SAMPLE Physician Medical Documentation / Coding:

LimFlow Transcatheter Arterialization of the Deep Veins (TADV)

LimFlow® Transforming CLTI

Patient Hx:

63-year-old male with Chronic Limb Threatening Ischemia (CLTI) and suffering from tissue loss of the right foot with prior failed attempts at revascularization. He has been a type 1 diabetic for the past 20 years and is currently on insulin. Patient has been ambulating using a cane. He has trouble sleeping due to his pain. Plan for right lower extremity transcatheter arterialization of the deep veins (TADV) using the LimFlow System, in order to restore blood supply to the lower right leg and salvage limb. Risks and benefits were discussed with the patient, and he elected to proceed.

Description of Procedure(s) Performed:

After informed consent was obtained, the patient was brought back to the operating room and placed supine on the OR table. General anesthesia was induced. Preoperative antibiotics were given. The patient's right lower extremity was prepped and draped in the usual sterile fashion.

A sterile tourniquet was applied to the right calf and inflated while obtaining venous access. We obtained percutaneous access in the Lateral Plantar Vein using ultrasound-guided micropuncture technique. An 0.018 wire was inserted and upsized to a 4Fr sheath. A glidewire was advanced through the Lateral Plantar Vein into the Posterior Tibial Vein.

Attention was then turned to the patient's right groin. We first obtained antegrade percutaneous access in the right common femoral artery using fluoroscopic and ultrasound guidance. A 0.018 wire was inserted and upsized to a 5Fr sheath over a J wire, which was advanced into the Superficial Femoral Artery (SFA). We obtained a right lower extremity angiogram, which demonstrated the right Posterior Tibial Artery had no origin disease, but occluded in the mid-calf, while the Anterior Tibial (AT) was the dominant runoff to the foot.

The J wire was exchanged for a stiff Amplatz wire. The sheath was upsized to a 7Fr destination sheath. Systemic heparin was administered. We used an end-hole catheter and 0.014 wire to select the posterior tibial artery.

We advanced the LimFlow ARC® Arterial Catheter into the proximal Right Posterior Tibial Artery. We advanced the LimFlow V-Ceiver® Venous Catheter to the Posterior Tibial vein from the Lateral Plantar Vein sheath at the same approximate level. The fluoroscopy unit was rotated in such a way as to overlay the crossing device and snare.

The LimFlow crossing device (ARC) needle was deployed into the Posterior Tibial Vein. A 0.014 wire was advanced through the crossing device into the venous snare (V-Ceiver) where it was captured and subsequently withdrawn through the venous sheath, providing through and through wire access. The arteriovenous connection was ballooned with a 3.5x40 balloon. Next, the forward cutting LimFlow Vector® Valvulotome was advanced from the arterial sheath across the arteriovenous connection into the Posterior Tibial Vein. The valvulotome was deployed and advanced down the vein in order to lyse the venous valves to the distal-most aspect of the Lateral Plantar Vein. A 5 x 200 balloon was used to angioplasty the donor vein to confirm adequate valve effacement and absence of stricture within the donor vein in preparation for stent placement.

We then deployed two LimFlow cylindrical stent grafts (5.5mm x 150mm and 5.5mm x 200mm) in the Posterior Tibial Vein from the ankle extending proximally up the calf. Next the tapered conical stent (3.5-5.5mm x 60 mm) was deployed proximally across the level of the arteriovenous connection. The stent grafts were post-dilated to 3.5mm in the arterial segment and 5.5mm in the venous segment.

Plantar sheath was retracted to allow for wiring of the metatarsal aspect of the Lateral Plantar Vein. We reintroduced the valvulotome (Vector) and advanced to efface any remaining valves in the distal aspect of the Lateral Plantar Vein. A 3.0 x 80 balloon was placed Lateral Plantar Vein and inflated. The pedal sheath was removed and venous access hemostasis was obtained. The balloon was then deflated and removed.

A completion angiogram demonstrated widely patent Posterior Tibial stents and robust filling of the pedal venous system. A closure device was deployed, the femoral sheath was removed, and manual pressure was held for 15 minutes until hemostasis was obtained. Dry sterile dressings were applied. Handheld Doppler was performed at the distal Posterior Tibial Vein, Lateral Plantar Vein, and outflow Greater Saphenous Vein and an audible pulsatile signal was heard at all points.

Plan of care:

Duplex obtained. Patient deemed medically ready for discharge to home. Front-wheeled walker delivered to him for home use. Will return in 2 weeks for non-invasive imaging.

Medical Documentation Reminders

- ☐ Hospital Admission Status: For inpatient stays, CMS requires medical necessity to be established based on the physician expectation of the patient requiring at least 2 midnights of inpatient care;[1]
- ☐ Documentation to support the history of tried and failed revascularization procedures and medical management to determine that patient has no further options than lower limb amputation, if appliable;
- ☐ Documentation to support the transcatheter arterialization procedure of the respective artery and vein that is being treated, i.e: right posterior tibial artery, right posterior tibial vein;
- ☐ Documentation to support the patient's primary AND secondary (co-morbid or complicating) conditions;
- ☐ Place of Service: Hospital Inpatient (21) or Hospital Outpatient (22)

Physician and Hospital Outpatient CPT Code Capture (*not an all-inclusive list):

- ☐ **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

Hospital Inpatient ICD-10 PCS Code Capture (*not an all-inclusive list):

- ☐ **041M3JS:** Bypass right popliteal artery to lower extremity vein with synthetic substitute, percutaneous approach
- ☐ **041N3JS:** Bypass left popliteal artery to lower extremity vein with synthetic substitute, percutaneous approach
- ☐ **041P3JS:** Bypass right anterior tibial artery to lower extremity vein with synthetic substitute, percutaneous approach
- ☐ **041Q3JS:** Bypass right anterior tibial artery to lower extremity vein with synthetic substitute, percutaneous approach
- ☐ **041R3JS:** Bypass right posterior tibial artery to lower extremity vein with synthetic substitute, percutaneous approach
- ☐ **041S3JS:** Bypass left posterior tibial artery to lower extremity vein with synthetic substitute, percutaneous approach
- ☐ **041T3JS:** Bypass right peroneal artery to lower extremity vein with synthetic substitute, percutaneous approach
- ☐ **041U3JS:** Bypass left peroneal artery to lower extremity vein with synthetic substitute, percutaneous approach

ICD-10-CM Diagnosis Codes to Support Medical Necessity (*not an all-inclusive list):

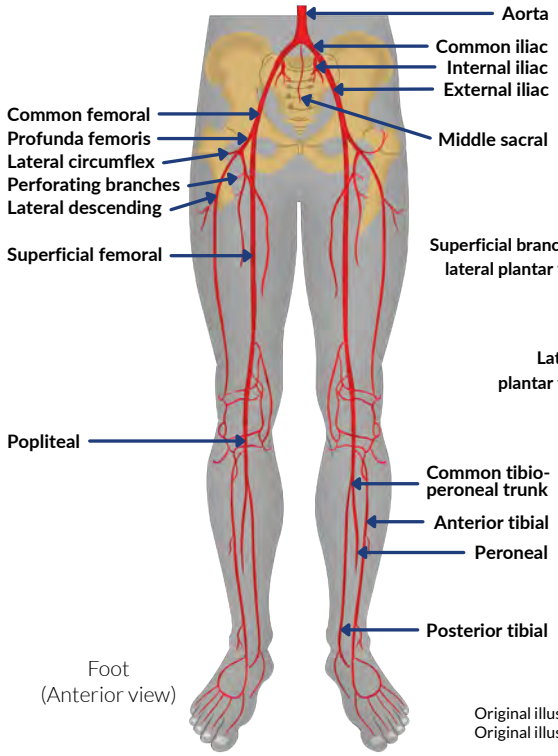
- ☐ **I70.231-I70.239:** Atherosclerosis of native arteries of right leg with ulceration
- ☐ **I70.241-I70.249:** Atherosclerosis of native arteries of left leg with ulceration
- ☐ **I70.261-I70.263:** Atherosclerosis of native arteries of legs with gangrene

With these ICD-10-CM Dx Codes, CPT requests use of an additional code to identify severity of ulcer (L97 – L98.59), if applicable.*

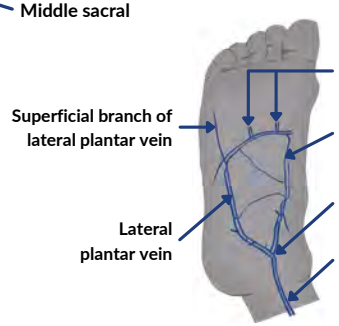
Potential Patient Secondary ICD-10 CM Dx Codes (*not an all-inclusive list):

- ☐ **I70.92:** Chronic total occlusion of artery of the extremities
- ☐ **E11.52:** Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
- ☐ **N18.6:** End stage renal disease

Arteries of the Leg



Foot
(Anterior view)



Foot
(Plantar view)

Original illustration based on pelvic and lower extremity arteries.
Original illustration based on plantar venous anatomy.

If you have questions, please email our Health Economics and Market Access Team at reimbursement@inarimedical.com

This example is for illustrative purposes only, it does not constitute medical or legal advice, and is not intended to provide guidance on documentation, diagnosis, or payment. It is the health care provider's responsibility to accurately report the patient diagnosis, the services provided, and the procedures performed, consistent with the payor's guidelines. Likewise, site of service decisions (e.g., inpatient or outpatient) are based on medical necessity and should be determined by the physician in consultation with the patient and consistent with any payor guidelines or licensing provisions. CPT® 2024 Professional Edition

*Codes shown are examples of common primary and secondary diagnoses billed with LimFlow Transcatheter Arterialization of the Deep Veins (TADV) codes based on a MedPAR analysis of FY2020-2022 claims. The entity billing Medicare and/or third-party payors is solely responsible for the accuracy of the codes assigned. Items and services that are billed to payors must be medically necessary and supported by appropriate documentation in the medical record.

References:
1. https://www.cms.gov/newsroom/fact-sheets/fact-sheet-two-midnight-rule-0

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.

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