Endologix | DETOUR™ System

Effective January 1, 2024

The DETOUR System used in the first fully percutaneous transmural arterial bypass therapy is granted Transitional Pass-Through Payment

What is the Transitional Pass-Through Payment?

The Centers for Medicare & Medicaid Services (CMS) created the Transitional Pass-Through Payment program (TPT) to facilitate patient access to new and innovative devices that substantially improve the diagnosis or treatment of Medicare beneficiaries. TPT provides an incremental payment in addition to the payment made through the outpatient Medicare Ambulatory Payment Classification (APC) payment system.

Why was the DETOUR System granted TPT?

The DETOUR System was granted the TPT by CMS because it meets the eligibility criteria.

Newness: The DETOUR System offers the first fully percutaneous arterial bypass of long complex stenoses and occlusions in the femoral artery.

Cost: The DETOUR System meets the TPT cost criteria.

Substantial Clinical Improvement: The DETOUR System received Breakthrough Device Designation from FDA, meeting the TPT substantial clinical improvement criteria.

How to code for add-on payment

The Healthcare Common Procedure Coding System (HCPCS) code for the DETOUR System is C1604 and becomes effective on January 1, 2024. Hospitals should report this code in addition to the CPT code 0505T on claim forms for procedures involving the DETOUR System to receive the add-on payment for eligible outpatient cases.

For more information

If you have any questions, please reach out to Chip Richter at crichter@endologix.com or DETOUR@PTABAccess.com.

TPT - General Information

Eligible facilities	• Hospitals participating in the Medicare outpatient prospective payment system are eligible.
Qualified patients	• Traditional Medicare and dual-eligible (Medicare-Medicaid) fee-for-service patients are qualified.
Pass-through payment	• The pass-through payment is calculated by multiplying the hospital charges for DETOUR System by the cost-to-charge (CCR) ratio, and then subtracting the device offset amount, resulting in the pass-through payment amount. • The pass-through payment is then added to the APC amount for the total payment.

TPT - General Information (continued)

Effective date	• January 1, 2024 to December 31, 2026 (CY 2024 through 2026)
Duration	• TPT is approved for a minimum of 2 years and no more than 3 years
HCPCS code	• C1604 Graft, transmural transvenous arterial bypass (implantable), with all delivery components.

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.

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