Peripheral Arterial Disease

Clinical Guidelines for Medical Necessity Review

Version: V2.0
Effective Date: September 16, 2022

Important Notices

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Other Notices:

Guideline Information:

Disease Area: Cardiology
Care Path Group: General Cardiology
Care Path Name: Peripheral Arterial Disease
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Literature review current through: September 16, 2022
Document last updated: September 16, 2022

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Care Path Overview

Care Path Clinical Discussion

Peripheral arterial disease (PAD) in the lower extremities is the narrowing or blockage of the blood vessels that carry oxygenated blood from the heart to the end organs. Atherosclerosis, or the buildup of fatty plaque and inflammatory debris in the arterial walls to the legs, is the primary cause of PAD. The prevalence of PAD increases with age. Risk factors for PAD include (but are not limited to) smoking, high blood pressure, diabetes, and high cholesterol.[1-3] PAD is also a potent marker for cardiovascular disease morbidity and mortality.

Atherothrombosis is a generalized and progressive process that leads to significant cardiovascular ischemic events. Sudden atherosclerotic plaque disruption leads to platelet activation and thrombus formation. Atherothrombosis is the underlying condition that causes acute arterial ischemic events in the legs. Non-interventional treatments (e.g., risk factor modification or pharmacologic therapy) can lower the risk of atherothrombotic events in patients with PAD.[1] Interventional treatments (e.g., balloon angioplasty, stent placement, surgical revascularization) can improve arterial flow to the affected area and decrease the risk of detrimental effects in distal parts of the legs.[4]

PAD in the lower extremities is frequently asymptomatic, and up to 40% of patients have asymptomatic PAD (i.e., PAD is underdiagnosed and therefore undertreated).[5,6] A classic PAD symptom is intermittent claudication (IC). IC is a clinical syndrome that manifests as cramping or aching pain in the legs with physical activity that resolves with rest.[1,7]

Although intermittent claudication is generally not a limb-threatening condition, it can lead to quality of life deterioration and muscular deconditioning. In its most severe form, PAD can lead to rest pain, non-healing wounds of the lower extremities, gangrene, and (if untreated) loss of a limb or life. [8,9]

Leg pain is a relatively common symptom in the outpatient setting. The evaluation of leg pain must rule out serious pathology before a physician considers benign causes. A detailed history and physical exam allow the clinician to determine the etiology of the patient's symptoms and to determine the next appropriate diagnostic plan or treatment option.[10,11]

Optimal medical care (OMC) including PAD risk factor modification is the typical treatment for non-limb-threatening conditions. Limb-threatening conditions such as rest pain, lower extremity ulceration, or tissue loss will likely require a vascular intervention to decrease the risk of limb loss. Acute limb-threatening arterial ischemia and critical limb ischemia (acute or chronic) fall outside these guidelines' scope.

Acute limb-threatening arterial ischemia and critical limb ischemia (acute or chronic) fall outside the scope of these guidelines.

The information contained herein gives a general overview of the pathway of this specific diagnosis, beginning with the initial presentation, recommended assessments, and treatment options as supported by the medical literature and existing guidelines. It should be noted that the care of patients can be complex. The information below is meant to support clinical decision-making in adult patients. It is not necessarily applicable to every case, as the entire clinical picture (including comorbidities, history, etc.) should be considered.

Key Information

- ➢ History, physical exam, and risk factors will guide clinical decision-making (i.e., lifestyle-limiting conditions versus limb-threatening conditions).
- ➢ PAD is typically diagnosed by a primary care physician and is often underdiagnosed and undertreated in primary care offices.[6,12]
- ➢ Simple, non-invasive arterial imaging (e.g., ABI with or without duplex ultrasound) will allow the clinician to quantify the degree of arterial obstruction and establish a baseline; ABI is a powerful predictor of cardiovascular mortality.[13]
- ➢ Advanced non-invasive imaging (e.g., CTA, MRA) is appropriate when simple non-invasive imaging is inadequate for diagnosis or if the medical decision-making has determined that a vascular intervention would improve quality of life (QOL).
- ➢ Invasive imaging (e.g., catheter-based angiography, intravascular ultrasound) can delineate the vascular anatomy further when non-invasive imaging is inadequate or when an intervention is planned.
- ➢ Invasive procedures (e.g., angioplasty, atherectomy, stent placement, or surgical bypass procedures) can improve QOL for some patients.
- ➢ Avoid invasive imaging and invasive procedures in clinical situations where QOL is not a relevant factor (e.g., non-ambulatory or severely debilitated patients with contraindications to intervention).[14]

Definitions

- **Peripheral artery disease (PAD):** The narrowing or blockage of the arteries that carry oxygenated blood from the heart to the extremities. Atherosclerosis is the primary cause of PAD.
- **Non-limb-threatening ischemia (e.g., intermittent claudication):** Exertional leg muscle pain (ache or cramp) resolving with rest.
- **Limb-threatening ischemia or critical limb ischemia (CLI:)** An advanced stage of peripheral artery disease (PAD) that manifests as ischemic rest pain, vascular ulcers, or gangrene. CLI does **NOT** fall under the scope of these guidelines.
- **Optimal medical care (OMC)**: Risk factor modification in association with a home exercise program and (when appropriate) concomitant pharmacotherapy.
- **Ankle brachial index (ABI):** A simple non-invasive test for PAD that compares the blood pressure measured at your ankle with the blood pressure measured at your arm. A low ankle-brachial index can

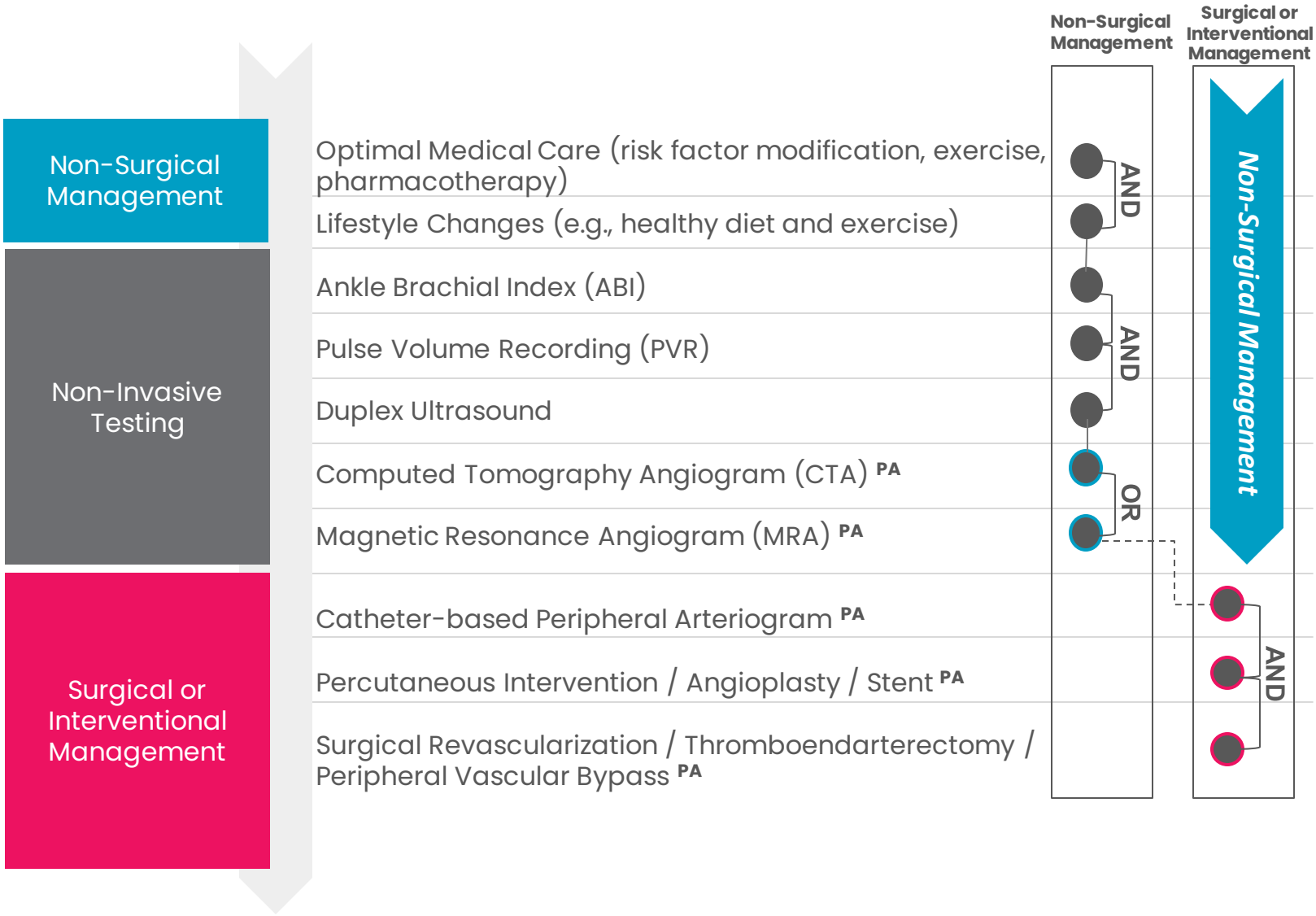
indicate narrowing or blockage of the arteries in your legs. A markedly elevated ABI (i.e., greater than 1.3) is abnormal and suggests a non-compressible (stiff) artery or possibly acute limb-threatening arterial ischemia or critical limb ischemia (acute or chronic.).

- **Pulse volume recording (PVR):** A non-invasive test in which physicians use blood pressure cuffs and a hand-held ultrasound device (i.e., Doppler) to determine the presence, severity, and general location of peripheral arterial occlusive disease.
- **Hybrid vascular procedures:** utilize both open surgical techniques and endovascular interventions in the management of PAD.

Peripheral Arterial Disease

What is a "Cohere Care Path"?

These Care Paths organize the services typically considered most clinically optimal and likely to be automatically approved. These service recommendations also include the suggested sequencing and quantity or frequency determined clinically appropriate and medically necessary for the management of most patient care scenarios in this Care Path's diagnostic cohort.



Key

PA = Service may require prior authorization
★ = Denotes preferred service
AND = Services completed concurrently
OR = Services generally mutually exclusive

= Non-surgical management prior authorization group of services
= Surgical management prior authorization group of services
= Subsequent service
= Management path moves to a different management path

Care Path Diagnostic Criteria

Disease Classification

Peripheral arterial disease, atherosclerosis, claudication.

ICD-10 Codes Associated with Classification

ICD-10 Code	Code Description/Definition
I70	Atherosclerosis
I70.2	Atherosclerosis of native arteries of the extremities
I70.20	Unspecified atherosclerosis of native arteries of extremities
I70.201	Unspecified atherosclerosis of native arteries of extremities, right leg
I70.202	Unspecified atherosclerosis of native arteries of extremities, left leg
I70.203	Unspecified atherosclerosis of native arteries of extremities, bilateral legs
I70.208	Unspecified atherosclerosis of native arteries of extremities, other extremity
I70.209	Unspecified atherosclerosis of native arteries of extremities, unspecified extremity
I70.21	Atherosclerosis of native arteries of extremities with intermittent claudication
I70.211	Atherosclerosis, claudication, right
I70.212	Atherosclerosis, claudication, left
I70.213	Atherosclerosis, claudication, bilateral
I70.218	Atherosclerosis of native arteries of extremities with intermittent claudication, other extremity
I70.219	Atherosclerosis of native arteries of extremities with intermittent claudication, unspecified extremity
I70.29	Other atherosclerosis of native arteries of extremities
I70.291	Other atherosclerosis of native arteries of extremities, right leg
I70.292	Other atherosclerosis of native arteries of extremities, left leg

I70.293	Other atherosclerosis of native arteries of extremities, bilateral legs
I70.298	Other atherosclerosis of native arteries of extremities, other extremity
I70.299	Other atherosclerosis of native arteries of extremities, unspecified extremity
I70.3	Atherosclerosis of unspecified type of bypass graft(s) of the extremities
I70.30	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities
I70.301	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, right leg
I70.302	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, left leg
I70.303	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, bilateral legs
I70.308	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, other extremity
I70.309	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, unspecified extremity
I70.31	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication
I70.311	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, right leg
I70.312	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, left leg
I70.313	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.318	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.319	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, unspecified extremity
I70.39	Other atherosclerosis of unspecified type of bypass graft(s) of the extremities
I70.391	Other atherosclerosis of unspecified type of bypass graft(s) of the

	extremities, right leg
I70.392	Other atherosclerosis of unspecified type of bypass graft(s) of the extremities, left leg
I70.393	Other atherosclerosis of unspecified type of bypass graft(s) of the extremities, bilateral legs
I70.398	Other atherosclerosis of unspecified type of bypass graft(s) of the extremities, other extremity
I70.399	Other atherosclerosis of unspecified type of bypass graft(s) of the extremities, unspecified extremity
I70.4	Atherosclerosis of autologous vein bypass graft(s) of the extremities
I70.40	Unspecified atherosclerosis of autologous vein bypass graft(s) of the extremities
I70.401	Unspecified atherosclerosis of autologous vein bypass graft(s) of the extremities, right leg
I70.402	Unspecified atherosclerosis of autologous vein bypass graft(s) of the extremities, left leg
I70.403	Unspecified atherosclerosis of autologous vein bypass graft(s) of the extremities, bilateral legs
I70.408	Unspecified atherosclerosis of autologous vein bypass graft(s) of the extremities, other extremity
I70.409	Unspecified atherosclerosis of autologous vein bypass graft(s) of the extremities, unspecified extremity
I70.41	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication
I70.411	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication, right leg
I70.412	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication, left leg
I70.413	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.418	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.419	Atherosclerosis of autologous vein bypass graft(s) of the extremities

	with intermittent claudication, unspecified extremity
I70.49	Other atherosclerosis of autologous vein bypass graft(s) of the extremities
I70.491	Other atherosclerosis of autologous vein bypass graft(s) of the extremities, right leg
I70.492	Other atherosclerosis of autologous vein bypass graft(s) of the extremities, left leg
I70.493	Other atherosclerosis of autologous vein bypass graft(s) of the extremities, bilateral legs
I70.498	Other atherosclerosis of autologous vein bypass graft(s) of the extremities, other extremity
I70.499	Other atherosclerosis of autologous vein bypass graft(s) of the extremities, unspecified extremity
I70.5	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities
I70.50	Unspecified atherosclerosis of nonautologous biological bypass graft(s) of the extremities
I70.501	Unspecified atherosclerosis of nonautologous biological bypass graft(s) of the extremities, right leg
I70.502	Unspecified atherosclerosis of nonautologous biological bypass graft(s) of the extremities, left leg
I70.503	Unspecified atherosclerosis of nonautologous biological bypass graft(s) of the extremities, bilateral legs
I70.508	Unspecified atherosclerosis of nonautologous biological bypass graft(s) of the extremities, other extremity
I70.509	Unspecified atherosclerosis of nonautologous biological bypass graft(s) of the extremities, unspecified extremity
I70.51	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities intermittent claudication
I70.511	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, right leg
I70.512	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, left leg

I70.513	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.518	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.519	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, unspecified extremity
I70.59	Other atherosclerosis of nonautologous biological bypass graft(s) of the extremities
I70.591	Other atherosclerosis of nonautologous biological bypass graft(s) of the extremities, right leg
I70.592	Other atherosclerosis of nonautologous biological bypass graft(s) of the extremities, left leg
I70.593	Other atherosclerosis of nonautologous biological bypass graft(s) of the extremities, bilateral legs
I70.598	Other atherosclerosis of nonautologous biological bypass graft(s) of the extremities, other extremity
I70.599	Other atherosclerosis of nonautologous biological bypass graft(s) of the extremities, unspecified extremity
I70.6	Atherosclerosis of nonbiological bypass graft(s) of the extremities
I70.60	Unspecified atherosclerosis of nonbiological bypass graft(s) of the extremities
I70.601	Unspecified atherosclerosis of nonbiological bypass graft(s) of the extremities, right leg
I70.602	Unspecified atherosclerosis of nonbiological bypass graft(s) of the extremities, left leg
I70.603	Unspecified atherosclerosis of nonbiological bypass graft(s) of the extremities, bilateral legs
I70.608	Unspecified atherosclerosis of nonbiological bypass graft(s) of the extremities, other extremity
I70.609	Unspecified atherosclerosis of nonbiological bypass graft(s) of the extremities, unspecified extremity
I70.61	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication

I70.611	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication, right leg
I70.612	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication, left leg
I70.613	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.618	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.619	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication, unspecified extremity
I70.69	Other atherosclerosis of nonbiological bypass graft(s) of the extremities
I70.691	Other atherosclerosis of nonbiological bypass graft(s) of the extremities, right leg
I70.692	Other atherosclerosis of nonbiological bypass graft(s) of the extremities, left leg
I70.693	Other atherosclerosis of nonbiological bypass graft(s) of the extremities, bilateral legs
I70.698	Other atherosclerosis of nonbiological bypass graft(s) of the extremities, other extremity
I70.699	Other atherosclerosis of nonbiological bypass graft(s) of the extremities, unspecified extremity
I70.7	Atherosclerosis of other type of bypass graft(s) of the extremities
I70.70	Unspecified atherosclerosis of other type of bypass graft(s) of the extremities
I70.701	Unspecified atherosclerosis of other type of bypass graft(s) of the extremities, right leg
I70.702	Unspecified atherosclerosis of other type of bypass graft(s) of the extremities, left leg
I70.703	Unspecified atherosclerosis of other type of bypass graft(s) of the extremities, bilateral legs
I70.708	Unspecified atherosclerosis of other type of bypass graft(s) of the extremities, other extremity

I70.709	Unspecified atherosclerosis of other type of bypass graft(s) of the extremities, unspecified extremity
I70.71	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication
I70.711	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication, right leg
I70.712	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication, left leg
I70.713	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.718	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.719	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication, unspecified extremity
I70.79	Other atherosclerosis of other type of bypass graft(s) of the extremities
I70.791	Other atherosclerosis of other type of bypass graft(s) of the extremities, right leg
I70.792	Other atherosclerosis of other type of bypass graft(s) of the extremities, left leg
I70.793	Other atherosclerosis of other type of bypass graft(s) of the extremities, bilateral legs
I70.798	Other atherosclerosis of other type of bypass graft(s) of the extremities, other extremity
I70.799	Other atherosclerosis of other type of bypass graft(s) of the extremities, unspecified extremity
I70.8	Atherosclerosis of other arteries
I70.9	Other and unspecified atherosclerosis
I70.90	Unspecified atherosclerosis
I70.92	Chronic total occlusion of artery of the extremities
I73	Other peripheral vascular diseases
I73.8	Other specified peripheral vascular diseases

I73.89	Other specified peripheral vascular diseases
I73.9	Peripheral vascular disease, unspecified
I74	Arterial embolism and thrombosis
I74.2	Embolism and thrombosis of arteries of the upper extremities
I74.3	Embolism and thrombosis of arteries of the lower extremities
I74.4	Embolism and thrombosis of arteries of extremities, unspecified
I74.5	Embolism and thrombosis of iliac artery
I74.8	Embolism and thrombosis of other arteries
I74.9	Embolism and thrombosis of unspecified artery
I75	Atheroembolism
I75.0	Atheroembolism of extremities
I75.01	Atheroembolism of upper extremity
I75.011	Atheroembolism of right upper extremity
I75.012	Atheroembolism of left upper extremity
I75.013	Atheroembolism of bilateral upper extremities
I75.019	Atheroembolism of unspecified upper extremity
I75.02	Atheroembolism of lower extremity
I75.021	Atheroembolism of right lower extremity
I75.022	Atheroembolism of left lower extremity
I75.023	Atheroembolism of bilateral lower extremities
I75.029	Atheroembolism of unspecified lower extremity
I75.8	Atheroembolism of other sites
I75.89	Atheroembolism of other site
I77	Other disorders of arteries and arterioles
I77.1	Stricture of artery
I77.8	Other specified disorders of arteries and arterioles
I77.89	Other specified disorders of arteries and arterioles
I79	Disorders of arteries, arterioles and capillaries in diseases classified elsewhere
I79.8	Other disorders of arteries, arterioles and capillaries in diseases

	classified elsewhere

**Acute limb-threatening arterial ischemia and critical limb ischemia (acute or chronic) fall outside the scope of these guidelines.*

Presentation and Etiology

PAD can typically be diagnosed with a careful history and physical exam. Ankle brachial index (ABI), in combination with pulse volume recording (PVR), is a simple and cost-effective way to diagnose PAD (see table below.) More detailed non-invasive imaging (computed tomography angiogram or CTA, magnetic resonance angiogram or MRA) or invasive imaging (arteriography) is generally only needed when planning an intervention.[13-16]

Clinical Presentation and ABI/PVR Metrics for Rating PAD Severity [2,3]

Clinical Presentation	ABI	Waveform
Variable claudication*	Greater than 1.3-1.4	Variable
No symptoms	Greater than 0.9	Normal
Mildly claudication	0.5 - 0.8	Mildly abnormal
Moderate claudication	0.3 - 0.5	Moderately abnormal
Severe claudication	Less than 0.3	Severely abnormal

*An ABI greater than 1.3-1.4 is generally indicative of patients with a non-compressible (stiff) artery or possibly acute limb-threatening arterial ischemia or critical limb ischemia (acute or chronic.) Patients with the acute limb ischemia or chronic limb ischemia fall outside the scope of these guidelines.

TASC II Criteria [2,3]

The TASC criteria were designed to serve as clinical guidelines for clinicians who diagnose and treat patients with PAD. Therefore, these criteria may not apply to specific clinical circumstances. The treating clinician should ultimately recommend the most appropriate treatment for the patient based on a clinical evaluation, including risks, benefits, and alternatives.

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)

A non-interventional approach is recommended as the initial plan of care in patients with non-limb-threatening PAD due to its proven efficacy. This includes [11,17]:

- Optimal medical care.
- Risk factor modification:[11,17,18]
  - Smoking cessation.
  - Weight management.
  - Glycemic control (dietary modifications).
  - Statins.
  - Blood pressure management.
  - Supervised exercise therapy.[7]

A failure to improve with the non-interventional treatment above may be a clinical indication for intervention. An intervention may be appropriate if all of the below are true [14-16]:

- The patient fails to show significant clinical improvement despite documented compliance with optimal medical care.
- The patient has attempted smoking cessation.
- The patient considers their symptoms to be lifestyle-limiting.

Clinical Presentations [1-3]

- Non-limb threatening conditions:
  - Intermittent claudication (IC).
  - Leriche syndrome: A classic triad of findings in male patients (below) that suggest the presence of aorto-iliac arterial occlusive disease.
    - IC of the thighs, pelvis, and/or buttocks
    - Diminished femoral pulses
    - Erectile dysfunction

Typical Physical Exam Findings [1-3]

- Non-limb threatening conditions include:
  - Diminished peripheral pulses.
  - Temperature changes.
  - Hair loss.
  - Skin changes of vascular insufficiency.

Typical Diagnostic Findings [1-3]

- Duplex ultrasound/Ankle Brachial Index (ABI) findings include:
  - Reduced ABI.

    - Diminution of the (normal) triphasic pulse volume recording waveform.
    - Physical evidence of arterial occlusive disease of the lower extremity arterial circulation.
- Computed tomography angiogram (CTA) or magnetic resonance angiogram (MRA) findings include:
    - Arterial stenoses or occlusions.
- Catheter-based angiogram findings include:
    - Arterial stenoses or occlusions.

Care Path Services & Medical Necessity Criteria

Non-Invasive Testing

Service: Computed Tomography Angiogram (CTA), Lower Extremity Arteries

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** Repeat imaging may be appropriate if there is a significant clinical change since the initial imaging study/intervention.
- **Recommended Clinical Approach:** Abdominal computed tomography angiogram (CTA) with bilateral lower extremity run-off (with the administration of iodinated contrast) is one of the recommended CT imaging modality for PAD.[19-20] Considerations of additional phase, dual-energy, dynamic sequences, positioning of the patient, and marker use are at the discretion of the protocoling radiologist.[21-25] The ordering clinician is required to provide appropriate documentation of clinical indication for a CTA. This should include a pertinent history to justify the request.[26-27]
- **Exclusion criteria:** CTA images may be suboptimal in areas of heavy arterial calcification in distal target arteries.[20]

Medical Necessity Criteria

Indications

➔ **CTA** is considered appropriate if **ALL** of the following are **TRUE**:
- ◆ The patient fails to show significant clinical improvement despite documented compliance with optimal medical care.[19]
- ◆ The patient has attempted smoking cessation.
- ◆ The patient considers their symptoms to be lifestyle-limiting.
- ◆ Revascularization is being considered.[19]

Non-Indications

➔ **CTA** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ The area to be imaged has heavy arterial calcification.[20]

➔ **CTA** may not be appropriate if **ANY** of the following is **TRUE**[21-25]:
- ◆ The patient takes metformin.
- ◆ The patient has contrast dye hypersensitivity.

- The patient has impaired renal function, and angiographic contrast is utilized for the study.[26-27]
- The patient is pregnant.
- The patient has critical limb ischemia (e.g., ulcers, rest pain, gangrene) requiring inpatient care.

Site of Service Criteria:

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
75635	Computed tomographic angiography, abdominal aorta and bilateral iliofemoral lower extremity runoff, with contrast material(s), including noncontrast images, if performed, and image postprocessing.

Service: Magnetic Resonance Angiogram (MRA), Lower Extremity Arteries

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** Considerations of additional phase, dynamic sequences, positioning of the patient, and use of markers at the discretion of the protocoling radiologist. Repeat imaging may be appropriate if there is a significant clinical change since the time of the initial imaging study/intervention.
- **Recommended Clinical Approach:** Magnetic resonance angiography (MRA) is a proven and valuable tool for the evaluation, assessment of severity, and follow-up of lower extremity arterial circulation diseases. Unlike computed tomographic angiography (CTA), it avoids the need for ionizing radiation and exposure to iodinated contrast agents.[20,27] Contrast-enhanced MRA (CE-MRA) is equivalent to conventional angiography in evaluating diseases of many portions of the vascular system and pretreatment planning.[28-32] MRA of the lower extremity can be performed with or without the use of contrast agents. Although CE-MRA is generally preferred, non–contrast-enhanced techniques are increasingly available and may be a viable option for patients with impaired renal function or who cannot tolerate gadolinium-based contrast agents.[20,27,31]
- **Exclusions:** MRI of the lower extremity, MRI/MRA of the upper extremity, MRA/MRI of head and neck, and cardiac MRI are excluded from this care path.

Medical Necessity Criteria

Indications

➔ **MRA** is considered appropriate if **ALL** of the following are **TRUE**:
- ◆ The patient fails to show significant clinical improvement despite documented compliance with optimal medical care.
- ◆ The patient has attempted smoking cessation.[27]
- ◆ The patient considers their symptoms to be lifestyle-limiting.
- ◆ Revascularization is being considered.[26]

Non-Indications

➔ **MRA** is not considered appropriate if **ANY** of the following is **TRUE**[28,32]:
- ◆ The patient has non-compatible implanted devices.[27]
- ◆ The patient has metallic intraocular foreign bodies.

➔ **MRA** may not be appropriate if **ANY** of the following is **TRUE**[28,32]:
- ◆ The patient is severely claustrophobic.

- There is a potential for adverse reactions to contrast media.
- The patient is physically unable to stay in a recumbent position for the duration of the study.
- If the patient has renal insufficiency (eGFR less than 30 mL/min per 1.73 m^2) and if gadolinium contrast is requested, an MRI/MRA may not be considered appropriate.[20]
- The patient is pregnant (Avoid MRA if possible in the first trimester if gadolinium use is planned).
- The patient has critical limb ischemia (e.g., ulcers, rest pain, gangrene) requiring inpatient care.

Site of Service Criteria:

Outpatient.

HCPCS Code	Code Description/Definition
73725	MRA lower extremity with or without contrast
72198	MRA pelvis with or without contrast

Non-Surgical Management

Service: Cardiac Rehabilitation

General Guidelines

- **Units, Frequency, & Duration:** Cardiac rehabilitation is generally appropriate for 36 sessions, 60 minutes each, typically over 12 - 18 weeks. Additional sessions can be requested.[33]
- **Criteria for Subsequent Requests:** Current guidelines do not support the need for repeat cardiac rehabilitation in the absence of a new cardiac event.
- **Recommended Clinical Approach:** Cardiac rehabilitation (CR) is an evidence-based intervention that uses patient education, health behavior modification, and exercise training to improve secondary prevention outcomes and is recognized as an integral component of care for patients with cardiovascular disease.[33-34] Referral to CR is recommended within 12 months after a myocardial infarction (MI), percutaneous coronary intervention, or coronary artery bypass graft surgery or in the setting of stable angina or symptomatic peripheral arterial disease (i.e., intermittent claudication).[33] Referral to CR is also recommended after heart valve surgery or cardiac transplantation, or in the setting of chronic heart failure (NYHA Class I-III) with reduced ejection fraction (HFrEF).[33] The effects of cardiac rehabilitation on mortality, cardiovascular events, hospitalizations, or health-related quality of life are less certain in patients with atrial fibrillation, Adult Congenital Heart Disease, and after permanent pacemaker/ICD implantation, but are described as useful by various National and International specialty societies.[35-37]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Cardiac Rehabilitation** is considered appropriate if **ANY** of the following are **TRUE** (within a one year period)[36-38]:

- Acute myocardial infarction
- Acute coronary artery syndrome
- Chronic stable angina
- Chronic congestive heart failure (NYHA Class I-III, including with LV assist devices)
- After coronary artery bypass surgery
- After a percutaneous coronary intervention
- After valvular surgery

- Cardiac transplantation
- Symptomatic peripheral arterial disease
- Atrial fibrillation
- Adult Congenital Heart Disease
- After permanent pacemaker/ICD implantation

Non-Indications

➔ **Cardiac Rehabilitation** may not be considered appropriate if **ANY** of the following are present[38]:

- Active unstable angina
- Decompensated cardiac failure
- Active dangerous or complex arrhythmias
- Dissecting aneurysm
- Myocarditis
- Acute pericarditis
- Severe obstruction of the left ventricular outflow tract
- Severe hypertension
- Exertional hypotension or syncope
- Severe orthopedic limitations
- Recent systemic or pulmonary embolus
- Severe or symptomatic aortic stenosis
- Previous cardiac rehabilitation in the absence of a new cardiac event.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
S9472	Cardiac rehabilitation program, nonphysician provider, per diem
93798	Physician or other qualified healthcare professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)

Surgical or Interventional Management

Service: Catheter-Based Angiogram, Lower Extremity Arteries

General Guidelines

- **Units, Frequency, & Duration:** Once.
- **Criteria for Subsequent Requests:** Repeat imaging may be appropriate if there is a significant clinical change since the initial imaging study/intervention.
- **Recommended Clinical Approach:**
    - Catheter-based angiography may be appropriate as the initial advanced imaging modality when the clinician determines that there is a high likelihood that the patient is a candidate for a minimally invasive intervention (e.g., angioplasty, atherectomy, or stent placement).[39]
    - The ordering clinician must provide appropriate documentation of clinical indication. This should include a pertinent history to justify the request.
    - Multi-view fluoroscopy usually provides adequate imaging of the arterial anatomy to plan and perform arterial interventions.
    - IVUS can provide additional anatomic information (i.e., vessel diameter and plaque anatomy), which can improve the effectiveness of arterial interventions.
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Catheter-Based Angiogram** is considered appropriate if **ALL** of the following are **TRUE**:
- ◆ The patient fails to show significant clinical improvement despite documented compliance with optimal medical care.
- ◆ The patient has attempted smoking cessation.
- ◆ The patient considers their symptoms to be lifestyle-limiting.
- ◆ The patient had alternative imaging (e.g., MRA, CTA) but has not achieved diagnostic results.
- ◆ Revascularization is being considered.

➔ **Catheter-Based Angiogram** may be considered appropriate if **ANY** of the following is **TRUE:**
- ◆ Proceeding directly to invasive angiography for anatomic assessment and to determine revascularization strategy is reasonable if ANY of the following are true:

- Lack of availability of noninvasive imaging studies for anatomic assessment (e.g., duplex ultrasound, CTA, or MRA).
- Noninvasive studies for anatomic assessment (e.g., CTA and/or MRA) is perceived to be a greater risk to the patient than invasive angiography.[16]

Non-Indications

- ➔ **Catheter-Based Angiogram** is not considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ The patient is unwilling to undergo interventional therapy if angiography discovers disease.
  - ◆ The risk of the procedure is judged to be high because of concurrent medical problems.
- ➔ **Catheter-Based Angiogram** may not be considered appropriate if **ANY** of the following is **TRUE** [4,39]:
  - ◆ Severe allergy to contrast media.
  - ◆ Severe renal insufficiency.
  - ◆ The patient is pregnant.
  - ◆ The patient uses metformin.
  - ◆ There was prior vascular surgery at the proposed access site (e.g., femoral access at the site of a prior femoral reconstruction).
  - ◆ There is a known or suspected arterial aneurysm or significant vascular anomaly (e.g., AV fistula) at the proposed access site.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
36245	Insertion of catheter into first order abdominal branch of artery, within a vascular family
36246	Insertion of catheter into initial second order abdominal branch of artery, within a vascular family
36247	Insertion of catheter into initial third order abdominal branch of artery, within a vascular family
37252	Radiologic supervision and interpretation with the IVUS procedure and are used for procedures involving both arteries and/or veins. Reported once per procedure for the first vessel studied with IVUS.
37253	Radiologic supervision and interpretation with the IVUS

	procedure and are used for procedures involving both arteries and/or veins. Each initial vessel.
75716	Angiography, extremity, bilateral, radiological
75710	Angiography, extremity, unilateral, radiological

Service: Percutaneous Intervention/Angioplasty/Stent/Atherectomy

General Guidelines

- **Units, Frequency, & Duration:** Once.
- **Criteria for Subsequent Requests:** Repeat imaging with intervention may be appropriate if there is a significant clinical change since the initial imaging study/intervention.[19]
- **Recommended Clinical Approach:** The ordering clinician is required to provide appropriate documentation to justify the performance of percutaneous intervention. This should include a pertinent history to justify the request.[40]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Percutaneous intervention** is considered appropriate if **ALL** of the following are **TRUE**[4,5,39]:

- The patient fails to show significant clinical improvement despite documented compliance with optimal medical care.[41]
- The patient has attempted smoking cessation.
- The patient considers their symptoms to be lifestyle-limiting.[40]
- The patient is considered a suitable candidate for percutaneous intervention based on documentation from the most recent encounter and TASC criteria (e.g., TASC A, B, or C).[2,3]

Non-Indications

➔ **Percutaneous intervention** is not considered appropriate if **ANY** of the following is **TRUE**[4,5,39]:

- 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;
  - The patient's age or existing co-morbid conditions indicate the risk of a complication.
  - The patient is permanently non-ambulatory OR the patient's activity level is severely limited.
- Evidence of occlusion without accompanying clinical symptoms (i.e., claudication).
- Isolated tibial artery occlusive disease.

- The patient is **NOT** considered a suitable candidate for percutaneous intervention based on documentation from the most recent encounter and TASC criteria (i.e., TASC D).[2,3]

➔ **Percutaneous Intervention** may not be considered appropriate if **ANY** of the following is **TRUE** [4,39]:

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

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

37220*	Unilateral open endovascular revascularization of initial iliac artery with transluminal angioplasty
37221*	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within same vessel, when performed
37223	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within same vessel, when performed (List separately in addition to code for primary procedure)
37224	Unilateral open endovascular revascularization of femoral artery 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	Unilateral open endovascular revascularization of initial peroneal artery with transluminal angioplasty, Unilateral open endovascular revascularization of initial tibial artery with transluminal angioplasty, Unilateral percutaneous endovascular revascularization of initial peroneal artery with transluminal angioplasty, Unilateral percutaneous endovascular revascularization of initial tibial artery with transluminal angioplasty
37229	Unilateral open endovascular revascularization of initial peroneal artery with atherectomy, Unilateral open endovascular revascularization of initial peroneal artery with atherectomy and angioplasty within the same vessel, Unilateral open endovascular revascularization of initial tibial artery with atherectomy, Unilateral open endovascular revascularization of initial tibial artery with atherectomy and angioplasty within the same vessel, Unilateral percutaneous endovascular revascularization of initial peroneal artery with atherectomy, Unilateral percutaneous endovascular revascularization of initial peroneal artery with atherectomy and angioplasty within the same vessel, Unilateral percutaneous endovascular revascularization of initial tibial artery with atherectomy, Unilateral percutaneous endovascular revascularization of initial tibial artery with atherectomy and angioplasty within the same vessel
37230	Unilateral open endovascular revascularization of initial peroneal artery with transluminal stent placement, Unilateral open endovascular revascularization of initial peroneal artery with transluminal stent placement and angioplasty within the same vessel, Unilateral open endovascular revascularization of initial tibial artery with transluminal stent placement, Unilateral open endovascular revascularization of initial tibial artery with transluminal stent placement and angioplasty within the same vessel, Unilateral percutaneous endovascular revascularization of initial peroneal artery with transluminal stent placement, Unilateral percutaneous endovascular

	revascularization of initial peroneal artery with transluminal stent placement and angioplasty within the same vessel, Unilateral percutaneous endovascular revascularization of initial tibial artery with transluminal stent placement, Unilateral percutaneous endovascular revascularization of initial tibial artery with transluminal stent placement and angioplasty within the same vessel
37231	Unilateral open endovascular revascularization of initial peroneal artery with transluminal stent placement and atherectomy, Unilateral open endovascular revascularization of initial peroneal artery with transluminal stent placement, atherectomy, and angioplasty within the same vessel, Unilateral open endovascular revascularization of initial tibial artery with transluminal stent placement and atherectomy, Unilateral open endovascular revascularization of initial tibial artery with transluminal stent placement, atherectomy, and angioplasty within the same vessel, Unilateral percutaneous endovascular revascularization of initial peroneal artery with transluminal stent placement and atherectomy, Unilateral percutaneous endovascular revascularization of initial peroneal artery with transluminal stent placement, atherectomy, and angioplasty within the same vessel, Unilateral percutaneous endovascular revascularization of initial tibial artery with transluminal stent placement and atherectomy, Unilateral percutaneous endovascular revascularization of initial tibial artery with transluminal stent placement, atherectomy, and angioplasty within the same vessel
0505T	Reopening of arteries in thigh and behind knee with placement of stent via catheter using imaging guidance

Service: Surgical Revascularization/Thromboendarterectomy/Peripheral Vascular Bypass

General Guidelines:

- **Units, Frequency, & Duration:** Once.
- **Criteria for Subsequent Requests:** Repeat intervention is **only** appropriate if:
  - There is a significant clinical change subsequent after the initial procedure.
  - Follow-up studies suggest significant recurrent disease, disease progression, or impending failure of the prior intervention.[42]
- **Recommended Clinical Approach:**
  - The ordering clinician is required to provide appropriate documentation to justify the performance of percutaneous intervention.[40]
  - Surgical intervention (bypass/endarterectomy/hybrid procedures) may be appropriate for patients with lifestyle-limiting symptoms and a reasonable life expectancy.[40]
  - Surgical revascularization may be appropriate for patients who are not candidates for percutaneous revascularization due to disease location or extent. [4,5]
- **Exclusions:** None.

Medical Necessity Criteria:

Indications

➔ **Surgical Revascularization** (including hybrid procedures that combine open surgical intervention with angioplasty or stenting) may be considered appropriate if **ALL** of the following are **TRUE** [4,5,39]:

- The patient fails to show significant clinical improvement despite documented compliance with optimal medical care.
- The patient has attempted smoking cessation.
- The patient considers their symptoms to be lifestyle-limiting.
- One or more of the following is true:
  - The patient failed to improve with percutaneous intervention.[42]
  - The patient is not considered a suitable candidate for percutaneous intervention based on documentation from the most recent encounter and meets TASC criteria (e.g., TASC D).[2,3]

Non-Indications

- ➔ **Surgical Revascularization** is not considered appropriate if **ANY** of the following is **TRUE** [4,5,39]:
  - 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[40]:
    - The patient's age or existing co-morbid conditions indicate the risk of a complication.
    - The patient is permanently non-ambulatory, has a fixed contracture, OR the patient's activity level is severely limited.
  - There are any absolute contraindications to anesthesia.
  - The patient has an absolute contraindication to a surgical procedure (e.g., cardiopulmonary risk factors, bleeding diathesis).
  - There is evidence of occlusion without accompanying clinical symptoms (i.e., claudication).[42]
  - The patient is considered a suitable candidate for percutaneous intervention based on documentation from the most recent encounter and TASC criteria (e.g., TASC A, B, or C).[2,3]

- ➔ **Surgical Revascularization** (including hybrid procedures that combine open surgical intervention with angioplasty or stenting) may not be considered appropriate if **ANY** of the following is **TRUE** [4,39]:
  - Severe allergy to contrast media.
  - Severe renal insufficiency.
  - The patient is pregnant.
  - The patient uses metformin.
  - The patient is extremely over or underweight.
  - Fixed contracture of the affected extremity.

Site of Service Criteria

Inpatient or outpatient

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
35371	Thromboendarterectomy, common femoral artery
35372	Thromboendarterectomy, deep femoral artery
35351	Thromboendarterectomy, iliac
35355	Thromboendarterectomy, iliofemoral
35302	Thromboendarterectomy, popliteal artery
37799	Unlisted procedure, vascular surgery

Surgical Risk Factors

Patient Medical Risk Stratification

Patient Risk Score	Patient Characteristic	Min Range	Max Range	Guidance
1- Very Low Risk	No known medical problems			
2- Low Risk	Hypertension		180/110 mm Hg	
2- Low Risk	Asthma	peak flow >80% of predicted or personal best value		
2- Low Risk	Prior history of alcohol abuse			Screen for liver disease and malnutrition
2- Low Risk	Prior history of tobacco use			
3- Intermediate Risk	Asthma	peak flow <80% of predicted or personal best value		
3- Intermediate Risk	Active alcohol abuse			
3- Intermediate Risk	Age	65	75	
3- Intermediate Risk	History of treated, stable coronary artery disease (CAD)			
3- Intermediate Risk	Stable atrial fibrillation			
3- Intermediate Risk	Diabetes mellitus	HbA1C >7%		
3- Intermediate Risk	Morbid obesity	BMI 30	BMI 40	
3- Intermediate Risk	Anemia	hemoglobin <11 (females), <12 (males)		Workup to identify etiology
3- Intermediate Risk	HIV	CD4 <200 cells/mm3		Get clearance from HIV specialist
3- Intermediate Risk	Rheumatologic disease			Preoperative consultation with rheumatologist re: perioperative medication management
3- Intermediate Risk	Peripheral vascular disease or history of peripheral vascular bypass	ankle-brachial pressure index (ABPI) <0.9		Preoperative consultation with vascular surgeon

3- Intermediate Risk	History of venous thromboembolism (VTE)			
3- Intermediate Risk	Well-controlled obstructive sleep apnea			
3- Intermediate Risk	Malnutrition	transferrin <200 mg/dL albumin <3.5 g/dL prealbumin <22.5 mg/dL total lymphocyte count <1200-1500 cell/mm3 BMI <18		Preoperative consultation with nutritionist
3- Intermediate Risk	Active tobacco Use			Enroll patient in smoking cessation program
3- Intermediate Risk	Known allergy or hypersensitivity to medication needed for procedure			
4- High Risk	Advanced Renal Disease (Creatinine > 2)			
4- High Risk	Diabetes mellitus with complications	HbA1c >8%		
4- High Risk	Age	76	85	
4- High Risk	Oxygen dependent pulmonary disease			
4- High Risk	Sickle cell anemia			
4- High Risk	Obesity	BMI 40		
4- High Risk	Cirrhosis, history of hepatic decompensation or variceal bleeding			
4- High Risk	Impaired cognition; dementia			
4- High Risk	Compensated CHF			
4- High Risk	Cerebrovascular disease			
4- High Risk	Uncontrolled or suspected obstructive sleep apnea (OSA)			
4- High Risk	Renal insufficiency	serum creatinine >1.5 mg/dL or creatinine clearance <100 mL/min		

4- High Risk	Opioid dependence			
5- Very High Risk	Percutaneous Coronary Intervention (PCI) within 1 month			
5- Very High Risk	Cardiovascular: unstable angina, recent myocardial infarction (60 days), uncontrolled atrial fibrillation or other high-grade abnormal rhythm, severe valvular disease, decompensated heart failure			
5- Very High Risk	Primary pulmonary hypertension			Preoperative consultation with pulmonologist warranted
5- Very High Risk	Cirrhosis or severe liver disease, history of hepatic decompensation or variceal bleeding			
5- Very High Risk	Severe frailty, dependence for ADLs, or history of 3 or more falls in last 6 mos			
5- Very High Risk	Obesity		BMI >50	
5- Very High Risk	Age		>85	
5- Very High Risk	History of VTE with CI to anticoagulation, failure of anticoagulation, cessation of anticoagulation therapy secondary to bleeding			Preoperative consultation with hematologist or internist
5- Very High Risk	Renal failure requiring dialysis			
5- Very High Risk	Immunosuppression			
5- Very High Risk	Chronic Pain			

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Clinical Guideline Revision History/Information

Original Date: March 10, 2022	
Review History	
March 10, 2022 (V.1)	**Physician author:** Steven A. Kagan, MD RVT **Peer reviewed by:** Islam M. Othman, MD (Interventional Cardiologist), Carter Newton, MD FACC (Cardiologist), Russell Rotondo, MD FACC (Cardiologist) **Approving Physician:** Russell Rotondo, MD FACC (Cardiologist)
September 16, 2022 (V.2)	**Peer reviewed by:** Steven A. Kagan, MD RVT **Approving Physician:** Russell Rotondo, MD FACC (Cardiologist)