

Seeking Payer Approval for DETOUR Documentation Roadmap

Insurance authorization for the DETOUR procedure is most successful when the physician's clinical documentation includes the following elements:

1. Clearly Outlines the Patient's Presentation

Primary Diagnosis (ICD-10)

- I70.2xx – Atherosclerosis of native arteries of extremities
- I70.3xx – Atherosclerosis with ulceration
- I70.4xx – Atherosclerosis with gangrene
- Other: _____

A. Claudication

Document:

- Presence of lifestyle-limiting claudication (impairment of activities of daily living, vocational, and/or recreational activities).
- Inadequate response to conservative medical therapy (e.g., smoking cessation attempts, supervised exercise therapy, pharmacologic therapy).
- Patient is a suboptimal candidate for surgical or alternative endovascular treatments.

B. Chronic Limb-Threatening Ischemia (CLTI)

Document one or more of:

- Ischemic rest pain
- Nonhealing wounds/ulcers (≥ 2 weeks)
- Gangrene (one or both legs)
- Patient is a suboptimal candidate for surgical or alternative endovascular treatments.

C. Acute Limb Ischemia

(< 2 weeks duration) in a marginally viable, immediately viable, or threatened limb.

- Patient is a suboptimal candidate for surgical or alternative endovascular treatments.

2. Objectively Supports the Presentation

A. Imaging Findings

Document evidence of occlusive arterial disease, including one or more of:

- Ankle-brachial index (ABI) ≤ 0.90 (rest or exercise)
- Monophasic waveform on ultrasound

Include:

- Confirmed anatomic location and degree of significant occlusive disease (percentage stenosis $>50\%$) demonstrated by non-invasive or invasive studies (Duplex ultrasound, CT angiography, or catheter-based angiography).

B. Lesion Description

Include descriptors such as:

- "Rutherford Classification Grade III–IV"
- "TASC C and/or TASC D lesion"
- "Occlusion/diseased segment >20 cm in length"

3. Explains Assessment and Plan

A. Functional Limitations

Clearly describe the patient's limitations, for example:

- "The patient experiences constant leg pain, including rest pain, which interferes with activities of daily living (e.g., walking, stair climbing) and/or ability to work."

B. Suboptimal Outcomes or Failure of Prior Treatments

Examples:

- "Following previous endovascular interventions (atherectomy, DCB, etc.), there is further disease progression, including in-stent restenosis (ISR)."
- "Despite prior endovascular interventions, the patient continues to exhibit limb ischemia."
- "After previous open surgical bypass, failure has occurred due to..." – "insufficient inflow, insufficient outflow, progression of disease below the bypass."

C. Confirm Absence of Contraindications

Document that the patient does not have:

- Distal CFA diameter <7 mm
- Increased risk of DVT (e.g., recent DVT, thrombophilia, disseminated malignancy)
- Untreated flow-limiting aortoiliac occlusive disease
- Lack of a patent single-vessel tibial runoff to the ankle

- Coagulopathy, bleeding diathesis, or thrombocytopenia that cannot be medically managed
- Hypersensitivity or contraindications to nitinol, PTFE, aspirin, heparin, antiplatelet agents, anticoagulants, thrombolytics, or contrast agents that cannot be managed medically

D. Rationale for Not Being an Optimal Candidate for Surgical or Alternative Endovascular Treatments

Examples:

- "The patient's comorbidities (e.g., COPD, low ejection fraction, CAD, elevated infection risk) significantly increase anesthesia (and other procedural) risks."
- "Due to being the primary income provider, the patient cannot tolerate the prolonged recovery associated with open fem-pop bypass."
- "The patient has failed multiple prior procedures; therefore, a new treatment modality is required to prevent further progression, including risk of amputation."

E. Patient Consent

Document consent, such as:

- "The patient understands the risks and potential benefits of the DETOUR/PTAB procedure and agrees to comply with necessary anticoagulant and antiplatelet therapy."

Where should I direct additional questions?

If you have any questions, please reach out to the Endologix Health Economics & Reimbursement team:

Paula Davis (Western US) at pdavis@endologix.com

Tuck Wieler (Eastern US) at twieler@endologix.com

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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.

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