

The LimFlow TADV System*
is the first and only
FDA PMA-Approved Device
for TADV

2025 LimFlow TADV REIMBURSEMENT GUIDE

The LimFlow Transcatheter Arterialization of the Deep Veins (TADV) System LimFlow ARC* & LimFlow Vector* Valvulotome LimFlow Extension & Crossing Stent Grafts

*LimFlow® TADV System includes the LimFlow System or LimFlow Stent Grafts, and LimFlow ARC, LimFlow Vector, and LimFlow V-Ceiver. The LimFlow System and LimFlow Stent Grafts are indicated for the treatment of chronic limb-threatening ischemia with no suitable endovascular or surgical revascularization options and are at risk of major amputation. Please refer to the Important Safety Information for these products for more details.



IMPORTANT - Please Note:

This Procedural Payment Guide for Transcatheter Arterialization of the Deep Veins (TADV) provides coding and reimbursement information for physicians and healthcare facilities. The codes included in this guide are intended to represent typical TADV procedures. The reimbursement rates shown in this guide are based on the 2025 Medicare national payment rates. Actual reimbursement will vary for each provider and facility.

Disclaimer: The information in this document is provided for educational and illustrative purposes only and is not intended to be used for making coding or billing decisions. This coding information is based upon publicly available information, is current as of January 1, 2025 and is subject to change without notice. The coding and billing information included in this document has not necessarily been drafted to comply with third-party payor requirements. Accordingly, you should review and confirm the appropriate codes and billing requirements of each of your third-party payors when billing for procedures involving the use of LimFlow's products, including consulting with your reimbursement specialists and/or legal counsel. LimFlow provides no assurance that any product or service billed with the codes listed herein will be covered or that the listed payment amount will be paid by any payor. The existence of a code does not guarantee coverage or reimbursement for services performed utilizing LimFlow products.

LimFlow is not recommending, endorsing, or making any representations or warranties regarding (i) the selection or use of any HCPCS, CPT, or ICD-10 codes for the use of its products or for related services, or (ii) compliance with any billing protocols or procedures, requirements, or prerequisites. A patient's treating physician is solely responsible for determining the medical necessity of performing a procedure and the proper site for the delivery of services. Physicians and facilities are responsible for exercising their independent clinical judgment to select appropriate codes for each patient and procedure, and to submit accurate and appropriate codes, charges, and modifiers for services rendered, in accordance with third-party payor requirements. Diagnosis codes should be determined by a patient's treating physician based upon his or her clinical judgment. The diagnosis codes in this document are only intended to serve as examples of codes that may identify no-option CLTI patients and should not be used for your patients unless you independently determine, based upon your clinical evaluation of a patient, that the ICD-10-CM code appropriately describes the patient's medical condition. The inclusion of higher-complexity or add-on codes in this document is not intended as a recommendation or suggestion that you perform or bill for such procedures. You should only utilize such codes if they accurately reflect the medically necessary procedures that you performed.

Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Please note that while this guide is intended to provide coding information for TADV procedures, the LimFlow TADV System is currently the only FDA PMA-Approved device for TADV.

2025 Billing and Coding Guide Facility and Physician

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Overview of Medicare Payment Policies

Inpatient Facility Reimbursement

Medicare uses the International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) to identify procedures in the hospital inpatient setting. Inpatient hospital services are paid via Medicare Severity-Adjusted Diagnostic Related Group Payments (MS-DRGs). The MS-DRG payment is assigned for the patient's entire length of stay and will be based on several variables, including the admitting diagnosis, patient comorbidities, and services provided during the hospital stay.

Hospital Outpatient Facility & ASC Reimbursement

In the hospital outpatient and ambulatory surgical center (ASC) settings, Medicare assigns procedures and services reported with CPT and HCPCS codes to ambulatory payment classification (APCs) payment groups. Each APC has an assigned payment rate. Hospital outpatient services and services furnished in an ASC are reimbursed under Medicare's Outpatient Prospective Payment System (OPPS) and ASC Payment System based on the APC assigned.

Physician Reimbursement

Physician services are reported using CPT and HCPCS codes. Medicare reimburses physician services according to the Medicare Physician Fee Schedule (MPFS), which is based on Relative Value Units (RVUs). RVUs are intended to measure physician work, practice expense and malpractice insurance. RVUs may differ by place of service.

Coverage by Payer Type

Traditional Medicare (Parts A/B)

Currently, there are no national or local coverage determinations (NCDs/LCDs) in place for the Transcatheter Arterialization of Deep Veins (TADV) procedure utilizing the LimFlow TADV System, represented by CPT code 0620T. This is common for innovative procedures, such as LimFlow TADV, as it takes time for explicit coverage policies to be implemented. LimFlow TADV is covered on a case-by-case basis. Generally, traditional Medicare covers FDA-approved therapies that are deemed reasonable and necessary.* Medicare beneficiaries meeting the FDA PMA-Approved indication should have access to LimFlow TADV. Please contact your Medicare Administrator Contractor (MAC) for pre-procedure guidance.

Medicare Advantage (MA) (Part C)

MA plans are required to provide the same coverage as traditional Medicare. However, in the absence of an NCD/LCD, MA plans may refer to their commercial coverage policy for guidance. Requesting prior authorization is strongly recommended and may be required.

Commercial Payers

Coverage and prior authorization requirements can vary by payer, plan, and individual policy. Requesting prior authorization is strongly recommended and may be required.

Medicaid

Coverage guidance varies by state. Contact your state authority for details. Requesting prior authorization is strongly recommended and may be required.

*42 C.F.R. § 405.201

For additional resources to navigate prior authorization and coverage for LimFlow TADV patients, visit LimFlow.com or contact <u>reimbursement@inarimedical.com</u>.

Coding for LimFlow TADV Procedure

Hospital Inpatient Facility Reimbursement

ICD-10 Procedural Coding System (PCS)

The International Classification of Diseases, 10th Edition, Procedure Coding System codes are used by hospitals to report procedures performed in the inpatient setting.

ICD-10 PCS Table Excerpt

The ICD-10-PCS code for **LimFlow** is constructed from code table 041. Transcatheter arterialization of the deep veins (TADV) with the LimFlow System is uniquely identified by the table excerpt below.

041	ICD-10-PCS Table Excerpt		
Section Body System Operation	 Medical and Surgical Lower Arteries Bypass: Altering the route of passage of the contents of a tubular body 		
Body Part Approach Device Qualifier			

	Body Part	Approach	Device	Qualifier
М	Popliteal Artery, Right	3 Percutaneous	J Synthetic Substitute	J Lower Extremity Vein
N	Popliteal Artery, Left			
P	Anterior Tibial Artery, Right			
Q	Anterior Tibial Artery, Left			
R	Posterior Tibial Artery, Right			
S	Posterior Tibial Artery, Left			
Т	Peroneal Artery, Right			
U	Peroneal Artery, Left			

Code	Description
041_3JS	Bypass to Lower Extremity Vein with Synthetic Substitute, Percutaneous Approach

Code	Description
041R3JS	Bypass Right Posterior Tibial Artery to Lower Extremity Vein with Synthetic Substitute, Percutaneous Approach

Hospital Inpatient Continued

ICD-10-PCS Codes

The following table lists ICD-10-PCS codes that describe the TADV procedure using the FDA PMA-approved therapy **LimFlow** System. Please refer to clinical documentation for appropriate ICD-10-PCS code selection.

ICD-10- PCS code ¹	Description
041M3JS	Bypass right popliteal artery to lower extremity vein with synthetic substitute, percutaneous approach
041N3JS	Bypass right 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 left 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

Medicare-Severity Diagnosis Related Groups (MS-DRGs)

Medicare reimburses hospitals for inpatient services using MS-DRGs. Common MS-DRGs for patients admitted and treated with the **LimFlow** TADV procedure are included in the following table:

MS-DRG ²	Description	FY 2025 Medicare National	Unadjusted Average Rate
252	Other Vascular Procedures w/ MCC*	\$24,481	+ NTAP
253	Other Vascular Procedures w/ CC**	\$18,220	Max of \$16,250***

^{^^}MS-DRG assignment is based on a combination of the diagnoses and procedure codes reported by the provider for the encounter. Patients receiving LimFlow typically have a qualifying CC or MCC given their severity. For example, a chronic total occlusion of the artery of the extremities (ICD-10 diagnosis code: I70.92) is a qualifying comorbidity and characteristic of no-option CLTI patients. While the MS-DRGs listed in this guide represent likely assignments, Inari cannot guarantee assignment to a specific MS-DRG.

^{*}MCC = Major Complication or Comorbidity

^{**}CC = Complication or Comorbidity

^{***}For more information on Medicare's New Technology Add-on Payment (NTAP) for LimFlow TADV, please visit https://limflow.com/us/reimbursement-resources/

Hospital Outpatient and Ambulatory Surgery Center Reimbursement

Category III CPT Code & 2025 Medicare National Payment Rates

To facilitate tracking of the new **LimFlow** TADV procedure, the AMA has assigned a Category III CPT code. This Category III CPT went into effect on January 1, 2021.

	Ambulatory Surgery Center		Hospital Outpatient ³		
ICD code description ⁴	ASC Status Indicator	Payment	APC	OPPS Status Indicator	APC Payment
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 road mapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed	N**	\$31,714	APC 1579 New Tech APC Level 42	S*	\$35,000

^{*}OPPS Payment Status Indicator "S": Identifies a procedure or service that is not subject to multiple procedure discounting. Paid under OPPS; separate APC payment.³

HCPCS Code

HCPCS Level II codes are used by providers and suppliers to identify and report drugs, devices, supplies, services, and some procedures.

The **LimFlow TADV System** Kit should be reported as a single line item under HCPCS C1889 as it is an integrated system.

Device code⁵	Description
C1889 Implantable/insertable device, not otherwise classified	

^{**}ASC Payment Status Indicator "N": Identifies a procedure or service that is not subject to multiple procedure discounting. Paid under ASC; separate payment.4

Physician Reimbursement

Category III CPT Code & 2025 Medicare National Payment Rates

The American Medical Association (AMA) has assigned the following Category III CPT code for the new TADV procedure, e.g., LimFlow TADV.

		Physic	ian Fees (POS 21, 22 or 24) ⁶
ICD code⁴	Description	RVU	Payment in Facility
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	N/A	Carrier-Priced*

^{*} Category III codes are not nationally valued. Each Medicare Administrative Contractor (MAC) is responsible for establishing its own payment rate for 0620T. These payment rates may or may not be made public. For example, First Coast Service Options (FCSO), the local MAC for Florida, has established a public carrier price of \$1414.22 for 0620T in the facility for all localities in their jurisdictions for 2025.⁷

Category III CPT Crosswalk For Establishing Physician Payment

In the absence of established RVUs for Category III CPT codes, payors rely on the use of a comparator Category I CPT code to set an RVU rate for codes without established payment. Physicians should provide a coding crosswalk to an existing Category I CPT code procedure, similar in physician time, effort, and complexity, to help guide the payor/claims processor in setting a fair and accurate reimbursement level. It will be important to document the services provided regarding resources and time for appropriate payment valuation.

It is the responsibility of the treating physician to choose the most appropriate CPT code comparator that is best representative of the work and complexity associated with the Category III CPT TADV procedure code.

Contact reimbursement@inarimedical.com for specific physician payer pricing questions

ICD-10-CM Diagnosis Codes

Payors assess the ICD-10-CM codes included on the claim to determine if the procedure/service was medically necessary for the treatment of the participant.

The following table lists commonly used principal diagnosis codes for patients being treated with LimFlow TADV for no-option CLTI.*

ICD-10- PCS code ¹	Description
	Atherosclerosis of native arteries of right leg with ulceration:
170.231	Thigh
170.232	Calf
170.233	Ankle
170.234	Heel and midfoot
170.235	Other part of foot
170.238	Other part of lower leg
170.239	Unspecified site
	Atherosclerosis of native arteries of left leg with ulceration:
I70.241	Thigh
170.242	Calf
170.243	Ankle
170.244	Heel and midfoot
170.245	Other part of foot
170.248	Other part of lower leg
170.249	Unspecified site
	Atherosclerosis of native arteries of extremities with gangrene:
170.261	Right leg
170.262	Left leg
170.263	Bilateral legs

^{*}Notes in the Tabular section and entries in the index of the ICD-10-CM instruct user to code CLTI as arteriosclerosis with critical limb ischemia With the above CLTI ICD-10-CM Dx Codes, CPT requests use of an additional code to identify severity of ulcer (L97 – L98.59), if applicable.

Secondary Diagnosis Codes Common With TADV Procedures*

ICD-10- CM code	Description	
170.92	Chronic total occlusion of artery of the extremities	
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene	
150.22	Chronic systolic (congestive) heart failure	
D62	Acute posthemorrhagic anemia	
N18.6	End stage renal disease	

^{*}Codes shown are examples of common secondary diagnoses billed with TADV ICD-10-PCS 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.

For questions related to coding, billing, and reimbursement, please contact our reimbursement hotline at **reimbursement@inarimedical.com**. Visit us at **www.limflow.com**.

References:

- 1. Centers for Medicare & Medicaid Services. International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) (Available on CMS website).
- 2. 2025 CMS IPPS Final Rule, CMS-1785-F (available on CMS website).
- 3. 2024 CMS OPPS/ASC Final Rule, CMS-FC, Addendum B https://www.cms.gov/medicare/payment/prospective-payment-systems/hospitaloutpatient/regulations-notices/cms-1809-fc https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and/cms-1809-fc.
- 4. Current Procedural Terminology (CPT®) is a registered trademark of the American Medical Association (AMA). Copyright 2025 AMA. All rights reserved.
- 5. Healthcare Common Procedure Coding System (HCPCS) Level II codes are maintained by the Centers for Medicare and Medicaid Services.
 - https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update.
- 6. 2025 CMS PFS Final Rule, CMS-F, Addendum B https://www.cms.gov/medicare/payment/fee-schedules/physician/federalregulation-notices/cms-1807-f
- 7. FCSO Part B Fee Schedule. Record Effective 01/01/2023.

Important Safety Information

LimFlow System and LimFlow Stent Grafts Intended Use/Indications for Use: The LimFlow System and LimFlow Stent Grafts are 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. Review complete Instructions for Use, Indications for Use, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product. 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: Review complete Instructions for Use, Indications for Use, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product.

*LimFlow® TADV System includes the LimFlow System or LimFlow Stent Grafts, and LimFlow ARC, LimFlow Vector, and LimFlow V-Ceiver. Please refer to the Important Safety Information for these products for more details.

For all non-Inari products, please review manufacturer complete Instructions for Use, Indications for Use, Warnings, Precautions, Possible Adverse Effects and Contraindications.

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

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