LIMFLOW ACCESS PROGRAM

The LimFlow Access Program offers services to navigate the insurance process and submit requests on behalf of either the provider or patient.

Insurance Benefit Verifications

Preauthorization or Predetermination Requests

Appeal Submissions:

- Redetermination – Medicare Administrative Contractors
- Reconsideration – Qualified Independent Contractor
- Determination – Office of Medicare Hearings and Appeals (ALJ)
- Review by Medicare Appeals Council
- Peer to Peer Reviews
- Commercial payer appeals

To enroll in the LimFlow Access Program, or to receive resources to support your conversations with payers around LimFlow TADV, please contact Walnut Hill Medical at:

E-Mail: LimFlow@WalnutHillMedical.com
Phone: 1-888-585-4006
Fax: 945-218-6417
Monday – Friday, 9am – 6pm Central Time

LimFlow
Transforming CLTI

What is Chronic Limb-Threatening Ischemia (CLTI)?

Chronic Limb-Threatening Ischemia (CLTI) is the most severe form of Peripheral Artery Disease (PAD) and often occurs in patients suffering from diabetes, coronary artery disease, obesity, high cholesterol, and/or high blood pressure. Patients with CLTI often experience profound, chronic pain and develop wounds or infections that lead to major limb amputation, an event closely associated with increased mortality and reduced quality of life.

To relieve the symptoms of CLTI, patients today are treated primarily with conventional endovascular or open bypass surgery. In many late-stage patients, however, neither treatment option is feasible due to extensive disease in the target arteries or other anatomical constraints and are considered "no-option."

Who is LimFlow? What is the TADV Procedure?

LimFlow is a pioneer in the development of minimally invasive technology for the treatment of Chronic Limb-Threatening Ischemia (CLTI), for patients who are considered to be "no-option" CLTI patients.

The LimFlow Transcatheter Arterialization of Deep Veins (TADV) System, which received FDA Breakthrough Device Designation and then Pre-Market Approval on September 11, 2023, is designed to reestablish blood flow in the deep veins for no-option CLTI patients, by diverting blood around diseased arteries in the leg and into the tibial veins that feed the foot, bringing blood and oxygen to tissues in the foot. An abundance of oxygen in the tissue can relieve pain and promote healing of chronic wounds for many patients, while avoiding major limb amputation, and improving the patients' quality of life, thus reducing patient mortality.

The pivotal study results for the LimFlow TADV procedure were published in *The New England Journal of Medicine* and show significant reductions in major amputation, mortality, and pain, and significant improvements in functional limb salvage and wound healing for a no-option CLTI patients.[1]

This critical LimFlow TADV procedure enables physicians to offer an alternative to amputation for end-stage CLTI patients and enable functional limb preservation.

The 2024 AHA/ACC Multi-Society Guideline for the Management of Lower Extremity Peripheral Arterial Disease recommend venous arterialization as a treatment option for no-option CLTI patients and specifically mention the evidence for LimFlow TADV in the guidelines.[2]

> **Guideline Recommendations for Approach to 'No-Option' Patient with CLTI (Section 10.3.3)**
> *In patients with CLTI for whom arterialization revascularization in not an option and a lack of outflow to the foot is observed, venous arterialization may be considered for limb preservation (2b recommendation)*

Current Coding Landscape for the LimFlow TADV System:

To facilitate tracking of the LimFlow TADV procedure, effective January 1, 2021, the AMA has assigned Category III CPT code 0620T:

> *Endovascular venous arterialization, tibial or peroneal vein, 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 roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed.*

Category III CPT codes are not referred to the AMA-Specialty RVS Update Committee (RUC) for valuation because no relative value units (RVUs) are assigned to these codes. Payments for these services or procedures are based on the policies of payers and not on a yearly fee schedule.

Coverage and reimbursement are not guaranteed, and the use of CPT Code 0620T may require additional documentation to be submitted to payers in order to justify the medical necessity of the procedure performed.

Disclaimer: The coding, coverage, and payment information contained herein is gathered from various resources and is subject to change without notice. Inari-LimFlow cannot guarantee success in obtaining third-party insurance payments. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine and submit appropriate codes, charges, and modifiers for services that are rendered. Providers should contact their third-party payers for specific information on their coding, coverage, and payment policies.

Important Safety Information

LimFlow System Intended Use/Indications for Use: The LimFlow System is indicated for patients who have chronic limb-threatening ischemia with no suitable endovascular or surgical revascularization options and are at risk of major amputation. **Contraindications:** Patients with deep venous thrombus in target vein; Patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy. **Warnings and Precautions:** Use in patients with concomitant hepatic insufficiency has not been evaluated; Use in patients with poor cardiac output, e.g., NYHA Class IV, has not been evaluated; Use in pregnant and breastfeeding women has not been evaluated; Implanting the device in the distal half of the calcaneus may result in stent fracture. **Adverse Events:** Acute renal impairment requiring dialysis; Cardiac arrest, Death, Embolization, Graft rupture, trans-graft leak, site leak; Hematoma; Insufficient blood flow to foot; Ischemia; Myocardial infarction; Occlusion; Pain; Peripheral edema; Procedural bleeding; Restenosis of stented segment; Sepsis / Infection; Stent damage, implant migration; Stent graft fracture; Stent graft misplacement, deformation, or migration; The need for surgical or endovascular interventions to rectify an access site problem; Thrombosis; Vessel dissection, perforation, injury; Vessel spasm. Please reference product Instructions for Use for more information regarding indications, warnings, precautions, contraindications, and adverse events. **LimFlow ARC Intended Use/Indications for Use:** The LimFlow ARC is intended to facilitate placement and positioning of guidewires and catheters within the peripheral vasculature. The LimFlow ARC is not intended for use in the coronary or cerebral vasculature. **LimFlow V-Ceiver Intended Use/Indications for Use:** The LimFlow V-Ceiver is intended for use in the cardiovascular system to manipulate and retrieve guidewires specified in the IFU. **LimFlow Vector Intended Use/Indications for Use:** The LimFlow Vector is intended for the treatment of vascular disorders and more particularly for excising or disrupting venous valves.

Important Information: Prior to use, refer to the Instructions for Use for indications, contraindications, suggested procedure, warnings, adverse events, and precautions.

Caution: Federal (USA) law restricts these devices to sale by or on the order of a licensed healthcare practitioner.

[1] Shishehbor M, et al. Transcatheter Arterialization of Deep Veins in Chronic Limb-Threatening Ischemia. N Engl J Med. 2023;388(13):1171-80.
[2] Gornik HL, et al. J Am Coll Cardiol. 2024;83;2497-2604