cohere h e A L T H

Cohere Medicare Advantage Policy -Left Heart Catheterization, Coronary Angiography and/or Bypass Angiography

Clinical Guidelines for Medical Necessity Review

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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

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Table of Contents

Important Notices	2
Table of Contents	3
Medical Necessity Criteria	4
Service: Left Heart Catheterization, Coronary Angiography and/or Bypass Angiography	r 4
Benefit Category	4
Recommended Clinical Approach	4
Evaluation of Clinical Benefits and Potential Harms	4
Medical Necessity Criteria	6
Indications	6
Non-Indications	8
Level of Care Criteria	8
Procedure Codes (CPT/HCPCS)	8
Medical Evidence	10
References	12
Clinical Guideline Revision History/Information	15

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.⁶ 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 TRUE¹⁻¹²:
 - Anginal syndrome with **ALL** of the following characteristics 3.3:
 - **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 TRUE¹:
 - 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

References

- Centers for Medicare and Medicaid Services (CMS). Local coverage determination: Cardiac catheterization and coronary angiography (L33557). Revision Effective Date October 1, 2019. Accessed May 22, 2024. https://www.cms.gov/medicare-coverage-database/search.aspx.
- 2. 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. *J Am Coll Cardiol*. 2012;59(22):1995-2027. doi: 10.1016/j.jacc.2012.03.003.
- Gulati M, Levy PD, Mukherjee D, et al. 2021 AHA/ACC/ASE/Chest/Saem/SCCT/SCMR guideline for the evaluation and diagnosis of chest pain. J Am Coll Cardiol. October 2021. doi: 0.1016/j.jacc.2021.07.053.
- 4. Blankenship JC, Moussa ID, Chambers CC, et al. Staging of multivessel percutaneous coronary interventions: An expert consensus statement from the Society for Cardiovascular Angiography and Interventions. *Catheter Cardiovasc Interv.* 2012;79:1138-1152.
- Fihn SD, Gardin JM, Abrams J, et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *Circulation*. 2012 Dec 18;126(25):e354-471. doi: 10.1161/CIR.0b013e318277d6a0. PMID: 23166211.
- 6. Sorajja P, Borlaug BA, Dimas VV, et al. SCAI/HFSA clinical expert consensus document on the use of invasive hemodynamics for the diagnosis and management of cardiovascular disease. *Catheter Cardiovasc Interv*. 2017 Jun 1;89(7):E233-E247. doi: 10.1002/ccd.26888. PMID: 28489331.
- Ommen SR, Mital S, Burke MA, et al. 2020 AHA/ACC guideline for the diagnosis and treatment of patients with hypertrophic cardiomyopathy: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2020 Dec 22;142(25):e558-e631. doi: 10.1161/CIR.000000000000937. PMID: 33215931.
- 8. 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.

- McDonagh TA, Metra M, ESC Scientific Document Group, et al. 2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart J.* 2021 Sep 21;42(36):3599–3726. doi: 10.1093/eurheartj/ehab368. PMID: 34447992.
- Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2021 Feb 2;143(5):e72-e227. doi: 10.1161/CIR.000000000000923. PMID: 33332150.
- Doherty JU, Kort S, Mehran R, et al. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/ SCCT/SCMR/STS 2019 appropriate use criteria for multimodality imaging 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.
- 12. Knuuti J, Wijns W, ESC Scientific Document Group, et al. 2019 ESC Guidelines for the diagnosis and management of chronic coronary syndromes. *Eur Heart J*. 2020 Jan 14;41(3):407-477. doi: 10.1093/eurheartj/ehz425. PMID: 31504439.
- Diamond GA, Forrester JS, Hirsch M, et al. Application of conditional probability analysis to the clinical diagnosis of coronary artery disease. *J Clin Invest*. 1980 May;65(5):1210–21. doi: 10.1172/JCI109776. PMID: 6767741; PMCID: PMC371455.
- Choi KH, Yang JH, Seo JH, et al. Discriminative role of invasive left heart catheterization in patients suspected of heart failure with preserved ejection fraction. J Am Heart Assoc. 2023 Mar 21;12(6):e027581. doi: 10.1161/JAHA.122.027581. PMID: 36892042; PMCID: PMC10111528.
- Ruiz-Rodriguez E, Asfour A, Lolay G, et al. Systematic review and meta-analysis of major cardiovascular outcomes for radial versus femoral access in patients with acute coronary syndrome. South Med J. 2016 Jan;109(1):61-76. doi: 10.14423/SMJ.0000000000000404. PMID: 26741877; PMCID: PMC4842321.
- Lawton JS, Tamis-Holland JE, et al. 2021 ACC/AHA/SCAI guideline for coronary artery revascularization: A report of the American College of Cardiology/American Heart Association JointCommittee on Clinical Practice Guidelines. J Am Coll Cardiol. 2022;79:e21-e129.

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