LifeWise
Health Plan of Washington

# MEDICAL POLICY – 7.01.594

# Percutaneous Revascularization Procedures for Lower Extremity Peripheral Arterial Disease

BCBSA Ref. Policy: 7.01.178

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|---|---|---|
| Effective Date: | April 6, 2025 | RELATED MEDICAL POLICIES: |
| Last Revised: | Dec. 10, 2024 | 8.01.55 Stem Cell Therapy for Peripheral Arterial Disease |
| Replaces: | 7.01.178 | |

**Select a hyperlink below to be directed to that section.**



∞ Clicking this icon returns you to the hyperlinks menu above.

## Introduction

Peripheral arterial disease (PAD) occurs when arteries in the lower body become narrowed or blocked due to plaque buildup, reducing blood supply and causing pain, cramping, or sores that don't heal. Percutaneous revascularization procedures for lower extremity PAD are minimally invasive treatments used to restore blood flow to the legs and feet. These procedures involve inserting a thin tube (catheter) through the skin into the blocked artery. Using imaging guidance, doctors use techniques such as:

- Angioplasty: Inflating a small balloon to open the artery.
- Stenting: Placing a metal mesh tube to keep the artery open.
- Atherectomy: Removing plaque from the artery walls.

These treatments are intended to improve circulation, relieve symptoms, and prevent serious complications, such as infections or amputations, without requiring open surgery. This policy describes when percutaneous revascularization procedures may be considered medically necessary.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

| Procedure | Medical Necessity |
|---|---|
| **Percutaneous revascularization using:**<br>• **Balloon angioplasty**<br>• **Stent procedures**<br>• **Atherectomy** | **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:**<br>• Functionally limiting claudication (e.g., impairment of activities of daily living, difficulty ambulating) (see **Related Information**)<br>**AND**<br>• Inadequate response to 3 months of conservative therapy, including structured exercise (see **Related Information)**, pharmacologic therapy (e.g., anti-platelet [aspirin, clopidogrel], cilostazol), and attempted smoking cessation, if applicable<br>**AND**<br>• Documentation of occlusive arterial disease with one of the following:<br>  ○ Ankle-brachial index (ABI) ≤ 0.90 (i.e., resting or exercise) (see **Appendix**)<br>  ○ Monophasic waveform by ultrasound (see **Related Information**)<br>**AND**<br>• Confirmed anatomical location of significant occlusive disease (stenosis of >50%) by non-invasive or invasive evaluation (e.g., Duplex ultrasound, CT angiography, MR angiography) or contrast injection angiography<br><br>**Percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy for treatment of chronic** |

| Procedure | Medical Necessity |
|---|---|
| | **limb-threatening ischemia may be considered medically necessary when ALL the following criteria are met**<br>• **One** or more of the following is present:<br>  ○ Ischemic rest pain<br>  ○ Non-healing wound(s)/ulcers (present for ≥2 weeks duration)<br>  ○ Gangrene in one or both legs<br>**AND**<br>• Documentation of occlusive arterial disease with one of the following:<br>  ○ Ankle-brachial index (ABI) ≤ 0.90 (i.e., resting or exercise) (see **Appendix**)<br>  ○ Monophasic waveform by ultrasound (see **Related Information**)<br>**AND**<br>• Confirmed anatomical location of significant occlusive disease (stenosis of >50%) by non-invasive or invasive evaluation (e.g., Duplex ultrasound, CT angiography, MR angiography) or contrast injection angiography<br><br>**Percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy for treatment of acute limb ischemia may be considered medically necessary**<br><br>**Percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy in individuals with asymptomatic lower extremity peripheral arterial disease is considered not medically necessary** |

| Procedure | Investigational |
|---|---|
| **Percutaneous revascularization using:**<br>• **Lithotripsy** | **Percutaneous revascularization using lithotripsy in individuals with lower extremity peripheral arterial disease is considered investigational in all situations.** |

## Documentation Requirements

**The patient's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:**

- For chronic symptomatic lower extremity peripheral arterial disease with all of the following:
  - Functionally limiting claudication (e.g., impairment of activities of daily living, difficulty ambulating), **AND**
  - Inadequate response to 3 months of conservative therapy, including structured exercise, pharmacologic therapy (e.g., anti-platelet [aspirin, clopidogrel], cilostazol), and attempted smoking cessation, if applicable, **AND**
  - Documentation of occlusive arterial disease with one of the following:
    - Ankle-brachial index (ABI) ≤ 0.90 (i.e., resting or exercise)
    - Monophasic waveform by ultrasound, **AND**
  - Confirmed anatomical location of significant occlusive disease (stenosis of >50%) by non-invasive or invasive evaluation (e.g., Duplex ultrasound, CT angiography, MR angiography) or contrast injection angiography
- For chronic limb-threatening ischemia with all of the following:
  - **One** or more of the following is present:
    - Ischemic rest pain
    - Non-healing wound(s)/ulcers (present for ≥2 weeks duration)
    - Gangrene in one or both legs, **AND**
  - Documentation of occlusive arterial disease with one of the following:
    - Ankle-brachial index (ABI) ≤ 0.90 (i.e., resting or exercise)
    - Monophasic waveform by ultrasound, **AND**
  - Confirmed anatomical location of significant occlusive disease (stenosis of >50%) by non-invasive or invasive evaluation (e.g., Duplex ultrasound, CT angiography, MR angiography) or contrast injection angiography
- For treatment of acute limb ischemia

## Coding

| Code | Description |
|---|---|
| **CPT** | |
| 37220 | Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty |

| Code | Description |
|---|---|
| 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 |
| 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) |

| Code | Description |
|---|---|
| 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) |
| O505T | 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 |
| 0238T | Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel |
| **HCPCS** | |
| 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 |
| 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 |

| Code | Description |
|---|---|
| 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 Information

## Definition of Terms

**Claudication** is pain or cramping in a muscle group (usually of the lower extremity or buttocks) that occurs with walking or exercise and is relieved with rest. It is a symptom of peripheral artery disease. The word is derived from the Latin term, "to limp."

**Monophasic waveform by ultrasound** is an abnormal ultrasound finding that is seen downstream from stenoses or in collateral vessels formed around the occlusive disease

## 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.

## 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-minutes 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 individuals 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 (i.e., endovascular or surgical), and should take into account the individual's goals, treatment preferences, and perception of risk. Individual engagement is also essential to facilitate smoking cessation, medication adherence, and participation in structured exercise."[1,]

## Evidence Review

### Description

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.

### Background

### Peripheral Arterial Disease

Guidelines recognize four clinical subsets of peripheral arterial disease (PAD).[1,]

- Asymptomatic PAD is characterized by reporting of no leg symptoms. Individuals 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 individuals 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 individuals with PAD present with symptoms of typical claudication, while most individuals with PAD present with other exertional leg symptoms not typical of claudication. All individuals 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 threatened, irreversible.

## Prevalence and Risk Factors

Individuals 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.[2,3]

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 individuals 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. In individuals 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 ($\leq$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.

## 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.

## Summary of Evidence

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 (e.g., 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 individuals 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 individuals 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 individuals 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 individuals who have undergone a revascularization 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.

## Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1**.

## Table 1. Summary of Key Trials

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| **Ongoing** | | | |
| NCT06112171 | Performance of the Shockwave Medical Peripheral Lithotripsy System vs Standard Balloon Angioplasty for Lesion Preparation Prior to Supera Stent Implantation in the Treatment of Symptomatic Severely Calcified Femoropopliteal Lesions in PAD (CRACK-IT) | 120 | Dec 2030 |
| NCT06457685[a] | Pulse Intravascular Lithotripsy™ (Pulse IVL™) to Open Vessels With Calcific Walls and Enhance Vascular Compliance and Remodeling for Peripheral Artery Disease (POWER PAD 2) | 120 | Mar 2026 |
| NCT05007925[a] | Prospective, Multi-center, Single-arm Study of the Shockwave Medical Peripheral Intravascular Lithotripsy (IVL) System for Treatment of Calcified Peripheral Arterial Disease (PAD) in Below-the-Knee (BTK) Arteries | 250 | Oct 2025 |

NCT: national clinical trial. [a] Denotes industry-sponsored or cosponsored trial.

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that

are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## American College of Cardiology/American Heart Association, 2024

In 2024, the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines published a Guideline for the Management of Lower Extremity PAD.[1,] The Guideline was developed in collaboration with and endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Podiatric Medical Association, Association of Black Cardiologists, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine, Society for Vascular Nursing, Society for Vascular Surgery, Society of Interventional Radiology, and Vascular & Endovascular Surgery Society. The Guideline included the following statements relevant to this policy (**Table 2** and **Table 3**):

## Table 2. Revascularization for Asymptomatic Peripheral Artery Disease

| Recommendation | Class of Recommendation | Level of Evidence |
|---|---|---|
| 1. In patients with asymptomatic PAD, it is reasonable to perform revascularization procedures (endovascular or surgical) to reconstruct diseased arteries if needed for the safety, feasibility, or effectiveness of other procedures (e.g., transfemoral aortic valve replacement, mechanical circulatory support, endovascular aortic aneurysm repair). | 2A | B-NR |
| 2. In patients with asymptomatic PAD, revascularization procedures (endovascular or surgical) should not be performed solely to prevent progression of disease. | 3 | b-NR |

## Table 3. Revascularization for Claudication (Chronic Symptomatic Peripheral Artery Disease)

| Recommendation | Class of Recommendation | Level of Evidence |
|---|---|---|

| | | |
|---|---|---|
| 1. In patients with **functionally limiting claudication** who are being considered for revascularization, potential benefits with respect to QOL, walking performance, and overall functional status should be weighed against the risks and durability of intervention and possible need for repeated procedures | 1 | B-NR |
| 2. In patients with **functionally limiting claudication** and an inadequate response to GDMT (including structured exercise), revascularization is a reasonable treatment option to improve walking function and QOL | 2a | B-R |
| 3. In patients with **claudication who have had an adequate clinical response to GDMT** (including structured exercise), revascularization is not recommended. | 3: No Benefit | C-EO |
| 4. In patients with **functionally limiting claudication and hemodynamically significant aortoiliac or femoropopliteal disease with inadequate response to GDMT** (including structured exercise), endovascular revascularization is effective to improve walking performance and QOL. | 1 | A |
| 5. In patients with functionally limiting claudication and hemodynamically significant aortoiliac or femoropopliteal disease with inadequate response to GDMT (including structured exercise), surgical revascularization is reasonable if perioperative risk is acceptable, and technical factors suggest advantages over endovascular approaches | 2a | B-NR |
| 6. In patients with functionally limiting claudication and hemodynamically significant common femoral artery disease with inadequate response to GDMT (including structured exercise), surgical endarterectomy is reasonable, especially if endovascular approaches adversely affect profunda femoris artery pathways | 2a | B-R |
| 7. In patients with functionally limiting claudication and hemodynamically significant common femoral artery disease with inadequate response to GDMT (including structured exercise), endovascular approaches may be considered in those at high risk for surgical revascularization and/or if anatomical factors are favorable (i.e., no adverse effect on profunda femoris artery pathways). | 2b | B-R |
| 8. In patients with functionally limiting claudication and isolated hemodynamically significant infrapopliteal disease with inadequate response to GDMT (including structured exercise), the effectiveness of endovascular revascularization is unknown | 2b | C-LD |

| | | |
|---|---|---|
| 9. In patients with functionally limiting claudication and isolated hemodynamically significant infrapopliteal disease with inadequate response to GDMT (including structured exercise), the effectiveness of surgical revascularization is unknown. | 2b | C-LD |

The Guideline states that "The appropriateness of particular endovascular therapies for the treatment of claudication is beyond the scope of this document but has been addressed in other multisocietal statements" and cites the statements detailed below.

## American College of Cardiology, et al (2018)

In 2018, the American College of Cardiology, American Heart Association/Society for Cardiovascular Angiography and Intervention, Society of Interventional Radiology, and Society for Vascular Medicine published Appropriate Use Criteria for Peripheral Artery Intervention.[47,] Appropriate use scores for endovascular treatment of relevant indications are shown in **Table 4.**

## Table 4. Appropriate Use Criteria for Peripheral Artery Intervention

| Indication | Appropriate Use Score for Endovascular Treatment |
|---|---|
| Intermittent Claudication; No Prior Guideline-Directed Medical Therapy | Rarely Appropriate (2) |
| **Intermittent Claudication Despite Guideline-Directed Medical Therapy—Stenotic Lesions** | |
| Aortoiliac | Appropriate (8) |
| Superficial femoral artery and popliteal artery | Appropriate (7) |
| Below the knee | May Be Appropriate (5) |
| **Intermittent Claudication Despite Guideline-Directed Medical Therapy—Chronic Total Occlusion** | |

| | |
|---|---|
| Aortoiliac | Appropriate (7) |
| Superficial femoral artery and popliteal artery | May Be Appropriate (6) |
| Below the knee | May Be Appropriate (4) |
| **Critical Limb Ischemia** | |
| Aortoiliac | Appropriate (8.5) |
| Superficial femoral artery and popliteal artery | Appropriate (8) |
| Below the knee | Appropriate (8) |
| **Access in Support of Other Life-Saving Interventions** | |
| Access for coronary intervention | Appropriate (7) |
| Access for hemodynamic support | Appropriate (7) |
| Access for large vascular or valvular intervention | Appropriate (7) |

The document also includes appropriate criteria for choice of endovascular procedure (atherectomy, balloon angioplasty, or stent) for different clinical situations, but does not mention lithotripsy.

## Society for Interventional Radiology

In 2020, the Society for Interventional Radiology published guidelines on device selection in aorto-iliac arterial interventions.[48] The guidelines provide recommendations for the use of balloon angioplasty, stent procedures, and atherectomy in different clinical situations. Although specific guidelines for lithotripsy are not mentioned, the document mentions lithotripsy under the "Adjunctive Therapies" section and note that long-term data is needed.

## Society for Vascular Surgery

In 2015, the Society for Vascular Surgery published guidelines for the management of asymptomatic PAD and intermittent claudication.[2] Relevant recommendations are summarized below.

**Asymptomatic Peripheral Artery Disease**

3.1. We recommend multidisciplinary comprehensive smoking cessation interventions for individuals with asymptomatic PAD who use tobacco (repeatedly until tobacco use has stopped).1 A
3.2. We recommend providing education about the signs and symptoms of PAD progression to asymptomatic individuals with PAD. 1 Ungraded
3.3. We recommend against invasive treatments for PAD in the absence of symptoms, regardless of hemodynamic measures or imaging findings demonstrating PAD. 1 B

**Intermittent Claudication- Invasive Treatments**

5.1. We recommend endovascular therapy or surgical treatment of IC for individuals with significant functional or lifestyle-limiting disability when there is a reasonable likelihood of symptomatic improvement with treatment, when pharmacologic or exercise therapy, or both, have failed, and when the benefits of treatment outweigh the potential risks. 1B

5.2. We recommend an individualized approach to select an invasive treatment for IC. The modality offered should provide a reasonable likelihood of sustained benefit to the individual (>50% likelihood of clinical efficacy for at least 2 years). For revascularization, anatomic patency (freedom from hemodynamically significant restenosis) is considered a prerequisite for sustained efficacy.

In 2022, the Society published Appropriate Use Criteria for Management of Intermittent Claudication.[49,] Revascularization was rated as B>R (benefit outweighs risk) for selected individuals with severe lifestyle-limiting intermittent claudication symptoms despite treatment with optimal medical therapy and an adequate trial of exercise. The panel noted, "specific types of endovascular interventions (e.g., angioplasty, stenting, atherectomy) were not included in these AUC owing to the large number of additional scenarios that would be required. Furthermore, the amount and quality of data available regarding the outcomes of interventions for multilevel disease and specific types of endovascular interventions are limited. Thus, if included, the ratings would have relied primarily on expert opinion." Lithotripsy was not mentioned in the document.

## US Preventive Services Task Force Recommendations

In 2018, the USPSTF concluded that the current evidence is insufficient to assess the balance of benefits and harms of screening for PAD and cardiovascular disease risk with the ankle-brachial index (ABI) in asymptomatic adults.

## Medicare National Coverage

There is no national coverage determination.

## Regulatory Status

In 2016, the Shockwave Medical Peripheral Lithotripsy (IVL) System received 510(k) clearance (K161384) 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 (K142983). Additional predicates were the Bard Peripheral Vascular VascuTrak PTA Dilatation Catheter (K103459) and the EKOS Corporation EKOS Lysus Micro-Infusion System (K060422). FDA Product Code: PPN

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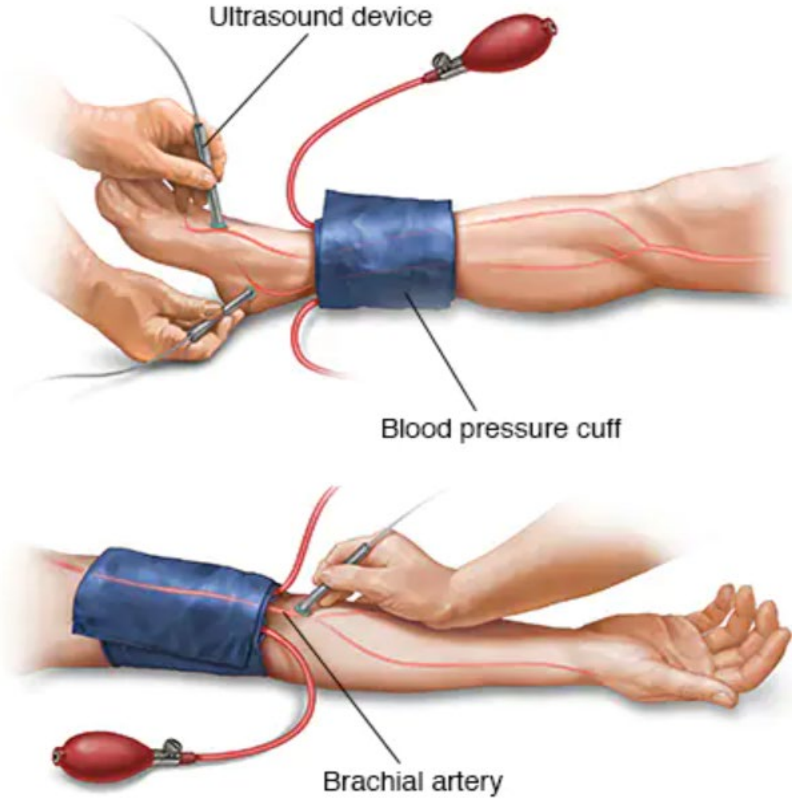
## Appendix




The ankle-brachial index test compares the blood pressure in the ankle with the blood pressure in the arm. A low ankle-brachial index number can mean there is narrowing or blockage of the arteries in the legs.

Ankle-brachial index testing might be done before and right after walking on a treadmill. This is called an exercise ankle-brachial index test. It can find out how badly the arteries are narrowed when walking.

**Source:** **https://www.mayoclinic.org/tests-procedures/ankle-brachial-index/about/pac-20392934.** Accessed November 13, 2024.

## History

| Date | Comments |
|---|---|
| 01/01/25 | New policy, approved December 10, 2024, effective for dates of service on or after April 6, 2025, following 90-day provider notification. Policy created with literature review through August 15, 2024. Percutaneous revascularization procedures are considered medically necessary in adults with chronic symptomatic lower extremity peripheral arterial disease with guideline-based criteria, adults with chronic limb-threatening ischemia, and adults with acute limb ischemia. Percutaneous revascularization procedures in adults with asymptomatic lower extremity peripheral arterial disease are considered not medically necessary. Percutaneous revascularization procedures using lithotripsy are considered investigational in adults with lower extremity peripheral arterial disease. Added HCPCS codes C7531, C7534, C7535, C9764-C9767 and C9772-C9775 to match criteria updates. |



**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.