

Cohere Medical Policy -Lower Extremity Arterial Revascularization

Clinical Policy for Medical Necessity Review

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Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medical Policy - Lower Extremity Arterial Revascularization

Type: [X] Adult (18+ yo) | [X] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Lower Extremity Arterial Revascularization

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere
 Health medical policy, medical necessity will be determined based on
 established clinical best practices, as supported by evidence-based
 literature, peer-reviewed sources, professional society guidelines, and
 state or national recommendations, unless otherwise directed by the
 health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
 - o How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Lower extremity peripheral artery disease (PAD) is a condition where blood flow is restricted in the arteries of the legs due to narrowing or blockage caused by plaque build-up. Pain, numbness, and tissue damage to the legs and feet may result from lack of blood flow and surgical intervention may be required. Lower extremity arterial revascularization is a surgical procedure that can be performed in patients to restore blood flow to the legs and feet, improving pain and quality of life.

Medical Necessity Criteria

Indications

Lower extremity arterial revascularization (percutaneous) is considered appropriate for **ANY** of the following 1-4:

- The patient has chronic limb-threatening arterial occlusive disease (CLTI), and **ALL** of the following are **TRUE**:
 - ANY of the following:
 - Ischemic rest pain with ALL of the following:
 - Severe persistent pain in the foot or toes, typically occurring when the limb is at rest or elevated and is relieved by placing the limb in a lowered position 5-7; AND
 - **ANY** of the following⁸:
 - Resting ankle pressure (AP) less than 40 mm/Hg; OR
 - Flat or barely pulsative ankle or metatarsal PVR; OR
 - Toe pressure (TP) less than 30 mm/Hg; OR
 - ABI less than or equal to 0.5; OR
 - Gangrene; OR
 - Ischemic wound progresses or fails to reduce in size by greater than or equal to 50% within 2-4 weeks of wound management¹; **AND**
 - The clinician determines that the patient is an appropriate candidate for intervention and provides appropriate clinical documentation supporting the clinical decision-making process, including ANY of the following:
 - Angiographic (CTA, MRA, invasive angiogram) lesion greater than or equal to $70\%^{7.9}$; **OR**

- **ALL** of the following^{7,9}:
 - Angiogram demonstrates 50-70% stenosis (i.e., the cause of limited perfusion); AND
 - **ANY** of the following:
 - Resting intravascular pressure measurements (greater than 10 mmHg); OR
 - Provoked (greater than or equal to 10 mmHg) intravascular pressure measurements to determine the hemodynamic significance of lesions⁷; **OR**
- Lower extremity duplex Doppler with peak systolic velocity (PSV) greater than 3 m/s or velocity ratio 4:1²; **OR**
- Absent vascular flow; AND
- The procedure is **ANY** of the following:
 - Percutaneous transluminal angioplasty (PTA) and/or stent for aortoiliac arterial occlusive disease¹; **OR**
 - PTA and/or stent for femoral-popliteal arterial occlusive disease¹; **OR**
 - Atherectomy for femoral-popliteal arterial occlusive disease with documentation of **ANY** of the following⁴:
 - The procedure is a documented laser atherectomy for in-stent restenosis (ISR); OR
 - Documented moderate to severe calcification (arc of calcification extends circumferentially to greater than or equal to 180 degrees in a vessel that has failed PTA or, in the opinion of the provider, is not dilatable)10; OR
 - PTA in an infrapopliteal (tibial or peroneal) vessel⁴; OR
 - Atherectomy for infrapopliteal occlusive disease with documentation of **ANY** of the following*4:
 - Documented moderate to severe calcification (i.e., arc of calcification extends circumferentially to greater than or equal to 180 degrees in a vessel that has failed PTA); OR
 - Is documented by the provider to not be dilatable OR
 - Occlusion; OR
 - Aneurysm (stent); OR
 - Flow-limiting dissection after intervention (stent); OR
- The patient has non-limb threatening/intermittent claudication arterial occlusive disease, and ALL of the following are TRUE^{1-2, 6, 1}:
 - The patient fails to show significant clinical improvement despite documented compliance with optimal medical care (OMC)(e.g.,

- smoking cessation, weight management, glycemic control, statin therapy, blood pressure management, supervised exercise program, pharmacotherapy [e.g., anti-platelet, cilostazol]); **AND**
- The patient reports their symptoms to be negatively affecting activities of daily living (ADLs); AND
- The clinician determines that the patient is an appropriate candidate for intervention and provides appropriate clinical documentation supporting the clinical decision-making process, including ANY of the following:
 - Angiographic (CTA, MRA, invasive angiogram) lesion greater than or equal to 70⁷; OR
 - **ALL** of the following⁷:
 - Angiogram demonstrates stenosis of 50% to 70%; AND
 - ANY of the following:
 - Resting intravascular pressure measurements (greater than 10 mmHg); OR
 - Provoked (greater than or equal to 10 mmHg) intravascular pressure measurements are required to determine the hemodynamic significance of lesions²; OR
 - Lower extremity duplex Doppler with **ANY** of the following:
 - Peak systolic velocity (PSV) greater than 3 m/sec; OR
 - A velocity ratio greater than 4:1²; **OR**
 - Occlusion; OR
 - ANY of the following**:
 - PTA and/or stent for aortoiliac arterial occlusive disease⁴; OR
 - PTA and/or stent for femoral-popliteal arterial occlusive disease⁴;
 - Atherectomy for femoral-popliteal arterial occlusive disease with documentation of ANY of the following⁴:
 - The procedure is a documented laser atherectomy for in-stent restenosis; OR
 - Documented moderate to severe calcification (i.e., arc of calcification extends circumferentially to greater than or equal to 180 degrees in a vessel that has failed PTA or, in the opinion of the provider, is not dilatable)¹⁰; OR
- The procedure is considered appropriate in the presence or absence of symptoms, and ANY of the following is TRUE:
 - Bail-out stenting for flow-limiting dissection after the procedure¹; OR

- Stenting for aneurysm or pseudoaneurysm¹; OR
- Threatened bypass graft for PTA/stenting and ANY of the following:
 - Drop in ABI of 0.15 or greater⁷; OR
 - Stenosis in graft/inflow or outflow of greater than 50% by lower extremity arterial Doppler (LEAD) or CTA/MRA.²

*NOTE: Infrapopliteal interventions besides a balloon angioplasty (PTA) in the setting of limb-threatening arterial occlusive disease of the extremities may be subject to prospective and/or retrospective review. Inframalleolar revascularization should be extremely rare. Multilevel arterial revascularization procedures may be indicated in the setting of limb-threatening ischemia (e.g., suprainguinal, infrainguinal, and/or infrapopliteal) with appropriate documentation.

**NOTE: Infrapopliteal interventions (endovascular or surgical) are rarely indicated in the treatment of non-limb-threatening arterial occlusive disease of the extremities. All infrapopliteal interventions in the setting of non-limb-threatening arterial occlusive disease of the extremities will be subject to review.

Non-Indications

Lower extremity arterial revascularization is not considered appropriate if **ANY** of the following is **TRUE**^{1-4, 6-7}:

- Revascularization performed in a patient with peripheral artery disease solely to prevent progression to CLTI; OR
- ANY of the following conditions¹²⁻¹⁴:
 - Pure venous ulcers; OR
 - Pure traumatic wounds; OR
 - Embolic disease; OR
 - Nonatherosclerotic chronic vascular conditions of the lower extremity (e.g., vasculitis, Buerger disease, radiation arteritis); OR
- A successful arterial intervention could increase the risk of the patient developing a limb-threatening condition or would not extend the quality or length of life, such as ANY of the following:
 - The patient's age or existing co-morbid conditions indicate the risk of a complication; OR

- The patient is permanently non-ambulatory or the patient's activity level is severely limited; OR
- Evidence of occlusion without accompanying clinical symptoms (i.e., claudication); OR
- Isolated tibial artery occlusive disease in patients with claudication; OR
- ANY of the following procedures as they are clinically unproven and not medically necessary, as there is inconclusive evidence of their effectiveness:
 - Atherectomy for iliac disease (CPT 0238T)¹⁵; **OR**
 - Endovenous femoral-popliteal arterial revascularization (CPT 0505T).

NOTE:

Rutherford/Fontaine Peripheral Arterial Disease Classification System		
Rutherford Stage	Fontaine Stage	Description/Definition
0	I	Asymptomatic
1	lla	Mild claudication
2	IIb	Moderate claudication
3	IIb	Severe claudication
4	III	Rest pain
5	IV	Ischemic ulcers of the digits of the foot (minor tissue loss)
6	IV	Severe ischemic ulcers or gangrene (major tissue loss)

WIFi Classification System: Risk stratification based on wound, ischemia, and foot infection (MILLS)		
Component	Grade	Description
Wound (W)	0	No ulcer or gangrene (ischemic pain at rest)

	1	Small or superficial ulcer on leg or foot, without gangrene (SDA or SC)
	2	Deep ulcer with exposed bone, joint or tendon with or without gangrene limited to digits
	3	Deep, extensive ulcer involving forefoot and/or midfoot with or without calcaneal involvement with or without extensive gangrene (CR of the foot or nontraditional TMA)
Ischemia (I)	Grade	ABI/SBP of the ankle/TP, TcPO2
	0	Greater than or equal to 0.80/Greater than 100 mmHg/Greater than or equal to 60 mmHg
	1	0.6-0.79/70-100 mmHg/40-59 mmHg
	2	0.4-0.59/50-70 mmHg/30-39 mmHg
	3	Less than or equal to 0.39/Less than or equal to 50 mm/Hg/Less than 30 mmHg
Foot Infection (fi)	Grade	Description
	0	Uninfected
	1	Mild local infection, involving only the skin and subcutaneous tissue, erythema greater than 0.5 to less than or equal to 2 cm
	2	Moderate local infection, with erythema greater than 2 cm or involving deeper structures
	3	Severe local infection with signs of SIRS

WIfI = Wound, Ischemia, and foot Infection; **SDA** = simple digital amputation; **SC** = skin coverage; **MDA** = multiple digital amputations; **TMA** = transmetatarsal amputation; **CR** = complex reconstruction; **ABI** = ankle-brachial index; **SBP** = systolic blood pressure; **TP** = toe pressure (SBP of

toe); **TCPO2** = transcutaneous oxygen pressure; **SIRS** = systemic inflammatory response syndrome.

TASC Classification of Femoral Popliteal Lesions		
TASC A Lesions	Single stenosis ≤10 cm in length Single occlusions less than ≤5 cm in length	
TASC B Lesions	Multiple stenoses or occlusions each ≤5 cm Single stenosis ≤15 cm Heavily calcified occlusions ≤5 cm Single popliteal stenosis	
TASC C Lesions	Multiple stenoses or occlusions totaling ≥15 cm Recurrent stenoses or occlusions after failing treatment (Two endovascular interventions).	
TASC D Lesions	Chronic total occlusion of common femoral artery or superficial femoral artery (>20 cm) Chronic total occlusion of popliteal artery and proximal trifurcation vessels.	

TASC Classification of Aortoiliac Lesions		
TASC A Lesions	Unilateral or bilateral common iliac artery stenoses Unilateral or bilateral short (≤3 cm) external iliac artery stenosis	
TASC B Lesions	Short (3 cm) stenosis of infrarenal aorta Unilateral common iliac artery occlusion External iliac artery stenosis/stenoses totaling 3-10 cm Unilateral external iliac artery occlusion	
TASC C Lesions	Bilateral common iliac artery (CIA) occlusions Bilateral external iliac artery (EIA) stenoses 3-10cm long not extending into the common femoral artery (CFA) Unilateral external iliac artery (EIA) stenosis extending into the common femoral artery (CFA) Heavily calcified unilateral external iliac artery (EIA) occlusion	
TASC D Lesions	Diffuse disease involving the aorta and both iliac arteries Diffuse multiple stenoses Unilateral occlusion of both external iliac artery (EIA) and common iliac artery (CIA) Bilateral occlusion of external iliac artery (EIA)	

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	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
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
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

Medical Evidence

Conte et al. (2019) developed global vascular guidelines for the management of chronic limb-threatening ischemia. The group proposed a new anatomic scheme for threatened limbs, the Global Limb Anatomic Staging System (GLASS). This integrated, limb-based approach is based on a set of clinical assumptions and simplified approaches to stratification. They make a strong recommendation for revascularization to all average-risk patients with advanced limb-threatening conditions and significant perfusion deficits. There was a weak recommendation for revascularization in average-risk patients with intermediate limb threat (based on a scoring tool such as WIfi). It is stated that more in-depth study is required regarding the relationship between regional ischemia and patterns of infrapopliteal and pedal disease.\frac{1}{2}

Woo and colleagues (2022) published the Society of Vascular Surgery appropriate use criteria for management of intermittent claudication. 2280 unique intermittent claudication treatment scenarios were rated. Invasive treatment recommendations were made for patients who have completed exercise therapy, are nonsmokers, and are on optimal medical therapy, with severe lifestyle limitations. The group stated that there is unclear benefit and possible harm related to invasive intervention in the infrapopliteal segment for intermittent claudication.⁶

Gerhard-Herman et al. (2017) developed the 2016 AHA/ACC guideline for the management of patients with lower extremity peripheral artery disease. Strong evidence-based recommendations were made for revascularization in the setting of CLTI to minimize tissue loss. Interdisciplinary team evaluation is strongly recommended prior to intervention. The BASIL randomized controlled trial (RCT)(Bypass versus Angioplasty in Severe Ischemia of the Leg) revealed that endovascular revascularization is an effective option for those patients with chronic limb-threatening ischemia as compared with open surgery. The group stated that multiple RCTs are ongoing that compare surgical and endovascular treatment.¹⁶

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Policy Revision History/Information

Original Date: May 28, 2024		
Review History		
Version 2	07/29/2024	Re-formatted document, updated indications and non-indications/references
Version 3	07/31/2025	Annual Review Revised indications and non-indications for clarity: Removed requirements within main bullets regarding specific Rutherford or Fontaine scoring criteria. Clarified language relating to CLTI and ischemic rest pain, upper levels of lesion stenosis reduced from 75% to 70% per current guidelines in both CLTI and non-limb threatening intermittent claudication. Clarified non-indications related to CPT 0238T and 0505T with specific language. Removed references no longer applicable: (McDermott, Bachoo, Dippel, Wang) Added references (Gornik, Hardman, Patel, Feldman) supporting revised criteria.