## **Clinical Guidelines**

### **Peripheral Vascular Intervention**

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eviCore healthcare Clinical Decision Support Tool Diagnostic Strategies: This tool addresses common symptoms and symptom complexes. Imaging requests for individuals with atypical symptoms or clinical presentations that are not specifically addressed will require physician review. Consultation with the referring physician, specialist and/or individual's Primary Care Physician (PCP) may provide additional insight.

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## Glossary

#### Terms and abbreviations

- Aneurysm Defined as a diameter 1.5x the normal arterial diameter.
- **Angioplasty** A procedure that utilizes a catheter with a balloon that is inflated to enlarge a stenotic area.
- **Ankle-Brachial Index (ABI)** Ratio of the systolic blood pressure (SBP) measured at the ankle to the brachial SBP.
- Atherectomy A procedure that utilizes a catheter with a sharp blade or laser on the end of the catheter to remove plaque from a blood vessel.
- **Critical limb ischemia** Severe stenosis or occlusion in the vessels supplying the lower extremity such that limb loss will result without treatment. Symptoms of critical limb ischemia in the lower extremities include non-healing wounds, gangrene and ischemic rest pain.
- **Dissection** Disruption of the media layer of the aorta with bleeding within and along the wall of the aorta.
- **Graft** Fabric material used to replace a segment of an artery or bypass an occluded segment of artery.
- **High-grade stenosis** A high grade stenosis is defined as a stenosis limiting flow by at least 80% or greater.
- **Ischemic rest pain** Pain arises from severe arterial occlusive disease in the lower extremities such that the patient experiences pain in the distal aspect of the foot and toes while the limb is in the supine position as would occur with sleep. The pain is relieved with the limb in the dependent position or "dangling from the bed" as the limb is depending on gravity to assist with perfusion.
- **Pseudo-aneurysm** Outpouching of blood resulting from disruption of the arterial wall with extravasation of blood contained by periarterial connective tissue and not by the arterial wall layers.
- **PTA** Percutaneous transluminal angioplasty.
- Stent A metal scaffold placed inside the artery to maintain patency.
- Stent-graft A metal scaffold covered by fabric material placed inside an artery.
- Velocity ratio (V1/V2) Ratio of peak systolic velocity in the diseased segment of blood vessel demonstrating elevated flow velocities to the peak systolic velocity of blood flow in normal vessel just proximal to area of concern in arteries, or just distal in veins.

## **Arterial Intervention Guidelines**

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# Documentation requirements for arterial intervention requests

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#### **General requirements**

#### Introduction

eviCore applies an evidence-based approach to evaluate the most appropriate medically necessary care for each patient. This evaluation requires submission of legible medical records pertinent to the test, treatment, or procedure requested by the provider.

#### Information to establish medical necessity

Medical necessity for the request cannot be established when the medical records provided cannot be read or do not include sufficiently detailed information to understand the patient's current clinical status.

Specific elements of a patient's medical records commonly required to establish medical necessity include, but are not limited to

- Recent (within 6 months) in-person clinical evaluation which includes a detailed history and physical examination
- Laboratory studies
- Imaging studies
- Pathology reports
- Procedure reports
- Reports from other providers participating in treatment of the relevant condition

#### Documentation requirements for arterial intervention requests

Documentation requirements needed to complete a prior authorization request for vascular surgery include **ALL** of the following:

- Procedure proposed
- Condition being treated
- Detailed documentation of provider-directed conservative treatment, duration and frequency of treatment, and the response to such treatments, if applicable
- Detailed documentation of location and size of aneurysmal disease, if present
- Detailed documentation regarding nature of the critical limb ischemia: non-healing wound or ischemic rest pain, if applicable

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- Recent (within 6 months) written reports of any of the following diagnostic imaging modalities acceptable for purposes of the Vascular Surgery guidelines:
  - Ankle-brachial indices, segmental pressures and pulse volume recordings as applicable
  - $\circ~$  Arterial duplex including carotid, lower extremity and abdominal
  - o CTA abdomen/pelvis with or without lower extremity run-off
  - o MRA abdomen/pelvis with or without lower extremity run-off
  - o Angiogram
- Recent (within 6 months) clinical evaluation documenting:
  - Patient symptoms (if lifestyle-limiting, detailed documentation regarding quality of life parameters that are affected)
  - Physical exam findings

#### Emergent and urgent requests

Individuals being evaluated for vascular/endovascular surgery should be screened for the presence of a medical condition that warrants urgent/emergent definitive surgical treatment. Provider directed non-surgical management is **not** required when there is documentation, supported by imaging studies or clinical assessment, of any of the following urgent/emergent conditions:

- Critical limb ischemia
- Symptomatic carotid stenosis
- Crescendo TIA's (multiple recurrent episodes of TIA over hours to days)
- Symptomatic or ruptured aneurysms

An urgent/emergent request based on 2018 NCQA standards for utilization management occurs when the time frame for making routine or non-life threatening determinations on care **either**:

- Could seriously jeopardize the life, health, or safety of the member or others, due to the member's psychological state
- In the opinion of a practitioner with knowledge of the member's medical or behavioral condition, would subject the member to adverse health consequences without the care or treatment that is the subject of the request.

Procedures to treat arterial disease may be indicated on an intra-operative basis

#### Supporting information

Prior-authorization requests should be submitted at least two weeks prior to the anticipated date of an elective surgery.

## Peripheral vascular, non-coronary stents

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#### **General information**

Atherosclerosis is a systemic disease and patients will often present with multi-level disease. Intraoperative decision making may lead to changes in the original procedure requested. Sequential procedures may also be indicated during the procedure to maintain or re-establish patency. These additional procedures are necessary because the initial approach was unsuccessful or only partially successful with regard to patency of the target vessel.

Procedures for peripheral atherosclerosis can include:

- Surgery, including surgical exposure of vessels, endarterectomy or bypass
- Open or percutaneous thrombectomy
- Open or percutaneous embolectomy
- Atherectomy
- Catheter directed thrombolysis
- Additional PTA or stent placement

#### Coding

#### Procedures

Peripheral vascular non-coronary stent procedures

Procedure description	CPT®
Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty	37220
Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	37221
Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)	37222
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 (List separately in addition to code for primary procedure)	37223

Procedure description	CPT®
Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty	37224
Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed	37225
Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	37226
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	37227
Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty	37228
Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed	37229
Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), 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) and atherectomy, includes angioplasty within the same vessel, when performed	37231
Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)	37232
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)	37233

Procedure description	CPT®
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)	37234
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 (List separately in addition to code for primary procedure)	37235
Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery	37236
Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery (List separately in addition to code for primary procedure)	37237
Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein	37238
Transluminal balloon angioplasty (except lower extremity artery(ies) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; initial artery	37246
Transluminal balloon angioplasty (except lower extremity artery(ies) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; each additional artery (List separately in addition to code for primary procedure)	37247
Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel	0238T

#### Peripheral vascular, non-coronary stent - criteria

#### **General Guidelines**

It is expected that all lesions needing treatment will be addressed in one procedure. Staging of interventions is **not** indicated unless there is justification in the medical record. Valid reasons include any of the following:

- Patient instability
- Fluoroscopy use in excess of what is widely considered a safe radiation dosage
- A need to convert to general anesthesia but resources are not available
- Contrast volume given is greater than 250 ml

Primary stenting is medically necessary when Percutaneous Transluminal Angioplasty (PTA) alone is not expected to provide a durable result for patients with **either** of the following:

- Arterial occlusions that carry a high risk for distal embolization or rapid recurrence
- Occlusive lesions such as significantly calcified lesions, eccentric lesions, lesions related to external compression, and ostial lesions.

#### Lower extremity arterial indications

#### Initial treatment

Treatment of stenotic or occluded arteries perfusing the lower extremities (aorto-iliac, superficial femoral, popliteal and infra-popliteal arteries) is considered medical necessary when **all** of the following are met:

- Clinical history documents **one** of the following conditions:
  - o Critical limb ischemia documented in the clinical note by any of the following:
    - Non-healing ischemic wounds present for ≥two weeks despite ongoing provider-directed wound care of at least two weeks
    - Gangrene where revascularization is felt to be needed to allow for minor amputation
    - Ischemic rest pain demonstrated by:
      - Symptomatology suggestive of rest pain (e.g., pain in the foot while recumbent that is relieved when foot is dependent present ≥2 weeks) and either
        - Objective evidence of ABI's <0.5 in non-diabetics
        - Monophasic waveforms at the feet on noninvasive studies in individuals noted to have noncompressible vessels on ABI such as diabetics or patients with end-stage renal disease
  - $\circ$  Lifestyle limiting claudication when there is documentation of **all** of the following:
    - A failed trial of three months of provider directed conservative therapy which includes structured exercise walking program
    - Functional limitations that significantly impact the quality of life and/or occupation of the patient

- Risk factor modification including smoking cessation, optimization of lipids, and glycemic control are part of the medical evaluation and management
- Symptoms correspond with the location of arterial insufficiency
  - aorto-iliac -lower back, hip, buttock, or thigh
  - superficial femoral claudication in the calf muscle area
  - popliteal calf or foot
  - infra popliteal arteries- ankle and foot
- Imaging performed prior to the planned procedure confirms location and degree of stenosis (≥70%)

#### **Repeat intervention**

- Re-intervention in a patient who has previously undergone angioplasty/stenting or bypass in the lower extremity arteries (aorto-iliac, superficial femoral and infrapopliteal arteries) for critical limb ischemia considered medically necessary for any one of the following:
  - Previous Endovascular Intervention: Drop in ABI of ≥0.15 on routine surveillance or duplex finding of peak systolic velocity (PSV) ≥190 cm/s or Velocity ratio ≥1.5 AND one of the following:
    - Recurrence of rest pain and/or claudication as documented by clinical notes
    - Progression of wound as defined by any increase in size of the wound, new infection or lack of 50% area reduction in 4 weeks
  - Previous Lower Extremity Bypass: Drop in ABI of ≥0.15 on routine surveillance AND one of the following:
    - Recurrence of rest pain and/or claudication as documented by clinical notes
    - Progression of wound as defined by any increase in size of the wound, new infection or lack of 50% area reduction in 4 weeks OR
    - If Vein bypass: PSV ≥180 cm/s or Velocity ratio ≥2, or end diastolic velocity (EDV) <45 cm/s</li>
    - If Prosthetic bypass: low graft velocity <45 cm/s</p>
- Re-intervention in a patient who has previously undergone angioplasty/stenting for claudication is appropriate when there is recurrent symptomatology in the setting of noninvasive studies demonstrating **any** of the following:
  - Drop in ABI of ≥0.15 or a drop from a normal ABI back to an abnormal ABI (<0.9)</li>
  - o Recurrent lesion seen on recent duplex (within three months)
  - New lesion seen on recent duplex (within three months)
- In asymptomatic patients:
  - o If Vein bypass: PSV ≥180 cm/s or Velocity ratio ≥2, or EDV <45 cm/s</li>
  - If Prosthetic bypass: low graft velocity <45 cm/s</li>
  - Stent with high grade stenosis defined as PSV  $\ge$  275 cm/s or Velocity ratio  $\ge$  3.5
- Stent placement in infra-popliteal vessels is almost never indicated and in those cases, the rationale for stent placement must be thoroughly explained in the record.

#### Atherectomy

Atherectomy can be approved as an adjunct to angioplasty prior to stenting in lesions that are ≥70% stenosis caused by a highly calcified eccentric plaque; AND able to pass a wire fully across the lesion into the true lumen; AND all of the following

- Treatment of target lesion will establish inline flow to the foot, with at least 1 runoff vessel.
- Lesion is 20 cm or less in length
- Rutherford chronic ischemia classification 2 or higher, documented in clinical notes
- Debulking to <30% diameter stenosis is attainable.

#### Additional information

#### Peripheral vascular, non-coronary stents non-indications

Stent placement in infrapopliteal vessels is not medically necessary except in rare cases where it is deemed necessary intraoperatively.

PTA or stent is not considered medically necessary in either:

- Individuals who are asymptomatic
- Lesions that are **not** high-grade or critical (≥70%)

#### Intravascular Ultrasound (IVUS)

IVUS for the treatment of lower extremity arterial occlusive disease is considered **not** medically necessary as there is insufficient evidence to support its routine use for this type of treatment.

#### **Supporting information**

Atherosclerotic plaque can lead to stenosis and even occlusion of the peripheral vasculature. High-grade stenosis can lead to chronic ischemia of the end tissue, with resultant symptoms of arterial insufficiency. In the lower extremities, this can lead to claudication and/or critical limb ischemia. Treatment of stenotic or occlusive lesions can be performed with angioplasty alone which involves placing a balloon through a wire across the lesion and dilating the lesion to residual stenosis of <30%. Stenting involves placing a metal stent permanent implant across a lesion dilating it with a balloon and leaving it in place effectively crushing and fixing the plaque against the arterial wall. Angioplasty can be performed alone or in conjunction with stenting. A stent may be placed as a planned adjunct to PTA rather than in response to a sub-optimal or failed PTA (so-called primary stent deployment).

Coverage for non-coronary vascular stents depends on the use of an FDA-approved stent for an FDA approved indication

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