Lower Extremity Endovascular Procedures (for North Carolina Only)

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➲ Instructions for Use

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Related Policies

- Pneumatic Compression Devices (for North Carolina Only)
- Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for North Carolina Only)

Application

This Medical Policy only applies to the state of North Carolina.

Coverage Rationale

Note: This policy does not apply to upper extremities.

Endovascular revascularization procedures (e.g., stents, angioplasty, and/or atherectomy) are proven and medically necessary for treating non-limb-threatening lower extremity ischemia in individuals with Claudication due to atherosclerotic disease of the aortoiliac and/or femoropopliteal arteries when all the following criteria are met:

- Impaired ability to work and/or perform activities of daily living (ADL); and
- **All** the following conservative therapies have been tried and failed:
  - At least twelve (12) weeks of Supervised Exercise Therapy or a Structured Community-Based Exercise Program; and
  - Pharmacologic therapy (e.g., lipid lowering therapy, antihypertensive therapy, antiplatelet therapy, and/or anticoagulants); and
  - Smoking cessation, if applicable

  and
- Ischemic peripheral artery disease with Ankle-Brachial Index (ABI) ≤ 0.90; and
- Imaging results of the target vessel [e.g., duplex ultrasound, computed tomography angiography (CTA), magnetic resonance angiography (MRA), or digital subtraction angiography] show anatomic location and a moderate severe stenosis ≥ 50% or greater; if duplex ultrasound does not demonstrate a stenosis 50% or greater, another imaging modality will be necessary to demonstrate the extent of stenosis

Retreatment of a previously treated vessel due to in-stent restenosis is proven and medically necessary for treating non-limb-threatening lower extremity ischemia in individuals with Claudication due to atherosclerotic disease of the aortoiliac and/or femoropopliteal arteries when all the following criteria are met:

- Recurrent symptoms; and
- Impaired ability to work and/or perform activities of daily living (ADL); and

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- Imaging results of the previously treated vessel [e.g., duplex ultrasound, computed tomography angiography (CTA), magnetic resonance angiography (MRA), or digital subtraction angiography] show anatomic location and a moderate-severe stenosis (50% or greater); if duplex ultrasound does not demonstrate a stenosis of 50% or greater, another imaging modality will be necessary to demonstrate the extent of stenosis

Endovascular revascularization procedures (e.g., stents, angioplasty and/or atherectomy) are proven and medically necessary for treating Chronic Limb-Threatening Ischemia (CLTI) with the diagnoses listed under Applicable Codes.

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 due to insufficient evidence of efficacy:
- Interventions performed for non-limb-threatening infrapopliteal (e.g., anterior tibial, posterior tibial, or peroneal) artery disease
- Individual is asymptomatic
- To prevent the progression of Claudication to CLTI
- Transluminal peripheral atherectomy of the iliac artery
- Treatment of a nonviable limb

Endovenous femoropopliteal bypass using a stent graft is unproven and not medically necessary for treating peripheral artery disease due to insufficient evidence of efficacy.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the services requested.

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

Definitions

Ankle-Brachial Index (ABI): The ABI compares the systolic blood pressure in the ankle to the systolic blood pressure in the arm and indicates how well blood is flowing in the limbs An ABI less than 0.90 indicates peripheral artery disease (PAD) (Gornik et al., 2024).

Chronic Limb-Threatening Ischemia (CLTI): A condition characterized by chronic (≥ 2 weeks) ischemic rest pain, nonhealing wound/ulcers or gangrene in one or both legs attributable to objectively proven arterial occlusive disease. Current nomenclature has evolved from the previous commonly used term of critical limb ischemia (CLI) to reflect the chronic nature of this condition and its potentially limb-threatening nature with associated risk for amputation and to distinguish it from acute limb ischemia (ALI) (Gornik et al., 2024).

Claudication: Fatigue, cramping, aching, pain, or other discomfort of vascular origin in the muscles of the lower extremities that is consistently induced by walking and consistently relieved by rest (usually within approximately 10 minutes). Claudication that limits functional status is known as functionally limiting Claudication. Claudication is recognized as a manifestation of chronic symptomatic PAD (Gornik et al., 2024).

Structured Community-Based Exercise Program: Components of a Structured Community-Based Exercise Program include **all** the following (Gornik et al., 2024):
- Program takes place in the personal setting (e.g., home, community, neighborhood) of the individual rather than in a clinical setting.
- Qualified health care professional(s) prescribe an exercise regimen similar to that of a Supervised program.
- Program is self-directed with the guidance of healthcare professional(s) and is generally walking-based.
- Individual counseling ensures understanding of how to begin and maintain the program and how to progress the difficulty of the walking (by increasing distance or speed).

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- Program may incorporate behavioral change techniques, delivered by in-person or virtual health coaching or the use of activity monitors.
- Program may include periodic supervised exercise sessions to assess progress, reinforce adherence, and make exercise prescription alterations when appropriate.

Supervised Exercise Therapy: Components of Supervised Exercise Therapy include **all** of the following (Gornik et al., 2024):
- Primarily focuses on intermittent walking exercise on a treadmill, interspersed with rest periods when pain becomes moderate or severe.
- Program takes place in a hospital or outpatient facility and is often placed within a cardiac rehabilitation program setting; can be standalone if necessary.
- Program is directly supervised by qualified health care professional(s); generally clinical exercise physiologists or nurses with exercise training experience.
- Training is performed for a minimum of 30-45 minutes per 60-minute session. Supervised sessions are performed at least 3 times per week for a minimum of 12 weeks.
- Training involves intermittent bouts of walking to moderate-to-maximum Claudication pain or discomfort, alternating with periods of rest with incremental increases as function and symptoms improve. Goal is to progress to 30-45 minutes of active walking exercise during each session.
- Non-treadmill modalities (e.g., stationary bicycle) can be used when appropriate and continually assessed to determine when or if the patient can use a treadmill.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0238T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion
37220	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty
37221	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37222	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)
37223	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37227	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed

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CPT Code	Description
37228	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty
37229	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed
37230	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37231	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed
37232	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)
37233	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)
37234	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)
37235	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)

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Diagnosis Code	Description
E08.52	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy with gangrene
E09.52	Drug or chemical induced diabetes mellitus with diabetic peripheral angiopathy with gangrene
E10.52	Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E13.52	Other specified diabetes mellitus with diabetic peripheral angiopathy with gangrene
I70.221	Atherosclerosis of native arteries of extremities with rest pain, right leg
I70.222	Atherosclerosis of native arteries of extremities with rest pain, left leg
I70.223	Atherosclerosis of native arteries of extremities with rest pain, bilateral legs
I70.228	Atherosclerosis of native arteries of extremities with rest pain, other extremity
I70.229	Atherosclerosis of native arteries of extremities with rest pain, unspecified extremity
I70.231	Atherosclerosis of native arteries of right leg with ulceration of thigh
I70.232	Atherosclerosis of native arteries of right leg with ulceration of calf
I70.233	Atherosclerosis of native arteries of right leg with ulceration of ankle
I70.234	Atherosclerosis of native arteries of right leg with ulceration of heel and midfoot
I70.235	Atherosclerosis of native arteries of right leg with ulceration of other part of foot
I70.238	Atherosclerosis of native arteries of right leg with ulceration of other part of lower leg
I70.239	Atherosclerosis of native arteries of right leg with ulceration of unspecified site
I70.241	Atherosclerosis of native arteries of left leg with ulceration of thigh
I70.242	Atherosclerosis of native arteries of left leg with ulceration of calf
I70.243	Atherosclerosis of native arteries of left leg with ulceration of ankle
I70.244	Atherosclerosis of native arteries of left leg with ulceration of heel and midfoot
I70.245	Atherosclerosis of native arteries of left leg with ulceration of other part of foot
I70.248	Atherosclerosis of native arteries of left leg with ulceration of other part of lower leg
I70.249	Atherosclerosis of native arteries of left leg with ulceration of unspecified site

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Diagnosis Code	Description
I70.25	Atherosclerosis of native arteries of other extremities with ulceration
I70.261	Atherosclerosis of native arteries of extremities with gangrene, right leg
I70.262	Atherosclerosis of native arteries of extremities with gangrene, left leg
I70.263	Atherosclerosis of native arteries of extremities with gangrene, bilateral legs
I70.268	Atherosclerosis of native arteries of extremities with gangrene, other extremity
I70.269	Atherosclerosis of native arteries of extremities with gangrene, unspecified extremity
I70.321	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, right leg
I70.322	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, left leg
I70.323	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, bilateral legs
I70.329	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, unspecified extremity
I70.331	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of thigh
I70.332	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of calf
I70.333	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of ankle
I70.334	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of heel and midfoot
I70.335	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of other part of foot
I70.338	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of other part of lower leg
I70.339	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of unspecified site
I70.341	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of thigh
I70.342	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of calf
I70.343	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of ankle
I70.344	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of heel and midfoot
I70.345	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of other part of foot
I70.348	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of other part of lower leg
I70.349	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of unspecified site
I70.35	Atherosclerosis of unspecified type of bypass graft(s) of other extremity with ulceration
I70.361	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, right leg
I70.362	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, left leg
I70.363	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, bilateral legs
I70.369	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, unspecified extremity
I70.421	Atherosclerosis of autologous vein bypass graft(s) of the extremities with rest pain, right leg
I70.422	Atherosclerosis of autologous vein bypass graft(s) of the extremities with rest pain, left leg
I70.423	Atherosclerosis of autologous vein bypass graft(s) of the extremities with rest pain, bilateral legs
I70.428	Atherosclerosis of autologous vein bypass graft(s) of the extremities with rest pain, other extremity
I70.429	Atherosclerosis of autologous vein bypass graft(s) of the extremities with rest pain, unspecified extremity
I70.431	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of thigh
I70.432	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of calf
I70.433	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of ankle

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Diagnosis Code	Description
I70.434	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of heel and midfoot
I70.435	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of other part of foot
I70.438	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of other part of lower leg
I70.439	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of unspecified site
I70.441	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of thigh
I70.442	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of calf
I70.443	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of ankle
I70.444	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of heel and midfoot
I70.445	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of other part of foot
I70.448	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of other part of lower leg
I70.449	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of unspecified site
I70.461	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene, right leg
I70.462	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene, left leg
I70.463	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene, bilateral legs
I70.468	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene, other extremity
I70.469	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene, unspecified extremity
I70.521	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with rest pain, right leg
I70.522	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with rest pain, left leg
I70.523	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with rest pain, bilateral legs
I70.528	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with rest pain, other extremity
I70.529	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with rest pain, unspecified extremity
I70.531	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of thigh
I70.532	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of calf
I70.533	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of ankle
I70.534	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of heel and midfoot
I70.535	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of other part of foot
I70.538	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of other part of lower leg
I70.539	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of unspecified site
I70.541	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of thigh
I70.542	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of calf
I70.543	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of ankle
I70.544	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of heel and midfoot
I70.545	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of other part of foot
I70.548	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of other part of lower leg

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Diagnosis Code	Description
I70.549	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of unspecified site
I70.561	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with gangrene, right leg
I70.562	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with gangrene, left leg
I70.563	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with gangrene, bilateral legs
I70.568	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with gangrene, other extremity
I70.569	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with gangrene, unspecified extremity
I70.621	Atherosclerosis of nonbiological bypass graft(s) of the extremities with rest pain, right leg
I70.622	Atherosclerosis of nonbiological bypass graft(s) of the extremities with rest pain, left leg
I70.623	Atherosclerosis of nonbiological bypass graft(s) of the extremities with rest pain, bilateral legs
I70.628	Atherosclerosis of nonbiological bypass graft(s) of the extremities with rest pain, other extremity
I70.629	Atherosclerosis of nonbiological bypass graft(s) of the extremities with rest pain, unspecified extremity
I70.631	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of thigh
I70.632	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of calf
I70.633	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of ankle
I70.634	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of heel and midfoot
I70.635	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of other part of foot
I70.638	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of other part of lower leg
I70.639	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of unspecified site
I70.641	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of thigh
I70.642	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of calf
I70.643	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of ankle
I70.644	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of heel and midfoot
I70.645	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of other part of foot
I70.648	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of other part of lower leg
I70.649	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of unspecified site
I70.661	Atherosclerosis of nonbiological bypass graft(s) of the extremities with gangrene, right leg
I70.662	Atherosclerosis of nonbiological bypass graft(s) of the extremities with gangrene, left leg
I70.663	Atherosclerosis of nonbiological bypass graft(s) of the extremities with gangrene, bilateral legs
I70.668	Atherosclerosis of nonbiological bypass graft(s) of the extremities with gangrene, other extremity
I70.669	Atherosclerosis of nonbiological bypass graft(s) of the extremities with gangrene, unspecified extremity
I70.721	Atherosclerosis of other type of bypass graft(s) of the extremities with rest pain, right leg
I70.722	Atherosclerosis of other type of bypass graft(s) of the extremities with rest pain, left leg
I70.723	Atherosclerosis of other type of bypass graft(s) of the extremities with rest pain, bilateral legs
I70.728	Atherosclerosis of other type of bypass graft(s) of the extremities with rest pain, other extremity
I70.729	Atherosclerosis of other type of bypass graft(s) of the extremities with rest pain, unspecified extremity
I70.731	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of thigh
I70.732	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of calf

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Diagnosis Code	Description
I70.733	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of ankle
I70.734	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of heel and midfoot
I70.735	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of other part of foot
I70.738	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of other part of lower leg
I70.739	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of unspecified site
I70.741	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of thigh
I70.742	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of calf
I70.743	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of ankle
I70.744	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of heel and midfoot
I70.745	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of other part of foot
I70.748	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of other part of lower leg
I70.749	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of unspecified site
I70.761	Atherosclerosis of other type of bypass graft(s) of the extremities with gangrene, right leg
I70.762	Atherosclerosis of other type of bypass graft(s) of the extremities with gangrene, left leg
I70.763	Atherosclerosis of other type of bypass graft(s) of the extremities with gangrene, bilateral legs
I70.768	Atherosclerosis of other type of bypass graft(s) of the extremities with gangrene, other extremity
I70.769	Atherosclerosis of other type of bypass graft(s) of the extremities with gangrene, unspecified extremity
I72.3	Aneurysm of iliac artery
I72.4	Aneurysm of artery of lower extremity
I72.8	Aneurysm of other specified arteries
I72.9	Aneurysm of unspecified site
I73.00	Raynaud's syndrome without gangrene
I73.01	Raynaud's syndrome with gangrene
I73.1	Thromboangiitis obliterans [Buerger's disease]
I73.81	Erythromelalgia
I74.3	Embolism and thrombosis of arteries of the lower extremities
I74.4	Embolism and thrombosis of arteries of extremities, unspecified
I74.5	Embolism and thrombosis of iliac artery
I74.8	Embolism and thrombosis of other arteries
I74.9	Embolism and thrombosis of unspecified artery
I75.021	Atheroembolism of right lower extremity
I75.022	Atheroembolism of left lower extremity
I75.023	Atheroembolism of bilateral lower extremities
I75.029	Atheroembolism of unspecified lower extremity
I75.89	Atheroembolism of other site
I77.2	Rupture of artery
I77.70	Dissection of unspecified artery
I77.72	Dissection of iliac artery
I77.77	Dissection of artery of lower extremity
I77.79	Dissection of other specified artery
I96	Gangrene, not elsewhere classified
L03.115	Cellulitis of right lower limb
L03.116	Cellulitis of left lower limb

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Diagnosis Code	Description
M86.051	Acute hematogenous osteomyelitis, right femur
M86.052	Acute hematogenous osteomyelitis, left femur
M86.059	Acute hematogenous osteomyelitis, unspecified femur
M86.061	Acute hematogenous osteomyelitis, right tibia and fibula
M86.062	Acute hematogenous osteomyelitis, left tibia and fibula
M86.069	Acute hematogenous osteomyelitis, unspecified tibia and fibula
M86.071	Acute hematogenous osteomyelitis, right ankle and foot
M86.072	Acute hematogenous osteomyelitis, left ankle and foot
M86.079	Acute hematogenous osteomyelitis, unspecified ankle and foot
M86.08	Acute hematogenous osteomyelitis, other sites
M86.09	Acute hematogenous osteomyelitis, multiple sites
M86.10	Other acute osteomyelitis, unspecified site
M86.151	Other acute osteomyelitis, right femur
M86.152	Other acute osteomyelitis, left femur
M86.159	Other acute osteomyelitis, unspecified femur
M86.161	Other acute osteomyelitis, right tibia and fibula
M86.162	Other acute osteomyelitis, left tibia and fibula
M86.169	Other acute osteomyelitis, unspecified tibia and fibula
M86.171	Other acute osteomyelitis, right ankle and foot
M86.172	Other acute osteomyelitis, left ankle and foot
M86.179	Other acute osteomyelitis, unspecified ankle and foot
M86.18	Other acute osteomyelitis, other site
M86.19	Other acute osteomyelitis, multiple sites
M86.20	Subacute osteomyelitis, unspecified site
M86.251	Subacute osteomyelitis, right femur
M86.252	Subacute osteomyelitis, left femur
M86.259	Subacute osteomyelitis, unspecified femur
M86.261	Subacute osteomyelitis, right tibia and fibula
M86.262	Subacute osteomyelitis, left tibia and fibula
M86.269	Subacute osteomyelitis, unspecified tibia and fibula
M86.271	Subacute osteomyelitis, right ankle and foot
M86.272	Subacute osteomyelitis, left ankle and foot
M86.279	Subacute osteomyelitis, unspecified ankle and foot
M86.28	Subacute osteomyelitis, other site
M86.29	Subacute osteomyelitis, multiple sites
M86.30	Chronic multifocal osteomyelitis, unspecified site
M86.351	Chronic multifocal osteomyelitis, right femur
M86.352	Chronic multifocal osteomyelitis, left femur
M86.359	Chronic multifocal osteomyelitis, unspecified femur
M86.361	Chronic multifocal osteomyelitis, right tibia and fibula
M86.362	Chronic multifocal osteomyelitis, left tibia and fibula
M86.369	Chronic multifocal osteomyelitis, unspecified tibia and fibula
M86.371	Chronic multifocal osteomyelitis, right ankle and foot
M86.372	Chronic multifocal osteomyelitis, left ankle and foot
M86.379	Chronic multifocal osteomyelitis, unspecified ankle and foot

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Diagnosis Code	Description
M86.38	Chronic multifocal osteomyelitis, other site
M86.39	Chronic multifocal osteomyelitis, multiple sites
M86.40	Chronic osteomyelitis with draining sinus, unspecified site
M86.451	Chronic osteomyelitis with draining sinus, right femur
M86.452	Chronic osteomyelitis with draining sinus, left femur
M86.459	Chronic osteomyelitis with draining sinus, unspecified femur
M86.461	Chronic osteomyelitis with draining sinus, right tibia and fibula
M86.462	Chronic osteomyelitis with draining sinus, left tibia and fibula
M86.469	Chronic osteomyelitis with draining sinus, unspecified tibia and fibula
M86.471	Chronic osteomyelitis with draining sinus, right ankle and foot
M86.472	Chronic osteomyelitis with draining sinus, left ankle and foot
M86.479	Chronic osteomyelitis with draining sinus, unspecified ankle and foot
M86.48	Chronic osteomyelitis with draining sinus, other site
M86.49	Chronic osteomyelitis with draining sinus, multiple sites
M86.50	Other chronic hematogenous osteomyelitis, unspecified site
M86.551	Other chronic hematogenous osteomyelitis, right femur
M86.552	Other chronic hematogenous osteomyelitis, left femur
M86.559	Other chronic hematogenous osteomyelitis, unspecified femur
M86.561	Other chronic hematogenous osteomyelitis, right tibia and fibula
M86.562	Other chronic hematogenous osteomyelitis, left tibia and fibula
M86.571	Other chronic hematogenous osteomyelitis, right ankle and foot
M86.572	Other chronic hematogenous osteomyelitis, left ankle and foot
M86.579	Other chronic hematogenous osteomyelitis, unspecified ankle and foot
M86.58	Other chronic hematogenous osteomyelitis, other site
M86.59	Other chronic hematogenous osteomyelitis, multiple sites
M86.60	Other chronic osteomyelitis, unspecified site
M86.651	Other chronic osteomyelitis, right thigh
M86.652	Other chronic osteomyelitis, left thigh
M86.659	Other chronic osteomyelitis, unspecified thigh
M86.661	Other chronic osteomyelitis, right tibia and fibula
M86.662	Other chronic osteomyelitis, left tibia and fibula
M86.669	Other chronic osteomyelitis, unspecified tibia and fibula
M86.671	Other chronic osteomyelitis, right ankle and foot
M86.672	Other chronic osteomyelitis, left ankle and foot
M86.679	Other chronic osteomyelitis, unspecified ankle and foot
M86.68	Other chronic osteomyelitis, other site
M86.69	Other chronic osteomyelitis, multiple sites
M86.8X0	Other osteomyelitis, multiple sites
M86.8X5	Other osteomyelitis, thigh
M86.8X6	Other osteomyelitis, lower leg
M86.8X7	Other osteomyelitis, ankle and foot
M86.8X8	Other osteomyelitis, other site
M86.8X9	Other osteomyelitis, unspecified sites
M86.9	Osteomyelitis, unspecified
Q27.30	Arteriovenous malformation, site unspecified

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Diagnosis Code	Description
Q27.32	Arteriovenous malformation of vessel of lower limb
Q27.39	Arteriovenous malformation, other site
Q27.8	Other specified congenital malformations of peripheral vascular system
Q27.9	Congenital malformation of peripheral vascular system, unspecified
Q87.2	Congenital malformation syndromes predominantly involving limbs
S35.511A	Injury of right iliac artery, initial encounter
S35.512A	Injury of left iliac artery, initial encounter
S81.801A	Unspecified open wound, right lower leg, initial encounter
S81.802A	Unspecified open wound, left lower leg, initial encounter
S81.809A	Unspecified open wound, unspecified lower leg, initial encounter
S91.301A	Unspecified open wound, right foot, initial encounter
S91.302A	Unspecified open wound, left foot, initial encounter
S91.309A	Unspecified open wound, unspecified foot, initial encounter
T82.312A	Breakdown (mechanical) of femoral arterial graft (bypass), initial encounter
T82.318A	Breakdown (mechanical) of other vascular grafts, initial encounter
T82.319A	Breakdown (mechanical) of unspecified vascular grafts, initial encounter
T82.338A	Leakage of other vascular grafts, initial encounter
T82.392A	Other mechanical complication of femoral arterial graft (bypass), initial encounter
T82.398A	Other mechanical complication of other vascular grafts, initial encounter
T82.399A	Other mechanical complication of unspecified vascular grafts, initial encounter
T82.818A	Embolism due to vascular prosthetic devices, implants and grafts, initial encounter
T82.868A	Thrombosis due to vascular prosthetic devices, implants and grafts, initial encounter
T82.898A	Other specified complication of vascular prosthetic devices, implants and grafts, initial encounter

Description of Services

Peripheral artery disease (PAD) is a narrowing of vessels due to atherosclerosis that limits blood flow to the limbs. PAD most commonly affects arteries in the legs. While many people with PAD do not have any symptoms, some will have leg pain, numbness, or cramping during exercise that is relieved by rest (Claudication). Risk factors include age, smoking, diabetes, obesity, high blood pressure, and high cholesterol.

PAD is associated with an increased risk of heart attack, stroke, and, when left untreated, can lead to Chronic Limb Threatening Ischemia (CLTI). Treatment options include lifestyle changes, medications, endovascular techniques, and surgery. Endovascular techniques to treat Claudication and CLTI include balloon dilation (angioplasty), stents, endovenous stent grafts, and atherectomy. The technique chosen for endovascular treatment depends on many factors including lesion characteristics such as anatomic location, lesion length, and degree of calcification (Gornik et al., 2024; National Heart, Lung, and Blood Institute website).

Clinical Evidence

Pegler et al. (2025) conducted a systematic review and meta-analysis of randomized controlled trials comparing bypass surgery and endovascular revascularization in lower limb PAD. The population included individuals with intermittent claudication or CLTI undergoing an infrainguinal revascularization procedure. Fourteen cohorts were identified across thirteen studies (n = 3840). The primary outcome was major amputation. Secondary outcomes were mortality, reintervention, 30-day adverse events and 30-day mortality. There was no significant difference in major amputation or mortality between the bypass and endovascular groups. Patients who underwent bypass surgery had a significantly lower rate of reintervention. (The BEST-CLI trial by Farber et al. noted below is included in this review.)

The Best Endovascular Versus Best Surgical Therapy for Patients With Critical Limb Ischemia (BEST-CLI) Trial was a prospective, open label, multicenter, randomized controlled, multidisciplinary, superiority trial comparing treatment efficacy, functional outcomes, and quality of life in patients undergoing endovascular or open surgical revascularization.

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Clinical sites in the United States and internationally enrolled 1830 patients with chronic limb-threatening ischemia (CLTI) and infrainguinal PAD who were candidates for both treatment options. Patients were enrolled into one of two parallel trial cohorts. Patients with suitable single segment of great saphenous vein available for potential bypass were randomized within Cohort 1 (n = 1620), while patients without were randomized within Cohort 2 (n = 480). The primary outcome was a composite of a major adverse limb event (amputation above the ankle or a major limb reintervention) or death from any cause. In Cohort 1, after a median follow-up of 2.7 years, the incidence of a major adverse limb event or death was significantly lower in the surgical group than in the endovascular group. In Cohort 2, after a median follow-up of 1.6 years, the outcomes in the two groups were similar. The incidence of adverse events was similar in the two groups. Because investigators were allowed to use their preferred techniques, there was potential for selection and operator bias. Also, due to funding issues, the follow-up was longer in Cohort 1 than Cohort 2 (Farber et al., 2022). The study was funded by the National Heart, Lung and Blood Institute.

A Cochrane systematic review by Fakhry et al. (2018) assessed the effectiveness of endovascular revascularization compared with no specific therapy for intermittent claudication or compared with a conservative therapy option such as supervised exercise or drug therapy. The review included ten studies with a total of 1,087 participants. The results showed that endovascular revascularization and supervised exercise are comparable treatment options in improving walking distances and quality of life in individuals with intermittent claudication. Combination therapy (endovascular revascularization with either supervised exercise or drug therapy) seemed to result in greater improvements than those seen with supervised exercise or drug therapy alone. (The ERASE trial by Fakhry et al., 2015 and the CLEVER trial by Murphy et al., 2015, which were previously cited in this policy, are included in this systematic review.)

Malgor et al. (2015) conducted a systematic review to evaluate the efficacy of three treatment strategies for individuals with claudication. Primary outcome measures included mortality, amputation, walking distance, quality of life, patency, and measures of blood flow (ABI). The review included eight systematic reviews and 12 trials enrolling 1,548 patients. Compared with medical management, each of the three treatments (surgery, endovascular therapy, and exercise therapy) was associated with improved walking distance, claudication symptoms and quality of life. Evidence supporting superiority of one of the three approaches was limited. However, blood flow parameters improved faster and better with both forms of revascularization compared with exercise or medical management. Compared with endovascular therapy, open surgery may be associated with longer length of hospital stay and higher complication rates but resulted in more durable patency (moderate-quality evidence). (The CLEVER trial by Murphy et al., 2012, which was previously cited in this policy, is included in this systematic review.)

Vemulapalli et al. (2015) conducted a systematic review and a network meta-analysis to evaluate the comparative effectiveness of medical therapy, supervised exercise training, endovascular intervention and surgical revascularization in patients with claudication. Outcomes assessed included walking distance, claudication distance, all-cause mortality and quality of life. Thirty-five studies (n = 7,475) were included in the analysis. A meta-analysis of 16 studies suggested that, compared with usual care, maximal walking measures were improved to a greater extent with supervised exercise than with medical therapy or endovascular intervention. A meta-analysis of 12 studies demonstrated that exercise training and endovascular intervention, but not cilostazol, improved initial claudication measures compared with usual care. A meta-analysis of 13 studies suggested that although all treatment modalities were superior to usual care, there was no significant difference between modalities in respect to quality of life. The authors noted that heterogeneity in functional endpoints, single-arm observational study design and poor subgroup reporting significantly limit comparative effectiveness analysis in PAD. Further studies with attention to study design, standardized efficacy and safety endpoints, and appropriate subgroup reporting are needed. (The multicenter CLEVER trial by Murphy et al., 2012, which was previously cited in this policy, is included in this systematic review.)

Iliac Artery Atherectomy

There is insufficient quality evidence to support the safety and efficacy of iliac artery atherectomy. Most study designs are retrospective, single-arm or non-randomized. Studies include limited number of patients and have heterogeneity in design in terms of patient selection criteria, lesion characteristics, and devices used, which limits the generalizability of the results.

Atherectomy of the iliac artery is uncommon due to the risk of life-threatening perforation. Lee et al. (2018) assessed the feasibility and safety of orbital atherectomy for the treatment of iliac artery disease using retrospective data from the CONFIRM registries. Patients with at least one iliac artery lesion treated with orbital atherectomy (n = 62 patients; n = 68 lesions) were compared to patients with at least one superficial femoral artery lesion treated with orbital atherectomy (n = 1570 patients; n = 1809 lesions). Both groups had similar baseline demographics; however, the iliac artery group had a lower prevalence of diabetes. For lesion characteristics, the iliac artery group had shorter lesions and a higher percentage of severely calcified lesions. Procedural complication rate was defined as the composite of flow limiting dissection, perforation, slow flow, vessel closure, spasm, embolism, or thrombosis. The iliac group had one reported perforation and

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one reported vessel closure. The procedural complication rate was low in both groups; however, it was significantly lower in the iliac artery group. The authors note that a randomized trial with long-term follow-up is needed to determine the ideal revascularization strategy for patients with calcified iliac artery disease. The study is limited by the possible bias associated with observational design.

Endovenous Femoropopliteal Bypass

The DETOUR system utilizes a novel endovenous femoropopliteal bypass procedure for treating patients with moderate to severe PAD who have long occlusive lesions of the superficial femoral artery. The system uses stents routed through the femoral vein to restore blood flow to the leg. Clinical trials are ongoing. Larger high-quality studies evaluating the safety and efficacy of the procedure and comparing the DETOUR system with open surgical bypass are needed.

An ECRI Clinical Evidence Assessment stated that the DETOUR stent graft system appears to be safe and provides a less invasive treatment option for patients who may otherwise require open bypass surgery. Two available single-arm clinical trials reported participants experienced functional improvements one to three years after treatment with the DETOUR system, with relatively high primary patency and freedom from adverse events despite their lesion's large size and severity. However, available studies provide very-low-quality evidence that does not enable firm conclusions, and no studies compared the DETOUR system with other treatments for long-segment femoropopliteal occlusions and their effect on patient-oriented outcomes including adverse events, revascularization, and functional status (ECRI, 2023).

The DETOUR 2 investigational device exemption study is an ongoing prospective, single-arm, multicenter non-randomized study to evaluate the safety and effectiveness of the DETOUR system for percutaneous femoropopliteal bypass. A total of 202 participants in the United States and Europe with severe femoropopliteal artery disease were enrolled, with 200 treated with the DETOUR system. Prespecified end points included primary safety (composite of major adverse events) at 30 days, and effectiveness (primary patency defined as freedom from restenosis or clinically driven target lesion revascularization) at one year. The mean lesion length was 32.7 cm, of which 96% were chronic total occlusions and 70% were severely calcified. Technical success was achieved in 100% of patients treated. The primary safety end point was met with a 30-day freedom from major adverse event rate of 93.0%. The 1-year primary effectiveness end point was met with 72.1% primary patency at 12 months. Primary-assisted and secondary patency were 77.7% and 89.0%, respectively, at 12 months. The 12 month deep venous thrombosis incidence was 4.1% with no pulmonary emboli reported. Venous quality-of-life scores showed no significant changes from baseline. There was a Rutherford improvement of at least one class through 12 months in 97.2% of patients. The mean ankle-brachial index (ABI) also improved from 0.61 to 0.95 during this period. The authors also noted marked improvements in quality of life and functional status measures. This study is limited by lack of randomization, long-term follow-up and comparison to open surgical bypass (Lyden et al., 2024).

DETOUR I was a prospective, single-arm, multicenter non-randomized study with 78 participants. Technical and procedural success during the index procedure were both 96%. Primary stent graft patency rates were 81% at year one and 79% at year two. The authors concluded that the DETOUR system was a safe and effective percutaneous alternative to open surgical bypass (Krievins et al., 2020; Halena et al, 2022). Due to the novel transvenous approach of the DETOUR system and risk of thromboembolic complications, venous outcomes were also evaluated in the DETOUR I study. At one year, Schneider et al. (2021) reported a low rate of deep venous thrombotic and obstructive complications. Cross-sectional femoral vein luminal area was preserved, and in some participants, the compensatory vein diameter increased over time. After evaluating a subset of patients enrolled at one study site, Rumba et al. (2022) reported three-year results. (This study is included in the ECRI 2023 report). The femoral and popliteal vein remained patent with no compensatory enlargement, and there were no significant changes in venous symptom scores or physiologic function. The study is limited by the single-arm study design.

Clinical Practice Guidelines

American College of Cardiology (ACC)/American Heart Association (AHA)/Society for Cardiovascular Angiography and Interventions (SCAI)/Society of Interventional Radiology (SIR)/Society for Vascular Medicine (SVM)

In a multi-society report, Bailey et al. (2019) published appropriate use criteria for peripheral artery interventions. The panel recommends that patients with PAD and intermittent claudication should first be treated with guideline-directed medical therapy and structured exercise. Revascularization should be considered only in patients who continue to have lifestyle-limiting claudication despite these noninvasive approaches. In situations where medical therapy is insufficient, the selection of surgical or endovascular revascularization depends on several factors including patient risk level and lesion characteristics, such as anatomic location, length and presence of stenosis or occlusion. The panel also addresses secondary treatment options for lower extremity disease and considers endovascular procedures for in-stent restenosis appropriate in individuals with recurrent symptoms. The criteria indicate that atherectomy of the iliac artery is rarely

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appropriate in all clinical scenarios. This rating is due to an absence of data supporting the use of this technology compared with balloon angioplasty and stenting. For patients with CLTI, both endovascular or surgical revascularization procedures are considered appropriate and critical for the reduction of high morbidity and mortality rates associated with limb loss and cardiovascular events.

American Heart Association (AHA)/American College of Cardiology (ACC)

AHA/ACC guidelines for the management of lower extremity PAD address revascularization procedures for atherosclerotic and thrombotic disease and include diseases of the aortoiliac, femoropopliteal, and infrapopliteal arterial segments. The guidelines were developed in collaboration with the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), American Podiatric Medical Association (APMA), Association of Black Cardiologists (ABC), Society for Cardiovascular Angiography and Interventions (SCAI), Society for Vascular Medicine (SVM), Society for Vascular Nursing (SVN), Society for Vascular Surgery (SVS), Society of Interventional Radiology (SIR), and Vascular & Endovascular Surgery Society (VESS) (Gornik et al., 2024).

International Working Group on the Diabetic Foot (IWGDF)

IWGDF guidelines on the prevention and management of diabetes-related foot disease state that in patients with either an ankle pressure < 50mm Hg or an ABI < 0.4, consider urgent vascular imaging, always with detailed visualization of below-the-knee and pedal arteries, and revascularization. Also consider urgent assessment for revascularization if the toe pressure is < 30 mmHg or $TcPO_2$ is < 25 mmHg. Clinicians might also consider revascularization at higher pressure levels in patients with extensive tissue loss or infection (Schaper et al., 2024).

National Institute for Health and Care Excellence (NICE)

A National Institute for Health and Care Excellence (NICE) clinical guideline offers recommendations on the management of PAD (NICE, 2012; updated 2020).

Society for Vascular Surgery (SVS)

SVS guidelines provide a comprehensive set of recommendations for the evaluation and management of CLTI. Vein bypass may be preferred for average-risk patients with advanced limb threat and high complexity disease, while those with less complex anatomy, intermediate severity limb threat or high patient risk may be favored for endovascular intervention. All patients with CLTI should be afforded best medical therapy including the use of antithrombotic, lipid-lowering, antihypertensive and glycemic control agents, as well as counseling on smoking cessation, diet, exercise and preventive foot care (Conte et al., 2019).

In 2015, the SVS published a comprehensive set of recommendations for the evaluation and management of asymptomatic PAD and intermittent claudication (Conte et al., 2015). First-line treatment approaches for intermittent claudication include patient education, risk factor reduction, smoking cessation, optimization of medical therapies (OMT), and exercise. Revascularization in appropriately selected patients can relieve pain and improve function and health-related quality of life. Decision-making is complex and individualized, based on symptom severity, comorbid conditions, response to exercise/OMT, anatomic pattern of disease and risk/benefit for the proposed intervention. A 2025 focused update (Conte et al., 2025; Saadi et al., 2025) presented the following statements regarding revascularization:

- We recommend against performing revascularization in patients with asymptomatic PAD or intermittent claudication based solely on hemodynamic measurements or imaging findings. There is no evidence to support the use of revascularization for modifying disease progression. Level of recommendation: Grade 1; Level of evidence: C.
- In patients with intermittent claudication and no signs of CLTI, we suggest against the use of infrapopliteal revascularization, either alone or in combination with a more proximal intervention, due to lack of evidence of benefit and potential harm. Level of recommendation: Grade 2; Level of evidence: C.
- In patients with intermittent claudication who are selected for an endovascular intervention to treat femoropopliteal disease and have lesions exceeding 5 cm in length, we recommend the use of either bare metal stents or drug-eluting devices (balloons or stents) over plain balloon angioplasty to reduce the risk of restenosis and need for reintervention. Level of recommendation: Grade 1; Level of evidence: B.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA has approved several stents and stent systems for the treatment of PAD of the lower extremities. Refer to the following website (use product codes NIO and NIP) for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed July 23, 2025)

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The FDA has approved several catheter systems used for the treatment of PAD of the lower extremities. Refer to the following website (use product code DQY) for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 23, 2025)

In June 2020, the DETOUR system (Endologix) received FDA designation as a Breakthrough Device. The system consists of the TORUS stent graft and the ENDOCROSS™ Device. On June 7, 2023, the FDA granted full premarket approval of the DETOUR System for percutaneous revascularization in patients with symptomatic femoropopliteal lesions from 200 mm to 460 mm in length with chronic total occlusions (100 mm to 425 mm) or diffuse stenosis > 70% who may be considered suboptimal candidates for surgical or alternative endovascular treatments. The DETOUR System, or any of its components, is not for use in the coronary and cerebral vasculature. Refer to the following website for more information. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P220021.
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Policy History/Revision Information

Date	Summary of Changes

03/01/2026	**Coverage Rationale**
	• Revised medically necessary coverage criteria for endovascular revascularization procedures (e.g., stents, angioplasty, and/or atherectomy) for treating non-limb-threatening lower extremity ischemia in individuals with Claudication due to atherosclerotic disease of the aortoiliac and/or femoropopliteal arteries; replaced criterion requiring "imaging results show anatomic location and *severity of occlusion* (stenosis ≥ 50%) [e.g., duplex ultrasound, computed tomography angiography (CTA), magnetic resonance angiography (MRA) or *invasive* angiography]" with "imaging results *of the target vessel* (e.g., duplex ultrasound, computed tomography angiography (CTA), magnetic resonance angiography (MRA), or *digital subtraction* angiography) show anatomic location and *a moderate-severe* stenosis (50% or greater)"
	• Added language to indicate retreatment of a previously treated vessel due to in-stent restenosis is proven and medically necessary for treating non-limb-threatening lower extremity ischemia in individuals with Claudication due to atherosclerotic disease of the aortoiliac and/or femoropopliteal arteries when all the following criteria are met:
	  ○ Recurrent symptoms
	  ○ Impaired ability to work and/or perform activities of daily living (ADL)
	  ○ Imaging results of the previously treated vessel [e.g., duplex ultrasound, computed tomography angiography (CTA), magnetic resonance angiography (MRA), or digital subtraction angiography] show anatomic location and a moderate-severe stenosis (50% or greater); if duplex ultrasound does not demonstrate a stenosis of 50% or greater, another imaging modality will be necessary to demonstrate the extent of stenosis
	Medical Records Documentation Used for Reviews
	• Added language to indicate:
	  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service
	  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested
	  ○ The patient's medical record must contain documentation that fully supports the medical necessity for the requested services

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Date	Summary of Changes
	○ This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures ○ Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CSNCT0602.03

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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