LOUISIANA BLUE

Percutaneous Revascularization Procedures for Lower Extremity Peripheral Arterial Disease

Policy # 00934
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Extracranial Carotid Angioplasty/Stenting) is addressed separately in medical policy 00155.

Note: Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms) is addressed separately in medical policy 00198.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy in individuals with chronic symptomatic lower extremity peripheral arterial disease to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy in individuals with chronic symptomatic lower extremity peripheral arterial disease will be considered when **ALL** of the following criteria are met (see Policy Guidelines):

- Individual has functionally limiting claudication; **AND**
- Inadequate response to guideline-directed management and therapy (GDMT) after at least 3 months, including structured exercise program; **AND**
- The target lesion is located in the aortoiliac or femoropopliteal vessels; **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.

Based on review of available data, the Company may consider percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy for treatment of chronic limb-threatening ischemia (critical limb ischemia) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy for treatment of chronic limb-threatening ischemia (critical limb ischemia) will be considered when **ANY** of the following criteria are met:

- Individual has ischemic rest pain and abnormal hemodynamic parameters in the affected limb (e.g., diminished ankle-brachial index [ABI], toe-brachial index [TBI], abnormal pulse volume recordings [PVR], or Doppler waveforms); **OR**
- Individual has ischemic skin ulceration or gangrene.

Based on review of available data, the Company may consider percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy for treatment of acute limb ischemia to be **eligible for coverage.****

Based on review of available data, the Company may consider percutaneous revascularization of the stenotic lesion in iliac arteries using balloon angioplasty, stent procedures, or atherectomy (including in individuals with asymptomatic lower extremity peripheral arterial disease) when 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) to be **eligible for coverage.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy in all other situations, including but not limited to intervention on the anterior tibial artery, tibioperoneal trunk, peroneal artery, posterior tibial artery, and/or pedal arteries for treatment of claudication to be **investigational.***

Based on review of available data, the Company considers percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy in individuals with asymptomatic lower extremity peripheral arterial disease in all other situations to be **investigational.***

Based on review of available data, the Company considers percutaneous revascularization using lithotripsy in individuals with lower extremity peripheral arterial disease in all situations to be **investigational.***

Policy Guidelines

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.

Guideline-directed management and therapy (GDMT)
Optimal medical therapy for patients with peripheral arterial disease includes ALL of the following, unless contraindicated:

- Antiplatelet medication (e.g., Aspirin, clopidogrel, ticagrelor)
- High-intensity statin (e.g., atorvastatin 40-80 mg, rosuvastatin 20-40 mg)
- Angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker for hypertensive patients
- Treatment of diabetes and hypertension, if present
- Tobacco cessation which includes a trial of at least TWO (2) of the following treatments if the patient continues to smoke:
    - Varenicline
    - Nicotine replacement therapy
    - Bupropion
    - Behavioral therapy counseling or referral to a smoking cessation program

Structured Exercise Programs for Peripheral Arterial Disease
A structured exercise program is a core component of care for patients with peripheral artery disease. It 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 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.

Background/Overview

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 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. Ischemic rest pain often affects the forefoot and is worsened with limb elevation and relieved by dependency.
- Acute limb ischemia (ALI) 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. Acute clinical symptoms (<2-week duration) include pain, pallor, pulselessness, poikilothermia (coolness), paresthesias, and potential for paralysis. Causes of ALI include embolism, thrombosis within the native artery or at site of previous revascularization (graft or stent), trauma, or peripheral aneurysm with distal embolization. Severity is further classified using the Rutherford classification system. Category I ALI refers to a viable limb that is not immediately threatened. Category II refers to the threatened but salvageable limb. The category IIa limb is marginally threatened and salvageable, if promptly treated. The category IIb limb is immediately threatened and requires immediate revascularization if salvage is to be accomplished. The category III limb is irreversibly damaged, in which case resultant major tissue loss or permanent nerve damage is inevitable. The category III limb is nonsalvageable.

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. In patients 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 (i.e., exertional nonjoint-related leg symptoms) and normal or borderline resting ABI (>0.9 and $\leq$ 1.40), exercise ABI can be performed.

Noncompressible tibial arteries occur frequently in the setting of diabetes or CKD and may result in a falsely elevated ABI of >1.40 even when significant PAD is confirmed by imaging.

2024 report of the American College of Cardiology/ American Heart Association Joint Committee on Clinical Practice Guidelines states that "in patients with suspected PAD, toe pressure/ toe-brachial index (TBI) with waveforms should be performed when the resting ABI is > 1.40 (noncompressible)." A TBI of $\leq$0.70 is considered abnormal and allows for the diagnosis of PAD in patients with an ABI >1.40 who have history or physical examination findings suggestive of PAD.

Treatment
Standard treatment for claudication includes medical therapy, foot care, and structured exercise therapy.

Despite multiple available tools, smoking cessation support strategies are underutilized among patients with PAD. Clinicians caring for patients with PAD should include smoking cessation in the treatment plan and prescribe therapy based on current guidelines, including a 2018 ACC expert consensus decision pathway. Observational studies suggest that smoking cessation is associated with lower rates of major adverse limb events, including bypass graft failure and amputation, as well as death in patients with PAD. The risk of PAD development remains >2 times higher than that of

never-smokers for up to 10 to 20 years after quitting and does not return to the risk of a nonsmoker until after 30 years after quitting. Pharmacotherapy is more effective when combined with counseling. Three US Food and Drug Administration (FDA)-approved pharmacological approaches (i.e., varenicline, bupropion, and nicotine replacement therapy) used alone or in combination all increase smoking cessation rates.

Revascularization (endovascular, surgical, or hybrid) should be used to prevent limb loss in those with chronic limb-threatening ischemia and can be used to improve quality of life (QOL) and functional status in patients with claudication not responsive to medical therapy and structured exercise.

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.

Patients with CLTI have an advanced form of PAD that manifests as rest pain or minor or major tissue loss. Team-based, multispecialty care is optimal for management of CLTI. Revascularization, either percutaneous or surgical, is the standard treatment for CLTI, rather than the exception, to minimize tissue loss and preserve a functional limb and ambulatory status. Therapies for wound care, management of infection, and pressure offloading are important adjunctive components of care for CLTI in addition to revascularization.

Revascularization is indicated in patients with ALI and a salvageable limb to prevent irreversible tissue damage and major amputation. Both surgical thromboembolectomy and catheter-based thrombolysis are effective therapies for ALI. Ultrasound-accelerated, catheter-based thrombolysis and newer techniques including pharmacomechanical and vacuum-assisted percutaneous mechanical thrombectomy have expanded the endovascular armamentarium for the treatment of ALI. Patient-specific and anatomic factors and local resource availability are important in selecting the revascularization strategy for the individual patient with ALI. All patients should be monitored for compartment syndrome and reperfusion injury. After initial revascularization to address the thrombosis, definitive treatment of any underlying culprit lesion can be useful to optimize procedural success and prevent ALI recurrence.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2016, the Shockwave Medical Peripheral Lithotripsy (IVL) System received 510(k) clearance (K161384; FDA Product Code: PPN) 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).

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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.

Summary of Evidence

For individuals who are adults with symptomatic lower extremity peripheral arterial disease (aortoiliac or femoropopliteal vessels) 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 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.

Supplemental Information

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

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or 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 medical policy (Tables 1 and 2):

Table 1. 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 2. 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 (ie, 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.

Revascularization for Claudication: Infrapopliteal Disease
8. Most studies of endovascular revascularization for infrapopliteal disease have been conducted in the population of patients with CLTI. Isolated infrapopliteal disease is an uncommon cause of claudication. The long-term patency of infrapopliteal endovascular procedures is lower than for aortoiliac or femoropopliteal lesions, making infrapopliteal endovascular procedures more appropriate for the treatment of CLTI where short-term patency may be sufficient for wound healing. There are no RCTs of endovascular revascularization versus medical therapy and structured exercise for treatment of isolated infrapopliteal disease in patients with claudication, and thus the effectiveness of these procedures in this setting is unknown.

9. Isolated infrapopliteal disease is an uncommon cause of claudication, and treatment of isolated infrapopliteal disease is typically reserved for patients with CLTI. No RCTs have evaluated surgical revascularization versus medical therapy and exercise for patients with isolated infrapopliteal disease. In a registry-based study from Vascular Quality Initiative of patients with claudication who were treated with surgical revascularization, infrainguinal bypass to the infrapopliteal vessels was associated with higher rates of perioperative complications and major adverse limb events at 1-year follow-up compared with bypass to the popliteal arteries. Accordingly, the effectiveness of surgical revascularization for isolated infrapopliteal disease in patients with claudication is unknown.

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. Appropriate use scores for endovascular treatment of relevant indications are shown in Table 3.

Table 3. 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 appropriateness 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. 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. Relevant recommendations are summarized below.

Asymptomatic Peripheral Artery Disease
3.1. We recommend multidisciplinary comprehensive smoking cessation interventions for patients 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 patients 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 patients 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.1 B
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 patient (>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. Revascularization was rated as B>R (benefit outweighs risk) for selected patients 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 (eg, 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.

U.S. 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 for percutaneous revascularization procedures for PAD. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 4.

Table 4. 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.

References

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Policy History

Original Effective Date: 09/01/2025
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06/05/2025 Medical Policy Committee review
06/11/2025 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 06/2026

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0238T, 37220, 37221, 37222, 37223, 37224, 37225, 37226, 37227, 37228, 37229, 37230, 37231, 37232, 37233, 37234. 37235
HCPCS	C7531, C7534, C7535, C9764, C9765, C9766, C9767, C9772, C9773, C9774, C9775
ICD-10 Diagnosis	All Related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.