



Lower Extremity Arterial Revascularization – Single Service

Clinical Guidelines for Medical Necessity Review

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Lower Extremity Arterial Revascularization (Single Service)

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

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Medical Necessity Criteria

Service: Lower Extremity Arterial Revascularization

General Guidelines

- **Units, Frequency, & Duration:** Once
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach¹⁻³:**
 - Peripheral arterial disease (PAD) is the narrowing or blockage of the arteries that carry blood to the arms and legs, and is a potent marker for cardiovascular disease morbidity and mortality.^{4,5} PAD may be assessed and measured by the Rutherford, Fontaine, and/or Wifi classification systems (see tables below).
 - Non-interventional approach (i.e. optimal medical care [OMC]) is generally recommended as the initial plan of care in patients with non-limb-threatening PAD (Rutherford Stage 0-3 or Fontaine stage I to IIb) due to its proven efficacy. This includes actions such as smoking cessation, weight management, glycemic control, and pharmacotherapy.
 - Medical therapies are generally ineffective in patients with chronic limb-threatening ischemia (CLTI) Rutherford stage 4-6 or Fontaine stage III to V (see tables below). In addition, the WiFi classification system may also be used. Peripheral revascularization is generally required to reduce the risk of limb loss. Symptoms include ischemic limb pain at rest, non-healing ulcerations, or gangrene.
 - The optimal strategy for the management of an individual patient with CLTI (surgical vs. percutaneous intervention) is determined on a case-by-case basis by the treating physician and is influenced by the individual patient's clinical presentation and anatomy. The ordering clinician is required to provide appropriate documentation to justify the performance of surgery and/or percutaneous intervention. This should include a pertinent history to justify the request.⁶
- **Exclusions:** None

NOTE:

Rutherford/Fontaine Peripheral Arterial Disease Classification System		
Rutherford Stage	Fontaine Stage	Description/Definition
0	I	Asymptomatic
1	IIa	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		
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.

Medical Necessity Criteria

Indications

→ **Lower extremity arterial revascularization (surgical or percutaneous)** is considered appropriate for **ANY** of the following^{1,2,8,9}:

◆ **Lower extremity arterial revascularization (surgical or percutaneous) for chronic limb-threatening (Rutherford stage 4–6 or Fontaine stage III to IV–see table) arterial occlusive disease (CLTI)** is considered appropriate if 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 75%⁸; **OR**
- A stenosis of 50% to 75% by angiography may not be hemodynamically significant (i.e., the cause of limited perfusion). Resting (greater than 10 mmHg) or provoked (greater than or equal to 10 mmHg) intravascular pressure measurements may be needed to determine whether lesions are hemodynamically significant; **OR**
- Lower extremity duplex Doppler with peak systolic velocity (PSV) greater than 3 m/s or velocity ratio 4:1; **OR**

◆ **Lower extremity arterial revascularization (surgical or percutaneous) for non-limb threatening (Rutherford stage 0–3 or Fontaine stage I to IIb–see table) arterial occlusive disease** is considered appropriate if **ALL** of the following are **TRUE**¹⁻³:

- The patient fails to show significant clinical improvement despite documented compliance with OMC (smoking cessation, weight management, glycemic control, statin therapy, blood pressure management, supervised exercise program, pharmacotherapy [anti-platelet, cilostazol]); **AND**
- The patient has quit smoking; **AND**
- The patient reports their symptoms to be lifestyle-limiting; **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 (computed tomography angiography [CTA], magnetic resonance angiography [MRA], invasive angiogram)⁶ lesion greater than or equal to 75%²; **OR**

- A stenosis of 50% to 75% by angiography with documented resting (greater than 10 mmHg) or provoked (greater than or equal to 10 mmHg) intravascular pressure measurements⁶; **OR**
- Lower extremity duplex Doppler with peak systolic velocity (PSV) greater than 3 m/sec or a velocity ratio greater than 4:1.

Non-Indications

→ **Lower extremity arterial revascularization** is not considered appropriate if **ANY** of the following is **TRUE**^{1,2,6,8,9}

◆ **Lower extremity arterial revascularization (surgical or percutaneous)** and **ANY** of the following is **TRUE**:

- Revascularization performed in a patient with peripheral artery disease solely to prevent progression to CLTI⁴; **OR**
- Femoral-tibial artery bypasses with prosthetic graft material⁶; **OR**
- **ANY** of the following conditions^{1,10-12}:
 - 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; **OR**
- The patient is not considered a suitable candidate for percutaneous intervention based on documentation from the most recent physician encounter and TASC criteria (i.e., TASC D, see note below)^{13,14}; **OR**

◆ **Percutaneous Intervention** may not be considered appropriate if **ANY** of the following is **TRUE**^{8,16}:

- Severe allergy to contrast media; **OR**
- Severe renal insufficiency; **OR**
- The patient is pregnant; **OR**
- The patient uses metformin; **OR**
- The patient is extremely over or underweight; **OR**
- The patient has a fixed contracture of the affected extremity; **OR**
- There is a known or suspected arterial aneurysm or significant vascular anomaly (e.g., AV fistula) at the proposed access site.

NOTE:

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	<p>Bilateral common iliac artery (CIA) occlusions</p> <p>Bilateral external iliac artery (EIA) stenoses 3-10cm long not extending into the common femoral artery (CFA)</p> <p>Unilateral external iliac artery (EIA) stenosis extending into the common femoral artery (CFA)</p> <p>Heavily calcified unilateral external iliac artery (EIA) occlusion</p>
TASC D Lesions	<p>Diffuse disease involving the aorta and both iliac arteries</p> <p>Diffuse multiple stenoses</p> <p>Unilateral occlusion of both external iliac artery (EIA) and common iliac artery (CIA)</p> <p>Bilateral occlusion of external iliac artery (EIA)</p>

Site of Service Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0238T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion
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

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 Wlfi). It is stated that more in-depth study is required regarding the relationship between regional ischemia and patterns of infrapopliteal and pedal disease.¹

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.³

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.⁴

References

1. Conte MS, Bradbury AW, Kolh P, et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. *J Vasc Surg*. 2019;69(6):3S–125S.e40. doi:10.1016/j.jvs.2019.02.016.
2. Klein AJ, Jaff MR, Gray BH, et al. SCAI appropriate use criteria for peripheral arterial interventions: an update. *Catheter Cardiovasc Interv*. 2017;90(4): E90–E110.
3. Woo K, Syracuse JJ, Klingbell K, et al. Society for Vascular Surgery appropriate use criteria for management of intermittent claudication. *J Vasc Surg*. 2022; 76(1): 3–22 e21.
4. Criqui MH, Langer RD, Fronek A, et al. Mortality over a period of 10 years in patients with peripheral arterial disease. *N Engl J Med*. 1992;326(6): 381–386.
5. McDermott, MM. The ankle-brachial index as a predictor of survival in patients with peripheral vascular disease. *J Gen Intern Med*. 1994; 9(8): 445–449.
6. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC guideline on the management of patients With lower extremity peripheral artery disease. *J Am Coll Cardiol*. 2017;69(11). <http://dx.doi.org/10.1016/j.jacc.2016.11.007>.
7. Mills JL, Conte MS, Armstrong DG, et al. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: risk stratification based on wound, ischemia, and foot infection (WIFI). *J Vasc Surg*. 2014;59(1): 220–234 e221–222.
8. American College of Radiology (ACR). ACR Appropriateness Criteria. Lower extremity arterial claudication—imaging assessment for revascularization. Revised 2022. <https://acsearch.acr.org/docs/69411/Narrative/>
9. Bailey SR, Beckman JA, Dao TD, et al. ACC/AHA/SCAI/SIR/SVM 2018 appropriate use criteria for peripheral artery intervention. *J Am Coll Cardiol*. 2019;73(2).
10. Bachoo P, Thorpe PA, Maxwell H, Welch K. Endovascular stents for intermittent claudication. *Cochrane Database Syst Rev*. 2010;(1): CD003228.
11. Dippel et al. Randomized controlled study of excimer laser atherectomy for treatment of femoropopliteal in-stent restenosis: initial EXCITE ISR results. *J Am Coll Cardiol*. 2015;8(1): 92–101.
12. Topfer LA, Spry C. New technologies for the treatment of peripheral artery disease. In: CADTH Issues in Emerging Health Technologies. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2016-. 172. <https://www.ncbi.nlm.nih.gov/books/NBK519606/>.

13. Patel MR, Bailey SR, Bonow RO, et al. ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS 2012 appropriate use criteria for diagnostic catheterization: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society of Critical Care Medicine, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol.* 2012;59(22):1995–2027. doi:10.1016/j.jacc.2012.03.003.
14. Norgren L, Hiatt WR, Dormandy JA et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). *JVS Vasc Insights.* 2017. doi: 10.1016/j.jvs.2006.12.037.
15. Jaff MR, White CJ, Hiatt WR, et al. An update on methods for revascularization and expansion of the TASC lesion classification to include below-the-knee arteries: a supplement to the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II): the TASC Steering Committee. *Ann Vasc Dis.* 2015;8(4). 343–357. doi:10.3400/avd.tasc.15-01000.
16. Wang C, Asch D, Callahan MJ. ACR manual on contrast media. 2023. acr.org.

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