

Approval and implementation dates for specific health plans may vary. Please consult the applicable health plan for more details.

## Clinical Appropriateness Guidelines

# Cardiovascular

## Appropriate Use Criteria: Endovascular Revascularization for Management of Arterial Disease of the Lower Extremities

**Proprietary**

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## Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter “the Carelon Clinical Appropriateness Guidelines” or the “Guidelines”) are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. The Guidelines establish objective and evidence-based criteria for medical necessity determinations, where possible, that can be used in support of the following:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To address patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation and legal standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Resources reviewed include widely used treatment guidelines, randomized controlled trials or prospective cohort studies, and large systematic reviews or meta-analyses. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website. Copies of the Guidelines are also available upon oral or written request. Additional details, such as summaries of evidence, a list of the sources of evidence, and an explanation of the rationale that supports the adoption of the Guidelines, are included in each guideline document.

Although the Guidelines are publicly available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient’s condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines, and in the case of reviews for Medicare Advantage Plans, the Guidelines are only applied where there are not fully established CMS criteria. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

# General Clinical Guideline

## Clinical Appropriateness Framework

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Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention is likely to outweigh any potential harms, including from delay or decreased access to services that may result (net benefit).
- Widely used treatment guidelines and/or current clinical literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- There exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

Providers may be required to submit clinical documentation in support of a request for services. Such documentation must a) accurately reflect the clinical situation at the time of the requested service, and b) sufficiently document the ordering provider's clinical intent.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would justify a finding of clinical appropriateness. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account to the extent permitted by law.

## Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

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Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

## Repeat Diagnostic Intervention

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In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns

- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

## Repeat Therapeutic Intervention

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In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered. Requests for on-going services may depend on completion of previously authorized services in situations where a patient's response to authorized services is relevant to a determination of clinical appropriateness.

# Endovascular Revascularization for Management of Arterial Disease of the Lower Extremities

## General Information

### Overview

Endovascular procedures for the management of peripheral arterial disease of the lower extremities include balloon angioplasty, stent placement, atherectomy, lithotripsy, and endovascular venous arterialization. The vessels may be accessed through a small incision (open) or a vascular sheath (percutaneous). The management of patients with peripheral arterial disease of the lower extremities is dictated largely by the patient's symptom status. In general, patients can be classified as follows: asymptomatic, those with claudication, those with critical limb ischemia, and those with acute limb ischemia. Endovascular procedures may be used in primary (lesion has not previously been treated) or secondary (lesion has previously been treated) management of peripheral arterial disease.

### Guideline Scope

This guideline addresses the appropriateness of endovascular revascularization procedures (open or percutaneous) in patients with peripheral arterial disease of the lower extremities including disease of the aortoiliac, femoral, popliteal, tibial, and peroneal arteries. Acute limb ischemia is a medical emergency managed in the emergency department or inpatient setting and is not addressed in this guideline.

### Definitions

**Optimal medical therapy for patients with peripheral arterial disease includes ALL of the following, unless contraindicated:**

- Antiplatelet medication (e.g., Aspirin, clopidogrel, ticagrelor)
- High-intensity statin
- ACE inhibitor or angiotensin receptor blocker for hypertensive patients
- Treatment of diabetes and hypertension, if present
- Tobacco cessation which includes a trial of at least **TWO (2)** of the following treatments if the patient continues to smoke:
  - Varenicline
  - Nicotine replacement therapy
  - Bupropion
  - Behavioral therapy

**Structured exercise programs**, which may be directly supervised or home based, are designed to have the patient “walk through” his/her claudication and increase exercise tolerance and walking distance over time. Exercise sessions lasting at least 30 minutes should be performed 3 times a week for an initial period of 12 weeks.

**Secondary stenting** describes stent deployment when results of balloon angioplasty are suboptimal. Suboptimal results include residual diameter stenosis greater than 50%, persistent translesional pressure gradient, or flow-limiting dissection.

**Intermittent claudication** is reproducible pain or cramping in a specific muscle group that occurs with exercise and is relieved with rest.

Initial treatment of claudication involves risk factor management with optimal medical therapy and a supervised or home-based structured exercise program. Revascularization should be reserved for patients who despite an adequate trial of conservative therapy have persistent claudication which significantly limits lifestyle or occupation.

**Critical Limb Ischemia (CLI) (also known as chronic limb threatening ischemia (CLTI))** includes ischemic rest pain or non-healing wounds for greater than 2 weeks associated with one or more abnormal hemodynamic parameters, or gangrene. Critical limb ischemia often requires urgent revascularization for limb salvage.

Ischemic rest pain is typically forefoot pain that worsens with elevation and improves with dependency.

## Clinical Indications

### Critical Limb Ischemia (Chronic Limb Threatening Ischemia)

Standalone balloon angioplasty, primary stenting, secondary stenting, or atherectomy is considered medically necessary for critical limb ischemia in **ANY** of the following scenarios:

- Ischemic rest pain involving **ALL** of the following:
  - Pain in the foot that worsens with elevation of the foot and improves with dependency of the foot
  - Abnormal hemodynamic parameters in the affected limb (e.g. Diminished ABI or TBI or abnormal PVR or Doppler waveforms)
- Ischemic skin ulceration present for > 2 weeks despite wound care with abnormal hemodynamic parameters in the affected limb.
- Gangrene

### Claudication

Standalone balloon angioplasty, primary stenting, or secondary stenting is considered medically necessary for claudication when **ALL** of the following are met:

- Significant lifestyle impairment or vocational limitation due to claudication with no other conditions causing significant limitations to walking.
- Lack of improvement following at least three (3) months of conservative therapy\* that includes **BOTH** of the following:
  - A structured exercise program (supervised or home based)
  - [Optimal medical therapy](#) as defined above
- The target lesion is located in the aortoiliac or femoropopliteal vessels. (Intervention on the anterior tibial artery, tibioperoneal trunk, peroneal artery, posterior tibial artery, and/or pedal arteries is not medically necessary for treatment of claudication).

*\*Note: When improvement is evident at 3 months, an additional 3 months of conservative therapy should be undertaken before a decision is made regarding revascularization.*

Atherectomy is medically necessary for claudication when **ALL** of the following are met:

- Significant lifestyle impairment or vocational limitation due to claudication with no other conditions causing significant limitations to walking.
- Lack of improvement following at least three (3) months of conservative therapy\* that includes **BOTH** of the following:
  - A structured exercise program (supervised or home based)
  - [Optimal medical therapy](#) as defined above

- The target lesion is located in the aortoiliac or femoropopliteal vessels (intervention on the anterior tibial artery, tibioperoneal trunk, peroneal artery, posterior tibial artery, and/or pedal arteries is not medically necessary for treatment of claudication).
- Atherectomy is performed due to suboptimal results\*\* from angioplasty or stenting on the same vessel during the same index procedure.

\*\* (Suboptimal results=flow limiting dissection or > 50% residual stenosis)

*\*Note: When improvement is evident at 3 months, an additional 3 months of conservative therapy should be undertaken before a decision is made regarding revascularization.*

## Prior revascularization with restenosis

Standalone balloon angioplasty, primary stenting, secondary stenting or atherectomy of a previously treated vessel segment is considered medically necessary in **ANY** of the following scenarios:

- Symptomatic patients with hemodynamically significant restenosis at the site of previous endovascular revascularization
- Symptomatic or asymptomatic patients with hemodynamically significant stenosis in a venous or prosthetic bypass graft

## Treatment of peripheral arterial disease to provide access for an endovascular procedure

Standalone balloon angioplasty, primary stenting, or secondary stenting of the iliac arteries is considered medically necessary in patients with a stenotic lesion in order to facilitate vascular access for percutaneous coronary intervention, endovascular repair of aortic aneurysm, percutaneous valvular replacement/repair, or other medically necessary vascular interventions in the abdominal, pelvic or thoracic vasculature.

## Endovascular venous arterialization

Endovascular venous arterialization of the tibial or peroneal veins is considered medically necessary in patients with critical limb ischemia and non-healing ulcers who have no other transcatheter or surgical treatment options.

## Rationale

### CRITICAL LIMB-THREATENING ISCHEMIA and CLAUDICATION

Evidence-based guidelines emphasize that central to the care of patients with CLTI is revascularization to improve blood flow with goals of preventing amputation and minimizing tissue loss so that limb function can be preserved as well as for wound healing and relief of PAD-associated pain. Surgical and endovascular approaches have both been shown to be effective in preventing amputation in CLTI.<sup>1</sup>

In patients with functionally limiting claudication and inadequate response to GDMT (including structured exercise), endovascular revascularization for aortoiliac and femoropopliteal disease (excluding the common femoral artery) is effective for improving walking performance and quality of life. For common femoral artery disease, they state that endovascular techniques “may be considered in those at high risk for surgical revascularization and/or if anatomical factors are favorable (i.e., no adverse effect on profunda femoris artery pathways).” The effect of revascularization in patients with claudication and infrapopliteal disease is unknown, as isolated infrapopliteal disease is an uncommon cause for claudication and therefore there is little data and no RCTs.<sup>1</sup> In the setting of infrapopliteal disease, the 2022 Appropriate Use Criteria from the Society for Vascular Surgery rated all interventions, open or endovascular, to be “risk outweighs benefits” for treatment of intermittent claudication.<sup>2</sup>

The above multi-society guideline recommendations do not address the appropriateness of particular therapeutic approaches. Additionally, guidelines from the Society for Vascular Surgery do not distinguish between angioplasty, stenting, and atherectomy in their recommendations related to endovascular revascularization.<sup>2</sup> While there are previous guidelines that distinguish between angioplasty, stenting, and atherectomy, the body of evidence regarding atherectomy at that time was limited. A 2019 Clinical Practice Guideline from the Society for Vascular Surgery states that “PBA, drug-coated balloon (DCB) angioplasty, stent placement (bare-metal stent, drug-eluting stent [DES], or covered stent), and atherectomy may all be reasonable options in specific circumstances and lesion anatomies. However, unfortunately, there are few high-quality comparative data to guide the choice of a specific endovascular approach in CLTI.”<sup>3</sup> Some retrospective studies have shown a higher risk of amputation after atherectomy<sup>4</sup> so atherectomy should only be used as a secondary treatment for claudication.”



## REVASCLARIZATION PRIOR TO OTHER PROCEDURES

Evidence-based guidelines state that “it is reasonable to perform revascularization procedures (endovascular or surgical) to reconstruct diseased arteries if needed for the safety, feasibility, or effectiveness of other procedures (eg, transfemoral aortic valve replacement, mechanical circulatory support, endovascular aortic aneurysm repair).” These guidelines also recommend against performing revascularization solely to prevent disease progression, noting that “no data suggest that invasive treatment while PAD is asymptomatic will alter its natural history,” and further noting the increased risk of subsequent complications in patients who have undergone revascularization procedures.<sup>1</sup>

## LITHOTRIPSY

There is limited high-quality data currently available regarding the superiority of intravascular lithotripsy, though there have been studies showing feasibility of this approach in both coronary and peripheral arteries.<sup>5</sup> Further randomized trials comparing lithotripsy to other procedures standardly performed on calcified vessels are needed. A 2024 guideline from the National Institute for Care Excellence states that there is moderate evidence to suggest that intravascular lithotripsy is safe. Further, they state, “The evidence suggests that the procedure is associated with a reduced need for a stent to keep the vessel open. But there is not enough long-term evidence, or evidence about how many amputations will be prevented by having this procedure. More evidence is also needed on patients’ quality of life.”<sup>6</sup>

Endovascular venous arterialization has been shown to improve amputation-free survival in patients with non-healing ulcers and no other endovascular or surgical revascularization option.<sup>7</sup>

Endovenous femoral-popliteal arterial revascularization with transcatheter placement of intravascular stent

Endovenous femoral-popliteal arterial revascularization<sup>8</sup> with transcatheter placement of intravascular stent is a newer procedure used as an alternative to endovascular revascularization with angioplasty, stent or atherectomy or to surgical bypass. There is limited data comparing this technique to other endovascular or surgical revascularization techniques.

## Exclusions

The use of endovenous femoral-popliteal arterial revascularization with transcatheter placement of intravascular stent is considered **not medically necessary** for all indications.

The use of intravascular lithotripsy is considered **not medically necessary** for all indications.

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## Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

### CPT/HCPCS

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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 road mapping 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
0620T	Endovascular venous arterialization, tibial or peroneal vein, 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 road mapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed
37220	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty
37221	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37222	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty
37223	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37227	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed
37228	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty
37229	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed

37230	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37231	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed
37232	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty
37233	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)
37234	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)
37235	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed
C7531	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(ies), unilateral, with transluminal angioplasty with intravascular ultrasound (initial noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation
C7534	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(ies), unilateral, with atherectomy, includes angioplasty within the same vessel, when performed with intravascular ultrasound (initial noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation
C7535	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(ies), unilateral, with transluminal stent placement(s), includes angioplasty within the same vessel, when performed, with intravascular ultrasound (initial noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation
C9764	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed
C9765	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
C9766	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed
C9767	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed
C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed
C9773	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
C9774	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed
C9775	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed

# History

Status	Review Date	Effective Date	Action
Revised	01/30/2025	09/20/2025	Independent Multispecialty Physician Panel (IMPP) review. Definitions updated, Added indications for atherectomy in patients with claudication in some clinical scenarios. Added indication for treatment of asymptomatic stenosis in prosthetic bypass grafts. Removed the exclusion of atherectomy.
Revised	01/23/2024	10/20/2024	IMPP review. Added indication for endovascular venous arterialization. Added exclusions for endovenous femoral-popliteal arterial revascularization and intravascular lithotripsy. Added references. Added HCPCS codes C9764, C9765, C9766, C9767, C9772, C9773, C9774, C9775.
Updated codes 04/01/2024	01/23/2024	Unchanged	Independent Multispecialty Physician Panel (IMPP) review. Added exclusion for atherectomy. Added required language to the General Clinical Guideline per new Medicare regulations. Added CPT code 0620T and HCPCS codes C7531, C7534, C7535.
Revised	01/24/2023	06/18/2023	IMPP review. Removed use of cilostazol as a required component of conservative therapy and optimal medical therapy. Added clarification for symptomatic patients with restenosis at the site of previous endovascular revascularization.
Created/ Reaffirmed	08/29/2022	01/01/2023	IMPP review. Restructured for clarity. Added references. Guideline reaffirmed. Original effective date.
Reaffirmed	12/03/2020	-	IMPP review. Updated references. Guideline reaffirmed.
Reviewed	12/12/2019	-	Literature Review. Added reference.
Reviewed	03/25/2019	-	IMPP review.