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

Notices & Disclaimers:

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

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 This policy may be superseded by existing and applicable Centers for Medicare & Medicaid Services (CMS) statutes.

Other Notices:

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: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

Table of Contents

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 following[2-3]:

- ◆ 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 IVUS[4]; **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 following[4]:
    - 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]

References

1. Lawton J, Tamis-Holland J, Bangalore S, Bates E, Beckie T, et al. 2021 ACC/AHA/SCAI guideline for coronary artery revascularization: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. Dec 09, 2021. Epublished DOI: 10.1016/j.jacc.2021.09.006.
2. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Percutaneous coronary intervention (L33623). Revision Effective Date November 7, 2019. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33623. Accessed June 3, 2024.
3. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Percutaneous coronary interventions (L34761). Revision Effective Date December 28, 2023. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34761&ver=32&bc=0. Accessed June 3, 2024.
4. Patel MR, Calhoon JH, Dehmer GJ, Grantham JA, Maddox TM, Maron DJ, Smith PK. ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate use criteria for coronary revascularization in patients with stable ischemic heart disease: A report of the American College of Cardiology Appropriate Use CriteriaTask Force, American Association for ThoracicSurgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. 2017;69:2212–41.
5. 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*. 2021. doi: 0.1016/j.jacc.2021.07.053.
6. 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.
7. Neumann F, Sousa-Uva M, Ahlsson A, Alfonso F, Banning A, et al. 2018 ESC/EACTS guidelines on myocardial revascularization. *Eur Heart J.* 2019 40, 87–165 doi:10.1093/eurheartj/ehy394.

8. Roffi M, Patrono C, Collet J, Mueller C, Valgimigli M, et al. 2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation: Task Force for the Management of Acute Coronary Syndromes in Patients Presenting without Persistent ST-Segment Elevation of the European Society of Cardiology (ESC). *Eur Heart J.* 2016;37(3):267-315. doi:10.1093/eurheartj/ehv320.
9. Virani S, Newby L, Arnold S, Bittner V, Brewer L, et al. 2023 AHA/ACC/ACCP/ ASPC/NLA/PCNA guideline for the management of patients with chronic coronary disease: a report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2023;82:833-955.

Clinical Guideline Revision History/Information

Original Date: June 3, 2024		
Review History		
Version 2	6/11/2024	422.101 Disclaimer Added