# Cohere Medicare Advantage Policy - Lower Extremity Arterial Revascularization

*Clinical Guidelines for Medical Necessity Review*

**Version:** 1
**Effective Date:** March 27, 2025

# Important Notices

## Notices & Disclaimers:

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## Other Notices:



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## Guideline Information:

**Specialty Area:** Cardiovascular Disease
**Guideline Name:** Cohere Medicare Advantage Policy - Lower Extremity Arterial Revascularization
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**Type:** [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

**Table of Contents**

# Medical Necessity Criteria

***Service: Lower Extremity Arterial Revascularization***

## Benefit Category

Not applicable.

## Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.

- There are no applicable NCDs and/or LCDs for Lower Extremity Arterial Revascularization.

## Recommended Clinical Approach

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. PAD may be assessed and measured by the Rutherford, Fontaine, and/or WIfi classification systems (see Tables 1 and 2 below). A 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, statin therapy, blood pressure management, a supervised exercise program (SEP), and pharmacotherapy (e.g., anti-platelet, cilostazol). Medical therapies are generally ineffective in patients with chronic limb-threatening ischemia (CLTI) Rutherford stage 4-6 or Fontaine stage III to V (see Table 1 below). 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 history, clinical presentation, and anatomy. The ordering clinician is required to provide appropriate documentation to justify the performance of surgery and/or percutaneous intervention.[1-7]

## Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of lower extremity arterial revascularization. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Complications associated with lower extremity arterial revascularization include arterial perforation, distal embolism, or myocardial infarction.[1]
- Although rare, adverse reactions to anesthesia or contrast agents used during the procedure may occur. As with any surgical procedure, there is a risk of infection at the surgical site.[1]
- Restenosis, or re-narrowing of the artery, can occur and may require additional procedures.[1]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- This procedure improves blood flow and restores adequate blood circulation to the affected limb.[1]
- Restoring blood flow can reduce or eliminate pain and cramping.[1]
- Improved limb function can allow patients to resume activities of daily living (ADLs).[1]
- Reduction in complications and adverse effects from unnecessary procedures.[2]
- Improved patient outcomes through timely and appropriate access to the procedure. In patients with critical limb ischemia, this procedure decreases the likelihood of amputation.[2]
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

## Medical Necessity Criteria

### Indications

- ➔ **Lower extremity arterial revascularization (percutaneous)** is considered appropriate if **ANY** of the following is **TRUE**[1–9]:
  - ◆ The patient has chronic limb-threatening arterial occlusive disease (CLTI), and **ALL** of the following are **TRUE**:
    - The disease is classified as Rutherford stage 4-6 or Fontaine stage III to I (see Table 1)[9–11]; **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 75%[7]; **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[7]; **OR**
      - Lower extremity duplex Doppler with peak systolic velocity (PSV) greater than 3 m/s or velocity ratio 4:1[7]; **AND**
    - **ANY** of the following:

- Percutaneous transluminal angioplasty (PTA) and/or stent for aortoiliac disease arterial occlusive disease[1]; **OR**
- PTA and/or stent for femoral-popliteal arterial occlusive disease[1]; **OR**
- Atherectomy for femoral-popliteal arterial occlusive disease with documentation of **ANY** of the following[9]:
  - In-stent restenosis (ISR)(only laser atherectomy is Class IIa and should documented in the medical record); **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[12]); **OR**
- PTA in an infrapopliteal (tibial or peroneal) vessel[9]; **OR**
- Atherectomy and/or stent for infrapopliteal occlusive disease with documentation of the following*[9]:
  - 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[12]); **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**[1–4]:
  - The disease is classified as Rutherford stage 0-3 or Fontaine stage I to IIb (see Table 1)[9–11]; **AND**
  - The patient fails to show significant clinical improvement despite documented compliance with optimal medical care (OMC)(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 (computed tomography angiography [CTA], magnetic resonance angiography [MRA], invasive angiogram lesion greater than or equal to 75%)[7]; **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 measurements[7]; **OR**
    - Lower extremity duplex Doppler with peak systolic velocity (PSV) greater than 3 m/sec or a velocity ratio greater than 4:1[7]; **AND**
- **ANY** of the following**:
    - PTA and/or stent for aortoiliac disease arterial occlusive disease[9]; **OR**
    - PTA and/or stent for femoral-popliteal arterial occlusive disease[9]; **OR**
    - Atherectomy for femoral-popliteal arterial occlusive disease with documentation of **ANY** of the following[9]:
        - In-stent restenosis (ISR)(only laser atherectomy is Class IIa and should documented in the medical record); **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[12]); **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 procedure[1]; **OR**
- Stenting for aneurysm or pseudoaneurysm[1]; **OR**
- Threatened bypass graft for PTA/stenting and **ANY** of the following:
    - Drop in ABI of 0.15 or greater[7]; **OR**

        - Stenosis in graft/inflow or outflow of greater than 50% by lower extremity arterial Doppler (LEAD) or CTA/MRA[7].

*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**[1–3,7–9]:
    - ◆ **ANY** of the following:
        - Revascularization performed in a patient with peripheral artery disease solely to prevent progression to CLTI; **OR**
        - **ANY** of the following conditions[13–15]:
            - 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 Tables 3 and 4).[16–18]

## Tables

**Table 1.**

| Rutherford/Fontaine Peripheral Arterial Disease Classification System[9–11] | | |
|---|---|---|
| **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) |

**Table 2.**

| WIFi Classification System: Risk stratification based on wound, ischemia, and foot infection[17] | | |
|---|---|---|
| **Wound (W)** | **Grade** | **Description** |
| | 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.

**Table 3.**

| TASC Classification of Femoral Popliteal Lesions[18] | |
|---|---|
| TASC A Lesions | Single stenosis ≤10 cm in length<br>Single occlusions less than ≤5 cm in length |
| TASC B Lesions | Multiple stenoses or occlusions each ≤5 cm<br>Single stenosis ≤15 cm<br>Heavily calcified occlusions ≤5 cm<br>Single popliteal stenosis |
| TASC C Lesions | Multiple stenoses or occlusions totaling ≥15 cm<br>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)<br>Chronic total occlusion of popliteal artery and proximal trifurcation vessels. |

**Table 4.**

| TASC Classification of Aortoiliac Lesions[18] | |
|---|---|
| TASC A Lesions | Unilateral or bilateral common iliac artery stenoses<br>Unilateral or bilateral short (≤3 cm) external iliac artery stenosis |
| TASC B Lesions | Short (3 cm) stenosis of infrarenal aorta<br>Unilateral common iliac artery occlusion<br>External iliac artery stenosis/stenoses totaling 3-10 cm<br>Unilateral external iliac artery occlusion |
| TASC C Lesions | Bilateral common iliac artery (CIA) occlusions<br>Bilateral external iliac artery (EIA) stenoses 3-10cm long not extending into the common femoral artery (CFA)<br>Unilateral external iliac artery (EIA) stenosis extending into the common femoral artery (CFA)<br>Heavily calcified unilateral external iliac artery (EIA) occlusion |
| TASC D Lesions | Diffuse disease involving the aorta and both iliac arteries<br>Diffuse multiple stenoses<br>Unilateral occlusion of both external iliac artery (EIA) and common iliac artery (CIA)<br>Bilateral occlusion of external iliac artery (EIA) |

## Level of Care 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 |

**Disclaimer:** G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

# 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 a more in-depth study is required regarding the relationship between regional ischemia and patterns of infrapopliteal and pedal disease.[2]

Woo et al (2022) published the Society of Vascular Surgery appropriate use criteria for the management of intermittent claudication. Twenty-two hundred and eighty 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 an unclear benefit and possible harm related to invasive intervention in the infrapopliteal segment for intermittent claudication.[4]

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 (bypass versus angioplasty in severe ischemia of the leg) randomized controlled trial (RCT) 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.[7]

# References


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# Clinical Guideline Revision History/Information

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