

# Peripheral Artery Revascularization of the Lower Extremities



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## Medicare Advantage Medical Coverage Policy

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#### Disclaimer

The Medical Coverage Policies are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

## Related Medicare Advantage Medical/Pharmacy Coverage Policies

[Transcatheter Peripheral Vascular Stents – Chest, Abdomen and Pelvis](#)

## Related Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA). Refer to CMS website for the most current applicable [CMS Online Manual System \(IOMs\)](#) and [Transmittals](#).

Type	Title	Document ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
NCD	Percutaneous Transluminal Angioplasty (PTA)	20.7		

LCD LCA	Non-Coronary Vascular Stents	L35998 A57590	J5 - Wisconsin Physicians Service Insurance Corporation  J8 - Wisconsin Physicians Service Insurance Corporation	IA, KS, MO, NE  IN, MI
LCD LCA	Diagnostic Abdominal Aortography and Renal Angiography	L35092 A56682	JH - Novitas Solutions, Inc. (Part A/B MAC)  JL - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, LA, MS, NM, OK, TX  DE, D.C., MD, NJ, PA

### Description

Peripheral artery disease (PAD) is a chronic circulation disorder primarily caused by atherosclerosis (plaque buildup inside the arteries) which results in the narrowing or blockage of blood flow to the extremities. Risk factors include, but may not be limited to, diabetes, high cholesterol, hypertension and smoking.

More advanced PAD symptoms in the lower extremities indicating a significant or complete artery blockage include the following:

- **Claudication**, also known as **intermittent claudication (IC)**, is characterized by fatigue, discomfort, cramping or aching pain in the muscles of the lower extremities that is consistently caused by exercise and consistently relieved by rest (within 10 minutes).<sup>3</sup>
- **Critical/chronic limb-threatening ischemia (CLTI)**, also known as **critical/chronic limb ischemia (CLI)**, is characterized by chronic (greater than two weeks) ischemic rest pain, nonhealing wound/ulcers or gangrene in one or both legs attributable to objectively proven arterial occlusive disease by ankle-brachial index (ABI), toe-brachial index (TBI), transcutaneous oximetry or oxygen tension measurement (TCPO<sub>2</sub>) or skin perfusion pressure testing.<sup>3</sup>

The management of an individual with lower extremity PAD is aimed at relieving symptoms and lowering the risk of cardiovascular disease progression and complications. Optimal guideline-directed medical therapy (GDMT) involves cardiovascular risk factor reduction, exercise, lifestyle modification and pharmacologic therapies.

For an individual with significant or disabling symptoms of claudication unresponsive to exercise, lifestyle adjustment and pharmacologic therapy, intervention (percutaneous, surgical) may be reasonable. For CLTI, revascularization is a priority to establish arterial blood flow.<sup>49</sup> Further diagnostic

testing (eg, computed tomographic angiography [CTA], magnetic resonance angiography [MRA], and/or catheter-based invasive angiography) may be indicated to determine if the individual is a candidate for intervention.

**Surgical bypass procedures for PAD** are not discussed in the context of this policy.

**Endovascular revascularization** interventions are procedures in which a catheter is inserted percutaneously (through the skin) or under direct visualization after open exposure of the artery for the treatment of vascular disease. Most endovascular procedures are performed percutaneously but can be performed via open access if needed. Endovascular treatment options include the following:

- **Angioplasty** – balloon at the tip of a catheter inserted into an artery that has been narrowed by the accumulation of plaque (fatty deposits) and inflated to clear and widen the arterial opening to improve blood flow.
- **Atherectomy** – removal of atherosclerotic plaque from an artery using a catheter fitted with a cutting device, laser or spinning tool to open narrow or blocked arteries.
- **Stent** – a tubular support placed inside a blood vessel to relieve a blockage or obstruction.

**Intravascular lithotripsy (IVL)** is a novel method that combines ultrasound mechanical pulse waves with angioplasty to treat moderate to severe calcific PAD. IVL uses acoustic pressure waves that travel through soft tissue to disrupt calcified lesions before balloon angioplasty. The Shockwave peripheral intravascular lithotripsy system is an example of such a device.

Alternative revascularization methods include, but are not limited to, the following:

**Deep vein arterialization (DVA)** is a technique aimed at providing an option for an individual with CLTI who has no surgical or endovascular revascularization options due to comorbidities or the absence of a viable conduit or distal target vessel.<sup>14</sup> DVA is performed using transcatheter placement of intravascular stent graft(s) and either endovascular venous arterialization of the tibial or peroneal vein or endovenous femoral-popliteal arterial revascularization. A connection is created between an arterial inflow and a distal venous target to provide adequate blood flow to resolve rest pain and heal chronic wounds. This procedure severs the venous valves to render them incompetent, allowing oxygenated blood to flow forward to the foot. Self-expanding stents are placed to maintain permanent conduits for blood flow.<sup>23</sup>

**Percutaneous transmural arterial bypass (PTAB)** is used to treat PAD in an individual with long-segment, complex femoropopliteal occlusions as an alternative to open (surgical) bypass or other endovascular treatments. The DETOUR System is an FDA-approved, fully percutaneous femoral-popliteal bypass system that uses fluoroscopic guidance to move a covered stent graft from the popliteal artery into the femoral vein and from the femoral vein into the superficial femoral artery in an overlapping manner using two independent interconnections or anastomoses. The system treats large lesions (20 to 46 cm) by creating a lumen stent bypass that allows unobstructed blood flow from the superficial femoral artery to the popliteal artery.<sup>53</sup>

## Coverage Determination

*iCare follows the Medicare requirements that only allow coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

*iCare applies any applicable National Coverage Determination (NCD) and any applicable Local Coverage Determinations (LCDs) applicable to the services and jurisdiction at issue. See the “Related Documents” Section above for any such NCDs or LCDs.*

### **Percutaneous Transluminal Angioplasty**

While NCD 20.7 states that percutaneous transluminal angioplasty (PTA) (with and without the placement of a stent) is “covered when used for” the “treatment of atherosclerotic obstructive lesions in the lower extremities, i.e. the iliac, femoral and popliteal arteries,” it does not provide additional guidance as to when the use of PTA (with and without stent) should be considered reasonable and necessary.<sup>13</sup> For jurisdictions without an LCD, iCare determines medical necessity for PTA (with or without stent placement) based on the criteria contained in LCD – Non-Coronary Vascular Stents (L35998) and LCD – Diagnostic Abdominal Aortography and Renal Angiography (L35092).

*If a determination cannot be made based on the criteria above because such criteria is not fully established and/or not applicable to the jurisdiction at issue, iCare may consider the following to interpret or supplement such criteria in order to determine medical necessity consistently:*

### **Aorto-iliac and Superficial Femoral Arteries**

**Endovascular revascularization with percutaneous transluminal angioplasty (PTA) (with or without stent) of the lower extremities (aorto-iliac and superficial femoral arteries only)** will be considered medically reasonable and necessary when the following requirements are met:

- CLTI when limb-threatening lower extremity (LE) ischemia is present and documented<sup>3,5,12,40</sup>; **OR**
- CLTI with threatened bypass graft (eg, femoral-popliteal, femoral-tibial bypass graft)<sup>2,5,6,31</sup>; **OR**
- Claudication when **all** of the following requirements have been met:
  - Inadequate response to three months of optimal [guideline-directed medical therapy \(GDMT\)](#) within the past 12 months<sup>3,5</sup>; **AND**
  - Impairment of activities of daily living and work<sup>3,5,12</sup>; **AND**
  - Individual has undergone a structured exercise program (eg, supervised or home based)<sup>3,5,12</sup>; **AND**
  - Presence of anatomically suitable lesion for intervention with documentation of **any** of the following:

- Lesion greater than 70% stenosis on angiography (eg, CTA, invasive angiography, MRA)<sup>3,36,43</sup>; **OR**
- Lesion 50% to 70% stenosis on angiography (eg, CTA, invasive angiography, MRA)<sup>3,36,43</sup>; **AND**
  - ❖ Resting or provoked intravascular transluminal (pre- to post-stenosis) pressure gradient measurement greater than or equal to 10 mmHg<sup>3,36,43</sup>; **OR**
- LE Duplex doppler with peak systolic velocity (PSV) greater than 300 cm/s or PSV ratio greater than 4.0<sup>36,43</sup>

\*Optimal GDMT includes Class I recommendations for antiplatelet therapy, cilostazol, statins, glycemic and hypertension control, exercise program, smoking cessation including planning, counseling, or behavior modification and pharmacotherapy if needed.<sup>3</sup>

**Atherectomy of the lower extremities (*superficial femoral arteries only*)** will be considered medically reasonable and necessary when **any** of the following indications are met:

- CLTI for lesions that are greater than or equal to 70% stenosis caused by moderate to severe calcification (greater than or equal to 180 degrees of calcification involving both sides of the vessel at the same location) in an undilatable lesion<sup>5,36,37</sup>; **OR**
- CLTI with threatened bypass graft (eg, femoral-popliteal, femoral-tibial bypass graft)<sup>3,5,40</sup>; **OR**
- Intended definitive or adjunctive therapy for documented in-stent restenosis (ISR)<sup>37</sup>

### **Infrapopliteal Arteries**

**Percutaneous transluminal angioplasty (PTA) of the *infrapopliteal arteries*** will be considered medically reasonable and necessary when ~~the following requirements are met:~~ used to treat CLTI with severe stenosis greater than or equal to 70% luminal diameter and Rutherford stage 4 – 6.<sup>3,5,6,12,38</sup>

- ~~CLTI with severe stenosis greater than or equal to 70% luminal diameter and Rutherford stage 4 – 6~~<sup>2,5,6,12,38</sup>

**PTA with or without stent of the *infrapopliteal arteries*** will be considered medically reasonable and necessary when used to treat threatened bypass graft (eg, femoral-popliteal, femoral-tibial bypass graft).<sup>2,5,6,31</sup>

**Atherectomy of the *infrapopliteal arteries*** will be considered medically reasonable and necessary when used to treat CLTI with threatened bypass graft (eg, femoral-popliteal, femoral-tibial bypass grafts).<sup>3,5,40</sup>

**Noncoronary stents can be approved only if they are US Food & Drug Administration (FDA) approved. Noncoronary vascular stents are covered only after a thorough examination and treatment of symptoms, and when percutaneous transluminal angioplasty (PTA) of the vessel alone has not, or is not expected to,**

adequately alleviate the symptoms, making surgery the likely alternative. A noncoronary intravascular stent(s) that carries an Investigational Device Exemption (IDE) may be covered under Medicare.<sup>12</sup>

**Intravascular ultrasound** will be considered medically reasonable and necessary when used as an adjunct to endovascular revascularization of the lower extremities (aorto-iliac, superficial femoral, infrapopliteal).<sup>25,35</sup>

*The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms (eg, adverse effects including, but not limited to, bleeding, contrast-induced nephropathy, hematoma and infection).<sup>48</sup> Endovascular revascularization services that do not meet the criteria above are not medically necessary and may result in unnecessary exposure to potential complications. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.*

## Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

### Infrapopliteal Arteries

**Endovascular revascularization procedures (PTA, stent, atherectomy) of the lower extremities (infrapopliteal arteries only)** will not be considered medically reasonable and necessary for the following indications:

- Intermittent claudication<sup>3,5,6,43</sup>; **OR**
- Nonurgent revascularization isolated to the infrapopliteal arteries<sup>3,5,43</sup>

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of these services in clinical management for these indications.

The following **endovascular revascularization interventions** will not be considered medically reasonable and necessary:

- Atherectomy for the treatment of PAD in the aorto-iliac ~~or infrapopliteal~~ arteries<sup>9,10,14,31,39,40,43,44</sup>
- Atherectomy in the infrapopliteal arteries for any indication other than treatment of threatened bypass graft<sup>5,9,10,14,40,43</sup>
- Atherectomy for the treatment of IC in the superficial femoral arteries<sup>24,36,37</sup>

- Deep vein arterialization (DVA) using either endovascular venous arterialization of the tibial or peroneal vein or endovenous femoral-popliteal arterial revascularization<sup>6,23,34</sup>
- Intravascular lithotripsy of the lower extremities (aorto-iliac, superficial femoral, infrapopliteal arteries)<sup>1,9,29,39</sup>
- Percutaneous transmural arterial bypass (PTAB) for the treatment of symptomatic, long segment femoropopliteal arterial lesions<sup>26,53</sup>

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

## Summary of Evidence

### ***Atherectomy***

Published evidence evaluating the safety and efficacy of atherectomy to treat PAD in the aorto-iliac arteries and intermittent claudication (IC) in the superficial femoral arteries fails to show superiority over angioplasty. The current body of evidence on atherectomy in the **infrapopliteal arteries** for indications other than to treat threatened bypass grafts is largely based on observational studies that are limited by heterogeneous inclusion criteria and inconsistencies in methodology. Benfor et al.<sup>9</sup> evaluated a total of 15 studies including 2179 cases with vessel preparation. Of five studies comparing atherectomy with or without PTA to PTA alone, only one study favors atherectomy. The remaining four studies fail to demonstrate statistically significant differences.<sup>9</sup> Ramkumar et al.<sup>32</sup> reviewed the Medicare-linked Vascular Quality Initiative (VQI) registry of more than 16,000 individuals and found the 5-year rate of major adverse limb events (eg, major amputation, reintervention) was 38% for atherectomy, 33% for PTA and 32% for stenting. The Society for Vascular Surgery (SVS)<sup>43</sup> appropriate use criteria for managing IC rates revascularization of the infrapopliteal segment for IC as “risk outweighs benefits” for all clinical scenarios.

Historically, the reference standard for infrapopliteal chronic limb threatening ischemia (CLTI) treatment has been surgical revascularization. With the increase in endovascular techniques, there remains a paucity of evidence comparing the efficacy of atherectomy and other PVI modalities in this challenging anatomic region. Chu et al.<sup>14</sup> found a higher proportion of atherectomy procedures for both CLTI and IC performed in an office-based setting in a multicenter retrospective analysis of VQI outcomes data. After propensity score matching for the CLTI group, study results show that atherectomy is associated with a significant increase in reintervention compared with balloon angioplasty and compared with stenting. The authors recommend caution in using atherectomy due to higher reintervention rates. Further studies are necessary to determine whether there is a subset of CLTI patients who would benefit from this intervention.<sup>14</sup> In the global CLTI management guidelines, the SVS<sup>40</sup> states that atherectomy for infrapopliteal CLTI is not superior to balloon angioplasty and cites a lack of high-quality comparative data. An intersocietal 2023 guideline update maintains the SVS position that the role and indications for atherectomy in infrapopliteal revascularization in the general population with CLTI remains to be clarified.<sup>44</sup>

Available studies regarding atherectomy in the **aorto-iliac arteries** are limited to single-arm, uncontrolled or observational studies with significant selection bias.<sup>10</sup> The Society for Cardiovascular Angiography & Interventions (SCAI)<sup>39</sup> rates atherectomy for intended definitive therapy in aorto-iliac arteries as level III (no benefit) for in-stent restenosis and mild to severe calcified focal and diffuse lesions and level III (harm) for all other clinical scenarios.

The SCAI<sup>37</sup> recommends atherectomy in the **femoropopliteal arteries** only for CLTI and as intended definitive or adjunctive therapy for in-stent restenosis or threatened bypass graft. Ratings of IIA and IIB for atherectomy in the femoral-popliteal arteries are indicated for moderate to severe calcified undilatable lesions, excluding treatment of IC.<sup>37</sup> In a retrospective analysis of 9100 Medicare patients, Kawaji et al.<sup>24</sup> found no statistical difference in open surgery or major amputation risks for atherectomy for IC versus nonatherectomy peripheral vascular intervention procedures, but higher reintervention rates with atherectomy.

Robust studies using randomized controlled trials are necessary to compare the safety and outcomes of atherectomy and angioplasty across clinical scenarios in the infrapopliteal and aortoiliac arteries and for IC in the femoropopliteal arteries. The long-term effectiveness and durability of atherectomy remains unclear.<sup>32</sup>

### ***Deep Venous Arterialization***

Studies of deep venous arterialization (DVA) are primarily retrospective case series with few studies using matched controls. Ho et al.<sup>23</sup> reviewed the medical literature and concluded that current early phase of DVA use is considered a final option for limb salvage before amputation. Rates of limb salvage vary from 25% to 100% for open DVA, 60% to 71% for percutaneous DVA and 46% to 69% in hybrid DVA approaches.<sup>23</sup> The authors conclude that the introduction of hybrid DVA approaches suggests that adequate forward flow in the distal venous target is critical to the success of the procedure.<sup>23</sup> In a small (n=105) prospective, single-group, multicenter study, Shishehbor et al.<sup>34</sup> evaluated transcatheter DVA with a 66.1% amputation-free survival rate over six months. Limb salvage was achieved in 76% and complete wound healing in 25% of study participants.<sup>34</sup> Further studies using larger enrollment with robust methodology and standardized techniques are necessary to assess safety, efficacy and positive clinical outcomes.<sup>3</sup>

### ***Endovascular Revascularization of the Infrapopliteal Arteries for Intermittent Claudication***

The Society for Vascular Surgery (SVS)<sup>43</sup> recommends against invasive intervention for the treatment of intermittent claudication (IC) in the infrapopliteal arteries, stating that open or endovascular revascularization in an individual with symptoms limited to IC is of “unclear benefit and could be harmful.”<sup>43</sup> The panelists unanimously agreed that isolated infrapopliteal lesions do not result in disabling claudication; therefore, the risks outweigh the benefits for endovascular revascularization.<sup>43</sup> The 2024 American Heart Association/American College of Cardiology (AHA/ACC)<sup>3</sup> guideline for lower extremity PAD assigns a weak (IIb) rating and unknown usefulness to infrapopliteal endovascular revascularization procedures to treat claudication. The Society for Cardiovascular Angiography & Interventions (SCAI)<sup>36</sup> states in a 2017 appropriate use criteria statement that infrapopliteal endovascular treatment is generally reserved for chronic limb threatening ischemia (CLTI). The current body of evidence on endovascular revascularization in the infrapopliteal arteries to treat refractory IC is limited to observational studies limited by poor methodological quality and inconsistencies in primary endpoints, heterogeneous inclusion criteria and lack of randomized controls.<sup>9</sup>



**Intravascular Lithotripsy**

Peer reviewed evidence-based literature describes intravascular lithotripsy (IVL) as a novel technique used to modify calcified plaque in the lower extremities. Recent studies focus primarily on femoropopliteal IVL and data on IVL for the infrapopliteal and other regions are limited. Adams et al.<sup>1</sup> conducted a prospective single-arm, non-randomized observational study to evaluate the performance of peripheral IVL for the treatment of multi-level calcified PAD. Although no definitive comparisons can be made without a control group, safety and efficacy outcomes were demonstrated comparable to prior studies.<sup>1</sup> Most study data is produced from small, single-arm, nonrandomized observational studies. A recent systematic review and meta-analysis examining vessel preparation in infrapopliteal artery PAD found no additional value with the use of vessel preparation including various atherectomy methods and intravascular lithotripsy.<sup>29</sup> Nugteren et al.<sup>29</sup> found that vessel preparation demonstrates similar 12-month outcomes compared with angioplasty alone; however, the included studies were limited by heterogeneous endpoints, poor to moderate study method quality and selection bias. With more primary data available in the future, the efficacy and safety of IVL should be evaluated based on more homogeneous interventional attributes. The current evidence is limited by the small number of nonrandomized, heterogeneous early trials. Further randomized, controlled studies are needed to accurately determine the safety and efficacy of IVL in multiple arterial segments.

**Percutaneous Transmural Arterial Bypass**

The DETOUR I trial is the first study to evaluate the safety and efficacy of the DETOUR system for percutaneous transmural arterial bypass (PTAB). Krievens et al.<sup>26</sup> completed a small prospective trial studying the endovascular treatment of lesions averaging greater than 250 mm in length. The average lesion length was 371 mm with severe calcification in two-thirds of the lesions, indicating a challenging population. Short-term patency was rated as “promising,” although results must be considered within the context of limitations including small sample size, limited follow-up length and nonrandomized study design.<sup>26</sup> The follow-up DETOUR II trial published in the US Food & Drug Administration (FDA) *Summary of Safety and Effectiveness Data*<sup>53</sup> is a prospective, nonrandomized multicenter case series (n=202) that evaluates primary patency, functional status, revascularization and major adverse events (MAEs) after 12 months. Freedom from major adverse events (MAE) at 30 days was 93%, 87% at six months and 80% at 12 months.<sup>53</sup> Longer-term follow-up with larger, randomized trials is needed to produce more definitive conclusions and to compare PTAB with other therapies.

**Coding Information**

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
36245	Selective catheter placement, arterial system; each first order abdominal, pelvic, or lower extremity artery branch, within a vascular family	

**Peripheral Artery Revascularization of the Lower Extremities**

36246	Selective catheter placement, arterial system; initial second order abdominal, pelvic, or lower extremity artery branch, within a vascular family	
36247	Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family	
36248	Selective catheter placement, arterial system; additional second order, third order, and beyond, abdominal, pelvic, or lower extremity artery branch, within a vascular family (List in addition to code for initial second or third order vessel as appropriate)	
37220	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty	
37221	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	
37222	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)	
37223	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty	
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed	
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	
37227	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed	
37228	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty	
37229	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed	

**Peripheral Artery Revascularization of the Lower Extremities**

37230	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	
37231	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed	
37232	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)	
37233	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	
37234	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	
37235	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	
37252	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; initial noncoronary vessel	
37253	Intravascular ultrasound (noncoronary vessel), each additional noncoronary vessel	
<b>CPT® Category III Code(s)</b>	<b>Description</b>	<b>Comments</b>
0238T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel	

**Peripheral Artery Revascularization of the Lower Extremities**

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	
0620T	Endovascular venous arterialization, tibial or peroneal vein, 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	
<b>HCPCS Code(s)</b>	<b>Description</b>	<b>Comments</b>
C7531	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(ies), unilateral, with transluminal angioplasty with intravascular ultrasound (initial noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation	
C7534	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(ies), unilateral, with atherectomy, includes angioplasty within the same vessel, when performed with intravascular ultrasound (initial noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation	
C7535	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(ies), unilateral, with transluminal stent placement(s), includes angioplasty within the same vessel, when performed, with intravascular ultrasound (initial noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation	
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed	
C9765	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	

C9766	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed	
C9767	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed	
C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed	
C9773	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	
C9774	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed	
C9775	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed	

## References

1. Adams G, Shammam N, Mangalmurti S, et al. Intravascular lithotripsy for treatment of calcified lower extremity arterial stenosis: initial analysis of the Disrupt PAD III study. *J Endovasc Ther.* 2020;27(3):473-480.
2. Ali H, Elbadawy A, Saleh M, Hasaballah A. Balloon angioplasty for revision of failing lower extremity bypass grafts. *J Vasc Surg.* 2015;62(1):93-100.
3. Almasri J, Adusumalli J, Asi N, et al. A systematic review and meta-analysis of revascularization outcomes of infrainguinal chronic limb-threatening ischemia. *J Vasc Surg.* 2019;69(6S):126S-136S.
4. American College of Cardiology (ACC). 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS guideline for the management of lower extremity peripheral artery disease. <https://www.acc.org>. Published May 14, 2024.
5. American College of Cardiology (ACC). ACC/AHA/SCA/SIR/SVM 2018 appropriate use criteria for peripheral artery intervention. <https://www.acc.org>. Published January 22, 2019.

6. American College of Cardiology (ACC). Below-the-knee endovascular revascularization: a position statement. <https://www.acc.org>. Published March 11, 2024.
7. American College of Cardiology (ACC). Practice guidelines for the management of patients with peripheral artery disease. <https://www.acc.org>. Published 2013.
8. American College of Radiology (ACR). Appropriateness Criteria. Lower extremity arterial claudication- imaging assessment for revascularization. <https://www.acr.org>. Published 2016. Updated 2022.
9. Benfor B, Sinha K, Lumsden AB, Roy TL. Scoping review of atherectomy and intravascular lithotripsy with or without balloon angioplasty in below-the-knee lesions. *J Vasc Surg Cases Innov Tech*. 2023;9(2):101185.
10. Brown CS, Eton RE, Yaser JM, et al. Assessment patterns of atherectomy use. *J Am Heart Assoc*. 2022;11(22):e023356.
11. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Diagnostic abdominal aortography and renal angiography (L35092). <https://www.cms.gov>. Published October 1, 2015. Updated November 7, 2019.
12. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Non-coronary vascular stents (L35998). <https://www.cms.gov>. Published October 1, 2015. Updated January 1, 2023.
13. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Percutaneous transluminal angioplasty (20.7). <https://www.cms.gov>. Published March 11, 2013. Updated October 11, 2023.
14. Chu D, Zheng X, Mao J, Ramsey L, Mukherjee D. Comparison of endovascular therapies for chronic limb-threatening ischemia and claudication. *J Vasc Surg*. 2024;79(4):875-886.e878.
15. Clair DG, Mustapha JA, Shishehbor MH, et al. PROMISE I: early feasibility study of the LimFlow System for percutaneous deep vein arterialization in no-option chronic limb-threatening ischemia: 12-month results. *J Vasc Surg*. 2021;74(5):1626-1635.
16. ClinicalKey. Bharmal M, Patel PM. Peripheral artery disease. In: Ferri F. *Ferri's Clinical Advisor* 2024. Elsevier; 2024:1067-1074.e1. <https://www.clinicalkey.com>.
17. ClinicalKey. Bonaca M, Creager M. Peripheral artery diseases. In: Libby P, Bonow R, Douglas L, et al. *Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine*. 12<sup>th</sup> ed. Elsevier; 2022:837-858. <https://www.clinicalkey.com>.
18. ClinicalKey. Kinlay S. Intervention for lower extremity arterial disease. In: Bhatt DL. *Cardiovascular*

*Intervention: A Companion to Braunwald's Heart Disease*. 2<sup>nd</sup> ed. Elsevier; 2024:337-361.  
<https://www.clinicalkey.com>.

19. ECRI Institute. Clinical Evidence Assessment. Detour System (Endologix, LLC) for treating peripheral artery disease. <https://www.ecri.org>. Published September 9, 2023. Updated December 13, 2023.
20. ECRI Institute. Clinical Evidence Assessment. Shockwave peripheral intravascular lithotripsy system (Shockwave Medical Inc.) for treating peripheral artery disease. <https://www.ecri.org>. Published January 13, 2017. Updated May 1, 2023.
21. Hayes, Inc. Evidence Analysis Research Brief. Atherectomy for management of chronic limb-threatening ischemia. <https://evidence.hayesinc.com>. Published June 21, 2024.
22. Hayes, Inc. Evolving Evidence Review. Intravascular lithotripsy for calcified peripheral arterial lesions. <https://evidence.hayesinc.com>. Published November 19, 2021. Updated July 21, 2023.
23. Ho VT, Gologorsky R, Kibrik P, et al. Open, percutaneous and hybrid deep venous arterialization technique for no-option foot salvage. *J Vasc Surg*. 2019;71(6):2152-2160.
24. Kawaji Q, Dun C, Walsh C, et al. Index atherectomy peripheral vascular interventions performed for claudication are associated with more reinterventions than non-atherectomy interventions. *J Vasc Surg*. 2022;76(2):489-98.e4.
25. Kereiakes DJ, Virmani R, Hokama JY, et al. Principles of intravascular lithotripsy for calcific plaque modification. *JACC Cardiovasc Interv*. 2021;14(12):1275-1292.
26. Krievens DK, Halena G, Scheinert D, et al. One-year results from the DETOUR I trial of the PQ Bypass DETOUR System for percutaneous femoropopliteal bypass. *J Vasc Surg*. 2020;72(5):1648-1658.e1642.
27. Loffroy R, Falvo N, Galland C, et al. Intravascular ultrasound in the endovascular treatment of patients with peripheral arterial disease: current role and future perspectives. *Front Cardiovasc Med*. 2020;7:551861.
28. Mustapha JA, Finton SM, Diaz-Sandoval D, Saab FA, Miller LE. Percutaneous transluminal angioplasty in patients with infrapopliteal arterial disease. *Circ Cardiovasc Interv*. 2016;9(5):e003468.
29. Nugteren MJ, Welling RH, Bakker OJ, Unlu C, Hazenberg CE. Vessel preparation in infrapopliteal arterial disease: a systematic review and meta-analysis. *J Endovasc Ther*. 2024;31(2):191-202.
30. Patel M, Conte M, Cutlip D et al. Evaluation and treatment of patients with lower extremity peripheral artery disease: consensus definitions from Peripheral Academic Research Consortium (PARC). *J Am Coll Cardiol*. 2015;65(9):931-941.
31. Patel SD, Zymvragoudakis V, Sheehan L. The efficacy of salvage interactions on threatened distal

bypass grafts. *J Vasc Surg.* 2016;63(1):126-132.

32. Ramkumar N, Martinez-Cambor P, Columbo JA, Osborne NH, Goodney PP, O'Malley AJ. Adverse events after atherectomy: analyzing long-term outcomes of endovascular lower extremity revascularization techniques. *J Am Heart Assoc.* 2019;8(12):e012081.
33. Rymer JA, Mulder H, Narcisse DI, Rockhold F, et al. Association of disease progression with cardiovascular and limb outcomes in patients with peripheral artery disease: insights from the EUCLID trial. *Circ Cardiovasc Interv.* 2020;13(10):e009326.
34. Shishehbor MH, Powell RH, Montero-Baker MF, et al. Transcatheter arterialization of deep veins in chronic limb-threatening ischemia. *N Engl J Med.* 2023;388(13):1171-1180.
35. Society for Cardiovascular Angiography & Interventions (SCAI). Intravascular ultrasound use in peripheral arterial and deep venous interventions: multidisciplinary expert opinion from SCAI/AVF/AVLS/SIR/SVM/SVS. <https://www.scai.org>. Published January 9, 2024.
36. Society for Cardiovascular Angiography & Interventions (SCAI). SCAI appropriate use criteria for peripheral arterial interventions: an update. <https://www.scai.org>. Published May 5, 2017.
37. Society for Cardiovascular Angiography & Interventions (SCAI). SCAI consensus guidelines for device selection in femoral-popliteal arterial interventions. <https://www.scai.org>. Published April 24, 2018.
38. Society for Cardiovascular Angiography & Interventions (SCAI). SCAI expert consensus statement for infrapopliteal arterial intervention appropriate use. <https://www.scai.org>. Published September 19, 2014.
39. Society for Cardiovascular Angiography & Interventions (SCAI). SCAI guidelines for device selection in aorto-iliac arterial interventions. <https://www.scai.org>. Published June 15, 2020.
40. Society for Vascular Surgery. Global vascular guidelines on the management of chronic limb threatening ischemia. <https://vascular.org>. Published June 2019.
41. Society for Vascular Surgery. Guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication. <https://vascular.org>. Published January 28, 2015.
42. Society for Vascular Surgery. Reporting standards of the Society for Vascular Surgery for endovascular treatment of chronic lower extremity peripheral artery disease. <https://vascular.org>. Published July 2022.
43. Society for Vascular Surgery. Society for Vascular Surgery appropriate use criteria for management of intermittent claudication. <https://vascular.org>. Published July 2022.



44. Society for Vascular Surgery (SVS). The intersocietal IWGDF, ESVS, SVS guidelines on peripheral artery disease in people with diabetes mellitus and a foot ulcer. <https://www.vascular.org>. Published September 19, 2023.
45. Tepe G, Brodmann M, Bachinsky W, et al. Intravascular lithotripsy for peripheral artery calcification: mid-term outcomes from the randomized Disrupt PAD III trial. *J Soc Cardiovasc Angiogr Interv*. 2022;1(4):100341.
46. UpToDate, Inc. Classification of acute and chronic lower extremity ischemia. <https://www.uptodate.com>. Updated April 2024.
47. UpToDate, Inc. Clinical features and diagnosis of acute lower extremity ischemia. <https://www.uptodate.com>. Updated March 2024.
48. UpToDate, Inc. Endovascular techniques for lower extremity revascularization. <https://www.uptodate.com>. Updated March 2024.
49. UpToDate, Inc. Management of chronic limb-threatening ischemia. <https://www.uptodate.com>. Updated March 2024.
50. UpToDate, Inc. Management of claudication due to peripheral artery disease. <https://www.uptodate.com>. Updated March 2024.
51. UpToDate, Inc. Overview of lower extremity peripheral artery disease. <https://www.uptodate.com>. Updated March 2024.
52. US Food & Drug Administration (FDA). 510(k) summary: Shockwave Medical peripheral intravascular lithotripsy (IVL) system. <https://www.fda.gov>. Published August 16, 2022.
53. US Food & Drug Administration (FDA). Summary of safety and effectiveness data: DETOUR System. <https://www.fda.gov>. Published June 7, 2023.

## Appendix

### Appendix A

#### Rutherford PAD Symptom Classification<sup>38</sup>

Classification	Symptoms
0	Asymptomatic
1	Mild claudication (eg, calf pain climbing more than two flights of stairs)
2	Moderate claudication (eg, calf pain climbing less than two flights of stairs)
3	Severe claudication (eg, calf pain climbing less than one flight of stairs)
4	Ischemic rest pain (eg, foot pain due to inadequate perfusion that improves with placing the foot in a dependent position)
5	Minor tissue loss (eg, cutaneous ischemic ulceration)
6	Major tissue loss (eg, skin necrosis and gangrene)

## Change Summary

01/02/2024 New Policy.

12/19/2023 Update, No Coverage Change.

05/28/2024 Annual Review, Coverage Change. Updated Coding Information

08/27/2024 Update, No Coverage Change

09/24/2024 Update, Coverage Change