Cohere Medicare Advantage Policy - Arterial Stenting

Clinical Policy for Medical Necessity Review

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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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Other Notices:

Policy Information:

Specialty Area: Cardiovascular Disease
Policy Name: Cohere Medicare Advantage Policy - Arterial Stenting
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

Table of Contents

Important Notices **2**
Medical Necessity Criteria **4**
Service: Arterial Stenting **4**
Related CMS Documents 4
Description 4
Medical Necessity Criteria 4
Indications 4
Non-Indications 8
Definitions 9
Level of Care Criteria 9
Procedure Codes (CPT/HCPCS) 9
Evaluation of Clinical Harms and Benefits 10
Medical Evidence **12**
References **14**
Clinical Guideline Revision History/Information **17**

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.[1-5]

- Local Coverage Determination (LCD). Non-coronary vascular stents. (L34062)
  - Billing and Coding: Non-coronary vascular stents. (A57590)
  - Billing and Coding: Endovascular repair of aortic and/or iliac aneurysms (A53124)
- Local Coverage Determination (LCD). Dialysis access maintenance. (L35998)
  - Billing and Coding: Dialysis access maintenance (A56460)

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.[1,4]

Medical Necessity Criteria

Indications

Arterial stenting is considered appropriate if **ALL** of the following are **TRUE**:

- **ANY** of the following[1]:
  - 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 symptoms[1]; **AND**
  - Surgical intervention would otherwise be considered as an alternative treatment for the patient[1]; **AND**
  - **ANY** of the following[1]:
    - 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**
    - That 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 following[1]:
    - 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 stenosis[1]; **OR**
  - Renal artery stenting for **ANY** of the following[1]:
    - 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 with **ANY** of the following[1]:
        - 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 with **ANY** of the following[1]:
        - 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 following[1]:
        - Gangrene[6,7]; **OR**
        - Ischemic rest pain[A,6,7]; **OR**
        - Non-healing wounds[6,7]; **OR**
    - Claudication with **ALL** of the following[1]:
        - Intermittent claudication characterized by exertional muscle pain which is relieved by rest[8]; **AND**
        - Physical exam findings indicating reduced blood flow (e.g.,decreased or absent pulses)[8]; **AND**
        - Ankle-brachial index (ABI) greater than or equal to 0.90 or toe-brachial index (TBI) greater than or equal to 0.70[8]; **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 program[1]; **AND**

    - Ongoing, significant activity-limiting disease[1]; **AND**
    - Anatomically suitable lesion for intervention[1]; **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 following[1]:
    - 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 following[1]:
    - 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 following[1]:
    - 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 scenarios[4]:
    - 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 conditions[9]:
    - Any symptomatic aneurysm; **OR**

- Asymptomatic lower extremity aneurysmal disease as indicated by **ANY** of the following[10-12]:
  - 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 following[13]:
  - 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])[14-18]; **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.[4]

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 WIfI ischemia grade 3).[6,7]

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.[9,14]
- 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.[9,14]

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.[15-18]
- 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.[14]

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.[19]

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.[20]

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