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Percutaneous Revascularization Procedures for Lower Extremity Peripheral Arterial Disease

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Coverage

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

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

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

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

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

Percutaneous revascularization using balloon angioplasty, stent procedures, or atherectomy in individuals with asymptomatic lower extremity peripheral arterial disease **is considered experimental, Investigational and/or unproven** in all other situations.

Percutaneous revascularization using lithotripsy in individuals with lower extremity peripheral arterial disease **is considered experimental, investigational and/or unproven** in all situations.

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.

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

Shared Decision Making
Clinical practice guidelines state, "Patient-centered discussions are critical in making appropriate decisions regarding revascularization and for building a trusting longitudinal relationship. More than 70% of 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 (i.e., 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." (1)

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.

Peripheral Arterial Disease
Guidelines recognize 4 clinical subsets of peripheral arterial disease (PAD). (1)

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

revascularization (graft or stent), trauma, peripheral aneurysm with distal embolization, or thrombosis. Severity is further classified using the Rutherford classification system (viable, salvageable/marginally threatened, salvageable/immediately threaten, irreversible).

Prevalence and Risk Factors

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

Screening and Diagnosis

Clinical assessment, including risk factor assessment, history, physical examination, and consideration of differential diagnoses, is performed before diagnostic testing. (2, 3)

For individuals at increased risk of PAD, vascular examination with a focus on the lower extremities is recommended. After the history and physical examination identify 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 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 to 0.99), normal (1.00 to 1.40), or noncompressible (>1.40). In individuals with suspected chronic symptomatic PAD and normal or borderline resting ABI, exercise ABI can be performed.

Treatment

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

Percutaneous revascularization includes catheter-based revascularization procedures using modalities such as percutaneous transluminal (balloon) angioplasty, drug-coated balloon angioplasty, stenting (bare-metal, drug-coated, or covered), and atherectomy.

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

Regulatory Status

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, infrapopliteal, 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

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Percutaneous Revascularization for Chronic Symptomatic Lower Extremity Peripheral Artery Disease Using Balloon Angioplasty, Stent Procedures, or Atherectomy

Clinical Context and Therapy Purpose

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is adults with chronic symptomatic lower extremity peripheral artery disease.

Interventions

The therapy being considered is percutaneous revascularization with the following procedures:

- Balloon angioplasty;
- Drug-coated balloon angioplasty;
- Stent procedures (bare-metal, drug coated, or covered);
- Atherectomy.

Comparators
Standard treatment for chronic symptomatic peripheral artery disease (PAD) includes medical therapy, foot care, and structured exercise therapy.

Outcomes
Primary outcomes include primary vessel patency, all-cause mortality, and cardiovascular (Table 1). Secondary outcomes include procedural success, target vessel revascularization rates, complication rates, morbidity assessments, quality of life, and clinical and symptomatic improvements. (4)

Outcomes at 6 months and 1 year are of interest.

Table 1. Health Outcome Measures Relevant to Individuals with Peripheral Artery Disease

Outcome	Measure (Units)	Description	Thresholds for Improvement/Decline or Clinically Meaningful Difference (if Known)
Primary Outcomes			
Primary vessel patency	Ankle brachial index (ABI) ratio (1)	The ratio of the higher systolic pressure in the ipsilateral dorsalis pedis and posterior tibial arteries divided by the higher of the left and right brachial artery systolic pressures.	Abnormal (≤ 0.90) Borderline (0.91-0.99) Normal (1.00-1.40) Noncompressible (>1.40)
	Duplex ultrasound (1)	This test includes assessment of vein patency, size (vein diameter), length of available vein, and other anatomic features such as branching and	NA

		presence of acute or previous thrombosis.	
	Angiography	A contrast dye is injected into the blood to highlight blood vessels, which are then visible in X-ray images. This is used to evaluate blood vessels and identify blockages.	NA
All-cause mortality	Number of deaths	Total number of deaths from any cause.	NA
Fatal and non-fatal cardiovascular events	Incidence (rate)	Cardiac events such as heart attack, stroke, arrhythmia, etc.	NA

NA: not applicable.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach', within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Wardle et al. (2020) conducted a systematic review and meta-analysis of studies investigating atherectomy in individuals with symptomatic PAD. (4) The review included 7 studies (N=527; number of treated lesions=581), comparing atherectomy versus balloon angioplasty (BA) and atherectomy versus BA with primary stenting. No studies compared atherectomy with bypass surgery. The evidence from this review was of very low certainty due to high risk of bias, imprecision, and inconsistency. The key findings indicated no clear difference between atherectomy and BA in primary patency rates at 6 months (risk ratio [RR]: 1.06; 95% confidence interval [CI]: 0.94 to 1.20; 3 studies, N=186) or at 12 months (RR: 1.20; 95% CI: 0.78 to 1.84; 2 studies, N=149), mortality rates (RR: 0.50; 95% CI: 0.10 to 2.66; 3 studies, N=210), initial technical failure rates (RR: 0.48; 95% CI: 0.22 to 1.08; 6 studies; number of treated

vessels=425), and target vessel revascularization (TVR) rates at 6 months (RR: 0.51; 95% CI: 0.06 to 4.42; 2 studies, number of treated vessel =136) or at 12 months (RR: 0.59; 95% CI: 0.25 to 1.42; 3 studies, number of treated vessels=176). Complication rates (RR: 0.69; 95% CI: 0.28 to 1.68; 6 studies; N=387) and embolization events (RR: 2.51; 95% CI: 0.64 to 9.80; 6 studies; N=387) also showed no clear difference between atherectomy and BA. However, atherectomy may be less likely to cause dissection (RR: 0.28; 95% CI: 0.14 to 0.54; 4 studies; N=290) and may be associated with a reduction in bailout stenting (RR: 0.26; 95% CI: 0.09 to 0.74; 4 studies, number of treated vessels=315). Four studies reported amputation rates, with only one amputation event recorded in a BA participant. Subgroup analysis comparing plain balloons/stents and drug-eluting balloons/stents did not detect any differences between the subgroups. One study (155 participants, 155 treated lesions) compared atherectomy versus BA and primary stenting, reporting one death (RR: 0.38; 95% CI: 0.04 to 3.23; N=155) and 3 complication events (RR: 7.04;95% CI: 0.80 to 62.23; N=155), both with very low-certainty evidence. There was no clear difference in cardiovascular events (RR: 0.38; 95% CI: 0.04 to 3.23; N=155) and no initial technical failure events. TVR rates at 6 and 24 months showed little difference between treatment arms (RR: 2.27; 95% CI: 0.95 to 5.46; N=155, and RR: 2.05; 95% CI: 0.96 to 4.37; N=155, respectively). The authors concluded that the evidence is very uncertain about the effect of atherectomy on patency, mortality, and cardiovascular event rates compared to plain balloon angioplasty, with or without stenting. Larger studies powered to detect clinically meaningful, patient-centered outcomes are required. A list of studies and their characteristics and the results of the meta-analyses are presented in Tables 2 to 4.

Gornik et al. (2024) conducted a systematic review to support clinical practice guidelines for the management of lower extremity PAD (Refer to the Practice Guidelines and Position Statements section for detailed recommendations). (1) Given the benefits of the less invasive measures of guideline-directed management and therapy and structured exercise, revascularization is a second-tier treatment for most patients with claudication.

The reviewers concluded that revascularization (open and endovascular) has shown effectiveness in mitigation of pain with walking and improving walking distance as well as QOL although tradeoffs in durability need to be considered. The reviewers noted that most studies of revascularization for individuals with chronic symptomatic PAD enrolled participants with claudication. They noted that the potential effects of revascularization on individuals with chronic symptomatic PAD with leg symptoms other than claudication is an area in need of further study.

Guidelines recommend selection of procedures based on lesion characteristics (e.g., anatomic location, lesion length, degree of calcification), operator experience, and the range of available technologies. Evaluation of the comparative effectiveness of different endovascular procedures was beyond the scope of this review.

Table 2. Comparison of Studies Included in Systematic Reviews and Meta-analyses

Study	Wardel et al. (2020) (4)
Ott et al. (2017) (5)	●

Zeller et al. (2017) (6)	●
Dattilo et al. (2014) (7)	●
Shammas et al. (2012) (8)	●
Shammas et al. (2011) (9)	●
Nakamura et al. (1995) (10)	●
Vroegindeweij et al. (1995) (11)	●

Table 3. Systematic Review and Meta-analyses Characteristics

Systematic Review	Dates	Trials	Participants	N (Range)	Design	Duration
Wardle et al. (2020) (4)	1995-2017	7	Individuals with symptomatic PAD	527 (39 to 155)	RCTs	6 to 24 months

PAD: peripheral artery disease; RCT: randomized controlled trial.

Table 4. Results of Systematic Review and Meta-analyses of Atherectomy versus Balloon Angioplasty for Peripheral Arterial Disease

Systematic Review	Primary patency at 6 months	Primary patency at 12 months	Mortality at 12 months	Fatal and non-fatal cardiovascular events at 24 months
Wardle et al. (2020) (4)				
Total N	186	149	210	160
Pooled effect (95% CI)	RR, 1.06 (0.94 to 1.20)	RR, 1.20 (0.78 to1.84)	RR, 0.50 (0.10 to2.66)	NR[a]
I^2 (p)	NR	NR	NR	NR

CI: confidence interval; RR: risk ratio; NR: not reported.

[a] Zeller et al. (2017) (6) reported cardiac failure and acute coronary syndrome as causes of death at 24 months, but it was unclear for which participants in which arms this was accountable for. Shammas et al. (2011) (9) declared embolic stroke and myocardial infarction to be secondary outcomes, but no events were recorded in either arm.

Section Summary: Percutaneous Revascularization Procedures for Chronic Symptomatic Lower Extremity Peripheral Artery Disease

A systematic review of RCTs has demonstrated that percutaneous and surgical revascularization for chronic symptomatic PAD can improve symptoms and QOL in individuals who have not responded to guideline directed medical treatment, including structured exercise. Guidelines recommend that the choice to proceed to revascularization and selection of procedure should be a shared decision-making process, based on clinical presentation, including severity of symptoms and anticipated natural history; degree of functional limitation and QOL impairment; response to medical therapy, including structured exercise; and the likelihood of a beneficial

short- and longer-term outcome, balanced against potential short-term (e.g., bleeding, infection, major adverse cardiovascular events [MACE]) and longer-term procedural risk.

Percutaneous Revascularization Procedures for Chronic Limb Threatening Ischemia Using Balloon Angioplasty, Stent Procedures, or Atherectomy

Clinical Context and Therapy Purpose

The purpose of percutaneous revascularization in individuals who have chronic limb-threatening ischemia (CLTI) is to promote wound healing and prevent limb amputation.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest are adults with CLTI.

Interventions

The therapy being considered is percutaneous revascularization with the following procedures:

- Balloon angioplasty;
- Stent procedure;
- Atherectomy.

Comparators

Revascularization is considered the standard treatment for patients with CLTI 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.

Outcomes

Wound healing and prevention of amputation are the primary goals of care for individuals with CLTI. Primary outcomes can include major adverse cardiac events (MACE) and major adverse limb events (MALE).

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Abouzid et al. (2024) conducted a systematic review and meta-analysis comparing endovascular therapy and surgical revascularization for CLTI. (12) The analysis included 16 studies (N=47,609). The results showed that surgery is associated with a lower risk of major adverse limb events (MALE) (odds ratio [OR]: 1.13; 95% confidence interval [CI]: 1.01 to 1.28, p=.04), while endovascular therapy is linked to lower rates of major adverse cardiovascular events (MACE) (OR: 0.62; 95% CI: 0.51 to 0.76; p<.00001), bleeding, wound complications, readmission, unplanned reoperation, acute renal failure, and shorter hospital stays. There was no significant difference in 30-day mortality between the two groups (OR: 0.94; 95% CI: 0.79 to 1.12; p=.52). The authors conclude the results suggest that the choice between endovascular therapy and surgery should be based on a multidisciplinary team approach, considering patient characteristics and anatomy. A list of studies and their characteristics and the results of the meta-analyses are presented in Table 5 to 7.

In 2024 the American College of Cardiology/American Heart Association Joint Committee conducted a systematic review to inform clinical practice guidelines, citing the BEST-CLI (Best Endovascular versus Best Surgical Therapy in Patients with CLI) and BASIL-2 (Bypass versus Angioplasty for Severe Ischaemia of the Leg) trials as further informing revascularization strategy in patients with CLTI. (1, 13, 14) The contrasting findings of the BEST-CLI and BASIL-2 trials highlight the need to consider patient clinical and anatomic characteristics when selecting the initial revascularization strategy for patients with CLTI, including consideration of patient risk estimation, staging of the limb for severity and anatomic pattern of disease, previous vascular interventions, and availability of conduit.

The guidelines additionally cite a systematic review of 13 studies looking at the natural history of patients with CLTI enrolled in medical and angiogenic therapy trials who did not receive revascularization in which a 22% all-cause mortality rate and a 22% rate of major amputation at a median follow-up of 12 months were observed. (15) Thus, all patients with CLTI should undergo assessment for revascularization. Data from RCTs and observational evidence inform revascularization strategy in CLTI. Both endovascular and surgical revascularization have been demonstrated to be effective treatments for preventing amputation in CLTI.

Table 5. Comparison of Studies Included in Systematic Reviews and Meta-analyses

Study	Abouzid et al. (2024) (12)
Farber et al. (2022) (13)	●
Kim et al. (2021) (16)	●
Latz et al. (2021) (17)	●
Lee et al. (2021 (18)	●
Lawaetz et al. (2020) (19)	●
Stavroulakis et al. (2020 (20)	●
Altreuther et al. (2019) (21)	●
Dayama et al. (2019) (22)	●
Bodewes et al. (2018) (23)	●

Fashandi et al. (2018) (24)	●
Shannon et al. (2018) (25)	●
Veraldi et al. (2018) (26)	●
Darling et al. (2017) (27)	●
Mehaffey et al. (2017) (28)	●
Siracuse et al. (2016) (29)	●
McQuade et al. (2010) (30)	●

Table 6. Systematic Review and Meta-analyses Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Abouzid et al. (2016) (12)	2010-2022	16	Patients with CLTI	47,609 (80 to 17,193)	RCTs and observational studies	NR to up to 5 years

CLTI: chronic limb-threatening ischemia; NR: not reported: RCT: randomized controlled trial.

Table 7a. Results of Systematic Review and Meta-analyses of Surgical Intervention versus Endovascular Technique

Study	Major adverse limb events	Major adverse cardiovascular events	Risk of bleeding	Wound complications
Abouzid et al. (2024) (12)				
Total N	44,051	47,249	10,361	28,467
Pooled effect (95% CI)	OR, 1.20 (1.03 to 1.41	OR, 0.66 (0.52 to 0.84)	OR, 0.29 (0.18 to 0.47)	OR, 0.14 (0.08 to 0.23)
I^2 (p)	70% (.0003)	75% (<.00001)	78% (.0001)	71% (.002)

CI: confidence interval; OR: odds ratio.

Table 7b. Results of Systematic Review and Meta-analyses of Surgical Intervention versus Endovascular Technique

Study	Readmission	Risk of unplanned reoperation	Length of hospital stay	Acute renal failure	30-day mortality
Abouzid et al. (2024) (12)					
Total N	27,528	13,959	20,914	28,044	45,569
Pooled effect (95% CI)	OR, 0.93 (0.87 to 1.00)	OR, 0.59 (0.42 to 0.83)	OR, -3.34 (-4.52 to -2.16)	OR, 0.74 (0.58 to 0.95)	OR, 0.95 (0.72 to 1.24)
I^2 (p)	36% (.18)	89% (<.00001)	92% (<.00001)	32% (.18)	42% (.08)

CI: confidence interval; OR: odds ratio.

Randomized Controlled Trials

Bradbury et al. (2023) conducted the BASIL-2 trial (N=345) comparing the effectiveness of vein bypass versus best endovascular treatment for patients with CLTI requiring infra-popliteal revascularization. (14) The trial was conducted at 41 vascular surgery sites in the UK, Sweden, and Denmark, and followed participants for a minimum of 2 years. The primary outcome was amputation-free survival, defined as the time to the first major amputation above the ankle or death from any cause, using the intention-to-treat population. Results showed that major amputation or death occurred in 63% of the vein bypass group compared to 53% of the best endovascular treatment group (adjusted hazard ratio [HR]: 1.35; 95% CI: 1.02 to 1.80; p=.037). Additionally, 53% of the vein bypass group and 45% of the best endovascular treatment group died (adjusted HR: 1.37; 95% CI: 1.00 to 1.87). The authors concluded that a best endovascular treatment first revascularization strategy was associated with better amputation-free survival, suggesting that more patients with CLTI should be considered for this approach. A limitation of the trial was that the planned enrollment was not met due to recruitment challenges.

Farber et al. (2022) conducted the BEST-CLI trial (N=1830) investigating the effectiveness of endovascular therapy versus surgical revascularization for patients with CLTI. (13) Cohort 1 included patients with an adequate single segment of great saphenous vein that could be used for surgery. In Cohort 1, the incidence of MALE or death was significantly lower in the surgical group compared to the endovascular group (42.6% vs 57.4%; HR: 0.68; 95% CI: 0.59 to 0.79; p<.001). Cohort 2 included patients who needed an alternative bypass conduit. In Cohort 2, the outcomes were similar between the surgical group and the endovascular group (42.8% vs 47.7%; HR: 0.79; 95% CI: 0.58 to 1.06; p=.12). The incidence of adverse events was similar in both groups across the two cohorts. A limitation of this study was selection bias because participant eligibility was determined locally and varied by site.

A summary of RCT characteristics and results are presented in Tables 8 and 9. Study relevance, and design and conduct limitations are presented in Tables 10 and 11.

Table 8. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Bradbury et al. (2023) (14) BASIL-2	United Kingdom, Sweden, Denmark	41	NR	Patients with CLTI	Vein bypass group (n=172)	Best endovascular treatment group (n=173)
Farber et al. (2022) (13) BEST-CLI	United States, Canada, Finland, Italy, New Zealand	150	2014-2019	Patients ≥18 years old with CLTI	Surgery (n=718)	Endovascular therapy (n=716)

CLTI: chronic limb-threatening ischemia; NR: not reported; RCT: randomized controlled trial.

Table 9. Summary of Key RCT Results

Study	No. amputation-free survival, n (%)	Above-ankle amputation of the index limb (n/total n (%)	Death from any cause, n (%)	MALE, n (%)	Major adverse limb event or perioperative death, n/total n (%)	MACE, n (%)	Major adverse cardiovascular event, n/total n (%)
Bradbury et al. (2023) (14) BASIL-2							
Vein bypass group (n=172)	108 (63%)		91 (53%)	71 (41%)		68 (40%)	
Best endovascular treatment group (n=173)	92 (53%)		77 (45%)	77 (45%)		73 (42%)	
HR (95% CI)	1.135 (1.02 to 1.80)		1.37 (1.00 to 1.87)	0.93 (0.67 to 1.29)		1.09 (0.78 to 1.53)	
P value	.037		NR	NR		NR	
Farber et al. (2022) (13) BEST-CLI							
Surgery (n=718)		74/709 (10.4)	234/709 (33.0)		139/687 (20.2)		269/718 (37.5)
Endovascular therapy (n=716)		106/711 (14.9)	267/711 (37.6)		246/708 (34.7)		309/716 (43.2)
HR (95% CI)		0.73 (0.54 to 0.98)	0.98 (0.82 to 1.17)		0.53 (0.43 to 0.65)		0.94 (0.80 to 1.11)
P value		NR	NR		NR		.48

CI: confidence interval; HR: hazard ratio; MACE: major adverse cardiovascular event; MALE: major adverse limb events; NR: not reported.

Table 10. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Bradbury et al. (2023) (14) BASIL-2					

Farber et al. (2022) (13) BEST-CLI					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 11. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Bradbury et al. (2023) (14) BASIL-2		1. Open-label				
Farber et al. (2022) (13) BEST-CLI	4. Selection bias because eligibility was determined locally and varied by site.	1. Open-label			4. Planned enrollment was not met due to recruitment challenges.	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Nonrandomized Studies

Nugteren et al. (2023) conducted a retrospective analysis of prospectively collected data from 29 consecutive participants with CLTI who were enrolled in the Disrupt PAD III Trial. (31) All consecutive patients treated with lithotripsy at 4 Dutch hospitals were included. The primary efficacy endpoints were primary patency, limb salvage, and amputation-free survival (AFS) at 12 months. The primary safety endpoint was the freedom from a composite of major adverse events (MAEs) through 30 days, defined as abrupt closure, distal embolization, perforation, emergency revascularization, major amputation, and death. The primary patency, limb salvage, and AFS for CLTI patients were 68.8%, 83.9%, and 57.1% at 12 months, respectively. During follow-up, 3 major amputations were performed due to progressive foot ulceration without infection, all within 3 months of intervention. A total of 5 patients died, whose causes of death were acute coronary syndrome (ACS), acute mesenteric ischemia, and in 3 patients a palliative course, including 1 due to progressive foot ulceration. The rate of MAE at 30 days was 13.3%. In 1 patient, the closure device failed and led to an acute occlusion, after which a femoral endarterectomy was performed to remove the closure device. Another patient was amputated after 16 days due to progressive foot ulceration. Two patients died within 30 days after the intervention because of an ACS and a palliative course due to treatment-requiring multi-morbidity and lack of perspective. The study was limited by a low sample size, heterogeneity in post-dilatation technique, lack of a control group, and lack of an independent core laboratory adjudication.

Section Summary: Percutaneous Revascularization Procedures for Chronic Limb Threatening Ischemia Using Balloon Angioplasty, Stent Procedures, or Atherectomy

Randomized controlled trials, observational studies, and a systematic review of RCTs and observational studies have demonstrated both endovascular and surgical revascularization have been demonstrated to be effective treatments for preventing amputation in CLTI. The RCTs, the BEST-CLI and BASIL-2 trials, had contrasting results highlighting the need to consider patient clinical and anatomic characteristics when selecting the initial revascularization strategy for patients with CLTI, including consideration of patient risk estimation, staging of the limb for severity and anatomic pattern of disease, previous vascular interventions, and availability of conduit. 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.

Percutaneous Revascularization Procedures for Acute Limb Ischemia Using Balloon Angioplasty, Stent Procedures, or Atherectomy

Clinical Context and Therapy Purpose

The purpose of percutaneous revascularization in individuals who have acute limb ischemia is to prevent irreversible tissue damage and major amputation.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest are adults with acute limb ischemia.

Interventions
The therapy being considered is percutaneous revascularization with the following procedures:
- Balloon angioplasty;
- Stent procedure;
- Atherectomy.

Comparators
Standard medical treatment for acute limb ischemia includes medications, exercise therapy,

Outcomes
Wound healing and prevention of amputation are the primary goals of care for individuals with acute limb ischemia. Primary outcomes can include major adverse cardiac events (MACE) and major adverse limb events (MALE).

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Veenstra et al. (2020) conducted a systematic review and meta-analysis on the safety and effectiveness of surgical revascularization versus catheter-driven thrombolysis (CDT) for treating acute limb ischemia. (32) A meta-analysis of 25 studies (N=4689) found no significant differences in limb salvage between thrombectomy and thrombolysis. However, thrombolysis was associated with a higher incidence of major vascular events compared to surgical treatment, (6.5% vs 4.4%; OR: 0.33; 95% CI: 0.13 to 0.87; p=.02; I^2=20%). Both CDT and surgery have comparable limb salvage rates, but CDT carries a higher risk of hemorrhagic complications. There were few RCTs included and future trials should ensure comparable study groups and

standardized outcome reporting practices. A list of studies and their characteristics and the results of the meta-analyses are presented in Tables 12 to 14.

Table 12. Comparison of Studies Included in Systematic Reviews and Meta-analyses

Study	Veenstra et al. (2020) (32)
Taha et al. (2015) (33)	●
deDonato et al. (2014) (34	●
Ouriel et al. (1998) (35)	●
Ouriel et al. (1996) (36)	●
Hoch et al. (1994) (37)	●
Ouriel et al. (1994) (38)	●
Stile (1994) (39)	●
Nilsson et al. (1992) (40)	●
Earnshaw et al. (1989) (41)	●
Seeger et al. (1987) (42)	●

Table 13. Systematic Review and Meta-analyses Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Veenstra et al. (2020) (32)	1987-2015	10	Patients with acute limb ischemia	4689 (20 to 544)	RCTs and observational	30 days to 1 year

RCT: randomized controlled trial.

Table 14. Results of Systematic Review and Meta-analyses of Surgical Revascularization versus Catheter-driven Thrombolysis

Study	Limb salvage at 30 days	Limb salvage at 6 months	Limb salvage at 1 year	Major vascular events
Veenstra et al. (2020) (32)				
Total N	Total N	Total N	Total N	Total N
Pooled effect (95% CI)	OR, 0.96 (0.53 to 1.74)	OR, 1.11 (0.76 to 1.61)	OR, 1.28 (0.82 to 1.98)	OR, 0.33 (0.13 to 0.87)
I^2 (p)	63% (.004)	47% (.07)	63% (.01)	20% (.29)

CI: confidence interval; OR: odds ratio.

Section Summary: Percutaneous Revascularization Procedures for Acute Limb Ischemia Using Balloon Angioplasty, Stent Procedures, or Atherectomy

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 CDT carries a higher risk of hemorrhagic complications.

Percutaneous Revascularization for Lower Extremity Peripheral Artery Disease Using Lithotripsy

Clinical Context and Therapy Purpose

Percutaneous revascularization for lower extremity PAD using lithotripsy is proposed as a vessel preparation option to facilitate definitive endovascular treatment in heavily calcified lesions.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is adults with lower extremity peripheral artery disease.

Interventions

The therapy being considered is percutaneous revascularization with lithotripsy. Lithotripsy uses multiple emitters mounted on a traditional angioplasty balloon catheter that provide pulsatile acoustic pressure energy to fracture superficial and deep calcium without affecting local soft tissues or liberating emboli.

Comparators

Standard care for peripheral artery disease includes smoking cessation, pharmacotherapy (antiplatelets, statins), and exercise.

Outcomes

The outcomes of interest are procedural success, patency, and safety outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Randomized Controlled Trial

Lithotripsy using the Shockwave system has been evaluated in 1 RCT, known as the Disrupt PAD III Trial (NCT02923193). (43) The trial compared vessel preparation with lithotripsy versus percutaneous transluminal angioplasty prior to drug-coated balloon in 306 individuals with symptomatic PAD (Table 15). The primary endpoint was core-lab adjudicated procedural

success. Secondary outcomes, evaluated at 30 days, included clinically driven target lesion revascularization, change in ankle-brachial index (ABI), change in Rutherford class, health utility based on response to the EuroQol-5 Dimension (EQ-5D) questionnaire, and walking capacity on the Walking Impairment Questionnaire (WIQ). Major adverse events assessed included unplanned surgical revascularization or major amputation (above ankle) of the target limb, symptomatic thrombus or embolus requiring treatment, and perforations requiring provisional stent placement or other treatment. The powered secondary endpoint was primary patency at 12 months, reported in a subsequent publication. (44)

Procedural success was achieved in 65.8% of individuals in the lithotripsy group, compared to 54.0% in the control group (p=.01). (43) Tepe et al. (2022) reported primary patency at 12 months, defined as freedom from clinically driven target lesion revascularization (CD-TLR) plus freedom from restenosis determined by duplex ultrasound (Table 16). (44) Acute percutaneous transluminal angioplasty (PTA) failure requiring stent placement during the index procedure was prespecified as a loss of primary patency. Primary patency at 1 year was superior in the lithotripsy group compared to the control group (80.5% vs 68.0%, p=.017). The difference was driven by the freedom from provisional stent placement rate; freedom from the individual endpoints of CD-TLR and restenosis at 1 year were similar between the 2 groups. The MAE rate at 12 months was similar in both groups. Both groups demonstrated improvement in ABI index, WIQ, EQ-5D, and Rutherford category, but there were no differences in the change from baseline to 1 year between treatment groups.

A summary of study characteristics and results are presented in Tables 15 and 16. Study relevance, and design and conduct limitations are presented in Tables 17 and 18. A major limitation of the study was a lack of comparison to other percutaneous revascularization procedures.

Table 15. Summary of Key RCT Characteristics

Study; Trial	Disrupt PAD III Trial (NCT02923193) (43)
Countries	Austria, Germany, New Zealand, United States
Sites	45
Dates	2017-2020
Participants	Symptomatic leg claudication or rest pain (Rutherford class 2 to 4) and angiographic evidence of >70% stenosis within the superficial femoral or popliteal artery, lesion length up to 180 mm (up to 100 mm for chronic total occlusion), reference vessel diameter 4 to 7mm, and moderate or severe calcification.
Intervention	n=153 Vessel preparation with lithotripsy using the Shockwave intravascular lithotripsy system prior to drug-coated balloon
Control	n=153 Standard percutaneous transluminal angioplasty prior to drug-coated balloon

Outcomes	**Primary:** Core lab–adjudicated procedural success (residual stenosis ≤30% without flow-limiting dissection) prior to drug-coated balloon or stenting **Secondary:** Clinically driven target lesion revascularization, 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.

EQ-5D: EuroQol-5 Dimension; mm: millimeter; NCT: national clinical trial; PAD: peripheral artery disease; RCT: randomized controlled trial.

Table 16. Summary of Key RCT Results

Study	Procedural Success (Primary Endpoint) (43)	Primary Patency at 12 months (Secondary Endpoint) (44)	Primary Patency at 24 months, n/total n (%) (44)	Major Adverse Events, % (43)
Disrupt PAD III Trial (NCT02923193) (43, 44)				
Lithotripsy	96/146 (65.8%)	99/123 (80.5%)	78/111 (70.3%)	0%
Standard PTA	67/133 (50.4%)	87/128 (68.0%)	58/113 (51.3%)	1.3%
P-value for difference	.01	.017	.003	.16

NCT: national clinical trial; PAD: peripheral artery disease; PTA: percutaneous transluminal angioplasty; RCT: randomized controlled trial.

Table 17. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Disrupt PAD III Trial (NCT02923193) (43)			5. No comparison to other percutaneous revascularization techniques.	5. Clinically significant difference not prespecified.	

NCT: national clinical trial; PAD: peripheral artery disease.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 18. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Disrupt PAD III Trial (NCT02923193) (43)		2, 3. Investigators and research staff not blinded.				

NCT: national clinical trial; PAD: peripheral artery disease.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Nonrandomized Studies

A number of nonrandomized studies have reported outcomes in consecutive patients undergoing lithotripsy for chronic symptomatic PAD or CLTI. These studies are limited by lack of a control group, small sample sizes, and heterogeneity in clinical and procedural characteristics. (45, 46)

Section Summary: Percutaneous Revascularization for Lower Extremity Peripheral Artery Disease Using Lithotripsy

One randomized controlled trial (RCT) and nonrandomized studies have been conducted on symptomatic lower extremity PAD who receive percutaneous revascularization. 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.

Percutaneous Revascularization Procedures for Asymptomatic Lower Extremity Peripheral Artery Disease

Clinical Context and Therapy Purpose

The purpose of percutaneous revascularization in individuals who have asymptomatic lower extremity peripheral artery disease (PAD) would be to prevent progression to symptomatic disease.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is adults with asymptomatic lower extremity peripheral artery disease (PAD).

Interventions

The therapy being considered is percutaneous revascularization with any of the following procedures:

- Balloon angioplasty
- Stent procedure
- Atherectomy
- Lithotripsy

Comparators

Standard care for asymptomatic PAD includes smoking cessation, pharmacotherapy (antiplatelets, statins), and exercise.

Outcomes

The outcomes of interest are progression to symptomatic PAD and procedure-related adverse events, including the need for revascularization.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Review

A systematic review conducted to support the ACC/AHA guideline for the management of lower extremity PAD identified no evidence that invasive treatment while PAD is asymptomatic will alter its natural history, and evidence showing that individuals who have undergone a revascularization procedure are at increased risk of subsequent complications, particularly major adverse limb events (MALE), including the need for additional subsequent revascularization procedures. (1) The reviewers concluded that no evidence supports a recommendation for early revascularization for asymptomatic individuals.

Section Summary: Percutaneous Revascularization Procedures for Asymptomatic Lower Extremity Peripheral Artery Disease

Although some individuals with asymptomatic PAD will progress to symptomatic disease, there is no evidence that performing early invasive revascularization procedures leads to a reduction in the development of symptomatic disease. Further, there is evidence that individuals who have undergone a revascularization procedure are at increased risk of subsequent complications, including the need for additional subsequent revascularization procedures. Therefore, the risks of the procedure do not outweigh any proposed benefits.

Summary of Evidence

For individuals who are adults with symptomatic lower extremity peripheral arterial disease (PAD) who receive percutaneous revascularization with balloon angioplasty, stent procedures, or atherectomy, the evidence includes randomized controlled trials (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 quality of life impairment; response to medical therapy, including structured exercise; and the likelihood of a beneficial short- and longer-term outcome, balanced against potential short-term (e.g., bleeding, infection, major adverse cardiovascular events [MACE]), 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 RCTs 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 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 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.

Practice Guidelines and Position Statements

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 19 and 20).

Table 19. Revascularization for Asymptomatic Peripheral Artery Disease

Recommendation	Class of Recommendation[a]	Level of Evidence[b]
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

PAD: peripheral artery disease.

[a] Class (strength) of recommendation: 1 (strong) = benefit >>> risk; 2a (moderate) = benefit >> risk; 2b (weak) = benefit ≥ risk; 3 (no benefit/moderate) = benefit = risk.

[b] Level (quality) of evidence: A = high-quality evidence from more than 1 RCT; B-R = moderate-quality evidence from 1 or more RCTs; B-NR = moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies; C-LD = limited data; C-EO =expert opinion.

Table 20. Revascularization for Claudication (Chronic Symptomatic Peripheral Artery Disease)

Recommendation	Class of Recommendation[a]	Level of Evidence[b]
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**	2A	B-R

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

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

GDMT: guideline-directed management and therapy; QOL: quality of life.
[a] Class (strength) of recommendation: 1 (strong) = benefit >>> risk; 2a (moderate) = benefit >> risk; 2b (weak) = benefit ≥ risk; 3 (no benefit/moderate) = benefit = risk.
[b] Level (quality) of evidence: A = high-quality evidence from more than 1 RCT; B-R = moderate-quality evidence from 1 or more RCTs; B-NR = moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies; C-LD = limited data; C-EO =expert opinion.

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

American College of Cardiology, et al. (2018)
In 2018, the American College of Cardiology, American Heart Association/Society for Cardiovascular Angiography and Intervention, Society of Interventional Radiology, and Society for Vascular Medicine published Appropriate Use Criteria for Peripheral Artery Intervention. (47) Appropriate use scores for endovascular treatment of relevant indications are shown in Table 21.

Table 21. 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. (48) The guidelines provide recommendations for the use of balloon angioplasty, stent procedures, and atherectomy in different clinical situations. Although specific guidelines for lithotripsy are not mentioned, the document mentions lithotripsy under the "Adjunctive Therapies" section and note that long-term data is needed.

Society for Vascular Surgery

In 2015, the Society for Vascular Surgery published guidelines for the management of asymptomatic (peripheral artery disease (PAD) and intermittent claudication (IC). (2) 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 (AUC) for Management of Intermittent Claudication. (49) 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 (e.g., angioplasty, stenting, atherectomy) were not included in these AUC owing to the large number of additional scenarios that would be required. Furthermore, the amount and quality of data available regarding the outcomes of interventions for multilevel disease and specific types of endovascular interventions are limited. Thus, if included, the ratings would have relied primarily on expert opinion." Lithotripsy was not mentioned in the document.

In 2025, the Society published a focused update of recommendations related to the management of IC. (50) Relevant recommendations to this evidence review are below:

- In patients who are being considered for revascularization for IC, we recommend that shared decision-making conversations should include each of the following risks and benefits: mortality, major adverse cardiovascular events (MACE), major adverse limb events (MALE) (amputation, reintervention, acute limb ischemia [ALI]), functional gain, and health-related quality of life (HR QoL) anticipated after revascularization. **Best practice statement.**
- In patients who are being considered for revascularization for IC, we recommend that shared decision-making conversations involve an assessment of individual risk factors known to influence risks and benefits. These include key comorbidities (diabetes mellitus [DM], coronary artery disease [CAD], congestive heart failure [CHF], chronic obstructive pulmonary disease [COPD]), history of prior limb revascularization, anatomic complexity of disease (i.e., multi-level disease, long segment disease, chronic total occlusions), and procedural strategy (i.e., open surgery vs endovascular revascularization [ER]). **Best practice statement.**
- We recommend against performing revascularization in patients with asymptomatic PAD or IC based solely on hemodynamic measurements or imaging findings. There is no evidence to support the use of revascularization for modifying disease progression. **Level of recommendation: grade 1; Level of evidence: C.**
- In patients with IC and no signs of chronic limb-threatening ischemia (CLTI), we suggest against the use of infrapopliteal revascularization, either alone or in combination with a more proximal intervention, due to lack of evidence of benefit and potential harm. **Level of recommendation: grade 2; Level of evidence: C.**

U.S. Preventive Services Task Force Recommendations (USPSTF)

in 2018, the USPSTF concluded that the current evidence is insufficient to assess the balance of benefits and harms of screening for peripheral artery disease (PAD) and cardiovascular disease risk with the ankle-brachial index (ABI) in asymptomatic adults. (51)

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this policy are listed in Table 22.

Table 22. 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	Apr 2026

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	37254, 37255, 37256, 37257, 37258, 37259, 37260, 37261, 37262, 37263, 37264, 37265, 37266, 37267, 37268, 37269, 37270, 37271, 37272, 37273, 37274, 37275, 37276, 37277, 37278, 37279, 37280, 37281, 37282, 37283, 37284, 37285, 37286, 37287, 37288, 37289, 37290, 37291, 37292, 37293, 37294, 37295, 37296, 37297, 37298, 37299, (37220, 37221, 37222, 37223, 37224, 37225, 37226, 37227, 37228, 37229, 37230, 37231, 37232, 37233, 37234, 37235 [Deleted 12/31/2025]), 0238T, 0505T

HCPCS Codes	C1761, C7531, C7534, C7535, C9764, C9765, C9766, C9767, C9772, C9773, C9774, C9775

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

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A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
01/01/2026	New medical document. Percutaneous revascularization procedures in individuals with chronic symptomatic lower extremity peripheral arterial disease, or in individuals with asymptomatic lower extremity peripheral arterial disease may be considered medically necessary when criteria in coverage are met. Percutaneous revascularization procedures are considered experimental, investigational and/or unproven for all other indications, or when criteria are not met. Coverage position for Intravascular lithotripsy (Shockwave Medical Intravascular Lithotripsy [IVL] System) previously addressed on ADM1001.032 Experimental, Investigational and/or Unproven Procedures/Services.