

# Cohere Medical Policy - Arterial Stenting, Other Clinical Guidelines for Medical Necessity Review

**Version:** 

Effective Date: December 12, 2024

# **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.

©2024 Cohere Health, Inc. All Rights Reserved.

#### Other Notices:

HCPCS® and CPT® copyright 2024 American Medical Association. All rights reserved.

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.

HCPCS and CPT are registered trademarks of the American Medical Association.

#### **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:**  $[\underline{X}]$  Adult (18+ yo) |  $[\underline{X}]$  Pediatric (0-17yo)

# **Table of Contents**

Important Notices	2
Medical Necessity Criteria	4
Service: Arterial Stenting, Other	4
Recommended Clinical Approach:	4
Medical Necessity Criteria	4
Indications	4
Non-Indications	7
Level of Care Criteria	7
Procedure Codes (CPT/HCPCS)	7
Medical Evidence	9
References	11
Clinical Guideline Revision History/Information	14

# **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 conditions<sup>6-7</sup>:
    - 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 risk<sup>12</sup>; 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 year<sup>13</sup>; OR
  - Gastric, gastroepiploic, pancreaticoduodenal, and gastroduodenal aneurysms of any size<sup>13</sup>; OR
  - Superior mesenteric artery aneurysms of any size<sup>13</sup>;
     OR
  - Celiac artery aneurysms greater than 2 cm in diameter<sup>13</sup>; 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
    - o 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 following<sup>3-4</sup>:
    - 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 stenosis<sup>14-17</sup>; 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**<sup>□18,22</sup>:
  - 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.<sup>11</sup> 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. 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.

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



# References

- 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.
- Lam A, Kim YJ, Fidelman N, et al.. ACR appropriateness criteria

   radiologic management of mesenteric ischemia: 2022 update. JACR.
   2022 Nov 1;19(11):S433-44. doi: 10.1016/j.jacr.2022.09.006. PMID: 36436968.
- 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 (resolution 6). Revised 2021. Accessed November 6, 2024. https://www.acr.org/-/media/ACR/Files/Practice-Parameters/RenalArt
  - 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.
- 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.
- 12. Farber A, Angle N, Avgerinos E, et al. The Society for Vascular Surgery clinical practice guidelines on popliteal artery aneurysms. *J Vasc Surg*. 2022 Jan 1;75(1):1095-205. doi: 10.1016/j.jvs.2021.04.040. PMID: 34023430.
- 13. Chaer RA, Abularrage CJ, Coleman DM, et al.The Society for Vascular Surgery clinical practice guidelines on the management of visceral aneurysms. *J Vasc Surg.* 2020 Jul 1;72(1):35-95. doi: 10.1016/j.jvs.2020.01.039. PMID: 32201007.
- Bou-Chaaya RG, Zhu Z, Duarte VE, et al. Percutaneous structural interventions in adult congenital heart disease: State-of-the-art review. Methodist Debakey Cardiovasc. J.. 2023;19(3):78. doi: 10.14797/mdcvj.1219. PMID: 37213883; PMCID: PMC10198245.
- 15. Lan IS, Yang W, Feinstein JA, et all. Virtual transcatheter interventions for peripheral pulmonary artery stenosis in Williams and Alagille syndromes. *JAMA*. 2022 Mar 15;11(6):e023532. doi: 10.1161/JAHA.121.023532. PMID: 35253446; PMCID: PMC9075299.
- 17. Stout KK, Daniels CJ, Aboulhosn JA, et al. 2018 AHA/ACC guideline for the management of adults with congenital heart disease: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *JACC*. 2019 Apr 2;73(12):e81-192. doi: 10.1016/j.jacc.2018.08.1028. PMID: 30121240.

- Forbes TJ, Gowda ST. Intravascular stent therapy for coarctation of the aorta. Methodist Debakey Cardiovasc. J. 2014 Apr;10(2):82-87. doi: 10.14797/mdcj-10-2-82. PMID: 25114759; PMCID: PMC4117325.
- 19. Holzer RJ, Gauvreau K, McEnaney K, et al. Long-term outcomes of the coarctation of the aorta stent trials. *Circ. Cardiovasc. Interv.*. 2021 Jun;14(6):e010308. doi: 10.1161/CIRCINTERVENTIONS.120.010308. PMID: 34039015.
- 20.Boe BA, Armstrong AK, Janse SA, et al. Percutaneous implantation of adult sized stents for coarctation of the aorta in children≤ 20 kg: A 12-year experience. *Circ. Cardiovasc. Interv.*. 2021 Feb;14(2):e009399. doi: 10.1161/CIRCINTERVENTIONS.120.009399. PMID: 33544625.
- 21. Writing Committee Members, Isselbacher EM, Preventza O, et al. 2022 ACC/AHA guideline for the diagnosis and management of aortic disease: A report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *JACC*. 2022 Dec 13;146(24):e334-e482. doi: 10.1161/CIR.000000000001106. PMID: 36322642; PMCID: PMC9876736.
- 22. Zierler RE, Jordan WD, Lal BK, et al. The Society for Vascular Surgery practice guidelines on follow-up after vascular surgery arterial procedures. *J Vasc Surg.* 2018 Jul 1;68(1):256-84. doi: 10.1016/j.jvs.2018.04.018. PMID: 29937033.

# Clinical Guideline Revision History/Information

Original Date: September 25, 2023			
Review History			
Version 2	12/12/2024	<ul> <li>Annual policy review and restructure:</li> <li>Updated recommended clinical approach to the current format.</li> <li>Consolidated upper extremity bullet points.</li> <li>Consolidated aneurysmal indications into one bullet.</li> <li>Replaced prior mesenteric ischemia indication with appropriate (e.g., non-emergent, non-acute) criteria.</li> <li>Added indication for secondary or repeat stenting.</li> <li>Removed one non-indication which was already covered by the choice of CPT codes.</li> <li>Updated medical evidence section.</li> <li>Updated references.</li> </ul>	