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

Clinical Appropriateness Guidelines

Cardiology

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

Proprietary

Table of Contents

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

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

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

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

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

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

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
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

General Information

Overview

Endovascular procedures for the management of peripheral arterial disease of the lower extremities include standalone balloon angioplasty, stent placement, or atherectomy. The vessel 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, and those with critical 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.

Patient Classification

Asymptomatic patients and those with atypical symptoms: Risk factor modification (healthy diet, smoking cessation, management of hypertension, hyperlipidemia, and diabetes) is the cornerstone of management of asymptomatic patients who are at risk for, or are known to have, peripheral arterial disease.

Patients with claudication: Risk factor modification (healthy diet, smoking cessation, management of hypertension, hyperlipidemia, and diabetes) should be undertaken in all patients with claudication. In addition, patients with claudication should participate in a supervised (preferably) or home-based structured exercise program. Pharmacologic agents such as cilostazol and antiplatelet agents should be used per current recommendations. Revascularization (whether surgical or endovascular) should be reserved for patients who despite an adequate trial of conservative therapy have persistent claudication which significantly limits lifestyle.

Critical limb ischemia as evidenced by ischemic rest pain, ischemic skin ulceration, gangrene, etc., requires urgent management with the optimal approach determined on a case-by-case basis. Patients with critical limb ischemia are at increased risk of both limb loss and cardiovascular death.

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 arterial occlusion is a medical emergency managed in the emergency room 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:

- Aspirin or clopidogrel
- High-intensity statin
- ACE inhibitor or angiotensin receptor blocker
- Treatment of diabetes and hypertension, if present
- Tobacco cessation which includes a trial of at least **TWO (2)** of the following agents:
    - Varenicline
    - Nicotine supplements
    - Bupropion

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.

Clinical Indications

No history of revascularization

Standalone balloon angioplasty, primary stenting, or secondary stenting is considered medically necessary in **EITHER** of the following scenarios:

- Critical limb ischemia
- Claudication and **ALL** of the following:
    - Significant lifestyle impairment or vocational limitation due to claudication
    - 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
    - Absence of another condition limiting exercise capacity (e.g., cardiac, pulmonary, or musculoskeletal disease) such that revascularization is expected to result in significant functional improvement
    - The target lesion is located in the aortoiliac or above-knee femoropopliteal vessels

**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.*

History of revascularization

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

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

Treatment of peripheral arterial disease prior to a vascular access procedure

Standalone balloon angioplasty, primary stenting, or secondary stenting is considered medically necessary in patients with a known stenotic lesion in order to facilitate vascular access for percutaneous coronary intervention, large vascular intervention (e.g., endovascular repair of abdominal aortic aneurysm), or percutaneous valvular replacement/repair.

Exclusions

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

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History

Status	Review Date	Effective Date	Action
Updated	01/23/2024	Unchanged	Independent Multispecialty Physician Panel (IMPP) review. Added exclusion for atherectomy. Added required language per new Medicare regulations.
Revised	01/24/2023	06/18/2023	Independent Multispecialty Physician Panel (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.