrhythmic death than guideline-directed therapy only during the first 90 days. Importantly, this study was conducted several years ago when there was only one WCD device on the market.¹⁷

Piccini et al. (2016) developed a science advisory for the American Heart Association for WCD therapy for the prevention of sudden cardiac death. They state that there is a paucity of prospective data (published, randomized clinical trials) supporting the use of the WCD. Though early ICD placement does appear to decrease the incidence of sudden cardiac death, overall survival benefit early after MI or new cardiomyopathy diagnosis has not been proven. Wearable defibrillators are useful in the immediate post-MI period, when an implantable defibrillator may be postponed due to the potential of myocardial recovery and improved ventricular function.⁹

Duncker and Veltmann performed a systematic review in 2016 of wearable cardioverter defibrillators. It is stated that a relevant proportion of patients receiving an ICD do not meet evidence-based criteria for implantation. A study of 91 patients after MI found that 45% of patients met ICD criteria of left ventricular ejection fraction less than or equal to 35% 40 days after MI. Six of the patients showed significant improvement at 3 months of follow-up. The study determined that patients with recent onset non-ischemic cardiomyopathy showed no benefit from early ICD implantation.¹⁸

The 2017 AHA/ACC/HRS guideline for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death contains two definite recommendations for WCDs. The first WCD recommendation is for patients with an ICD, a history of sudden cardiac arrest or sustained ventricular arrhythmia, and infection or other cause necessitating ICD removal. The second recommendation is for patients at increased risk for sudden cardiac death, but who are not ineligible for an ICD, such as awaiting cardiac transplant or having an LVEF of 35% or less, and are within 40 days of an MI. This group of patients may also have newly diagnosed non-ischemic

cardiomyopathy, revascularization within the past 90 days, myocarditis, secondary cardiomyopathy, or systemic infection, and thereby would be recommended for a WCD.¹⁰

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Policy Revision History/Information

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Review History		



Cohere Medicare Advantage Policy – Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)

Clinical Guidelines for Medical Necessity Review

Version: 3
Revision Date: March 6, 2025

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medicare Advantage Policy - Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)

Date of last literature review: 3/5/2025

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

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Medical Necessity Criteria

Service: Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)

Benefit Category

Inpatient Hospital Services
Outpatient Hospital Services
Physicians' Services

Related CMS Documents

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

- [National Coverage Analysis \(NCA\) Decision Memo. Implantable Pulmonary Artery Pressure Sensors For Heart Failure Management \(CAG-00466N\)](#)

Recommended Clinical Approach

This policy is based on a National Coverage Analysis (NCA) published on January 13, 2025 by the Centers for Medicare and Medicaid Services (CMS) and guidelines published in 2022 by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Failure Society of America (HFSA).¹⁻²

The CardioMEMS device is implanted in a pulmonary artery branch to remotely manage heart failure (HF). It allows earlier intervention to reduce congestive heart failure (CHF) exacerbations and hospitalizations. The effectiveness of using an implanted hemodynamic monitor for wireless pulmonary artery pressure monitoring to lower the risk of future HF hospitalizations continues to be debated. Specifically, this includes adult patients with New York Heart Association (NYHA) class II or III HF, a history of HF hospitalization within the past year, or elevated natriuretic peptide levels despite being on maximally tolerated stable doses of guideline-directed medical therapy (GDMT) and receiving optimal device therapy.

Among patients with NYHA class II or III HF with an HF hospitalization within the previous year, wireless monitoring of PA pressure by an implanted hemodynamic monitor provides uncertain value. Given this uncertainty of published recommendations, it is also reasonable and necessary to incorporate the inclusion and exclusion criteria from the two studies listed on the National Institutes of Health (NIH) website ClinicalTrials.gov. Abbott Medical Devices, the manufacturer of the CardioMEMS device, sponsored the *CardioMEMS HF System Post Approval Study* and the *Hemodynamic-GUIDEd Management of Heart Failure (GUIDE-HF) Study*.³⁻⁵ The patient must meet all inclusion criteria for approval, and no exclusion criteria should be present before consideration for prior approval.

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 wireless pulmonary artery pressure monitoring (CardioMEMS). 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:

- Adverse effects from delayed or denied treatment: Delays or denials in the use of CardioMEMS may lead to an increase in symptoms and complications such as recurrent hospitalizations among patients with class III heart failure (HF) as designated by the New York Heart Association (NYHA). The 2022 AHA/ACC/HFSA guideline for the management of HF highlights the importance of timely intervention to prevent adverse outcomes in patients with significant HF.²
- Physiologic changes: Patients may experience increased wall stress, sympathetic activation, arrhythmia, and elevated heart rate. Renal function may also decrease.⁶
- Risks with inappropriate surgical procedures: Patients are at-risk for infection, bleeding, hematomas, stroke or transient ischemic attack, heart attack, cardiovascular injury, embolism, injury to neurovascular structures, anesthetic risk, and the need for repeat or additional procedures due to complications. The *CardioMEMS HF System*

Post-Approval Study underscores the importance of appropriate patient selection to minimize surgical risks and enhance the benefits of wireless pulmonary artery pressure monitoring.^{3,5-6}

- Increased healthcare costs and complications: Examples include inappropriate use of emergency services and additional treatments. Proper use of CardioMEMS criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. The *Hemodynamic-GUIDEd Management of Heart Failure (GUIDE-HF) Study* supports appropriate diagnostic and treatment procedures to prevent unnecessary healthcare utilization.⁴

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to CardioMEMS 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. Heidenreich et al. (2022) noted the diagnostic accuracy of imaging and monitoring procedures in managing patients with HF.²
- Enhanced diagnostic accuracy: Complex cardiovascular conditions require advanced imaging and monitoring techniques to avoid potential risks that traditional imaging may pose to patients. Advanced imaging offers the advantage of detailed vascular assessment, aiding intervention decision-making.⁷
- Reduction in complications and adverse effects: Using CardioMEMS criteria helps avoid unnecessary interventions and associated risks to safeguard the patient. Wireless pulmonary artery pressure monitoring guidelines emphasize the importance of accurate diagnostics in preventing complications.²
- Enhanced overall patient satisfaction: Ensuring that CardioMEMS procedures are appropriately utilized leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications. The European Society of Cardiology (ESC) published a guideline for the diagnosis and treatment of acute and chronic HF – the ESC supports appropriate use criteria to minimize healthcare costs and prevent complications.⁸

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 requirements aim to balance the need for effective treatment with minimizing potential harms, providing numerous clinical benefits, and 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

- **Wireless pulmonary artery pressure monitoring (CardioMEMS)** is considered appropriate if **ALL** of the following are **TRUE**²:
- ◆ The implantable pulmonary artery pressure sensor (IPAPS) is part of a Coverage with Evidence Development (CED) study approved by the Centers for Medicare and Medicaid Services (CMS) including **ANY** of the following^{1,9}:
 - CardioMEMS HF System Coverage with Evidence Development Study (NCT06779552, Abbott); **OR**
 - Real-World Effectiveness of The Cordella Pulmonary Artery (PA) Sensor System in Patients With Chronic Heart Failure: A Comparative Analysis to Standard of Care Pharmacologic Therapy (LOWER-PAP) (NCT06783335, Edwards Lifesciences); **AND**
 - ◆ New York Heart Association (NYHA) class II or III HF within the past 30 days, before pulmonary artery pressure sensor (PAPS) implantation, regardless of left ventricular ejection fraction (LVEF)¹; **AND**
 - ◆ The patient was diagnosed with heart failure (HF) more than 3 months ago¹; **AND**
 - ◆ Age greater than or equal to 18 years; **AND**
 - ◆ **ANY** of the following¹:
 - History of HF hospitalization or urgent HF visit (e.g, emergency room or other outpatient visit requiring intravenous diuretic therapy) within the past 12 months; **OR**

- Elevated natriuretic peptides within the past 30 days; **AND**
- ◆ Optimal or maximally-tolerated (guideline-directed medical therapy (GDMT) before PAPS implantation including **ANY** of the following¹⁻²:
 - For EF less than or equal to 40% on beta-blockers for 3 months; on ACE/ARB/ARNI, SGLT2i, MRA, or diuretics for more than 1 month; or none if intolerant^A; **OR**
 - For EF 41-49% on beta-blockers, on ACE/ARB/ARNI, SGLT2i, MRA, or diuretics for more than 1 month or none if intolerant^B; **OR**
 - For EF greater than or equal to 50% on beta-blockers, on ACE/ARB/ARNI, SGLT2i, MRA, or diuretics for more than 1 month or none if intolerant^C; **AND**
- ◆ The patient has been evaluated for and received, if appropriate, an implantable cardioverter defibrillator (ICD), CRT-defibrillator (CRT-D), cardiac resynchronization therapy (CRT)-pacemaker (CRT-P) for at least 3 months before PAPS implantation¹⁻²; **AND**
- ◆ No major cardiovascular events within the last 3 months before PAPS implantation (e.g., myocardial infarction, unstable angina, percutaneous coronary intervention, open heart surgery, or stroke)¹; **AND**
- ◆ Have access to reliable connectivity to ensure daily collection and submission of IPAPS data¹; **AND**
- ◆ **ANY** of the following:
 - Must not have PAPS implantation occur during hospital admission for an acute HF episode¹; **OR**
 - Elevated brain natriuretic peptide (BNP or NT-proBNP) levels within the last 30 days are **ANY** of the following:
 - LVEF less than or equal to 40%: NT-proBNP greater than or equal to 1000 pg/mL (or BNP greater than or equal to 250 pg/mL)*²; **OR**
 - LVEF greater than 40%: NT-proBNP greater than or equal to 700 pg/mL (or BNP greater than or equal to 175 pg/mL)*²;
 - Thresholds for NT-proBNP and BNP (for LVEF less than or equal to 40% and LVEF greater than 40%) must be corrected for body mass index (BMI) using a 4% reduction per BMI unit over 25 kg/m²²; **AND**

◆ **ANY** of the following¹⁰⁻¹¹:

- BMI greater than 35 kg/m² with a chest circumference less than 65 inches; **OR**
- BMI less than or equal to 35.

^A Heidenreich et al. (2022), section 7.3. *Pharmacological Treatment for HFrEF*.

^B Heidenreich et al. (2022), section 7.6.1. *HF With Mildly Reduced Ejection Fraction (HFmrEF)*.

^C Heidenreich et al. (2022), section 7.7.1. *HF With Preserved Ejection Fraction*.

* [NT-proBNP and BNP Thresholds According to Ejection Fraction and BMI](#).⁷

Non-Indications

→ **Wireless pulmonary artery pressure monitoring (CardioMEMS)** is not considered appropriate if **ANY** of the following is **TRUE**^{5,7,11}:

- ◆ A major cardiovascular event (e.g., unstable angina, PCI, myocardial infarction, open heart surgery, stroke, etc.) within the previous 3 months; **OR**
- ◆ The patient cannot take dual antiplatelet or anticoagulants for 1-month post-implant; **OR**
- ◆ Intolerance to all neuro-hormonal antagonists (i.e., intolerance to angiotensin-converting enzyme inhibitors [ACE-I], angiotensin receptor blockers [ARB], angiotensin-neprilysin inhibitors [ARNi], hydralazine/isosorbide dinitrate and beta-blockers); **OR**
- ◆ Likely to undergo heart transplantation or ventricular assist device (VAD) within the next 12 months; **OR**
- ◆ Existing heart transplantation or VAD; **OR**
- ◆ ACC/AHA Stage D refractory HF (including having received or currently receiving pharmacologic circulatory support with inotropes); **OR**
- ◆ NYHA class IV HF patients; **OR**
- ◆ Implanted with mechanical right heart valve(s); **OR**
- ◆ Unrepaired severe valvular disease; **OR**
- ◆ Pregnant or planning to become pregnant in the next 12 months; **OR**
- ◆ Anticipated life expectancy of less than 12 months; **OR**

- ◆ Any condition that, in the opinion of the reviewer, would not allow for utilization of the CardioMEMSTM HF System to manage the subject using information gained from hemodynamic measurements to adjust medications; **OR**
- ◆ Presence of unexpectedly severe pulmonary hypertension (e.g., trans-pulmonary gradient greater than 15) at implant right heart catheterization (RHC); **OR**
- ◆ A history of non-compliance; **OR**
- ◆ Any other condition that would preclude CardioMEMS PA Sensor implantation.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

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

Medical Evidence

Lindenfield et al. (2024) conducted a meta-analysis to analyze the efficacy of hemodynamic monitors for managing heart failure and reduced ejection fraction (HFrEF). The authors examined the results from the GUIDE-HF (Hemodynamic-Guided Management of Heart Failure) Study, the CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients) Study, and the LAPTOP-HF (Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy) Study. A total of 1350 patients were included in the analysis of hospitalization rates over 12 months and survival at 12- and 24-month follow-ups. The authors conclude that hospitalizations for HF improved due to hemodynamic monitors. At 24-month follow-up, hospitalizations decreased by 36%. Mortality varied by study: GUIDE-HF demonstrated “no reduction in mortality,” while the CHAMPION study showed a trend of reduced mortality, and the LAPTOP-HF study demonstrated a 44% decrease.⁶

Lindenfield et al. (2021) performed an RCT on the effectiveness of pulmonary artery pressure monitoring to reduce mortality and HF events in patients with NYHA class II-IV HF (regardless of heart failure hospitalization [HFH] and level of natriuretic peptides). Results from the randomized arm of the GUIDE-HF trial identified a 28% reduction of HFH among the 1000 patients enrolled in the study. Compared with elevated brain natriuretic peptide (BNP) alone, patients with a previous HFH also had related benefits. (ClinicalTrials.gov Identifier NCT03387813).¹²

Shavelle et al. (2020) conducted a multi-center, prospective, open-label, observational, single-arm trial to determine the efficacy of pulmonary artery pressure-guided therapy. A total of 1200 patients who had NYHA class III HF with at least one hospitalization in the last 12 months due to HF were included. A 57% reduction of HFH was reported among patients; for all causes, HFH was reduced by 27% post-implantation. Patients with ejection fraction saw a 50% reduction in HFH - no differences were identified among subgroups for sex, race, and cause of HF. (ClinicalTrials.gov Identifier NCT02279888).¹⁰

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Clinical Guideline Revision History/Information

Original Date: May 24, 2024		
Review History		
Version 2	6/11/2024	422.101 Disclaimer added
Version 3	3/6/2025	• Annual review. • Aligned policy with CMS National Coverage Analysis (NCA) Decision Memo: Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (CAG-00466N). • Added a bullet to the harms section - "Physiologic changes: Patients may experience increased wall stress, sympathetic activation, arrhythmia, and elevated heart rate. Renal function may also decrease." (Lindenfeld et al., 2024). • Added a bullet to the benefits section - "Reduction in complications and adverse effects: Using CardioMEMS criteria helps avoid unnecessary interventions and associated risks to safeguard the patient. Wireless pulmonary artery pressure monitoring guidelines emphasize the importance of accurate diagnostics in preventing complications." (Heidenreich et al., 2022). • Added an indication requiring enrollment in a CMS-approved Coverage with Evidence Development (CED) study including any of the following: ○ CardioMEMS HF System Coverage with Evidence Development Study (NCT06779552, Abbott); OR ○ Real-World Effectiveness of The Cordella Pulmonary Artery (PA) Sensor System in Patients With Chronic Heart Failure: A

		Comparative Analysis to Standard of Care Pharmacologic Therapy (LOWER-PAP) (NCT06783335, Edwards Lifesciences). - Deleted 7 non-indications that were relative contraindications (Cohera includes absolute contraindications only). - Rewrote the Medical Evidence section (see Lindenfeld et al., 2024; Lindenfeld et al., 2021; and Shavelle et al., 2020).