

Medical Coverage Policy | Percutaneous Revascularization Procedures for Lower Extremity Peripheral Arterial Disease



EFFECTIVE DATE: 12|01|2025

POLICY LAST REVIEWED: 01|21|2026

OVERVIEW

Revascularization (either surgical or percutaneous) is a treatment option for certain individuals with lower extremity peripheral arterial disease. Percutaneous revascularization procedures include balloon angioplasty, stent procedures, and atherectomy. Lithotripsy is proposed as a vessel preparation option to facilitate definitive endovascular treatment in heavily calcified lesions.

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

CPT Codes 0238T, 0505T, C7531, C7534, C7535

Percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy in individuals with chronic symptomatic lower extremity peripheral arterial disease may be considered medically necessary when the following criteria are met:

- Functionally limiting claudication; AND
- Inadequate response to guideline-directed management and therapy (GDMT), including structured exercise; AND
- Potential benefits of revascularization on quality of life, walking performance, and functional status outweigh the risks and durability of the intervention and possible need for repeated procedures.

Percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy for treatment of chronic limb-threatening ischemia may be considered medically necessary.

Percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy for treatment of acute limb ischemia may be considered medically necessary.

Percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy in individuals with asymptomatic lower extremity peripheral arterial disease may be considered medically necessary if needed for the safety, feasibility, or effectiveness of other invasive, clinically necessary, life-saving procedures (e.g., transfemoral aortic valve replacement, mechanical circulatory support, endovascular aortic aneurysm repair).

PRIOR AUTHORIZATION

Medicare Advantage Plans and Commercial Products

CPT Codes 0238T, 0505T, C7531, C7534, C7535

Prior authorization is required for Medicare Advantage Plans and is recommended for Commercial Products.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

CPT Codes 0238T, 0505T, C7531, C7534, C7535

Percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy is considered medically necessary when the medical criteria above is met.

Percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products when the medical criteria above is not met as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CPT/HCPCS Codes 37262, 37279, C9764, C9765, C9766, C9767, C9772, C9773, C9774, C9775:

Percutaneous revascularization using lithotripsy in individuals with lower extremity peripheral arterial disease is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products in all situations as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable surgery benefits/coverage.

BACKGROUND

Peripheral Arterial Disease

Guidelines recognize 4 clinical subsets of peripheral arterial disease (PAD).

- Asymptomatic PAD is characterized by reporting of no leg symptoms. Patients with asymptomatic PAD may adapt their activity to avoid leg pain. Those who report no exertional leg symptoms may develop symptoms during an objective walking test. These patients have functional impairment that is comparable to those with claudication.
- Chronic symptomatic PAD (claudication) is characterized by exertional leg symptoms that can limit walking and resolve with rest. Typical claudication symptoms may be described as a pain, aching, cramping, or tired/fatigued feeling located in the buttocks, thigh, calf, or foot that occurs consistently during walking, does not start at rest, does not improve during walking, and is usually relieved within approximately 10 minutes of rest. Leg symptom descriptors also include tingling, numbness, burning, throbbing, or shooting. Chronic symptomatic PAD is associated with significant functional (walking) impairment. It is estimated that only one-third of patients with PAD present with symptoms of typical claudication, while most patients with PAD present with other exertional leg symptoms not typical of claudication. All patients with chronic symptomatic PAD, including those with atypical symptoms, have walking impairment.
- Chronic limb-threatening ischemia (CLTI) is a severe clinical subset of PAD, associated with ischemic rest pain, nonhealing wounds or ulcers, or gangrene with symptoms present longer than 2 weeks.
- Acute limb ischemia is the most severe clinical subset of PAD. It is characterized by a sudden decrease in arterial perfusion of the leg that threatens the viability of the limb. Causes of ALI include embolism, thrombosis within the native artery or at site of previous revascularization (graft or stent), trauma, peripheral aneurysm with distal embolization, or thrombosis. Severity is further classified using the Rutherford classification system (viable, salvageable/marginally threatened, salvageable/immediately threaten, irreversible).

Prevalence and Risk Factors

Patients at risk for PAD are identified based on demographic features, cardiovascular risk factors, or the presence of atherosclerotic vascular disease in other vascular beds. Black race is associated with increased risk for PAD, even after adjustment for conventional risk factors, and is also associated with major adverse cardiovascular events (MACE) and major adverse limb events.

Screening and Diagnosis

Clinical assessment, including risk factor assessment, history, physical examination, and consideration of differential diagnoses, is performed before diagnostic testing.

For individuals at increased risk of PAD, vascular examination with a focus on the lower extremities is recommended. After the history and physical examination identify patients at risk for PAD and with history of physical examination symptoms or signs of PAD, diagnostic testing to establish the diagnosis of PAD is

performed. Diagnostic testing for suspected PAD incorporates history and physical examination, ankle-brachial index (ABI), and additional physiological testing, as well as noninvasive and potentially invasive (angiography) imaging.

Measurement of the ankle-brachial index (ABI) is the primary method for establishing the diagnosis of PAD. Inpatients with history or physical examination findings suggestive of PAD, the resting ABI, with or without ankle pulse volume recordings (PVR) and/or Doppler waveforms, is recommended to establish the diagnosis. The resting ABI is reported as abnormal (<0.90), borderline ($0.91-0.99$), normal ($1.00-1.40$), or noncompressible (>1.40). In individuals with suspected chronic symptomatic PAD and normal or borderline resting ABI, exercise ABI can be performed.

Chronic Symptomatic Peripheral Arterial Disease

Diagnostic testing for suspected peripheral arterial disease (PAD) requires a multi-faceted approach that incorporates history and physical examination, ankle-brachial index (ABI), and additional physiological testing, as well as noninvasive and potentially invasive (angiography) imaging. Individuals with chronic symptomatic PAD report claudication or other non-joint-related exertional leg symptoms that limit walking performance.

Functional Status

Functional status is defined as an individual's ability to meet basic needs, fulfill usual roles, and maintain health and well-being (activities of daily living). Walking ability and performance, and mobility are components of functional status. Treadmill exercise ABI testing can be used to objectively assess functional status and walking performance. Among individuals with chronic symptomatic PAD, this exercise assessment can be used as a baseline measure of functional status and for evaluation of response to therapy.

Treatment

Standard treatment for claudication includes medical therapy, foot care, and structured exercise therapy. Percutaneous revascularization includes catheter-based revascularization procedures using modalities such as percutaneous transluminal (balloon) angioplasty, drug-coated balloon angioplasty, stenting (bare-metal, drug-coated, or covered), and atherectomy.

Revascularization, either percutaneous or surgical, is the standard treatment for CLTI.

Structured Exercise Programs for Peripheral Arterial Disease

A structured exercise program is an exercise program planned by a qualified health care professional that provides recommendations for exercise training with a goal of improving functional status over time. The program provides individualized recommendations for frequency, intensity, time, and type of exercise. Structured exercise programs are classified as supervised exercise therapy or structured community-based exercise programs. In supervised exercise therapy, training is performed for a minimum of 30 to 45 minutes per 60-minute session. Supervised sessions are performed at least 3 times per week for a minimum of 12 weeks.

Shared Decision Making

Clinical practice guidelines state, "Patient-centered discussions are critical in making appropriate decisions regarding revascularization and for building a trusting longitudinal relationship. More than 70% of patients prefer to have an active role in determining their treatment plan for claudication. Such discussions should be undertaken when considering whether to undergo a revascularization procedure, its timing, and approach for revascularization (ie, endovascular or surgical), and should take into account the patient's goals, treatment preferences, and perception of risk. Patient engagement is also essential to facilitate smoking cessation, medication adherence, and participation in structured exercise."

Regulatory Status

In 2016, the Shockwave Medical Peripheral Lithotripsy (IVL) System received 510(k) clearance for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the

iliac, femoral, ilio-femoral, popliteal, intrapopliteal, and renal arteries and is not for use in the coronary or cerebral vasculature. Initial clearance was based on a determination that the device was substantially equivalent to legally marketed predicate devices. The primary predicate for the Shockwave Medical Lithoplasty System is the Spectranetics, Inc. AngioSculpt PTA Scoring Balloon Catheter. Additional predicates were the Bard Peripheral Vascular VascuTrak PTA Dilatation Catheter and the EKOS Corporation EKOS Lysus Micro-Infusion System.

For individuals who are adults with symptomatic lower extremity peripheral arterial disease who receive percutaneous revascularization with balloon angioplasty, stent procedures, or atherectomy, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. Multiple studies have demonstrated that percutaneous and surgical revascularization for chronic symptomatic PAD can improve symptoms and quality of life in individuals who have not responded to guideline directed medical treatment, including structured exercise. Guidelines recommend that the choice to proceed to revascularization and selection of procedure should be a shared decision-making process, based on clinical presentation, including severity of symptoms and anticipated natural history; degree of functional limitation and QOL impairment; response to medical therapy, including structured exercise; and the likelihood of a beneficial short- and longer-term outcome, balanced against potential short-term (eg, bleeding, infection, major adverse cardiac events), and longer-term procedural risk. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with chronic limb-threatening ischemia (CLTI) who receive percutaneous revascularization with balloon angioplasty, stent procedures, or atherectomy, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. Revascularization is considered the standard treatment for patients with CLTI to minimize tissue loss and preserve a functional limb and ambulatory status. Both endovascular and surgical revascularization have been demonstrated to be effective treatments for preventing amputation in CLTI. In a systematic review of 13 studies of patients with CLTI enrolled in medical and angiogenic therapy trials who did not receive revascularization, a 22% all-cause mortality rate and a 22% rate of major amputation at a median follow-up of 12 months were observed. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with acute limb ischemia who receive percutaneous revascularization with balloon angioplasty, stent procedures, or atherectomy, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. A systematic review consisting of randomized controlled trials and observational studies demonstrated surgical revascularization is an effective treatment in patients with acute limb ischemia. Thrombolysis was associated with a higher incidence of major vascular events compared to surgical treatment (6.5% vs 4.4%). Both thrombolysis and surgery have comparable limb salvage rates, but thrombolysis carries a higher risk of hemorrhagic complications. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with symptomatic lower extremity peripheral arterial disease (PAD) who receive percutaneous revascularization using lithotripsy, the evidence includes 1 RCT and nonrandomized studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. The RCT demonstrated primary patency at 1 year was superior in the lithotripsy group compared to the control group (80.5% vs 68.0%, $P=.017$). A major limitation of the study was a lack of comparison to other percutaneous revascularization procedures. The nonrandomized studies are limited by their lack of a control group, small sample sizes, and heterogeneity in clinical and procedural characteristics. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with asymptomatic lower extremity peripheral arterial disease (PAD) who receive percutaneous revascularization using any procedure, the evidence includes RCTs, observational

studies, and systematic reviews. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. Although some individuals with asymptomatic PAD will progress to symptomatic disease, there is no evidence that performing early invasive revascularization procedures leads to a reduction in the development of symptomatic disease. Further, there is evidence that undergone are vascularization procedure are at increased risk of subsequent complications, including the need for additional subsequent revascularization procedures. Therefore, the risks of the procedure do not outweigh any proposed benefits. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT and HCPCS codes are considered medically necessary when the medical criteria above has been met:

- 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 road mapping 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
- C7531** Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(ies), unilateral, with transluminal angioplasty with intravascular ultrasound (initial noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation
- C7534** Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(ies), unilateral, with atherectomy, includes angioplasty within the same vessel, when performed with intravascular ultrasound (initial noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation
- C7535** Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(ies), unilateral, with transluminal stent placement(s), includes angioplasty within the same vessel, when performed, with intravascular ultrasound (initial noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation

The following HCPCS code(s) are considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

- 37262** Intravascular lithotripsy(ies), iliac vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (list separately in addition to code for primary procedure) (New Code Effective 1/1/2026)
- 37279** Intravascular lithotripsy(ies), femoral and popliteal vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (list separately in addition to code for primary procedure) (New Code Effective 1/1/2026)
- C9764** Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed
- C9765** Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
- C9766** Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed
- C9767** Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed

- C9772** Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed
- C9773** Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
- C9774** Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed
- C9775** Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed

RELATED POLICIES

Prior Authorization of Services, Treatments or Procedures

PUBLISHED

Provider Update, March 2026

Provider Update, October 2025

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