Arterial Stenting, Other

Clinical Guidelines for Medical Necessity Review

Version: 1.0
Effective Date: September 25, 2023

Important Notices

Notices & Disclaimers:

GUIDELINES 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 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.

Other Notices:

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Guideline Information:

Specialty Area: Cardiology
Guideline Name: Arterial Stenting, Other - Single Service

Literature review current through: 9/25/2023
Document last updated: 9/25/2023
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

Table of Contents

Medical Necessity Criteria

Service: Arterial Stenting, Other

General Guidelines:

- **Units, Frequency, & Duration:** Once
- **Criteria for Subsequent Requests:** Repeat imaging with placement of additional arterial stents may be appropriate if there is a significant clinical change since the initial intervention.
- **Recommended Clinical Approach:** Arterial stent placement is clinically indicated in numerous arterial vascular territories to treat occlusive or aneurysmal disease in the peripheral arteries. Bare metal stents (including bare metal drug-eluting stents) are generally not recommended for treating aneurysm disease, perforations, or arteriovenous fistulae. In addition, "off-label" use of arterial stents (i.e., the use of an arterial stent for a non-FDA-approved indication) is appropriate under specific clinical circumstances. This policy does not apply to procedures that are urgent or emergent.
- **Exclusions:** 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.
- **Definitions:**
    - Bare metal stent: A balloon expandable or self-expanding mesh tube that is placed in a diseased artery in order to improve or re-establish arterial blood flow through a narrowed or occluded vessel.
    - Covered stent: A balloon expandable or self-expanding mesh tube (covered with a fabric or graft material) that is placed in a diseased artery in order to improve or re-establish arterial blood flow through a narrowed or occluded vessel or treat an arterial aneurysm, perforation or arteriovenous fistula
    - Drug-eluting stent: A drug-coated (e.g., paclitaxel) balloon expandable or self-expanding mesh tube that is placed in a diseased artery in order to improve or re-establish arterial blood flow through a narrowed or occluded vessel AND reduce the risk of restenosis
    - PTA: Percutaneous transluminal angioplasty (i.e., balloon angioplasty)

- Stent graft (aka endovascular stent graft): A large bore self-expanding mesh tube (covered with a fabric or graft material) that is typically placed in a diseased artery in order to treat an underlying arterial aneurysm, dissection or perforation.

Medical Necessity Criteria

Indications

➔ **Arterial stent placement** is considered appropriate if **ANY** of the following is **TRUE**:

- The patient has symptomatic upper extremity arterial occlusive disease and **ANY** of the following is **TRUE**:
  - Symptomatic subclavian artery stenosis (greater than 50%) by invasive or noninvasive imaging causing **ANY** of the following clinical conditions:
    - Exercise-induced ipsilateral upper extremity fatigue (lifestyle-limiting); **OR**
    - Limb-threatening ischemia of the upper extremity (i.e. ulceration, tissue loss or gangrene); **OR**
    - Subclavian steal syndrome; **OR**
    - Symptomatic coronary artery disease in patients with a prior ipsilateral internal mammary coronary artery bypass; **OR**
  - Symptomatic axillary and/or brachial artery stenosis (greater than 50%) by invasive or noninvasive imaging causing **ANY** of the following clinical conditions:
    - Exercise-induced ipsilateral upper extremity fatigue (lifestyle-limiting); **OR**
    - Limb-threatening ischemia of the upper extremity (i.e. ulceration, tissue loss or gangrene); **OR**
- The patient has an Iliac artery aneurysm, and the request is for covered stents and stent grafts **ONLY** for **ANY** of the following:
  - All symptomatic iliac artery aneurysms; **OR**
  - Asymptomatic iliac artery aneurysms greater than or equal to 3 cm in diameter; **OR**
- The patient has a femoro-popliteal artery aneurysm, and the request is for covered stents and stent grafts **ONLY** for **ANY** of the following[6-7]:
  - Superficial femoral artery aneurysm greater than or equal to 2 times the diameter of the normal native SFA (with or without mural thrombus); **OR**
  - Popliteal artery aneurysm greater than or equal to 2 cm in diameter (with or without mural thrombus) **AND** must

include documentation that the patient has a high surgical risk; **OR**

- The patient has symptomatic mesenteric arterial ischemia with a documented stenosis greater than 70% within the celiac axis (CA) or superior mesenteric artery (SMA)[2]; **OR**
- The patient has symptomatic renal artery stenosis with **ANY** of the following[3-4]:
  - Bilateral RAS with greater than 70% stenosis of both arteries with intolerance OR blood pressure that is uncontrolled with optimal guideline medical therapy (GDMT) - this includes angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARB), and calcium channel blockers and diuretics; **OR**
  - Unilateral RAS in patients who are not tolerant to optimal medical therapy (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 less than or equal to 3 months; **OR**
  - Progressive kidney function impairment caused by stenosis OR impairment that is believed to be a result of bilateral renovascular disease or unilateral stenosis in a uninephric patient ; **OR**
  - Recurrent flash pulmonary edema or refractory heart failure secondary to renal artery occlusive disease; **OR**
- Complications of a procedure including **ANY** of the following:
  - Bare metal or covered stent placement may be clinically indicated in **ANY** of the following clinical scenarios:
    - Acute vessel occlusion immediately following a procedure; **OR**
    - Flow-limiting dissection; **OR**
    - Elastic recoil or refractory spasm; **OR**
    - Residual stenosis is greater than 30% at the most narrow point of the vascular lumen or evidence of a greater than 50% reduction of arterial stenosis in vessel diameter; **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 clinical scenarios:
    - Arterial perforation; **OR**
    - Arterial occlusion; **OR**
    - Pseudoaneurysm; **OR**
    - Arteriovenous fistula

Non-Indications

- ➔ **Arterial Stent** placement is not considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ Asymptomatic peripheral artery occlusive disease; **OR**
  - ◆ Known allergic reactions to stent or stent graft material (e.g., nitinol, dacron, ePTFE)

Site of Service Criteria

Inpatient or Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS/CPT 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

National and Professional Organizations

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*. 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]

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]

References

1. Wada T, Takayama K, Taoka T, et al. Long-term treatment outcomes after intravascular ultrasound evaluation and stent placement for atherosclerotic subclavian artery obstructive lesions. Neuroradiol J. 2014 Apr;27(2):213-21. doi: 10.15274/NRJ-2014-10023. Epub 2014 Apr 18. PMID: 24750712; PMCID: PMC4202855.
2. Bala M, Catena F, Kashuk J, et al. Acute mesenteric ischemia: Updated guidelines of the World Society of Emergency Surgery. World J Emerg Surg. 2022 Oct 19;17(1):54. doi: 10.1186/s13017-022-00443-x. PMID: 36261857; PMCID: PMC9580452.
3. American College of Radiology (ACR), Society of Interventional Radiology (SIR). ACR–SIR practice parameter for the performance of angiography, angioplasty, and stenting for the diagnosis and treatment of renal artery stenosis in adults. Revised 2021 (Resolution 6). Accessed August 16, 2023. https://www.acr.org/-/media/ACR/Files/Practice-Parameters/RenalArteryStenosis.pdf.
4. Parikh SA, Shishehbor MH, Gray BH, et al. SCAI expert consensus statement for renal artery stenting appropriate use. Catheter Cardiovasc Interv. 2014 Dec 1;84(7):1163-71. doi: 10.1002/ccd.25559. PMID: 25138644.
5. Rundback JH, Peeters P, George JC, et al. Results from the VISIBILITY Iliac Study: Primary and cohort outcomes at 9 months. J Endovasc Ther. 2017 Jun;24(3):342-348. doi: 10.1177/1526602817692960. PMID: 28351204; PMCID: PMC5438081.
6. Klein AJ, Jaff MR, Gray BH, et al. SCAI appropriate use criteria for peripheral arterial interventions: An update. Catheter Cardiovasc Interv. 2017 Oct 1;90(4):E90-E110. doi: 10.1002/ccd.27141. PMID: 28489285.
7. Joshi D, Gupta Y, Ganai B, et al. Endovascular versus open repair of asymptomatic popliteal artery aneurysm. Cochrane Database Syst Rev. 2019 Dec 23;12(12):CD010149. doi: 10.1002/14651858.CD010149.pub3. PMID: 31868929; PMCID: PMC6927522.
8. Wada T, Takayama K, Taoka T, et al. Long-term treatment outcomes after intravascular ultrasound evaluation and stent placement for atherosclerotic subclavian artery obstructive lesions. Neuroradiol J. 2014 Apr;27(2):213-21. doi: 10.15274/NRJ-2014-10023. Epub 2014 Apr 18. PMID: 24750712; PMCID: PMC4202855.
9. Wong VW, Major MR, Higgins JP. Nonoperative management of acute upper limb ischemia. Hand (N Y). 2016 Jun;11(2):131-43. doi: 10.1177/1558944716628499. PMID: 27390553; PMCID: PMC4920541.
10. Laird JR, Loja M, Zeller T, et al. iCAST balloon-expandable covered stent for iliac artery lesions: 3-year results from the iCARUS multicenter study.

J Vasc Interv Radiol. 2019 Jun;30(6):822-829.e4. doi: 10.1016/j.jvir.2018.12.707. PMID: 31031089.
11. Bailey SR, Beckman JA, Dao TD, et al. ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, and Society for Vascular Medicine. J Am Coll Cardiol. 2019 Jan 22;73(2):214-237. doi: 10.1016/j.jacc.2018.10.002. PMID: 30573393.

Clinical Guideline Revision History/Information

Original Date: September 25, 2023	
Review History	