Policy

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Purpose

Peripheral arterial disease is a common condition for which a variety of interventions may be appropriate. This policy outlines the medical necessity criteria for revascularization procedures.

Definitions, Abbreviations, and Acronyms

Acronym	Meaning
NCD	National Coverage Determination
LCD	Local Coverage Determination

Policy

Prior authorization is required for lower extremity peripheral artery revascularization services. This policy outlines the coverage criteria for these procedures. This policy is a supplemental document to NCD 20.7 Percutaneous Transluminal Angioplasty and L35998 Non-Coronary Vascular Stents and reiterates the guidance of this NCD and LCD.

Peripheral artery disease (PAD) is a chronic circulation disorder primarily caused by atherosclerosis. This narrowing of the vessels can lead to reduced blood flow to the extremity.

As peripheral artery disease progresses, symptoms may emerge indicating significant limitation to blood flow. These symptoms include:

- Claudication/Intermittent Claudication- exercise induced discomfort, cramping, or pain in the muscle that is relieved with rest
- Critical/Chronic Limb-Threatening Ischemia- Chronic limb-threatening ischemia (CLTI) is a clinical syndrome defined by the presence of peripheral artery disease (PAD) in combination with rest pain, gangrene, or a lower limb ulceration >2 weeks duration.

Endovascular revascularization interventions are procedures in which a catheter is inserted through the skin with the intent to restore blood flow. Endovascular treatment options include the following:

• Angioplasty – a catheter is inserted into the affected artery and the attached balloon is inflated to clear and widen the artery to improve or restore blood flow.

• Atherectomy – removal of atherosclerotic plaque from an artery using a catheter fitted with special equipment.

• Stent – a tubular support placed inside a blood vessel to relieve a blockage or obstruction.

NCD 20.7 Percutaneous Transluminal Angioplasty

This procedure involves inserting a balloon catheter into a narrow or occluded blood vessel to recanalize and dilate the vessel by inflating the balloon. The objective of percutaneous transluminal angioplasty (PTA) is to improve the blood flow through the diseased segment of a vessel so that vessel patency is increased and embolization is decreased.

PTA is an appropriate intervention for the following conditions:

- In the lower extremities, i.e., the iliac, femoral, and popliteal arteries, or in the upper extremities, i.e., the innominate, subclavian, axillary, and brachial arteries.
- Of the renal arteries for patients in whom there is an inadequate response to a thorough medical management of symptoms and for whom surgery is the likely alternative. PTA for this group of patients is an alternative to surgery, not simply an addition to medical management.
- Of arteriovenous dialysis fistulas and grafts when performed through either a venous or arterial approach.

L35998 Non-Coronary Vascular Stents

Included in this policy is a summary of the language found in L35998. For states in which the plan operates and no active LCD is available, the Plan adopts the language in L35998 in this policy to provide guidance for those states.

Vascular stents are used to enhance primary patency in arteries and veins, usually at the site of stenotic or occlusive lesions. Stents also may be used as an adjunct to technically inadequate Percutaneous Transluminal Angioplasty (PTA) or in cases where PTA alone will not be expected to provide a durable result. Peripheral vascular stenting may be indicated for patients with symptomatic arterial and venous disease resulting from an occlusive process.

PTA and stenting of vessels is covered only when all of the following conditions are met:

- The patient has undergone prior thorough medical evaluation and management of symptoms. See below under specific categories for guidelines on medical evaluation and management recommendations.
- Surgical intervention would otherwise be considered as an alternative treatment for the patient.
- A stent may be placed as a planned adjunct to PTA rather than in response to a suboptimal or failed PTA (so-called primary stent deployment). Primary stenting is

justified for situations where 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 occlusive lesions 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), or ostial renal artery stenosis.

Specific Arterial Indications for PTA and Stenting

- ***Brachiocephalic arteries:*** PTA and stenting may be indicated for treatment of flow-limiting stenosis resulting in conditions such as subclavian steal syndrome, upper extremity claudication, ischemic rest pain of the arm and hand, non-healing tissue ulceration and focal gangrene.
- ***Pulmonary artery:*** PTA and stenting may be indicated for certain people with congenital pulmonary artery stenosis.
- ***Renal artery:*** PTA and stenting may be indicated for renal artery stenosis. The following guidelines should be followed when making determination for RAS:
    - Renal artery stenting is considered appropriate for renal artery dissection; renal artery aneurysm and renal artery atherosclerosis greater than 50% in a transplanted kidney.
    - Renal artery stenting is considered appropriate under the following conditions:
        - Flash pulmonary edema or acute coronary syndrome (ACS) with severe hypertension;
        - Resistant HTN (Uncontrolled hypertension with failure of maximally tolerated doses of at least three antihypertensive agents, one of which is a diuretic, or intolerance to medications); or
        - Ischemic nephropathy with chronic kidney disease (CKD) with eGFR < 45 cc/min and global renal ischemia (unilateral significant renal artery stenosis with a solitary kidney or bilateral significant renal artery stenosis) without other explanation.
    - Renal artery stenting may be considered appropriate under the following conditions:
        - Unilateral renal artery stenosis with CKD (eGFR < 45cc/min).
        - Unilateral renal artery stenosis with prior episodes of congestive heart failure (Stage C).

        - Anatomically challenging or high-risk lesion (early bifurcation, small vessel, severe concentric calcification, and severe aortic atheroma or mural thrombus).
    - Renal artery stenting is rarely considered appropriate under the following conditions:
        - Unilateral, solitary, or bilateral renal artery stenosis with controlled BP and normal renal function.
        - Unilateral, solitary, or bilateral renal artery stenosis with kidney size < 7cm in pole-to-pole length.
        - Unilateral, solitary, or bilateral renal artery stenosis with chronic end stage renal disease on hemodialysis > 3 months.
        - Unilateral, solitary, or bilateral renal artery chronic total occlusion.
- ***Lower extremity arteries*** (aorto-iliac, superficial femoral and infra-popliteal arteries): PTA and stent placement in infra-popliteal vessels is not expected to be often indicated and in those cases the rationale for stent placement must be thoroughly explained in the record.
- PTA and stenting for critical limb ischemia is considered appropriate under the following conditions: Limb threatening lower extremity ischemia.
- PTA and stenting for claudication may be appropriate under the following conditions:
    - Individuals who have failed medical management and continue to have significant activity limiting disease, with an anatomically suitable lesion for intervention.
    - Medical management of peripheral artery disease (PAD) should include Class I recommendations for antiplatelet therapy, statins, smoking cessation including planning, counseling or behavior modification and pharmacotherapy if needed.
- ***Mesenteric vessels:*** This includes acute mesenteric ischemia, chronic mesenteric ischemia, mesenteric thrombosis, dissection, or any other vascular insufficiency resulting in gastrointestinal symptoms. Stenting of the mesenteric vessels is covered only when angioplasty of the vessels would not suffice and after the patient has had a thorough medical evaluation and management of symptoms, and for whom surgical intervention is the likely alternative. The eligible patients will be required to have multiple comorbidities documented making them poor candidates for open surgical procedures. In these situations, PTA and stent placement should be considered an alternative to surgery and not an addition to medical management.
- Hemodialysis access graft/fistula: This includes stenosis, restenosis, occlusion and pseudoaneurysm.

Specific Venous Stents

- Superior vena cava and subclavian/innominate veins stents: PTA and stenting are covered for superior vena cava syndrome, post-radiation venous stenosis, congenital stenosis, and thrombosis and embolism, including acute thrombophlebitis.
- Inferior vena cava and iliofemoral veins: This includes vena caval and iliofemoral venous occlusions and stenosis due to the following: post-radiation venous stenosis, congenital stenosis or webs, extrinsic venous compression (May-Thurner syndrome), thrombophlebitis, and symptomatic post-traumatic venous stenosis.

Limitations

1. The placement of a stent in a vessel for which there is no objective-related symptom or limitation of function is considered to be preventive, and therefore, not covered by Medicare.
2. Use of non-coronary vascular stents is covered only after the patient has had a thorough evaluation and treatment of symptoms and when PTA of the vessel alone has not, or is not expected to sufficiently resolve the symptoms making surgery the likely alternative.

Coverage Guidance

Endovascular revascularization procedures (e.g., stents, angioplasty and/or atherectomy) for treating lower extremity ischemia are proven and medically necessary in individuals who meet the following indication-specific criteria:

- Criteria are met:
    - Impaired ability to work and/or perform activities of daily living (ADL)
    - All of the following conservative therapies have been tried and failed:
        - At least twelve (12) weeks of a Supervised or Structured Exercise Program
        - Pharmacologic therapy
        - Smoking cessation, if applicable
    - Moderate to severe ischemic peripheral artery disease with ankle-brachial index (ABI) ≤0.69
    - Imaging results show anatomic location and severity of occlusion (stenosis≥ 50%) (e.g., duplex ultrasound, CTA, MRA or invasive angiography). If duplex ultrasound does not demonstrate a stenosis ≥ 50%, another imaging modality will be necessary to demonstrate the extent of stenosis.
- Chronic limb-threatening ischemia (CLTI) when all of the following criteria are met:
    - One or more of the following:
        - Pain at rest

        - Nonhealing wound or ulcer due to ischemia
        - Gangrene
    - Moderate to severe ischemic peripheral artery disease and any of the following:
        - Ankle-Brachial Index (ABI) ≤0.69; or
        - Ankle pressure <50 mmHg; or
        - Toe-Brachial Index ≤ 0.70; or
        - Toe pressure <30 mmHg; or
        - Transcutaneous Oxygen Pressure (TcPO2) <25 mmHg
    - Imaging results show anatomic location and severity of occlusion (stenosis≥ 50%) (e.g., duplex ultrasound, CTA, MRA or invasive angiography). If duplex ultrasound does not demonstrate a stenosis ≥ 50%, another imaging modality will be necessary to demonstrate the extent of stenosis.

Due to insufficient evidence of efficacy, endovascular revascularization procedures (e.g., stents, angioplasty and/or atherectomy) for treating lower extremity ischemia are unproven and not medically necessary in the following circumstances:

- Claudication due to isolated infrapopliteal (e.g., anterior tibial, posterior tibial or peroneal) artery disease
- To prevent the progression of claudication to CLTI
- Individual is asymptomatic
- Treatment of a nonviable limb
- Claudication due to atherosclerotic disease of the aortoiliac and/or femoropopliteal arteries when all of the following

Treatment of Claudication

For individuals with claudication due to lower extremity occlusive arterial disease, the use of either percutaneous or open exposure angioplasty is considered **medically necessary** for individuals who meet ALL the following criteria:

1. Presence of severe disability (inability to perform usual work or life-style activities) due to intermittent claudication; and
2. There has been an inadequate response to at least 6 months of conservative treatment including lifestyle initiatives for known risks (for example, smoking cessation and dietary changes), including supervised exercise training, and pharmacological therapy (for example, anti-platelet, cilostazol) unless contraindicated; and
3. The targeted lesion has one of the following anatomic characteristics:

a. Common iliac artery: unilateral or bilateral lesions of any length; or
b. External iliac: unilateral or bilateral lesions less than or equal to 3 cm in length; or
c. Femoral or popliteal artery: a single stenosis less than or equal to 10 cm in length or a single occlusion less than or equal to 5 cm in length; and

4. There is an absence of other conditions that would limit activity even if the claudication were improved (for example, angina or chronic pulmonary disease) with the endovascular intervention.

For individuals with claudication due to lower extremity occlusive arterial disease, the use of either percutaneous or open exposure primary stent placement is considered **medically necessary**, when the following criteria have been met:

1. Criteria above for angioplasty have been met; and
2. Stenosis or occlusion is present in the common iliac artery, external iliac artery; or
3. Stenosis or occlusion of intermediate-length (5-15 cm) is present in the femoropopliteal artery.

For individuals with claudication due to aortoiliac occlusive disease (AIOD), the use of covered stent devices is considered **medically necessary** in the presence of severe calcification or aneurysmal changes where the risk of rupture may be increased after unprotected dilation.

Salvage (Provisional) Therapy for Claudication

For individuals with claudication due to lower extremity occlusive arterial disease, the use of either percutaneous or open exposure stents or atherectomy devices as **salvage (provisional)** therapy for a suboptimal or failed result from balloon angioplasty is considered **medically necessary** when the residual stenosis or occlusion is present in either the femoral, popliteal, or tibial artery and ANY of the following criteria have been met:

- Residual diameter stenosis greater than 50%; or
- Persistent translesional pressure gradient; or
- Flow-limiting dissection is present.

Critical Limb Ischemia

For individuals with limb threatening CLI due to lower extremity occlusive arterial disease (ischemic rest pain and/or impending limb loss with skin ulceration, gangrene, infection) of the lower extremity, the use of endovascular procedures (angioplasty, stent placement, or atherectomy) is considered **medically necessary** as initial or salvage therapy for inflow (aorto- iliac) and outflow (infrainguinal) occlusive vascular disease.

Change Log

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1	New	12/15/2024	Stefanie Caswell	New
2	N/A	12/12/2025	Stefanie Caswell	Annual review, no change