

LOWER EXTREMITY REVASCULARIZATION

Documentation & Medical Necessity Tool

Clinical Documentation Tool | Lower Extremity Revascularization

Designed as a standalone medical-record entry for lower-extremity revascularization decision-making. Complete the applicable pathway only. Document clinical judgment where prompted; attach or reference objective testing and imaging.

1 PATIENT, LIMB & CLINICAL PRESENTATION

Patient _____ **DOB** _____
DOS _____ **Treating clinician** _____
Target limb ☐ Left ☐ Right ☐ Bilateral **Setting** ☐ Hospital OP ☐ ASC ☐ Inpatient
Clinical presentation: ☐ Functionally limiting claudication ☐ Ischemic rest pain ☐ Nonhealing wound/ulcer ☐ Gangrene/tissue loss ☐ Other: _____
Patient-specific impact / treatment goal: _____

2 OBJECTIVE PAD CONFIRMATION & ANATOMY

Physiologic testing: ABI R _____ L _____ Date _____ ☐ TBI ☐ TcPO2 ☐ Skin perfusion pressure ☐ Other _____
Imaging reviewed for revascularization planning: ☐ Duplex ☐ CTA ☐ MRA ☐ Catheter angiography Date(s) _____
Target anatomy / disease summary: Level(s) _____ ☐ Stenosis ☐ Occlusion/CTO ☐ Multilevel disease
Key anatomic findings relevant to treatment choice: _____

3 INDICATION PATHWAY - COMPLETE APPLICABLE SECTION

ICD-10-CM diagnosis: _____ **Diagnosis / indication:** ☐ Atherosclerosis/PAD with claudication ☐ Rest pain ☐ Ulceration/tissue loss ☐ Gangrene ☐ Other: _____

A. FUNCTIONALLY LIMITING CLAUDICATION

- ☐ Symptoms significantly limit normal work, walking, or activities important to the patient.
- ☐ Guideline-directed medical therapy (GDMT) documented, including antiplatelet/antithrombotic and statin therapy as clinically appropriate.
- ☐ At least 90 days of medical therapy / structured exercise documented, OR adequate response is not reasonably predicted / therapy is not feasible as documented.
- ☐ Despite conservative therapy, symptoms remain functionally limiting.
- ☐ Anatomy is appropriate for revascularization with reasonable likelihood of durable functional improvement.
- ☐ Risks, benefits and alternatives - including continued conservative therapy and surgical options - discussed with patient.

Functional limitation / response to therapy: _____

B. CHRONIC LIMB-THREATENING ISCHEMIA (CLTI)

- ☐ Rest pain, nonhealing wound/ulcer, gangrene or tissue loss is attributable to objectively confirmed PAD.
- ☐ Revascularization is intended to relieve ischemic pain, heal wounds/minimize tissue loss and/or preserve a functional limb.
- ☐ Anatomy, comorbidities, available conduit and patient preferences have been considered.
- ☐ For wounds/tissue loss, strategy is intended to establish inline flow and/or maximize perfusion to the wound bed when feasible.
- ☐ If bypass is being considered, autogenous vein availability has been evaluated when clinically indicated.
- ☐ If multilevel disease is present, inflow/outflow strategy has been considered.

Wound/rest-pain findings & treatment goal: _____

4 PATIENT-CENTERED REVASCULARIZATION DECISION

Relevant clinical factors considered: ☐ CAD ☐ COPD/O₂ dependence ☐ CKD/dialysis ☐ Diabetes/HbA1c ☐ Frailty ☐ Functional/ambulatory status ☐ Nutrition ☐ Living situation

Prior lower-extremity revascularization/interventions: ☐ None ☐ Yes - describe: _____

Perioperative / procedural risk and goals considered: ☐ Yes Key considerations: _____

Treatment plan: ☐ PTAB / DETOUR ☐ OTHER: _____

5 PLANNED PROCEDURE / TECHNIQUE

Planned treatment: ☐ PTAB / DETOUR ☐ OTHER: _____

Target vessel(s)/segment(s): _____

Clinical rationale for selected treatment: _____

For complex anatomy / when endovascular treatment is selected over surgery, document rationale:

6 SAFETY / COVERAGE LIMITATION SCREEN

- | | |
|--|---|
| ☐ Not asymptomatic PAD treated solely to prevent progression.
☐ No adequate positive response to GDMT/structured exercise that makes revascularization unnecessary.
☐ No non-salvageable limb due to acute limb ischemia. | ☐ Selected approach is supported by the patient's anatomy and clinical risk.
☐ If surgery is clearly preferred based on perioperative/technical factors, rationale for any endovascular approach is documented.
☐ Prior failed endovascular bypass, if applicable, has been considered in treatment selection. |
|--|---|

7 CLINICIAN ASSESSMENT & ATTESTATION

Assessment / medical necessity statement: The patient has symptomatic lower-extremity PAD meeting the applicable clinical pathway above. Objective testing and imaging have been reviewed, conservative therapy and alternatives have been considered as applicable, and the selected revascularization strategy is medically appropriate based on the patient's symptoms, anatomy, comorbidities, procedural risk, goals and preferences.

Additional clinical rationale (if needed): _____

Clinician signature: _____ **Date:** _____

Clinical documentation aid for lower-extremity revascularization. This tool does not replace clinical judgment or guarantee coverage/payment. Coverage and documentation requirements vary by payer and jurisdiction. Attach or reference supporting test reports, imaging, therapy history and wound documentation as applicable.

The reimbursement information provided below has been obtained from third party sources and is intended to be used as a general source of information only. It does not cover all possible patient care situations, payer rules, or scenarios. It is solely the provider's responsibility to determine the proper medical products and services to be provided to individual patients, and to report the procedures and codes, if any, that most appropriately describe the products or services rendered. Endologix does not promise or guarantee coverage or payment by Medicare or any other payers by providing this information. The information does not constitute legal advice and no warranty regarding the completeness or accuracy of the information is made or implied. The information provided is subject to change without notice as reimbursement laws, regulations, rules and policies change frequently. Providers must seek advice from Medicare and/or other specific payers to obtain the most accurate, current and appropriate information related to pre-authorization, coverage, billing and reimbursement. Endologix specifically disclaims and rejects any liability or responsibility for any actions or consequences resulting from the use of this information.

INDICATIONS FOR USE:

The DETOUR™ System is indicated for use for percutaneous revascularization in patients with symptomatic femoropopliteal lesions from 200mm to 460mm in length with chronic total occlusions (100mm to 425mm) or diffuse stenosis >70% who may be considered suboptimal candidates for surgical or alternative endovascular treatments. The DETOUR™ System, or any of its components, is not for use in the coronary and cerebral vasculature.

CONTRAINDICATIONS:

The DETOUR™ System is contraindicated in patients with:

- A distal common femoral artery (CFA) <7 mm in diameter.
- Increased risk of deep vein thrombosis (DVT), such as patients with a recent history of DVT, thrombophilia, and disseminated malignancy.
- Untreated flow-limiting aortoiliac occlusive disease.
- Lack of patent single vessel tibial runoff to ankle.
- Known coagulopathy, bleeding diathesis, or thrombocytopenia that cannot be medically managed.
- Known hypersensitivities, allergies or contraindications to: Nitinol; PTFE; aspirin; heparin; antiplatelet; anticoagulant or thrombolytic therapy; or contrast media that cannot otherwise be medically managed.

Refer to Instructions for Use for more information concerning Indications, Contraindications, Specific Anatomic Considerations, Warnings, Precautions, and Adverse Events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

NOTE: Not all product components are available in every country. Please consult with your Endologix representative to confirm product availability.

Endologix® is a registered trademark of Endologix LLC in the United States, Europe and Japan. All other trademarks are the property of their respective owners.

©2026 Endologix LLC. All rights reserved. MM3114-US Rev 01