Lower Extremity Endovascular Procedures (for Kentucky Only)

Policy Number: CS166KY.12
Effective Date: June 1, 2026

➲ Instructions for Use

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Related Policies

- Pneumatic Compression Devices (for Kentucky Only)
- Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Kentucky Only)

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

Note: This policy does not apply to upper extremities.

Endovascular revascularization procedures (e.g., stents, angioplasty, and/or atherectomy) for treating lower extremity ischemia are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Endovascular Intervention, Peripheral Artery.

Click here to view the InterQual® criteria.

Transluminal peripheral atherectomy of the iliac artery is unproven and not medically necessary due to insufficient evidence of efficacy.

Endovenous femoropopliteal bypass using a stent graft is unproven and not medically necessary for treating peripheral artery disease due to insufficient evidence of efficacy.

Intravascular lithotripsy for treating lower extremity ischemia is unproven and not medically necessary due to insufficient evidence of efficacy.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the services requested.

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of

pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0238T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural 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
37254	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel
37255	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)
37256	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel
37257	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)
37258	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37259	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)

CPT Code	Description
37260	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, initial vessel
37261	Revascularization, endovascular, open or percutaneous, iliac vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)
37262	Intravascular lithotripsy(ies), iliac vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)
37263	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel
37264	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)
37265	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel
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37267	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
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37271	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
37272	Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)
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CPT Code	Description
37279	Intravascular lithotripsy(ies), femoral and popliteal vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)
37280	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel
37281	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)
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37284	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal stent placement, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the stent placement and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel
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37288	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel

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37289	Revascularization, endovascular, open or percutaneous, tibial and peroneal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)
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37296	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, initial vessel
37297	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; straightforward lesion, each additional vessel (List separately in addition to code for primary procedure)

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37298	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, initial vessel
37299	Revascularization, endovascular, open or percutaneous, inframalleolar vascular territory, with transluminal angioplasty, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, unilateral; complex lesion, each additional vessel (List separately in addition to code for primary procedure)

Description of Services

Peripheral artery disease (PAD) is a narrowing of vessels due to atherosclerosis that limits blood flow to the limbs. PAD most commonly affects arteries in the legs. While many people with PAD do not have any symptoms, some will have leg pain, numbness or cramping during exercise that is relieved by rest (claudication). Risk factors include age, smoking, diabetes, obesity, high blood pressure, and high cholesterol.

PAD is associated with an increased risk of heart attack, and stroke, and when left untreated, can lead to Chronic Limb-Threatening Ischemia. Treatment options include lifestyle changes, medications, endovascular techniques, and surgery. Endovascular techniques to treat Claudication and Chronic Limb Threatening Ischemia include balloon dilation (angioplasty), stents, endovenous stent grafts and atherectomy. The technique chosen for endovascular treatment depends on many factors, including lesion characteristics such as anatomical location, lesion length, and degree of calcification (Gornik et al., 2024; National Heart, Lung, and Blood Institute website). Intravascular lithotripsy may be performed as an adjunct procedure to prepare a vessel for subsequent interventions, such as angioplasty. The technique uses ultrasound waves to disrupt calcium deposits in atherosclerotic plaque (ECRI, 2025).

Clinical Evidence

Endovascular Revascularization

Pegler et al. (2025) conducted a systematic review and meta-analysis of randomized controlled trials (RCTs) comparing bypass surgery and endovascular revascularization in lower limb peripheral artery disease (PAD). The population included individuals with intermittent claudication or chronic limb-threatening ischemia (CLTI) undergoing an infrainguinal revascularization procedure. Overall, 14 cohorts were identified across 13 studies (n = 3,840). The primary outcome was major amputation. Secondary outcomes were mortality, reintervention, 30-day adverse events and 30-day mortality. There was no significant difference in major amputation or mortality between the bypass and endovascular groups. Individuals who underwent bypass surgery had a significantly lower rate of reintervention. [The BEST-CLI (Best Endovascular Versus Best Surgical Therapy in Patients With Critical Limb Ischemia) trial by Farber et al. noted below is included in this review.]

The BEST-CLI trial was a prospective, open label, multicenter, randomized controlled, multidisciplinary, superiority trial comparing treatment efficacy, functional outcomes, and quality of life in participants undergoing endovascular or open surgical revascularization. Clinical sites in the United States internationally enrolled 1,830 participants with CLTI and infrainguinal PAD who were candidates for both treatment options. Participants were enrolled into one of two parallel trial cohorts. Participants with a suitable single segment of the great saphenous vein available for potential bypass were randomized in cohort 1 (n = 1,620), while participants without were randomized in cohort 2 (n = 480). The primary outcome was a composite of a major adverse limb event (amputation above the ankle or a major limb reintervention) or death from any cause. In cohort 1, after a median follow-up of 2.7 years, the incidence of a major adverse limb event or death was significantly lower in the surgical group than in the endovascular group. In cohort 2, after a median follow-up of 1.6 years, the outcomes in the two groups were similar. The incidence of adverse events was similar in the two groups. Because investigators were allowed to use their preferred techniques, there was a potential for selection and operator bias. Also, due to funding issues, the follow-up was longer in cohort 1 than cohort 2 (Farber et al., 2022). The study was funded by the National Heart, Lung, and Blood Institute.

A Cochrane systematic review by Fakhry et al. (2018) assessed the effectiveness of endovascular revascularization compared with that of no specific therapy for intermittent claudication or compared with a conservative therapy option

such as supervised exercise or drug therapy. The review included 10 studies with a total of 1,087 individuals. The results showed that endovascular revascularization and supervised exercise are comparable treatment options in improving walking distances and quality of life in individuals with intermittent claudication. Combination therapy (endovascular revascularization with either supervised exercise or drug therapy) seemed to result in greater improvements than those seen with supervised exercise or drug therapy alone. (The ERASE trial by Fakhry et al., 2015, and the CLEVER trial by Murphy et al., 2015, which were previously cited in this policy, are included in this systematic review.)

Malgor et al. (2015) conducted a systematic review to evaluate the efficacy of three treatment strategies for individuals with claudication. The primary outcome measures included mortality, amputation, walking distance, quality of life, patency, and measures of blood flow [Ankle-Brachial Index (ABI)]. The review included eight systematic reviews and 12 trials enrolling 1,548 individuals. Compared with medical management, each of the three treatments (surgery, endovascular therapy, and exercise therapy) was associated with improved walking distance, claudication symptoms and quality of life. Evidence supporting superiority of one of the three approaches was limited. However, blood flow parameters improved faster and better with both forms of revascularization compared with exercise or medical management. Compared with endovascular therapy, open surgery may be associated with longer length of hospital stay and higher complication rates but resulted in more durable patency (moderate-quality evidence). (The CLEVER trial by Murphy et al., 2012, which was previously cited in this policy, is included in this systematic review.)

Vemulapalli et al. (2015) conducted a systematic review and network meta-analysis to evaluate the comparative effectiveness of medical therapy, supervised exercise training, endovascular intervention, and surgical revascularization in individuals with claudication. The outcomes assessed included walking distance, claudication distance, all-cause mortality, and quality of life. Overall, 35 studies (n = 7,475) were included in the analysis. A meta-analysis of 16 studies suggested that, compared with usual care, maximal walking measures were improved to a greater extent with supervised exercise than with medical therapy or endovascular intervention. A meta-analysis of 12 studies demonstrated that exercise training and endovascular intervention, but not cilostazol, improved initial claudication measures compared with usual care. A meta-analysis of 13 studies suggested that although all treatment modalities were superior to usual care, there was no significant difference between modalities in respect to quality of life. The authors noted that the heterogeneity in functional end points, single-arm observational study design and poor subgroup reporting significantly limit a comparative effectiveness analysis in PAD. Further studies, with attention to study design, standardized efficacy and safety end points, and appropriate subgroup reporting, are needed. (The multicenter CLEVER trial by Murphy et al., 2012, which was previously cited in this policy, is included in this systematic review.)

Iliac Artery Atherectomy

There is insufficient quality evidence to support the safety and efficacy of iliac artery atherectomy. Most study designs are retrospective, single arm or nonrandomized. Studies include a limited number of individuals and have heterogeneity in design in terms of selection criteria for individuals, lesion characteristics, and devices used, which limit the generalizability of the results.

Atherectomy of the iliac artery is uncommon due to the risk of life-threatening perforation. Lee et al. (2018) assessed the feasibility and safety of orbital atherectomy for the treatment of iliac artery disease using retrospective data from the CONFIRM registries. Patients with at least one iliac artery lesion treated with orbital atherectomy (n = 62; 68 lesions) were compared with patients with at least one superficial femoral artery lesion treated with orbital atherectomy (n = 1,570; 1,809 lesions). Both groups had similar baseline demographics; however, the iliac artery group had a lower prevalence of diabetes. For lesion characteristics, the iliac artery group had shorter lesions and a higher percentage of severely calcified lesions. The procedural complication rate was defined as the composite of flow limiting dissection, perforation, slow flow, vessel closure, spasm, embolism, or thrombosis. The iliac group had one reported perforation and one reported vessel closure. The procedural complication rate was low in both groups; however, it was significantly lower in the iliac artery group. The authors noted that a randomized trial with long-term follow-up is needed to determine the ideal revascularization strategy for individuals with calcified iliac artery disease. The study is limited by the possible bias associated with the observational design.

Endovenous Femoropopliteal Bypass

The DETOUR system uses a novel endovenous femoropopliteal bypass procedure for treating individuals with moderate to severe PAD who have long occlusive lesions of the superficial femoral artery. The system uses stents routed through the femoral vein to restore blood flow to the leg. Clinical trials are ongoing. Larger high-quality studies evaluating the safety and efficacy of the procedure and comparing the DETOUR system with open surgical bypass are needed.

An ECRI Clinical Evidence Assessment stated that the DETOUR stent graft system appears to be safe and provides a less invasive treatment option for individuals who may otherwise require open bypass surgery. Two available single-arm

clinical trials reported that individuals experienced functional improvements 1 to 3 years after treatment with the DETOUR system, with relatively high primary patency and freedom from adverse events despite their lesion's large size and severity. However, available studies provide very-low-quality evidence that does not enable firm conclusions, and no studies compared the DETOUR system with other treatments for long-segment femoropopliteal occlusions and their effect on patient-oriented outcomes, including adverse events, revascularization, and functional status (ECRI, 2023).

The DETOUR 2 investigational device exemption study is an ongoing prospective, single-arm, multicenter nonrandomized study to evaluate the safety and effectiveness of the DETOUR system for percutaneous femoropopliteal bypass. A total of 202 participants in the United States and Europe with severe femoropopliteal artery disease were enrolled, with 200 treated with the DETOUR system. The prespecified end points included primary safety (composite of major adverse events) at 30 days and effectiveness (primary patency defined as freedom from restenosis or clinically driven target lesion revascularization) at 1 year. The mean lesion length was 32.7 cm; 96% of lesions were chronic total occlusions and 70% were severely calcified. Technical success was achieved in 100% of the participants treated. The primary safety end point was met, with a 30-day freedom from major adverse event rate of 93.0%. The 1-year primary effectiveness end point was met, with 72.1% primary patency at 12 months. Primary-assisted and secondary patency were 77.7% and 89.0%, respectively, at 12 months. The 12 month deep venous thrombosis incidence was 4.1%, with no pulmonary emboli reported. Venous quality-of-life scores showed no significant changes from baseline. There was a Rutherford improvement of at least one class through 12 months in 97.2% of participants. The mean ABI also improved from 0.61 to 0.95 during this period. The authors also noted marked improvements in quality of life and functional status measures. This study is limited by the lack of randomization, long-term follow-up, and comparison to open surgical bypass (Lyden et al., 2024).

DETOUR I was a prospective, single-arm, multicenter, nonrandomized study in 78 participants. Technical and procedural success during the index procedure were both 96%. Primary stent graft patency rates were 81% at year 1 and 79% at year 2. The authors concluded that the DETOUR system was a safe and effective percutaneous alternative to open surgical bypass (Krievins et al., 2020; Halena et al, 2022). Due to the novel transvenous approach of the DETOUR system and risk of thromboembolic complications, venous outcomes were also evaluated in the DETOUR I study. At 1 year, Schneider et al. (2021) reported a low rate of deep venous thrombotic and obstructive complications. The cross-sectional femoral vein luminal area was preserved, and in some participants, the compensatory vein diameter increased over time. After evaluating a subset of participants enrolled at one study site, Rumba et al. (2022) reported 3-year results. (this study is included in the ECRI 2023 report). The femoral and popliteal vein remained patent with no compensatory enlargement, and there were no significant changes in venous symptom scores or physiological function. The study is limited by the single-arm study design.

Intravascular Lithotripsy

Early outcomes with intravascular lithotripsy (IVL) are encouraging and warrant further studies, with longer-term follow-up, to assess the safety, efficacy, and durability of treatment on clinically relevant outcomes, including primary patency, target lesion revascularization, and major unplanned amputation.

An ECRI report evaluated the evidence on the Shockwave Peripheral Intravascular Lithotripsy System for treating PAD. An evidence base of two systematic reviews, one RCT, and five case series showed that Shockwave is safe and works as intended to treat PAD. IVL enables better preparation of calcified femoropopliteal lesions than with conventional percutaneous transluminal angioplasty (PTA) and results in less residual stenosis and fewer flow-limiting dissections during the procedure. However, whether Shockwave results in lower rates of target lesion revascularization or whether it improves quality of life and functional status compared with PTA cannot be determined because the single RCT assessed too few individuals or reported too few events to be conclusive. No studies compared Shockwave with other methods for preparing calcified lesions for treatment. Single-arm studies indicated that Shockwave is effective for treating stenosis in calcified arteries below the knee; however, comparative evidence is not available. How Shockwave compares with other treatments for this indication remains unclear. Additional evidence comparing IVL with other calcium modification techniques and with PTA is needed to validate available findings, support stronger conclusions, and help guide clinician decisions (ECRI, 2025).

A Hayes report evaluated the evidence on IVL using Shockwave balloon-based catheters for treating calcified peripheral artery lesions and found minimal support. Although the evidence suggests that IVL is an effective and reasonably safe procedure for treating PAD, most of the studies reviewed were rated poor or very poor quality due to methodological limitations, small sample sizes, and relatively short durations of follow-up. In most of the studies reviewed, IVL was used in conjunction with or as preparation for another treatment (e.g., drug-coated balloon, stenting); therefore, it is uncertain whether IVL is effective as a stand-alone treatment. Longer-term follow-up is needed to determine the durability of treatment for this condition (Hayes, 2025).

Sagris et al. (2024) performed a systematic review and meta-analysis to evaluate the safety and efficacy of IVL as a stand-alone treatment or in preparing highly calcified peripheral arteries prior to stenting for PAD. A total of 20 prospective and retrospective single-arm studies (n = 1,223) were included in the analysis. The primary outcomes were overall success rate, changes in lumen area, and vessel diameter. Secondary end points were periprocedural complications, including dissections, perforations, distal embolization, thrombus, no-reflow, and abrupt closure. Results showed a high procedural success rate, improved luminal diameter, and a reduction in vessel diameter stenosis. An analysis of secondary end points found low rates of dissection and rare cases of abrupt vessel closure, no-reflow phenomenon, perforations, thrombus formation, and distal embolization. A subgroup analysis of transcatheter aortic valve implantation, with IVL assistance, is out of scope for this policy. While IVL is a promising technique for plaque modification, future prospective studies are needed to validate these results. (This systematic review is included in the ECRI report noted above.)

Wong et al. (2022) performed a systematic review and meta-analysis to evaluate the safety and efficacy of IVL in lower extremity PAD. Individuals' characteristics, lesion calcification, pre-IVL and post-IVL diameter stenosis, complications, and stent rates were evaluated. Nine studies were included (681 individuals; 769 lesions). Most data were pulled from small, single-arm observational studies. The overall quality of the included studies was fair, indicating a moderate risk of bias. The majority of individuals had severely calcified arteries, with an overall pooled rate of 75.53%. Comparison between pre-IVL and post-IVL diameter stenosis showed a reduction of 59.3%. Vascular complications were rare, with flow-limiting or type D/E/F dissection occurring in only 1.25% of cases. The overall pooled event rate for stent placement was 15.89%. The authors concluded that IVL is a promising approach for calcified plaque modification in lower extremity PAD; however, the routine use of this procedure is not recommended. Further high-quality studies are needed to determine the efficacy of IVL for different clinical characteristics, such as lesion location and length, and to compare with other treatment modalities such as atherectomy. (This systematic review is included in the ECRI report noted above.)

The Disrupt PAD III multicenter RCT compared the outcomes of vessel preparation using IVL (n = 153) or PTA (n = 153) prior to drug-coated balloon treatment or stent placement in participants with heavily calcified femoropopliteal lesions. The primary end point was procedural success (residual stenosis ≤ 30% without flow-limiting dissection) prior to balloon treatment or stenting. The powered secondary end point was primary patency at 1 year. Mid-term results suggest that IVL may be a superior vessel preparation procedure compared with PTA in individuals with heavily calcified femoropopliteal arteries. IVL achieved significantly higher primary patency at 1 and 2 years and required less provisional stenting, embolic protection, and lower maximum balloon inflation pressures. These results demonstrate that IVL is a safe and durable therapy for preparing calcified peripheral arteries and reduces the need for adjunctive treatments like stenting. Major adverse events were low and similar between the groups at 1 year. No significant difference was seen in freedom from clinically driven target lesion revascularization or restenosis at 1 year. Study limitations include the intermediate duration of follow-up, single-blinded design, moderate attrition, and manufacturer sponsorship. Additional well-designed studies, with longer-term follow-up and larger sample sizes, are needed to confirm durability (Tepe et al., 2022; Tepe et al., 2021). (This RCT is included in the ECRI and Hayes reports noted above; Sagris et al., 2024; Wong et al., 2022.)

Clinical Practice Guidelines

American College of Cardiology (ACC)/American Heart Association (AHA)/Society for Cardiovascular Angiography and Interventions (SCAI)/Society of Interventional Radiology (SIR)/Society for Vascular Medicine (SVM)

In a multisociety report, Bailey et al. (2019) published appropriate use criteria for peripheral artery interventions. The panel recommended that patients with PAD and intermittent claudication should first be treated with guideline-directed medical therapy and structured exercise. Revascularization should be considered only in patients who continue to have lifestyle-limiting claudication despite these noninvasive approaches. In situations in which medical therapy is insufficient, the selection of surgical or endovascular revascularization depends on several factors, including patient risk level and lesion characteristics, such as anatomical location, length and presence of stenosis or occlusion. The panel also addressed secondary treatment options for lower extremity disease and considers endovascular procedures for in-stent restenosis appropriate in patients with recurrent symptoms. The criteria indicate that atherectomy of the iliac artery is rarely appropriate in all clinical scenarios. This rating is due to an absence of data supporting the use of this technology compared with balloon angioplasty and stenting. For patients with CLTI, both endovascular and surgical revascularization procedures are considered appropriate and critical for the reduction of high morbidity and mortality rates associated with limb loss and cardiovascular events.

American Heart Association (AHA)/American College of Cardiology (ACC)

The AHA/ACC guidelines for the management of lower extremity PAD address revascularization procedures for atherosclerotic and thrombotic disease and include diseases of the aortoiliac, femoropopliteal, and infrapopliteal arterial segments. The guidelines were developed in collaboration with the American Association of Cardiovascular and

Pulmonary Rehabilitation, American Podiatric Medical Association, Association of Black Cardiologists, Society for Cardiovascular Angiography and Interventions, SVM, Society for Vascular Nursing, Society for Vascular Surgery (SVS), SIR, and Vascular & Endovascular Surgery Society (Gornik et al., 2024).

International Working Group on the Diabetic Foot (IWGDF)

The IWGDF guidelines on the prevention and management of diabetes-related foot disease state that in patients with either an ankle pressure of < 50 mm Hg or an ABI of < 0.4, consider urgent vascular imaging, always with detailed visualization of below-the-knee and pedal arteries, and revascularization. Also consider urgent assessment for revascularization if the toe pressure is < 30 mmHg or peripheral transcutaneous oxygen pressure is < 25 mmHg. Clinicians might also consider revascularization at higher pressure levels in patients with extensive tissue loss or infection. The guidelines also state that the role of lithotripsy in the general population with CLTI and, in particular, those with diabetes, remains to be clarified (Schaper et al., 2024).

National Institute for Health and Care Excellence (NICE)

A NICE guideline states that IVL for calcified arteries in PAD should only be used with special arrangements for clinical governance, consent, and audit or research. There is a moderate amount of evidence suggesting that the procedure is safe, but evidence on long-term outcomes is needed (NICE, 2024).

A separate NICE guideline offers recommendations on the management of PAD (NICE, 2012; updated 2020).

Society for Vascular Surgery (SVS)

The SVS guidelines provide a comprehensive set of recommendations for the evaluation and management of CLTI. Vein bypass may be preferred for average-risk patients with advanced limb threat and high-complexity disease, while those with less complex anatomy, intermediate-severity limb threat, or high patient risk may be favored for endovascular intervention. All patients with CLTI should be afforded best medical therapy, including the use of antithrombotic, lipid-lowering, antihypertensive, and glycemic control agents as well as counseling on smoking cessation, diet, exercise, and preventive foot care (Conte et al., 2019).

In 2015, the SVS published a comprehensive set of recommendations for the evaluation and management of asymptomatic PAD and intermittent claudication. (Conte et al., 2015). First-line treatment approaches for intermittent claudication include patient education, risk factor reduction, smoking cessation, optimization of medical therapies, and exercise. Revascularization in appropriately selected patients can relieve pain and improve function and health-related quality of life. Decision-making is complex and individualized, based on symptom severity, comorbid conditions, response to exercise/optimization of medical therapies, anatomical pattern of disease and risk/benefit of the proposed intervention. A 2025 focused update (Conte et al., 2025; Saadi et al., 2025) presented the following statements regarding revascularization:

- SVS recommends against performing revascularization in patients with asymptomatic PAD or intermittent claudication 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 intermittent claudication and no signs of CLTI, SVS suggests 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.
- In patients with intermittent claudication who are selected for an endovascular intervention to treat femoropopliteal disease and have lesions exceeding 5 cm in length, SVS recommends the use of either bare metal stents or drug-eluting devices (balloons or stents) over plain balloon angioplasty to reduce the risk of restenosis and need for reintervention. Level of recommendation: grade 1; level of evidence: B.

Additionally, the guidelines note that data on the effectiveness of specialized balloons, such as IVL, are limited and require future study.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA has approved several stents and stent systems for the treatment of peripheral artery disease of the lower extremities. Refer to the following website (use product codes NIO and NIP) for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed November 18, 2025)

The FDA has approved several catheter systems used for the treatment of peripheral artery disease of the lower extremities. Refer to the following website (use product code DQY) for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed November 18, 2025)

In June 2020, the DETOUR system (Endologix) received FDA designation as a Breakthrough Device. The system consists of the TORUS stent graft and the ENDOCROSS™ Device. On June 7, 2023, the FDA granted full premarket approval of the DETOUR System for percutaneous revascularization in patients with symptomatic femoropopliteal lesions from 200 mm to 460 mm in length with chronic total occlusions (100 mm to 425 mm) or diffuse stenosis > 70% who may be considered suboptimal candidates for surgical or alternative endovascular treatments. The DETOUR System, or any of its components, are not for use in the coronary and cerebral vasculature. Refer to the following website for more information. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P220021. (Accessed November 18, 2025)

For information on intravascular lithotripsy systems cleared for marketing, refer to the following website (use product code PPN): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed November 18, 2025)

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Policy History/Revision Information

Date	Summary of Changes
06/01/2026	**Coverage Rationale** • Added language to indicate intravascular lithotripsy for treating lower extremity ischemia is unproven and not medically necessary due to insufficient evidence of efficacy **Applicable Codes** • Updated list of applicable CPT codes to reflect annual edits: ○ Added 37254, 37255, 37256, 37257, 37258, 37259, 37260, 37261, 37263, 37264, 37265, 37266, 37267, 37268, 37269, 37270, 37271, 37272, 37273, 37274, 37275, 37276, 37277, 37278, 37280, 37281, 37282, 37283, 37284, 37285, 37286, 37287, 37288, 37289, 37290, 37291, 37292, 37293, 37294, 37295, 37296, 37297, 37298, and 37299

Date	Summary of Changes
	○ Removed 37220, 37221, 37222, 37223, 37224, 37225, 37226, 37227, 37228, 37229, 37230, 37231, 37232, 37233, 37234, and 37235 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Archived previous policy version CS166KY.11

Instructions for Use

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