Lower Extremity Invasive Diagnostic and Endovascular Procedures

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Instructions for Use

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Coverage Rationale

Note: This policy does not apply to upper extremities.

Lower extremity vascular angiography is proven and medically necessary for evaluating arterial disease of the lower extremity.
For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 24th edition, 2020, Lower Extremity Angiography, ACG: A-0002 (AC).

Click here to view the MCG™ Care Guidelines.

Endovascular revascularization procedures (e.g., stents, angioplasty and/or atherectomy) for treating lower extremity ischemia are proven and medically necessary in individuals who meet the following indication-specific criteria:
- Claudication due to atherosclerotic disease of the aortoiliac and/or femoropopliteal arteries when all of the following criteria are met:
  - Impaired ability to work and/or perform activities of daily living (ADL)
  - All of the following conservative therapies have been tried and failed:
    - At least twelve (12) weeks of a Supervised or Structured Exercise Program
    - Pharmacologic therapy
    - Smoking cessation, if applicable
  - Moderate to severe ischemic peripheral artery disease with ankle-brachial index (ABI) ≤0.69
  - Imaging results show anatomic location and severity of occlusion (stenosis ≥ 50%) (e.g., duplex ultrasound, computed tomography angiography [CTA], magnetic resonance angiography [MRA] or invasive angiography)
- Chronic limb-threatening ischemia (CLTI) when all of the following criteria are met:
  - One or more of the following:
    - Pain at rest

    - Nonhealing wound or ulcer due to ischemia
    - Gangrene
  - Moderate to severe ischemic peripheral artery disease and any of the following:
    - Ankle-Brachial Index (ABI) ≤0.69 or
    - Ankle pressure <50 mmHg or
    - Toe-Brachial Index ≤ 0.70 or
    - Toe pressure <30 mmHg or
    - Transcutaneous Oxygen Pressure ($TcPO_2$) <25 mmHg
  - Imaging results show anatomic location and severity of occlusion (stenosis ≥ 50%) (e.g., duplex ultrasound, computed tomography angiography [CTA], magnetic resonance angiography [MRA] or invasive angiography)

Due to insufficient evidence of efficacy, endovascular revascularization procedures (e.g., stents, angioplasty and/or atherectomy) for treating lower extremity ischemia are unproven and not medically necessary in the following circumstances:

- Claudication due to isolated infrapopliteal (e.g., anterior tibial, posterior tibial or peroneal) artery disease
- To prevent the progression of claudication to CLTI
- Individual is asymptomatic
- Treatment of a nonviable limb

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT/HCPCS Codes*	Required Clinical Information
Lower Extremity Vascular Angiography	

75710
75716
	Medical notes documenting the following:
	• Signs and symptoms of arterial disease
	• One of the following:
	  ○ Unilateral: Results of Ankle Brachial Index (ABI)
	  ○ Bilateral: Results of Ankle Brachial Index (ABI), include and label results on each limb
	• Results of all imaging (CT, MRA, doppler ultrasound)
	• Functional impairment(s), including a list of Activity of Daily Living (ADLs) impaired
	• Previous vascular problem or surgery, including the location of the problem/ surgery
	• Physician treatment plan

Endovascular Revascularization Procedures (e.g., stents, angioplasty, and/or atherectomy)	

37220
37221
37224
37225
37226
37227
37228
37229
	Medical notes documenting the following:
	• Diagnosis
	• Relevant history and physical to include member symptoms and pertinent findings due ischemia
	• Treatments tried, failed, and/or contraindicated, including structured exercise program, pharmacologic therapy, and smoking cessation, if applicable
	• Details of functional disability(ies) interfering with work or activities of daily living
	• Documentation of moderate to severe ischemic peripheral artery disease using one of the following:
	  ○ Ankle-brachial index (ABI)
	  ○ Ankle pressure
	  ○ Toe-Brachial Index
	  ○ Toe pressure
	  ○ Transcutaneous Oxygen Pressure
	• Diagnostic images (e.g., duplex ultrasound, computed tomography angiography [CTA], magnetic resonance angiography [MRA], or invasive angiography) documenting the location and severity of occlusion

**For code descriptions, see the Applicable Codes section.*

Definitions

Ankle-Brachial Index (ABI): The ABI compares blood pressure in the ankle to blood pressure in the arm and indicates how well blood is flowing in the limbs (Gerhard-Herman et al., 2017). Studies have shown that ABI can differentiate between normal and diseased limbs with a sensitivity of 97% and a specificity of 100% and that the resting ABI is a significant predictor of disease severity (Mohler, 2003). An ABI less than 0.90 indicates peripheral artery disease (PAD).

- Mild: 0.70 to 0.89
- Moderate: 0.40 – 0.69
- Severe: less than 0.40

Chronic Limb-Threatening Ischemia (CLTI): A condition characterized by chronic (≥2 weeks) ischemic rest pain, nonhealing wound/ulcers or gangrene in one or both legs attributable to arterial occlusive disease (Gerhard-Herman et al., 2017). Also referred to as critical limb ischemia (CLI).

Claudication: Fatigue, discomfort, cramping or pain of vascular origin in the muscles of the lower extremities that is consistently induced by exercise and consistently relieved by rest (within 10 min) (Gerhard-Herman et al., 2017).

Structured Exercise Program: Components of a structured exercise program include all of the following (Gerhard-Herman, et al., 2017):

- Program takes place in the personal setting of the patient rather than in a clinical setting
- Program is self-directed with guidance of healthcare provider(s)
- Healthcare providers prescribe an exercise regimen similar to that of a Supervised Program
- Patient counseling ensures understanding of how to begin and maintain the program and how to progress the difficulty of the walking (by increasing distance or speed)
- Program may incorporate behavioral change techniques, such as health coaching or use of activity monitors.

Supervised Exercise Program: Components of a Supervised Exercise Program include all of the following (Gerhard-Herman, et al., 2017):

- Program takes place in a hospital or outpatient facility
- Program uses intermittent walking exercise as the treatment modality
- Program can be standalone or within a cardiac rehabilitation program
- Program is directly supervised by [qualified] healthcare provider(s)
- Training is performed for a minimum of 30–45 minutes per session and sessions are performed at least 3 times per week for a minimum of 12 weeks
- Training involves intermittent bouts of walking to moderate-to-maximum claudication, alternating with periods of rest
- Warm-up and cool-down periods precede and follow each session of walking.

Toe-Brachial Index (TBI): The TBI compares blood pressure in the toe to blood pressure in the arm and indicates how well blood is flowing in the limbs. The test may be performed when ABI results are abnormally high due to calcified arteries in the legs.

Transcutaneous Oxygen Pressure (TcPO2): A $TcPO_2$ test measures the oxygen level of tissue under the skin and may be used as an indirect measure of blood flow.

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 the member specific benefit plan document 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
37220	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty
37221	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37222	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)
37223	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37227	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed
37228	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty
37229	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed
37230	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37231	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed
37232	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)
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)
75710	Angiography, extremity, unilateral, radiological supervision and interpretation
75716	Angiography, extremity, bilateral, radiological supervision and interpretation

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. Some of the tests used to diagnose PAD are physical exam, Ankle-Brachial

Index (ABI), ankle pressure, Toe-Brachial Index, toe pressure, Transcutaneous Oxygen Pressure, noninvasive imaging and invasive angiography.

When left untreated, PAD can lead to an increased risk of heart attack, stroke and chronic limb-threatening ischemia (CLTI). Treatment options include lifestyle changes, medications, endovascular techniques and surgery. Endovascular techniques to treat claudication and chronic limb-threatening ischemia (CLTI) include balloon dilation (angioplasty), stents and atherectomy. The technique chosen for endovascular treatment depends on many factors including lesion characteristics such as anatomic location, lesion length and degree of calcification (Gerhard-Herman et al., 2017; National Heart, Lung and Blood Institute website).

Clinical Evidence

A Cochrane review by Fakhry et al. (2018) assessed the effectiveness of endovascular revascularization compared with no specific therapy for intermittent claudication, or compared with a conservative therapy option such as supervised exercise or drug therapy. The review included ten studies with a total of 1087 participants. 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.

Malgor et al. (2015) conducted a systematic review to evaluate the efficacy of three treatment strategies for individuals with claudication. Primary outcome measures included mortality, amputation, walking distance, quality of life, patency and measures of blood flow (ABI). The review included eight systematic reviews and 12 trials enrolling 1548 patients. 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).

Vemulapalli et al. (2015) conducted a systematic review and meta-analysis to evaluate the comparative effectiveness of medical therapy, supervised exercise training, endovascular intervention and surgical revascularization in patients with claudication. Outcomes assessed included walking distance, claudication distance, all-cause mortality and quality of life. Thirty-five studies (n=7475) 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 heterogeneity in functional endpoints, single-arm observational study design and poor subgroup reporting significantly limit comparative effectiveness analysis in PAD. Further studies with attention to study design, standardized efficacy and safety endpoints, and appropriate subgroup reporting are needed.

In the multicenter ERASE trial, Fakhry et al. (2015) assessed the effectiveness of endovascular revascularization plus supervised exercise (n=106) compared with supervised exercise alone (n=106) in patients with intermittent claudication. The primary end point was the difference in treadmill walking distance. Secondary end points included treadmill pain-free walking distance and quality of life measures. After one year of follow-up, a combination therapy of endovascular revascularization followed by supervised exercise resulted in significantly greater improvement in walking distances and health-related quality of life scores compared with supervised exercise alone.

In the multicenter CLEVER trial, Murphy et al. (2012) compared three treatment strategies for patients with claudication due to aortoiliac disease. A total of 111 patients were randomly assigned to optimal medical care (OMC) (n=22), OMC plus supervised exercise (n=43) or OMC plus stent revascularization (n=46). Patients in the OMC group received cilostazol 100 mg twice daily and written/oral advice about exercise. Patients in the supervised exercise program received OMC, plus 78 weeks of supervised exercise (hourly sessions 3 times per week). Patients in the stent group received OMC, plus stent revascularization of the aortoiliac arteries. The primary end point was the change in peak walking time on a graded treadmill test compared with baseline. Secondary end points included disease-specific quality of life measures. Among patients with moderate to severe

claudication due to aortoiliac disease, either a supervised exercise program or stent therapy was associated with the largest increase in treadmill walking time. At 6 months, the change in peak walking time was improved by 1.2 minutes with OMC alone, 5.8 minutes with supervised exercise and 3.7 minutes with stent revascularization. Disease-specific quality of life improved with both supervised exercise stent therapy compared with OMC, but the improvement was greater with stent therapy than structured exercise. At 18 months, both supervised exercise and stent therapy had better outcomes than OMC (Murphy et al., 2015). The change in peak walking time was 0.2 minutes with OMC, 3.2 minutes with stent revascularization and 5.0 minutes with a supervised exercise program. The durability of exercise intervention merits its consideration as a primary PAD claudication treatment. Clinicaltrials.gov #NCT00132743.

A National Institute for Health and Care Excellence (NICE) clinical guideline offers recommendations on the diagnosis and management of PAD (NICE, 2012; updated 2018).

Several randomized, controlled trials comparing contemporary surgical and endovascular treatments for patients with CLTI are ongoing.

Professional Societies

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 recommends 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 where medical therapy is insufficient, the selection of surgical or endovascular revascularization depends on several factors including patient risk level and lesion characteristics, such as anatomic location, length and presence of stenosis or occlusion. For patients with CLTI, both endovascular or 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 Diabetes Association (ADA)

ADA guidelines address the evaluation of PAD in diabetic individuals. Recommended testing is based on the presence and severity of symptoms. The guidelines state that urgent vascular imaging and revascularization should be considered in individuals with a diabetic foot ulcer and an ankle pressure <50 mmHg, toe pressure <30 mmHg, or a $TcPO_2$ <25 mmHg (ADA, 2020).

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

ACC guidelines for the diagnosis and management of patients with lower extremity PAD make the following recommendations for surgical and endovascular revascularization procedures (Gerhard-Herman et al., 2017):

Claudication

- Revascularization is a reasonable treatment option for the patient with lifestyle-limiting claudication with an inadequate response to guideline-directed management and therapy
- Endovascular procedures are effective as a revascularization option for patients with lifestyle-limiting claudication and hemodynamically significant aortoiliac occlusive disease
- Endovascular procedures are reasonable as a revascularization option for patients with lifestyle-limiting claudication and hemodynamically significant femoropopliteal disease
- The usefulness of endovascular procedures as a revascularization option for patients with claudication due to isolated infrapopliteal artery disease is unknown
- Endovascular procedures should not be performed in patients with PAD solely to prevent progression to CLTI

CLTI

- In patients with CLTI, revascularization should be performed when possible to minimize tissue loss

- An evaluation for revascularization options should be performed by an interdisciplinary care team before amputation in the patient with CLTI.
- Endovascular procedures are recommended to establish in-line blood flow to the foot in patients with nonhealing wounds or gangrene
- A staged approach to endovascular procedures is reasonable in patients with ischemic rest pain
- Evaluation of lesion characteristics can be useful in selecting the endovascular approach for CLTI

International Working Group on the Diabetic Foot (IWGDF)

IWGDF guidelines on the prevention and management of diabetic foot disease state that in patients with either an ankle pressure <50mm Hg or an ABI <0.5, consider urgent vascular imaging and, when findings suggest it is appropriate, revascularization. Also consider revascularization if the toe pressure is <30 mmHg or $TcPO_2$ is <25 mmHg. Clinicians might consider revascularization at higher pressure levels in patients with extensive tissue loss or infection (Schaper et al., 2020).

Society for Vascular Surgery (SVS)

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).

Separate SVS guidelines provide a comprehensive set of recommendations for the evaluation and management of asymptomatic disease and intermittent claudication. Emphasis is placed on risk factor modification, medical therapies and broader use of exercise programs to improve cardiovascular health and functional performance. Revascularization for intermittent claudication is an appropriate therapy for selected patients with disabling symptoms, after a careful risk-benefit analysis. Treatment should be individualized based on comorbid conditions, degree of functional impairment and anatomic factors. Invasive treatments for intermittent claudication should provide predictable functional improvements with reasonable durability. A minimum threshold of a >50% likelihood of sustained efficacy for at least 2 years is suggested as a benchmark. Endovascular approaches are favored for most candidates with aortoiliac disease and for selected patients with femoropopliteal disease in whom anatomic durability is expected to meet this minimum threshold. Conversely, caution is warranted in the use of interventions for intermittent claudication in anatomic settings where durability is limited (extensive calcification, small-caliber arteries, diffuse infrainguinal disease, poor runoff). Surgical bypass may be a preferred strategy in good-risk patients with these disease patterns or in those with prior endovascular failures. Common femoral artery disease should be treated surgically, and the saphenous vein is the preferred conduit for infrainguinal bypass grafting. Patients who undergo invasive treatments for intermittent claudication should be monitored regularly in a surveillance program to record subjective improvements, assess risk factors, optimize compliance with cardioprotective medications and monitor hemodynamic and patency status (Conte et al., 2015).

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 PAD of the lower extremities. See the following website (use product codes NIO and NIP) for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed August 21, 2020)

The FDA has approved several catheter systems used for the treatment of PAD of the lower extremities. See the following website (use product code DQY) for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed August 21, 2020)

Centers for Medicare and Medicaid Services (CMS)

Medicare covers lower extremity angiography when criteria are met. See the National Coverage Determinations (NCDs) for Digital Subtraction Angiography (220.9) and Magnetic Resonance Angiography (220.3). Also see the Local Coverage Determinations (LCDs) for Aortography and peripheral angiography, Diagnostic Abdominal Aortography and Renal Angiography and Non-Invasive Abdominal / Visceral Vascular Studies.

Medicare covers lower extremity revascularization procedures when criteria are met. Refer to the NCD for Percutaneous Transluminal Angioplasty (PTA) (20.7). Also see the LCDs for Endovenous Stenting, Non-Coronary Vascular Stents and Vascular Stenting of Lower Extremity Arteries.
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Policy History/Revision Information

Date	Summary of Changes

12/01/2020	**Coverage Rationale**
	• Revised coverage criteria for endovascular revascularization procedures for treating chronic limb-threatening ischemia; replaced criterion requiring "moderate to severe ischemic peripheral artery disease with ankle-brachial index (ABI) ≤0.69" with "moderate to severe ischemic peripheral artery disease *and any of the following*: an Ankle-Brachial Index (ABI) ≤0.69, *ankle pressure <50 mmHg, Toe-Brachial Index ≤ 0.70, toe pressure <30 mmHg, or Transcutaneous Oxygen Pressure (TcPO2) <25 mmHg*"
	Documentation Requirements
	• Updated required clinical information
	Definitions
	• Added definition of:
	  ○ Toe-Brachial Index (TBI)
	  ○ Transcutaneous Oxygen Pressure (TcPO2)
	Supporting Information
	• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information
	• Archived previous policy version 2020T0602C

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.