RETIRED

Valid for dates of service prior to 11/1/24 only
For dates of service 11/1 and after, see policy:
EviCore Cigna Commercial Membership | EviCore by Evernorth

Medical Coverage Policy

Effective Date..... 4/1/2024
Next Review Date..... 2/15/2025
Coverage Policy Number 0537

Percutaneous Revascularization of the Lower Extremities in Adults

Table of Contents

Related Coverage Resources

Venous Angioplasty and/or Stent Placement in Adults

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s).
Reimbursement is not allowed for services when billed for conditions or diagnoses that are not

covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses percutaneous arterial revascularization of the lower extremities for the treatment of occlusive peripheral arterial disease (PAD) in adults ≥ 18 years of age. This policy does not address percutaneous arterial revascularization of the lower extremities in individuals under 18 years of age.

Coverage Policy

Percutaneous revascularization procedures (e.g., angioplasty, stents, and/or atherectomy) for lower extremity peripheral arterial disease in an adult ≥ 18 years of age is considered medically necessary for one or more of the following indications:

- Claudication when ALL of the following criteria are met:
  - presence of lifestyle-limiting claudication (i.e., impairment of activities of daily living, vocational and/or recreational activities)
  - documentation of an inadequate response to conservative medical therapy (e.g., attempted smoking cessation, supervised exercise therapy, and/or pharmacologic therapy)
  - documentation of occlusive arterial disease:
    - one or more of the following:
      - ankle-brachial index ≤ 0.90 (i.e., resting or exercise)
      - monophasic waveform by ultrasound
  - confirmed anatomical location of significant occlusive disease (stenosis of greater than 50%) by non-invasive or invasive evaluation (e.g., Duplex ultrasound, CT angiography) or contrast injection angiography
- Chronic limb-threatening ischemia (CLTI) when ALL of the following criteria are met:
  - One or more of the following:
    - ischemic rest pain
    - nonhealing wound/ulcers (present for ≥ two weeks duration)
    - gangrene in one or both legs
  - documentation of occlusive arterial disease:
    - one or more of the following:
      - ankle-brachial index ≤ 0.90 (i.e., resting or exercise)
      - monophasic waveform by ultrasound
  - confirmed anatomical location of significant occlusive disease (stenosis of greater than 50%) by non-invasive or invasive evaluation (e.g., Duplex ultrasound, CT angiography) or contrast injection angiography
- Acute limb ischemia (present for < 2 weeks duration) in a marginally or immediately viable limb or a threatened limb

For all other indications including the following, percutaneous revascularization in an individual with lower extremity occlusive peripheral arterial disease is considered not medically necessary:

- claudication due to isolated infrapopliteal artery disease
- to prevent progression to chronic/critical limb ischemia
- claudication due to profunda femoral artery disease

Percutaneous revascularization for vessels supplying a nonviable limb is considered not medically necessary.

Intravascular lithotripsy in an individual with lower extremity occlusive peripheral arterial disease is considered experimental, investigational or unproven.

General Background

Peripheral arterial disease (PAD) occurs most commonly in the arteries of the pelvis and legs (the lower extremities). PAD, specifically atherosclerotic disease leading to peripheral artery obstruction, may be silent/asymptomatic or present with a variety of signs and symptoms indicative of extremity ischemia. The clinical manifestations of arterial insufficiency, regardless of etiology, are due to a lack of blood flow to the musculature relative to its metabolism, which results in pain in the affected muscle groups. Atherosclerotic PAD of the upper extremities is much less common. It is recommended that management of an individual with lower extremity PAD includes medical therapies aimed at reducing the risk for future cardiovascular events related to atherosclerosis, such as stroke, myocardial infarction, and peripheral arterial events (Berger, et al., 2023).

The prevalence of PAD varies according to the population studied, the diagnostic method used, and whether symptoms are included to derive estimates. Lower extremity PAD is estimated to affect approximately 8.5 million Americans above the age of 40 years. It has been estimated that 202 million people worldwide have PAD. The overall burden of PAD among adults in the United States is greater for women compared with men. Estimates vary by age and sex but generally indicate that 10-30% of patients with PAD have claudication. The incidence of critical limb ischemia (CLI) is approximately 22 per 100,000 per year, affecting 1-2% of patients with PAD. Less information is available on the prevalence and incidence of acute limb ischemia (ALI), with estimates among patients with symptomatic PAD of approximately 1-2% per year. The incidence of amputation ranges from 112-250 per million per year. Well-defined risk factors are associated with the development of PAD and include older age, hypertension, tobacco use, diabetes, and hypercholesterolemia, among others. The risk for development of PAD and intermittent claudication increases progressively with the number of risk factors (Bonaca, et al., 2019; Berger, et al., 2023; Gerhard-Herman, et al., 2016).

Due to the prevalence of PAD, the disparities that exist, and the preventable and treatable nature of the disease, the American Heart Association (2022) published a national action plan to guide providers in the prevention of complications, treatment, and improvement of quality of life for those living with the disease. According to the guide, PAD is significantly higher in Black men and women (16.9% and 13.2%, respectively) compared to White men and women (10.9% and 12.1%, respectively). The national average is 12.4%. It is estimated that by the year 2050, 19 million people will have PAD. Lower extremity PAD is associated with "significantly reduced function and quality of life, increased risk of hospitalization and amputation, high mortality, and high cost of care." According to the guide, one-third of patients diagnosed with PAD will die within five years of diagnosis and one-fifth will experience a myocardial infarction or stroke. A 2006 telephone survey of 2500 adults found that 14% knew that PAD could lead to amputations and 25% knew that PAD was linked to a higher risk of myocardial infarction and stroke. The authors provide several actionable goals to address this health concern that include: improving public awareness, enhancing professional education, improving detection and treatment, reducing the rates of PAD

associated lower extremity amputations through public health interventions, increasing research, and improving advocacy efforts.

Evidence of underlying atherosclerotic occlusive disease may be present in the absence of symptoms. It is estimated that there are three times as many asymptomatic individuals with lower extremity PAD as symptomatic individuals. Among asymptomatic individuals, atherosclerotic disease of the iliac and femoral arteries is most prevalent. Exertional pain in an individual with lower extremity PAD is termed claudication. Claudication is a reproducible discomfort of a group of muscles that is induced by exercise and relieved with rest. Claudication can present unilaterally or bilaterally, as thigh, buttock and hip, calf, or foot pain, singly or in combination. The severity of symptoms depends upon the number and degree of arterial narrowing, the collateral circulation, and the intensity of extremity use. Limb-threatening ischemia presents as ischemic pain, tissue loss, or both. Chronic severe reductions in limb perfusion present as ischemic rest pain, typically localized to the forefoot and toes, or as tissue loss (i.e., nonhealing ulcer, gangrene) (Berger, et al., 2023).

Measurement of the ankle-brachial index (ABI) is the primary method for establishing the diagnosis of PAD. An ABI of ≤ 0.90 has been demonstrated to have high sensitivity and specificity for the identification of PAD compared with the gold standard of invasive arteriography. An ABI less than 0.90 is considered diagnostic of PAD. Mild disease correlates with an ABI ranging from 0.70 to less than 0.90, whereas moderate disease correlates with an ABI ranging from 0.40 to less than 0.70, and severe disease is associated with an ABI less than 0.40 (Mohler, 2003).

Textbook literature discusses when to refer an individual to a vascular specialist based on the ABI and the risk of arterial disease. An ABI of 0.5-0.69 means moderate arterial disease and an ABI of < 0.5 means severe arterial disease suggesting referral to a vascular specialist. An ABI of 0.7-0.89 means some arterial disease suggesting treat risk factors. An ABI of 0.9-1.0 is borderline and 1-1.17 is normal not requiring referral to a vascular specialist (Collins, 2020).

The ABI is a comparison of the resting systolic blood pressure at the ankle to the higher systolic brachial pressure. Duplex ultrasonography is commonly used in conjunction with the ABI to identify the location and severity of arterial obstruction. For an individual with appropriate symptoms, but a normal ABI, an ABI can be obtained following exercise testing. A complete cardiovascular examination includes palpation of the peripheral pulses, inspection of the extremities, including the feet, and auscultation of accessible arteries for bruits. Pulse abnormalities and bruits increase the likelihood of PAD. It is recommended that an interdisciplinary care team of professionals representing different disciplines assist in the evaluation and management of the individual with PAD. Interdisciplinary care team members may include vascular medical and surgical specialists (i.e., vascular medicine, vascular surgery, interventional radiology and interventional cardiology) (Berger, et al., 2023; Gerhard-Herman, et al., 2016; Conte, et al., 2019).

In a research study by Li et al. (2013), the authors developed a computational multibranch model of the entire cardiovascular system including typical arterial units of lower/upper limb. The model was used to investigate the correlation between ABI and the stenosis in theory. The influences of stenosis located in different sites of the cardiovascular system on ABI were reported, as well as the variation tendency of ABI value caused by the stenosis with the increasing severity. The American College of Cardiology (ACC) and the American Heart Association (AHA) proposed to grade ABI into four levels. ACC/AHA had recommended the evaluation standards of normal ABI to be 0.91-1.30, and also a cutoff of 0.90 to define a low ABI value. The ABI value greater than 1.30 indicated that the vascular was uncompressible, suggesting that vascular calcification might have occurred. The ABI was generally unreliable for stenoses detection in such situations. The ABI value that ranged from 0.41 to 0.90 predicted the presence of mild-to-moderate stenoses. Severe

stenoses were diagnosed with the ABI value less than 0.41 in clinical data. The authors reported the correlation analysis between ABI and the chance of finding a 70% lesion in the respective artery. To find all the 70% blockages in femoral, popliteal and posterior tibial arteries would take an ABI of 0.69.

Classification of lower extremity PAD, by grading symptoms and the anatomic lesions responsible for these symptoms, provides an objective measure by which to follow patients clinically, and provides consistency when comparing medical and interventional treatment strategies in clinical studies. Several professional vascular societies have adopted the Rutherford scale that includes asymptomatic patients, three grades of claudication, and three grades of CLI ranging from rest pain alone to minor and major tissue loss. Another classification scale is the European Fontaine scale (Berger, et al., 2023; Bonaca, et al., 2019).

Arterial lesions can be classified by Trans-Atlantic Inter-Society Consensus (TASC II) as Type A, B, C, or D according to anatomic distribution, number and nature of lesions (stenosis, occlusion), and according to the overall success rates of treating the lesion using endovascular or surgical means. Type A lesions are relatively short and focal, and generally have excellent results with endovascular therapy. Type B lesions have good results using endovascular methods, which are preferred, unless open revascularization is required for another lesion in the same anatomic area. Type C lesions may have better long-term results with open revascularization such that endovascular techniques should be used if the patient is at high risk for open surgical repair. Type D lesions have poorer results with endovascular treatment, and thus, surgery is the primary treatment for low-to-moderate risk patients (Mills, 2021).

The management of patients with lower extremity PAD is aimed at relieving symptoms and lowering the risk of cardiovascular disease progression and complications. Medical management involves cardiovascular risk factor reduction, lifestyle modification, and other pharmacologic therapies to reduce the risk of atherosclerotic disease progression. With aggressive medical management, regression of noncalcified atherosclerotic lesions may be possible. Weight reduction and regular exercise are important (Berger, et al., 2023).

Preventive strategies are appropriate for symptomatic and asymptomatic individuals with lower extremity PAD. Preventive therapies include smoking cessation, antiplatelet therapy, lipid-lowering therapy, and treatment of hypertension and diabetes. Symptoms should be reevaluated after conservative treatments (e.g., risk factor reduction, exercise therapy, pharmacologic therapy) have been instituted and allowed to have an effect. If claudication symptoms persist and the individual has been responsive to lifestyle adjustment, they may be a candidate for an endovascular or open surgical intervention depending on the location and severity of lesions and medical risk. Patients with symptomatic PAD are at risk for developing new or recurrent lesions in the same or other vascular beds (Berger, et al., 2023).

In the absence of limb-threatening ischemia, symptoms of PAD tend to remain stable with medical therapy. Performing prophylactic intervention, whether percutaneous or surgical, in patients with minimal claudication provides little benefit, may cause harm, and is not indicated. For limb-threatening ischemia (e.g., rest pain, ulceration), revascularization is a priority to establish arterial blood flow. Once the decision has been made for interventional treatment, the individual should undergo vascular imaging to determine the arterial anatomy and extent of disease, and comprehensive medical assessment (Berger, et al., 2023; Bonaca, et al., 2019).

For disabling or significant symptoms unresponsive to lifestyle adjustment and pharmacologic therapy, percutaneous endovascular or surgical interventions are proposed for revascularization. These procedures are broadly categorized as endovascular interventions and surgical reconstruction, although hybrid procedures consisting of both endovascular and surgical

revascularization are also used. In determining the type of revascularization procedure, one important consideration is the location of the obstruction, which is broadly categorized as inflow, involving the aorta and iliac arteries; outflow, including the femoral and popliteal arteries; or run-off, affecting the tibial and peroneal arteries. Technological advances have resulted in a shifting of revascularization strategies from the traditional open surgical approaches toward less invasive percutaneous endovascular treatments, the most common being percutaneous transluminal angioplasty (PTA), often referred to as balloon angioplasty. Proposed endovascular interventions may include PTA with balloon dilation, stents, atherectomy, and thrombolysis (Kinlay, et al., 2019; Bonaca, et al., 2019).

With PTA, a catheter is inserted into the blocked artery and a small balloon on the catheter tip is inflated. The inflated balloon compresses the plaque against the artery wall, causing the artery to widen, thus, increasing or restoring blood flow in the artery. Often, in conjunction with angioplasty, a stent (a small mesh framework tube) may be deployed and left in the artery to help it remain open. It is recommended that image-guided, minimally invasive procedures such as angioplasty and vascular stenting be performed by a specially trained interventional radiologist in an interventional radiology suite or occasionally in the operating room. This procedure is often done on an outpatient basis. However, some patients may require admission following the procedure.

In contrast to coronary disease, few well-controlled studies have evaluated endovascular treatment of PAD. Many studies are single arm, and most focus on patency (lack of restenosis) and repeated revascularization over a relatively short period (Kinlay, et al., 2019).

U.S. Food and Drug Administration (FDA)
The FDA has approved numerous stents and stent systems through the Premarket Approval (PMA) process for the treatment of peripheral arterial disease (PAD) of the lower extremities.

Shockwave Medical Lithotripsy System (Shockwave Medical, Inc., Fremont, CA) was FDA 510(k) approved September 14, 2016 as a Class II device "for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries." The Shockwave S4 Peripheral Intravascular Lithotripsy (IVL) Catheter, FDA approved June 28, 2018, is available in four sizes and features shorter and smaller balloon configurations with smaller crossing profile and the presence of a hydrophilic coating intended for below-the-knee calcifications. On July 26, 2018, the Shockwave M5 Peripheral Intravascular Lithotripsy (IVL) Catheter, available in eight sizes to treat a range of peripheral arteries, was FDA approved followed by the updated Shockwave M5+ Peripheral IVL Catheter approved on April 22, 2021 (FDA, 2021; FDA, 2018).

Literature Review – Intravascular Lithotripsy
Intravascular lithotripsy (IVL) uses a percutaneous device to create acoustic pressure waves to break up intimal and medial vascular calcium in lesions. Energy is transmitted at one pulse per second with a pulse width of 1.1 microseconds via emitters within an integrated balloon. The balloon is inflated to low pressure with saline and contrast that is vaporized in small amounts by the electrical charge. This creates a bubble within the balloon that results in sonic pressure waves. The waves pass through the balloon and vascular tissue to break apart the calcium in the vessels. After thirty-pulse increments are created, the balloon is inflated to nominal pressure to maximize luminal gain. The cycle is repeated up to 300 total pulses until optimal vessel clearance is obtained. Once the lithotripsy is complete, a vascular stent can be placed (Butte, et al., 2020; Madhavan, et al., 2020).

Tepe et al. (2021) conducted a randomized controlled trial of 306 patients (aged 64-80 years) comparing short-term outcomes in patients with femoropopliteal artery calcification who received

vessel preparation with intravascular lithotripsy (IVL) (n=153) or percutaneous transluminal angioplasty (PTA) (n=153) prior to drug-coated balloon (DCB) for symptomatic peripheral artery disease. Eligible patients presented with: symptomatic leg claudication or rest pain; angiographic evidence of greater than or equal to 70% stenosis within the superficial femoral or popliteal artery; lesion length up to 180 mm (up to 100mm for chronic total occlusion); reference vessel diameter four to seven mm; and moderate or severe claudication. The IVL group received vessel preparation with a low-pressure lithotripsy balloon (Shockwave Medical Inc., Santa Clara, California) while the comparators were treated with a standard PTA. The primary endpoint was procedural success, determined by the angiographic core laboratory as residual stenosis less than or equal to 30% without flow-limiting dissection assessed immediately following vessel preparation and post-dilatation (if required) and prior to DCB treatment or provisional stent placement. Secondary endpoints were evaluated at the 30-day follow-up visit and included clinically driven target lesion revascularization (CD-TLR), change in ankle-brachial index, change in Rutherford class, health utility based on responses to the EQ-5D (EuroQol-5 Dimension) questionnaire, and walking capacity on the Walking Impairment Questionnaire. The primary outcome of procedural success was superior in the IVL group relative to the PTA group (65.8% [n=96 of 146] vs. 50.4% [n=67 of 133]; p=0.01). At the 30-day follow-up visit, hemodynamic, functional, and quality-of-life parameters were generally comparable between the groups with the exception of change in EQ-5D visual analog scale (a quantitative measure of health outcome reflecting the patient's own judgment), which favored the IVL group (9.1 vs. 4.3; p=0.01). Major adverse events included unplanned surgical revascularization or major (above ankle) amputation of the target limb, symptomatic thrombus or embolus requiring treatment, and perforations requiring provisional stent placement or other treatment. Limitations of the trial include short follow-ups and heterogeneous lesion locations. One- and two-year primary patency outcomes were reported by Tepe et al. (2022). At one and two years, 123 and 111 participants respectively were included for analysis in the IVL arm and 128 and 113 were in the PTA arm. Primary patency was defined as "freedom from clinically driven target lesion revascularization (CD-TLR) and freedom from restenosis as determined by duplex ultrasound (DUS) or angiogram ≥ 50% stenosis." PTA failure requiring stent placement at any time was considered a loss of primary patency. Secondary outcomes assessed included: ankle-brachial index, EQ-5D questionnaire, Walking Impairment Questionnaire (WIQ), and major adverse events. Significantly more participants achieved primary patency at one year in the IVL group compared to the PTA group (p = 0.017). Significantly fewer participants underwent provisional stent placement in the IVL group compared to the PTA group (p < 0.0001). However, freedom from CD-TLR and restenosis were similar between the two groups at one year. Adverse events were similar between the two groups at one year and included distal embolization and perforation. Author noted limitations of the study included the inability to generalize results to patients with chronic limb threatening ischemia. Additional limitations of the study include the small patient population, patient attrition, and failure to compare IVL to other established treatment modalities (e.g., atherectomy).

Madhavan et al. (2020) conducted an individual patient-level pooled data (IPD) meta-analysis of 336 patients (mean age 72.9 years) from five different IVL trials (DISRUPT PAD I, II, III, BTK, and CFA) to assess the procedural and short-term clinical outcomes in patients who underwent IVL for PAD. PAD III was a randomized controlled trial, and the other studies were prospective non-randomized trials. The average number of lesions per patient was one and the mean number of IVL pulses was 174.9 ± 113.4. Some of the patients within the PAD III and CFA studies underwent adjunctive lesion modification therapies, and a total of 62 patients received stent placement. The primary outcome measure was the final post-procedural percent diameter stenosis. Secondary outcome measures included: percent diameter stenosis post-IVL, final percent diameter stenosis less than 50%, final acute gain, and final acute gain indexed to baseline reference vessel diameter. The IVL trials resulted in percent diameter stenosis improvement compared to baseline measurements including high-risk subgroups, very low rate of procedural complications, and improvements in acute gain, net gain index and clinical markers. There was a single perforation

event that occurred after drug-coated balloon inflation, as well as three other lesion-level complications. Limitations of the trials include: single-arm studies with no comparators, proportion of patients received adjunctive device therapy, heterogeneous patient population and vascular beds, inconsistent discharge and follow-up assessments. Prospective randomized control trials comparing IVL to non-IVL are needed to support the outcomes of this analysis.

Professional Societies/Organizations
The American College of Cardiology (ACC) and American Heart Association (AHA) 2016 Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: The scope of this evidence-based guideline is limited to atherosclerotic disease of the lower extremity arteries (PAD) and includes disease of the aortoiliac, femoropopliteal, and infrapopliteal arterial segments. The authors state that this document supersedes recommendations related to lower extremity PAD in the ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial Disease and the 2011 ACCF/AHA Focused Update of the Guideline for the Management of Patients With Peripheral Artery Disease (Gerhard-Herman, et al., 2016).

The Class of Recommendation (COR) indicates the strength of the recommendation, encompassing the estimated magnitude and certainty of benefit in proportion to risk. The Level of Evidence (LOE) rates the quality of scientific evidence that supports the intervention on the basis of the type, quantity, and consistency of data from clinical trials and other sources.

Guideline Class of Recommendation (COR) and Level of Evidence (LOE) are described as follows:

Class (Strength) of Recommendation:
Class I (Strong) Benefit >>>Risk
Class IIa (Moderate) Benefit>>Risk
Class IIb (Weak) Benefit ≥ Risk
Class III No Benefit (Moderate) Benefit=Risk
Class III Harm (Strong) Risk>Benefit

Level (Quality) of Evidence:
Level A if the data were derived from high-quality evidence from more than one randomized clinical trial(RCT), meta-analyses of high-quality RCTs, or one or more RCTs corroborated by high-quality registry.
Level B-R when data were derived from moderate quality evidence from one or more RCTs, or meta-analyses of moderate-quality RCTs.
Level B-NR was used to denote moderate-quality evidence from one or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies. This designation was also used to denote moderate-quality evidence from meta-analyses of such studies.
Level C-LD when the primary source of the recommendation was randomized or nonrandomized observational or registry studies with limitations of design or execution, meta-analyses of such studies, or physiological or mechanistic studies of human subjects.
Level C-EO was defined as expert opinion based on the clinical experience of the writing group.

The guideline defines key PAD terms as follows:

- Claudication: Fatigue, discomfort, cramping, or pain of vascular origin in the muscles of the lower extremities that is consistently induced.
- Acute limb ischemia (ALI): Acute (<2 wk), severe hypoperfusion of the limb characterized by these features: pain, pallor, pulselessness, poikilothermia (cold), paresthesias, and paralysis by exercise and consistently relieved by rest (within 10 min).
  - Categories of ALI include:

    - Viable—Limb is not immediately threatened; no sensory loss; no muscle weakness; audible arterial and venous Doppler.
    - Threatened—Mild-to-moderate sensory or motor loss; inaudible arterial Doppler; audible venous Doppler; may be further divided into IIa (marginally threatened) or IIb (immediately threatened).
    - Irreversible—Major tissue loss or permanent nerve damage inevitable; profound sensory loss, anesthetic; profound muscle weakness or paralysis (rigor); inaudible arterial and venous Doppler
- Critical limb ischemia (CLI): a condition characterized by chronic (≥2 wk) ischemic rest pain, nonhealing wound/ulcers, or gangrene in 1 or both legs attributable to objectively proven arterial occlusive disease. The diagnosis of CLI is a constellation of both symptoms and signs. Arterial disease can be proved objectively with ABI, toe-brachial index, transcutaneous oxygen pressure, or skin perfusion pressure. Supplementary parameters, such as absolute ankle and toe pressures and pulse volume recordings, may also be used to assess for significant arterial occlusive disease. However, a very low ABI or TBI does not necessarily mean the patient has CLI. The term CLI implies chronicity and is to be distinguished from ALI.

The guideline states that an individualized approach to revascularization for claudication is recommended for each patient to optimize outcome. Revascularization is only one component of care for the patient with claudication. Every patient should have a customized care plan that also includes medical therapy, structured exercise therapy, and care to minimize tissue loss. If revascularization for claudication is undertaken, the revascularization strategy should be evidence based and can include endovascular revascularization, surgery, or both.

The guideline outlines a general recommendation for revascularization as a treatment option for claudication followed by specific recommendations for endovascular and surgical procedures if a revascularization strategy is undertaken. Endovascular techniques to treat claudication include balloon dilation (angioplasty), stents, and atherectomy. These techniques continue to evolve and now include covered stents, drug-eluting stents (DES), cutting balloons, and drug-coated balloons. The technique chosen for endovascular treatment is related to lesion characteristics (e.g., anatomic location, lesion length, degree of calcification) and operator experience.

The section of the guideline that addresses medical therapy for the patient with PAD states that patients with PAD should receive a comprehensive program of guideline-directed management and therapy (GDMT), including structured exercise and lifestyle modification, to reduce cardiovascular ischemic events and improve functional status. Smoking cessation is a vital component of care for patients with PAD who continue to smoke. A guideline-based program of pharmacotherapy to reduce cardiovascular ischemic events and limb-related events should be prescribed for each patient with PAD and is customized to individual risk factors, such as whether the patient also has diabetes mellitus. The term GDMT refers to care defined mainly by ACC/AHA Class I recommendations including the following:

- Antiplatelet therapy with aspirin alone (range 75–325 mg per day) or clopidogrel alone (75 mg per day) is recommended to reduce MI, stroke, and vascular death in patients with symptomatic PAD (COR I; LOE A).
- Treatment with a statin medication is indicated for all patients with PAD (COR I; LOE A).
- Antihypertensive therapy should be administered to patients with hypertension and PAD to reduce the risk of MI, stroke, heart failure, and cardiovascular death (COR I; LOE A).
- Patients with PAD who smoke cigarettes or use other forms of tobacco should be advised at every visit to quit (COR I; LOE A).

- Patients with PAD who smoke cigarettes should be assisted in developing a plan for quitting that includes pharmacotherapy (i.e., varenicline, bupropion, and/or nicotine replacement therapy) and/or referral to a smoking cessation program (COR I; LOE A).
- Management of diabetes mellitus in the patient with PAD should be coordinated between members of the healthcare team (COR I; LOE C-EO).
- Cilostazol is an effective therapy to improve symptoms and increase walking distance in patients with claudication (COR I; LOE A).
- In patients with claudication, a supervised exercise program is recommended to improve functional status and QoL and to reduce leg symptoms (COR I; LOE A).
- A supervised exercise program should be discussed as a treatment option for claudication before possible revascularization (COR I; LOE B-R).

Recommendations for resting ankle-brachial index (ABI) for diagnosing PAD:

- In patients with history or physical examination findings suggestive of PAD, the resting ABI, with or without segmental pressures and waveforms, is recommended to establish the diagnosis (COR I; LOE B-R).
- Resting ABI results should be reported as abnormal (ABI ≤0.90), borderline (ABI 0.91–0.99), normal (1.00–1.40), or noncompressible (ABI >1.40) (COR IIa; LOE B-NR).
- In patients at increased risk of PAD but without history or physical examination findings suggestive of PAD, measurement of the resting ABI is reasonable (COR IIa; LOE B-NR).
- In patients not at increased risk of PAD and without history or physical examination findings suggestive of PAD, the ABI is not recommended (COR III; LOE B-NR).

The guideline states that depending on the clinical presentation [e.g., claudication or chronic limb ischemia (CLI)] and the resting ABI values, additional physiological testing studies may be indicated, including exercise treadmill ABI testing, measurement of the toe-brachial index (TBI), and additional perfusion assessment measures (e.g., transcutaneous oxygen pressure [TcPO2], or skin perfusion pressure [SPP]). Studies for anatomic imaging assessment (duplex ultrasound, computed tomography angiography [CTA], or magnetic resonance angiography [MRA], invasive angiography) are generally reserved for highly symptomatic patients in whom revascularization is being considered. Depending on the modality, these studies may confer procedural risk.

The guideline has an algorithm for diagnostic testing for suspected chronic limb ischemia which states that if ABI ≤0.90 additional perfusion assessment, particularly if ABI > 0.70; (i.e., toe brachial index with waveforms, transcutaneous oxygen pressure, skin perfusion pressure)-Class IIa. If abnormal anatomic assessment (CT or MRA or invasive angiography)-Class I.

Recommendation for revascularization for claudication:

- Revascularization is a reasonable treatment option for the patient with lifestyle-limiting claudication with an inadequate response to GDMT (COR IIa; LOE A).

The guideline evidence summary states that a minority of patients with claudication (estimated at <10-15% over 5 years or more) will progress to chronic limb ischemia (CLI). The role of revascularization in claudication is improvement in claudication symptoms and functional status, and consequently in quality of life, rather than limb salvage. Revascularization is reasonable when the patient who is being treated with GDMT, including structured exercise therapy, presents with persistent lifestyle-limiting claudication. Lifestyle-limiting claudication is defined by the patient rather than by any test. It includes impairment of activities of daily living and/or vocational and/or recreational activities due to claudication.

Recommendations for endovascular revascularization for claudication:

- Endovascular procedures are effective as a revascularization option for patients with lifestyle-limiting claudication and hemodynamically significant aortoiliac occlusive disease (COR I; LOE A).
- Endovascular procedures are reasonable as a revascularization option for patients with lifestyle-limiting claudication and hemodynamically significant femoropopliteal disease (COR IIa; LOE B-R).
- The usefulness of endovascular procedures as a revascularization option for patients with claudication due to isolated infrapopliteal artery disease is unknown (COR IIb; LOE C-LD).
- Endovascular procedures should not be performed in patients with PAD solely to prevent progression to chronic limb ischemia (CLI) (COR III: Harm; LOE B-NR).

The guideline states that revascularization is performed on lesions that are deemed to be hemodynamically significant, and stenosis selected for endovascular treatment should have a reasonable likelihood of limiting perfusion to the distal limb. Stenosis of 50-75% diameter by angiography may not be hemodynamically significant, and resting or provoked intravascular pressure measurements may be used to determine whether lesions are significant.

Recommendations for surgical revascularization for claudication:

- When surgical revascularization is performed, bypass to the popliteal artery with autogenous vein is recommended in preference to prosthetic graft material (COR I; LOE A).
- Surgical procedures are reasonable as a revascularization option for patients with lifestyle-limiting claudication with inadequate response to GDMT, acceptable perioperative risk, and technical factors suggesting advantages over endovascular procedures (COR IIa; LOE B-NR).
- Femoral-tibial artery bypasses with prosthetic graft material should not be used for the treatment of claudication (COR III: Harm; LOE B-NR).
- Surgical procedures should not be performed in patients with PAD solely to prevent progression to CLI (COR III: Harm; LOE B-NR).

Recommendations for revascularization for chronic limb ischemia (CLI):

- In patients with CLI, revascularization should be performed, when possible, to minimize tissue loss (COR I; LOE B-NR).
- An evaluation for revascularization options should be performed by an interdisciplinary care team before amputation in the patient with CLI (COR I; LOE C-EO).
- Endovascular procedures are recommended to establish in-line blood flow to the foot in patients with nonhealing wounds or gangrene (COR I; LOE B-NR).
- A staged approach to endovascular procedures is reasonable in patients with ischemic rest pain (COR IIa; LOE C-LD).
- Evaluation of lesion characteristics can be useful in selecting the endovascular approach for CLI (COR IIa; LOE B-R).
- Use of angiosome-directed endovascular therapy may be reasonable for patients with CLI and nonhealing wounds or gangrene (COR IIb; LOE B-NR).
- When surgery is performed for CLI, bypass to the popliteal or infrapopliteal arteries (i.e., tibial, pedal) should be constructed with suitable autogenous vein (COR I; LOE A).
- Surgical procedures are recommended to establish in-line blood flow to the foot in patients with nonhealing wounds or gangrene (COR I; LOE C-LD).
- In patients with CLI for whom endovascular revascularization has failed and a suitable autogenous vein is not available, prosthetic material can be effective for bypass to the below-knee popliteal and tibial arteries (COR IIa; LOE B-R).
- A staged approach to surgical procedures is reasonable in patients with ischemic rest pain (COR IIa; LOE C-LD).

The guideline states that an individual with CLI is at increased risk of major cardiovascular ischemic events and amputation. Care of an individual with CLI includes evaluation for revascularization and wound healing therapies, with the objective to minimize tissue loss, completely heal wounds, and preserve a functional foot. Medical therapy to prevent cardiovascular ischemic events is an important component of care for an individual with CLI. The goal of surgical or endovascular revascularization is to provide in-line blood flow to the foot through at least one patent artery, which will help decrease ischemic pain and allow healing of any wounds, while preserving a functional limb. The lesion characteristics to consider include length, anatomic location, and extent of occlusive disease. Revascularization is not recommended in the setting of a nonviable limb. For an individual with multilevel disease who suffers from ischemic rest pain, in-flow lesions are generally addressed first. Depending on procedural characteristics, including contrast volume used, radiation exposure, and procedure time, out-flow lesions can be addressed in the same setting or at a later time if symptoms persist. This strategy for ischemic rest pain is distinct from the strategy recommended for CLI in a patient with a nonhealing wound or gangrene. In that scenario, restoration of direct in-line flow to the foot is essential for wound healing. Endovascular techniques continue to evolve rapidly, and there has been limited literature comparing techniques with regard to clinically significant outcomes, such as amputation or wound healing.

Recommendations for revascularization for acute limb ischemia (ALI):

- The revascularization strategy should be determined by local resources and patient factors (e.g., etiology and degree of ischemia) (COR I; LOE C-LD).

For marginally or immediately threatened limbs (Category IIa and IIb ALI), revascularization should be performed emergently (within 6 hours). For viable limbs (Category I ALI), revascularization should be performed an on urgent basis (within 6 to 24 hours). The revascularization strategy can range from catheter-directed thrombolysis to surgical thromboembolectomy. Available facilities and clinical expertise are factors that should be considered when determining the revascularization strategy. The technique that will provide the most rapid restoration of arterial flow with the least risk to the patient should be selected.

ACC/AHA/Society for Cardiovascular Angiography and Interventions (SCAI)/Society of Interventional Radiology (SIR)/Society for Vascular Medicine (SVM) 2018 Appropriate Use Criteria for Peripheral Artery Intervention: The Appropriate Use Criteria (AUC) recommendations for lower extremity revascularization in patients with claudication are based on expert consensus statements most recently summarized in the 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease. The authors note that the development of the AUC for peripheral artery intervention was challenging because supporting literature is not as developed or robust as for other topics covered.

Practice Guidelines on the Management of Patients with Peripheral Artery Disease (Compilation of 2005 and 2011 American College of Cardiology Foundation (ACCF)/AHA Guideline Recommendations): This 2013 guideline offers endovascular treatment recommendation for lower extremity PAD (Rooke, et al., 2013).

Endovascular Treatment for Claudication:

Class I

- Endovascular procedures are indicated for individuals with a vocational or lifestyle-limiting disability due to intermittent claudication when clinical features suggest a reasonable likelihood of symptomatic improvement with endovascular intervention and (a) there has been an inadequate response to exercise or pharmacological therapy and/or (b) there is a

very favorable risk-benefit ratio (e.g., focal aortoiliac occlusive disease). (Level of Evidence: A)
- Endovascular intervention is recommended as the preferred revascularization technique for TASC type A iliac and femoropopliteal arterial lesions. (Level of Evidence: B)
- Provisional stent placement is indicated for use in the iliac arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis >50%, or flow-limiting dissection). (Level of Evidence: B)
- Stenting is effective as primary therapy for common iliac artery stenosis and occlusions. (Level of Evidence: B)
- Stenting is effective as primary therapy in external iliac artery stenoses and occlusions. (Level of Evidence: C)

Class IIa
- Stents (and other adjunctive techniques such as lasers, cutting balloons, atherectomy devices, and thermal devices) can be useful in the femoral, popliteal, and tibial arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis >50%, or flow-limiting dissection). (Level of Evidence: C)

Class IIb
- The effectiveness of stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of femoral-popliteal arterial lesions (except to salvage a suboptimal result from balloon dilation) is not well-established. (Level of Evidence: A)
- The effectiveness of uncoated/uncovered stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of infrapopliteal lesions (except to salvage a suboptimal result from balloon dilation) is not well established. (Level of Evidence: C)

Class III
- Endovascular intervention is not indicated if there is no significant pressure gradient across a stenosis despite flow augmentation with vasodilators. (Level of Evidence: C)
- Primary stent placement is not recommended in the femoral, popliteal, or tibial arteries. (Level of Evidence: C)
- Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity PAD. (Level of Evidence: C)

Endovascular Treatment for Chronic Limb Ischemia:

Class I
- For combined inflow and outflow disease with CLI, inflow lesions should be addressed first. (Level of Evidence: C)
- For individuals with combined inflow and outflow disease in whom symptoms of CLI or infection persist after inflow revascularization, an outflow revascularization procedure should be performed. (Level of Evidence: B)

Class IIa
- For limb-threatening lower extremity ischemia and an estimated life expectancy of 2 years or less in patients in whom an autogenous vein conduit is not available, balloon angioplasty is reasonable to perform when possible as the initial procedure to improve distal blood flow. (Level of Evidence: B)
- For limb-threatening ischemia and an estimated life expectancy of more than 2 years, bypass surgery, when possible and when an autogenous vein conduit is available, is reasonable to perform as the initial treatment to improve distal blood flow. (Level of Evidence: B)

Society for Vascular Surgery (SVS): The SVS Lower Extremity Guidelines Writing Group published the SVS practice guidelines for atherosclerotic occlusive disease of the lower extremities (SVS, 2015). In this document they provide the following recommendations:

Diagnosis of peripheral arterial disease (PAD):

- Recommend using the ABI as the first-line noninvasive test to establish a diagnosis of PAD in individuals with symptoms or signs suggestive of disease. When the ABI is borderline or normal (>0.9) and symptoms of claudication are suggestive, we recommend an exercise ABI (Grade I; LOE A).
- In symptomatic patients who are being considered for revascularization, we suggest using physiologic noninvasive studies, such as segmental pressures and pulse volume recordings, to aid in the quantification of arterial insufficiency and help localize the level of obstruction (Grade 2; LOE C).
- In symptomatic patients in whom revascularization treatment is being considered, we recommend anatomic imaging studies, such as arterial duplex ultrasound, computed tomography angiography (CTA), magnetic resonance angiography (MRA), and contrast arteriography (Grade I; LOE B).

Management of asymptomatic disease:

- Recommend multidisciplinary comprehensive smoking cessation interventions for patients with asymptomatic PAD who use tobacco (repeatedly until tobacco use has stopped) (Grade I; LOE A).
- Recommend against invasive treatments for PAD in the absence of symptoms, regardless of hemodynamic measures or imaging findings demonstrating PAD (Grade I; LOE B).

Medical treatment for intermittent claudication (IC):

- Recommend multidisciplinary comprehensive smoking cessation interventions for patients with IC (repeatedly until tobacco use has stopped) (Grade I; LOE A).
- Recommend statin therapy in patients with symptomatic PAD (Grade I; LOE A).
- Recommend optimizing diabetes control (hemoglobin A1c goal of < 7%) in patients with IC if this goal can be achieved without hypoglycemia (Grade I; LOE B).
- Recommend the use of indicated b-blockers (e.g., for hypertension, cardiac indications) in patients with IC. There is no evidence supporting concerns about worsening claudication symptoms (Grade I; LOE B).
- In patients with IC due to atherosclerosis, we recommend antiplatelet therapy with aspirin (75-325 mg daily) (Grade I; LOE A).
- Recommend clopidogrel in doses of 75 mg daily as an effective alternative to aspirin for antiplatelet therapy in patients with IC (Grade I; LOE B).
- In patients with IC due to atherosclerosis, we suggest against using warfarin for the sole indication of reducing the risk of adverse cardiovascular events or vascular occlusions (Grade I; LOE C).
- Suggest against using folic acid and vitamin B12 supplements as a treatment of IC (Grade 2; LOE C).
- In patients with IC who do not have congestive heart failure, we suggest a 3-month trial of cilostazol (100 mg twice daily) to improve pain-free walking (Grade 2; LOE A).
- In patients with IC who cannot tolerate or have contraindications for cilostazol, we suggest a trial of pentoxifylline (400 mg thrice daily) to improve pain-free walking (Grade 2; LOE B).

Exercise therapy:

- Recommend as first-line therapy a supervised exercise program consisting of walking a minimum of three times per week (30-60 min/session) for at least 12 weeks to all suitable patients with IC (Grade I; LOE A).
- Recommend home-based exercise, with a goal of at least 30 minutes of walking three to five times per week when a supervised exercise program is unavailable or for long-term benefit after a supervised exercise program is completed (Grade I; LOE B).
- In patients who have undergone revascularization therapy for IC, we recommend exercise (either supervised or home based) for adjunctive functional benefits (Grade I; LOE B).
- Recommend that patients with IC be followed up annually to assess compliance with lifestyle measures (smoking cessation, exercise) and medical therapies as well as to determine if there is evidence of progression in symptoms or signs of PAD. Yearly ABI testing may be of value to provide objective evidence of disease progression (Grade I; LOE C).

General considerations on invasive treatment for intermittent claudication (IC):

- Recommend endovascular therapy (EVT) 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 (Grade I; LOE B).
- 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 (Grade I; LOE B).

Interventions for aortoiliac occlusive disease (AIOD) in intermittent claudication (IC):

- Recommend endovascular procedures over open surgery for focal AIOD causing IC (Grade I; LOE B).
- Recommend endovascular interventions as first-line revascularization therapy for most patients with common iliac artery or external iliac artery occlusive disease-causing IC (Grade I; LOE B).
- Recommend the selective use of bare metal stents or covered stents for aortoiliac angioplasty for common iliac artery or external iliac artery occlusive disease, or both, due to improved technical success and patency (Grade I; LOE B).
- Recommend the use of covered stents for treatment of AIOD in the presence of severe calcification or aneurysmal changes where the risk of rupture may be increased after unprotected dilation (Grade I; LOE C).
- For patients with diffuse AIOD (eg, extensive aortic disease, disease involving both common and external iliac arteries) undergoing revascularization, we suggest either endovascular or surgical intervention as first-line approaches. Endovascular interventions that may impair the potential for subsequent aortofemoral bypass in surgical candidates should be avoided (Grade I; LOE B).
- EVT of AIOD in the presence of aneurysmal disease should be undertaken cautiously. We recommend that the modality used should either achieve concomitant aneurysm exclusion or should not jeopardize the conduct of any future open or endovascular aneurysm repair (Grade I; LOE C).
- In all patients undergoing revascularization for AIOD, we recommend assessing the common femoral artery (CFA). If hemodynamically significant CFA disease is present, we recommend surgical therapy (endarterectomy) as first-line treatment (Grade I; LOE B).

Intervention for femoropopliteal occlusive disease (FPOD) in intermittent claudication (IC):

- Recommend endovascular procedures over open surgery for focal occlusive disease of the superficial femoral artery (SFA) artery not involving the origin at the femoral bifurcation (Grade I; LOE C).
- For focal lesions (<5 cm) in the SFA that have unsatisfactory technical results with balloon angioplasty, we suggest selective stenting (Grade 2; LOE C).
- For intermediate-length lesions (5-15 cm) in the SFA, we recommend the adjunctive use of self-expanding nitinol stents (with or without paclitaxel) to improve the midterm patency of angioplasty (Grade I; LOE B).
- Recommend against EVT of isolated infrapopliteal disease for IC because this treatment is of unproven benefit and possibly harmful (Grade I; LOE C).
- Recommend surgical bypass as an initial revascularization strategy for patients with diffuse FP disease, small caliber (<5 mm), or extensive calcification of the SFA, if they have favorable anatomy for bypass (popliteal artery target, good runoff) and have average or low operative risk (Grade I; LOE B).

The SVS guideline states that numerous studies have demonstrated the efficacy of both endovascular and surgical therapy for the relief of symptoms of claudication by reducing pain and improving walking distance as well as gains in quality of life and ambulatory function. Both forms of revascularization appear superior to medical therapy for limb-related outcomes, although not necessarily to supervised exercise training. In most claudicant patients being evaluated initially, a 6-month trial of smoking cessation, risk factor modification exercise, or cilostazol, or a combination, should be initiated before any invasive therapy.

The SVS guideline states that endovascular intervention on the profunda femoral artery for claudication symptoms is of unproven value and may carry substantial risk to this most important source of collateral flow in the limb. The multiple branch points within the profunda femoral artery make angioplasty and stenting complicated.

Joint guidelines of the Society for Vascular Surgery, European Society for Vascular Surgery, and World Federation of Vascular Societies: The Global vascular guidelines on the management of chronic limb-threatening ischemia (CLTI) focuses on the definition, evaluation, and management of CLTI with the goals of improving evidence-based care and highlighting critical research needs (Conte, et al., 2019). The following recommendations are included in the guideline:

- "Use objective hemodynamic tests to determine the presence and to quantify the severity of ischemia in all patients with suspected CLTI.
- Use a lower extremity threatened limb classification staging system (eg, SVS's WIfI classification system) that grades wound extent, degree of ischemia, and severity of infection to guide clinical management in all patients with suspected CLTI.
- Perform a detailed history to determine symptoms, past medical history, and cardiovascular risk factors in all patients with suspected CLTI.
- Perform a complete cardiovascular physical examination of all patients with suspected CLTI.
- Perform a complete examination of the foot, including an assessment of neuropathy and a probe-to-bone test of any open ulcers, in all patients with pedal tissue loss and suspected CLTI.
- Measure AP and ABI as the first-line noninvasive test in all patients with suspected CLTI.
- Measure TP and TBI in all patients with suspected CLTI and tissue loss.
- Consider using alternative methods for noninvasive assessment of perfusion, such as PVR, transcutaneous oximetry, or skin perfusion pressure, when ankle and toe pressures, indices, and waveforms cannot be assessed.

- Consider DUS imaging as the first arterial imaging modality in patients with suspected CLTI.
- Consider noninvasive vascular imaging modalities (DUS, CTA, MRA) when available before invasive catheter angiography in patients with suspected CLTI who are candidates for revascularization.
- Obtain high-quality angiographic imaging of the lower limb (with modalities and techniques to be determined by local availability of facilities and expertise). This should include the ankle and foot in all patients with suspected CLTI who are considered potential candidates for revascularization.
- Refer all patients with suspected CLTI to a vascular specialist for consideration of limb salvage, unless major amputation is considered medically urgent.
- Offer primary amputation or palliation to patients with limited life expectancy, poor functional status (eg, nonambulatory), or an unsalvageable limb after shared decision making.
- Do not perform revascularization in the absence of significant ischemia (WIfI ischemia grade 0) unless an isolated region of poor perfusion in conjunction with major tissue loss (eg, WIfI wound grade 2 or 3) can be effectively targeted and the wound progresses or fails to reduce in size by greater than or equal to 50% within 4 weeks despite appropriate infection control, wound care, and offloading.
- Do not perform revascularization in very-low risk limbs (eg, WIfI stage 1) unless the wound progresses or fails to reduce in size by greater than or equal to 50% within 4 weeks despite appropriate infection control, wound care, and offloading.
- Offer revascularization to all average-risk patients with advanced limb-threatening conditions (eg, WIfI stage 4) and significant perfusion deficits (eg, WIfI ischemia grades 2 and 3).
- Consider revascularization for average-risk patients with intermediate limb threat (eg, WIfI stages 2 and 3) and significant perfusion deficits (eg, WIfI ischemia grades 2 and 3).
- Consider revascularization in average-risk patients with advanced limb threat (eg, WIfI stage 4) and moderate ischemia (eg, WIfI ischemia grade 1).
- Consider revascularization in average-risk patients with intermediate limb threat (eg, WIfI stages 2 and 3) and moderate ischemia (eg, WIfI ischemia grade 1) if the wound progresses or fails to reduce in size by greater than or equal to 50% within 4 weeks despite appropriate infection control, wound care, and offloading.
- Obtain high-quality angiographic imaging with dedicated views of ankle and foot arteries to permit anatomic staging and procedural planning in all CLTI patients who are candidates for revascularization.
- Correct hemodynamically significant (greater than or equal to 50% stenosis) disease of the proximal deep femoral artery whenever technically feasible.
- Offer endovascular revascularization when technically feasible for high-risk patients with advanced limb threat (eg, WIfI stage 4) and significant perfusion deficits (eg, WIfI ischemia grades 2 and 3).
- Consider endovascular revascularization for high-risk patients with intermediate limb threat (eg, WIfI stages 2 and 3) and significant perfusion deficits (eg, WIfI ischemia grades 2 and 3).
- Consider endovascular revascularization for high-risk patients with advanced limb threat (eg, WIfI stage 4) and moderate ischemia (eg, WIfI ischemia grade 1) if the wound progresses or fails to reduce in size by greater than or equal to 50% within 4 weeks despite appropriate infection control, wound care, and offloading, when technically feasible.
- Consider endovascular revascularization for high-risk patients with intermediate limb threat (eg, WIfI stages 2 and 3) and moderate ischemia (eg, WIfI ischemia grade 1) if the wound progresses or fails to reduce in size by greater than or equal to 50% within 4 weeks despite appropriate infection control, wound care, and offloading, when technically feasible."

Society of Interventional Radiology and the Canadian Interventional Radiology Association: The Position Statement on Noninvasive Imaging of Peripheral Arterial Disease by the Society of Interventional Radiology and the Canadian Interventional Radiology Association recommendations for noninvasive lower-extremity imaging of PAD includes two broad categories: functional tests and anatomic tests (Dhanoa, et al., 2016). The functional or physiologic tests include the ankle-brachial index (ABI), segmental limb pressures, pulse volume recordings (PVRs), segmental Doppler waveforms, and oxygen testing. The anatomic tests include duplex ultrasound (US), computed tomography (CT), and magnetic resonance (MR) imaging. A noninvasive evaluation of patients with PAD is composed of several different testing modalities, each with specific purposes to identify various patient attributes. These components may differ among laboratories depending on local practice, availability of testing modalities, and training of the physicians and technologists.

Recommendations for Standard Testing:
Ankle-Brachial Index (ABI): Bilateral ABI calculations should be performed, which include bilateral brachial arteries and bilateral ankle pressures. The ABI should take the clinical situation into context to avoid false-negative calculations. The absolute ankle pressures should also be included in conjunction with the ABI calculation. Finally, in heavily calcified arteries, a toe brachial index (TBI) should be considered.

Segmental Limb Pressures: An ABI is a mandatory part of a physiologic examination. For segmental pressures, four cuffs can be used. The recommended location of the blood pressure cuffs are the upper thigh, lower thigh, upper calf, and ankle.

Segmental Pulse Volume Recordings (PVRs): PVRs are ideal for evaluating segmental disease and are not affected by calcification. They should be considered as part of a complete noninvasive examination.

Continuous-Wave Doppler Waveforms: Continuous-wave Doppler analysis should be performed at multiple segments when assessing the lower extremities for PAD. Continuous-wave Doppler analysis should be available as part of a complete noninvasive examination.

Exercise Testing: Exercise testing is useful to assist in the diagnosis of PAD in patients with claudication and should be available as a component of the evaluation because it unmasks PAD not evident at rest. Exercise testing is mandatory in all patients with normal resting examinations who have exertional symptoms. Exercise testing can also be used as a part of surveillance testing in post therapeutic PAD patients.

Ancillary Noninvasive Tests:
Reflection Photoplethysmography: Reflection photoplethysmography has utility in patients PAD and should be considered in the diabetic and chronic renal failure PAD subgroups.

Oxygen Tension: Oxygen tension can be used as an adjunctive tool to predict benefit for revascularization therapy. Oxygen tension measurements should be made with the patient at rest in a supine or recumbent position in a comfortable, warm room with the extremity covered by a sheet or blanket, breathing normobaric oxygen for at least 10 minutes. An increase of greater than 10 mm Hg of foot oxygen tension between normobaric room air and at least 10 minutes of a normobaric 100% oxygen challenge with a pulmonary oxygen saturation of greater than 90% is recommended as a positive outcome from a revascularization procedure of the lower extremities. In the setting of tissue loss, oxygen tension studies should be considered before and after revascularization procedures to serve as the baseline and surveillance after intervention. Post intervention oxygen tension studies should be performed more than one week after the

revascularization procedure, although oxygen tension values can exhibit continual increase for as long as 28 days.

Ultrasound (US): US grayscale imaging and Doppler imaging are recommended for assessment of PAD of the lower extremities. Periodic follow-up in patients who have undergone interventions and surveillance of patients with PAD should occur with US imaging; a standard surveillance protocol should include US evaluation twice in the first post interventional year and annually thereafter. Multiple sonographic modes (e.g., grayscale, power Doppler, color Doppler) are required to appropriately assess PAD in a single imaging session.

Ancillary Noninvasive Tests: In 2019 the AHA published an evidence-based Scientific Statement on optimal exercise programs for patients with peripheral artery disease (Treat-Jacobson, et al., 2019). The AHA states that exercise prescription should be individualized to each patient as tolerated.

The AHA exercise prescription for supervised exercise treadmill training in patients with claudication states:

- Intensity: 40%–60% maximal workload based on baseline treadmill test or workload that brings on claudication within 3–5 min during a 6-MWT (6-MWT indicates 6-minute walk test)
- Session duration: 30–50 min of intermittent exercise; goal is to accumulate at least 30 min of walking exercise
- Claudication intensity: Moderate to moderate/severe claudication as tolerated
- Work-to-rest ratio: Walking duration should be within 5–10 min to reach moderate to moderately severe claudication followed by rest until pain has dissipated (2–5 min)
- Frequency: At least 3 times per week
- Program duration: At least 12 weeks
- Progression: Every 1–2 weeks: increase duration of training session to achieve 50 min. As individuals can walk beyond 10 min without reaching prescribed claudication level, manipulate grade or speed of exercise prescription to keep the walking bouts within 5–10 min
- Maintenance: Lifelong maintenance at least 2 times per week

The Society for Vascular Medicine recommendation (2022): "Refrain from percutaneous or surgical revascularization of peripheral artery stenosis in patients without claudication or critical limb ischemia. Patients without symptoms will not benefit from attempts to improve circulation. No evidence exists to support improving circulation to prevent progression of disease. There is no proven preventive benefit, only symptomatic benefit".

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Percutaneous Transluminal Angioplasty (PTA) (20.7)	3/11/2013
LCD	Wisconsin Physicians Service Insurance Corporation	Non-Coronary Vascular Stents (L35998)	1/1/2023

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
37220	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty
37221	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37222	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)
37223	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37227	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed
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)

CPT®* Codes	Description
37233	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)
37234	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)
37235	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion

HCPCS Codes	Description
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 coronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation

Considered Experimental/Investigational/Unproven when used to report intravascular lithotripsy:

HCPCS Codes	Description
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

HCPCS Codes	Description
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

References

1. American Heart Association. PAD national action plan. Published: May 25, 2022. Accessed Dec 5, 2023. Available at URL address: https://professional.heart.org/en/science-news/pad-national-action-plan

2. Bailey SR, Beckman JA, Dao TD, Misra S, Sobieszczyk PS, White CJ, et al. ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, and Society for Vascular Medicine. J Am Coll Cardiol. 2019 Jan 22;73(2):214-237.

3. Berger JS, Davies M. Overview of lower extremity peripheral arterial disease. In: UpToDate, Collins KA (Ed), UpToDate, Waltham, MA. Last updated May 8, 2023 (Accessed on Dec 5, 2023).

4. Bonaca MP, Creager MA. Peripheral Artery Diseases. In: Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine. Philadelphia, PA: Elsevier; 2019: Ch. 64:1328-51.

5. Butt N, Khalid N, Shlofmitz E. Intravascular Lithotripsy. In: StatPearls. Treasure Island (FL): StatPearls Publishing; August 15, 2020.

6. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCDs) alphabetical index. Accessed Dec 4, 2023. Available at URL address: https://www.cms.gov/medicare-coverage-database/reports/local-coverage-proposed-lcds-alphabetical-report.aspx?proposedStatus=A&sortBy=title

7. Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) alphabetical index. Accessed Dec 4, 2023. Available at URL address: https://www.cms.gov/medicare-coverage-database/reports/national-coverage-ncd-report.aspx?chapter=all&sortBy=title

8. Collins TC. Peripheral Artery Disease. In: Conn's Current Therapy. Philadelphia, PA: Elsevier; 2020: 145-8.

9. Conte MS, Bradbury AW, Kolh P, et al. Global vascular guidelines on the management of chronic limb-threatening ischemia [published correction appears in J Vasc Surg. 2019 Aug;70(2):662]. J Vasc Surg. 2019;69(6S):3S-125S.e40.

10. Creager MA, Belkin M, Bluth EI, Casey DE Jr, Chaturvedi S, Dake MD, Fleg JL, Hirsch AT, Jaff MR, Kern JA, Malenka DJ, Martin ET, Mohler ER 3rd, Murphy T, Olin JW, Regensteiner JG, Rosenwasser RH, Sheehan P, Stewart KJ, Treat-Jacobson D, Upchurch GR Jr, White CJ, Ziffer JA. 2012 ACCF/AHA/ACR/SCAI/SIR/STS/SVM/SVN/SVS Key data elements and definitions for peripheral atherosclerotic vascular disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards (Writing Committee to develop Clinical Data Standards for peripheral atherosclerotic vascular disease). J Am Coll Cardiol. 2012 Jan 17;59(3):294-357.

11. Dhanoa D, Baerlocher MO, Benko AJ, Benenati JF, Kuo MD, Dariushnia SR, et al. Position Statement on Noninvasive Imaging of Peripheral Arterial Disease by the Society of Interventional Radiology and the Canadian Interventional Radiology Association. J Vasc Interv Radiol. 2016 Jul;27(7):947-51.

12. Gerhard-Herman MD, Gornik HL, Barrett C, Barshes NR, Corriere MA, Drachman DE, et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2017 Mar 21;69(11):e71-e126.

13. Gray BH, Diaz-Sandoval LJ, Dieter RS, Jaff MR, White CJ; Peripheral Vascular Disease Committee for the Society for Cardiovascular Angiography and Interventions. SCAI expert consensus statement for infrapopliteal arterial intervention appropriate use. Catheter Cardiovasc Interv. 2014 Oct 1;84(4):539-45.

14. Jaff MR, White CJ, Hiatt WR, Fowkes GR, Dormandy J, Razavi M, et al. An Update on Methods for Revascularization and Expansion of the TASC Lesion Classification to Include Below-the-Knee Arteries: A Supplement to the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II): The TASC Steering Comittee(.). Ann Vasc Dis. 2015;8(4):343-57.

15. Kinlay S, Bhatt DL. Treatment of Noncoronary Obstructive Vascular Disease. In: Brunwauld's Heart Disease: A Textbook of Cardiovascular Medicine. 11th ed. Philadelphia, PA: Elsevier; 2019:1365-82

16. Klein AJ, Feldman DN, Aronow HD, Gray BH, Gupta K, Gigliotti OS, et al; Peripheral Vascular Disease Committee for the Society for Cardiovascular Angiography and Interventions. SCAI expert consensus statement for aorto-iliac arterial intervention appropriate use. Catheter Cardiovasc Interv. 2014 Oct 1;84(4):520-8.

17. Li X, Wang L, Zhang C, Li S, Pu F, Fan Y, Li D. Why is ABI effective in detecting vascular stenosis? Investigation based on multibranch hemodynamic model. ScientificWorldJournal. 2013 Sep 5;2013:185691.

18. Madhavan MV, Shahim B, Mena-Hurtado C, Garcia L, Crowley A, Parikh SA. Efficacy and safety of intravascular lithotripsy for the treatment of peripheral arterial disease: An individual patient-level pooled data analysis. Catheter Cardiovasc Interv. 2020;95(5):959-968.

19. Mills JL. Classification of acute and chronic lower extremity ischemia. In: UpToDate, Collins KA (Ed), UpToDate, Waltham, MA. Last updated Feb 17, 2023 (Accessed Dec 5, 2023).

20. Mohler ER 3rd. Peripheral arterial disease: identification and implications. Arch Intern Med. 2003 Oct 27;163(19):2306-14.

21. Mukherjee D. Lower Extremity Interventions. In: Interventional Cardiology. 8th ed. Philadelphia, PA: Elsevier; 2020: 39, 627-643.e2.

22. Norgren L, Hiatt WR, Dormandy YES, Nehler MR, Harris KA, Fowkes FG; TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). J Vasc Surg. 2007 Jan; 45 Suppl S: S5-67.

23. Patel MR, Conte MS, Cutlip DE, Dib N, Geraghty P, Gray W, et al. Evaluation and treatment of patients with lower extremity peripheral artery disease: consensus definitions from Peripheral Academic Research Consortium (PARC). J Am Coll Cardiol. 2015 Mar 10;65(9):931-41.

24. RadiologyInfo.org for Patients. Angioplasty and vascular stenting. Page last reviewed Jun 1, 2022. Accessed Dec 5, 2023. Available at URL address: https://www.radiologyinfo.org/en/info.cfm?pg=angioplasty#overview

25. Rooke TW, Hirsch AT, Misra S, Sidawy AN, Beckman JA, Findeiss L, et al; American College of Cardiology Foundation Task Force; American Heart Association Task Force. Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013 Apr 9;61(14):1555-70.

26. Samtani SR. Patel PM. Peripheral Artery Disease. In: Ferri's Clinical Advisor 2020. Philadelphia, PA: Elsevier; 2019:1061-66e.

27. Smith SC Jr, Benjamin EJ, Bonow RO, Braun LT, Creager MA, Franklin BA, et al. AHA/ACCF secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update: a guideline from the American Heart Association and American College of Cardiology Foundation endorsed by the World Heart Federation and the Preventive Cardiovascular Nurses Association. J Am Coll Cardiol. 2011 Nov 29;58(23):2432-46.

28. Society for Vascular Surgery Lower Extremity Guidelines Writing Group, Conte MS, Pomposelli FB, Clair DG, Geraghty PJ, McKinsey JF, Mills JL, Moneta GL, Murad MH, Powell RJ, Reed AB, Schanzer A, Sidawy AN; Society for Vascular Surgery. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication. J Vasc Surg. 2015 Mar;61(3 Suppl):2S-41S.

29. Tepe G, Brodmann M, Werner M, et al. Intravascular Lithotripsy for Peripheral Artery Calcification: 30-Day Outcomes From the Randomized Disrupt PAD III Trial. JACC Cardiovasc Interv. 2021;14(12):1352-1361.

30. Tepe G, Brodmann M, Bachinsky W, Holden A, Zeller T, Mangalmurti S, Nolte-Ernsting C, Virmani R, Parikh SA, Gray WA. Intravascular lithotripsy for peripheral artery calcification: mid-term outcomes from the randomized disrupt PAD III trial. Journal of the Society for Cardiovascular Angiography & Interventions 1 (2022).

31. Treat-Jacobson D, McDermott MM, Bronas UG, Campia U, Collins TC, Criqui MH, et al; American Heart Association Council on Peripheral Vascular Disease; Council on Quality of Care and Outcomes Research; and Council on Cardiovascular and Stroke Nursing. Optimal Exercise Programs for Patients With Peripheral Artery Disease: A Scientific Statement From the American Heart Association. Circulation. 2019 Jan 22;139(4):e10-e33.

32. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Search Devices@FDA. Lithoplasty Peripheral Balloon Dilatation Catheter, Lithoplasty Generator And Connector Cable, Lithoplasty Connector Cable. Shockwave Medical, Inc. K161384. Date approved Sep 14, 2016. Accessed Dec 5, 2023. Available at: https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm

33. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Search Devices@FDA. Shockwave M5 Peripheral Intravascular Lithotripsy (IVL) Catheter. Shockwave Medical, Inc. K180958. Date approved Jul 26, 2018. Accessed Dec 5, 2023. Available at: https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm

34. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Search Devices@FDA. Shockwave Medical Intravascular Lithotripsy (IVL) System. Shockwave Medical, Inc. K180454. Date approved Jun 27, 2018. Accessed Dec 5, 2023. Available at: https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm

35. U.S. Food and Drug Administration. Premarket Approval (PMA). Accessed Dec 5, 2023. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• Revised the policy statement for claudication and CLTI to expand the ABI threshold from ≤ 0.69 to ≤0.90.	2/15/2024