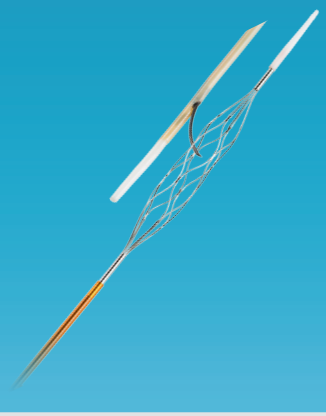
LimFlow®
Transforming CLTI

The LimFlow System is the ONLY FDA Approved Device For TADV

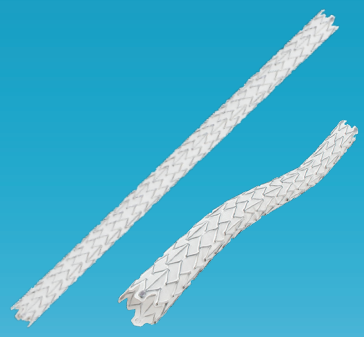
2024 LimFlow TADV REIMBURSEMENT GUIDE

LimFlow ARC & V-Ceiver



LimFlow Vector Valvulotome

LimFlow Extension & Crossing Stents



Transcatheter Arterialization of the Deep Veins (TADV) with the LimFlow System

The LimFlow System is approved by the FDA for the treatment of chronic limb-threatening ischemia (CLTI) for patients with no suitable endovascular or surgical revascularization options and are at risk for major amputation.

reimbursement@limflow.com **www.limflow.com**

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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 2024 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 **December 20, 2023** 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 System is currently the only FDA approved device for TADV.

2024 Billing and Coding Guide

FACILITY AND PHYSICIAN

CONTENTS

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 REIMBURSEMENT

In the hospital outpatient setting, 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 are reimbursed under Medicare's Outpatient Prospective Payment System (OPPS) 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.

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	**0**	Medical and Surgical
Body System	**4**	Lower Arteries
Operation	**1**	Bypass: Altering the route of passage of the contents of a tubular body

Body Part	Approach	Device	Qualifier
M Popliteal Artery, Right	**3** Percutaneous	**J** Synthetic Substitute	**S** 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			
T Peroneal Artery, Right			
U Peroneal Artery, Left			

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

LIMFLOW TADV PROCEDURE SAMPLE[1]

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-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 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 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 2024 Medicare National Unadjusted Average Rate
252	Other Vascular Procedures w/ MCC*	$23,482
253	Other Vascular Procedures w/ CC**	$17,862
254	Other Vascular Procedures w/o CC/ MCC	$12,148

*MCC = Major Complication or Comorbidity

**CC = Complication or Comorbidity

HOSPITAL OUTPATIENT FACILITY REIMBURSEMENT

CATEGORY III CPT CODE & 2024 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.

		Hospital Outpatient[3]		
CPT code[4]	Description	APC	OPPS Status Indicator	APC Payment
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 road mapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed	1578	S*	$27,501

*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 System Kit should be reported as a single line item under HCPCS C1889.

Device code[5]	Description
C1889	Implantable/insertable device, not otherwise classified

PHYSICIAN REIMBURSEMENT

CATEGORY III CPT CODE & 2024 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.

		Physician Fees (POS 21 or 22)[6]	
CPT Code	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 2024.[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.

The CPT codes below are comparator procedures codes for the TADV procedure. The time values included were obtained from the CMS-1784-F Work Time file dated December 19, 2023, and the RVUs were obtained from the CMS Addendum B dated December 19, 2023.[8]

While endovascular, TADV procedures are generally performed on an inpatient basis given the patient's severity and are considered more complex procedures given venous tortuosity, the heavy arterial calcification typically present in these patients, and the need to monitor the maturation of the new circuit and wounds.

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 LimFlow procedure code.

Potential Category I CPT Comparators for 0620T					
CPT Code	Brief Description	Physician Work RVUs	Total Physician RVUs (Facility)	2024 Medicare National Avg. Physician Payment (Facility)	Physician Intraoperative Service Time (min)
35566	Bypass graft, with vein; femoral-anterior tibial, posterior tibial, peroneal artery, or other distal vessels	32.35	48.60	$1,591	306
35556	Bypass graft, with vein; femoral-popliteal	26.75	40.76	$1,335	251
35666	Bypass graft, with other than vein; femoral-anterior tibial, posterior tibial, or peroneal artery	23.66	37.71	$1,235	150

REFERENCES

1. Centers for Medicare & Medicaid Services. International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) (Available on CMS website).
2. 2024 CMS IPPS Final Rule, CMS-1785-F (available on CMS website).
3. 2024 CMS OPPS/ASC Final Rule, CMS-1786-FC, Addendum B (Nov. 22, 2023) (available on CMS website).
4. Current Procedural Terminology (CPT®) is a registered trademark of the American Medical Association (AMA). Copyright 2023 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. 2024 CMS PFS Final Rule, CMS-1784-F, Addendum B (Nov. 2, 2023) (available on CMS website).
7. FCSO Part B Fee Schedule. Record Effective 01/01/2023.
8. 2024 CMS PFS Final Rule, CMS-1784-F, Physician Work Time (available on CMS website).

For assistance with coding, billing, and reimbursement, please contact our Prior Authorization and Reimbursement Support Services:

Pacific Therapy Access

On Behalf Of:

LimFlow®
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General Reimbursement Questions
reimbursement@limflow.com
(888) 695-3858

Prior Authorization Support
limflow@pacifictherapyaccess.com
(888) 585-4006

Visit us at www.limflow.com

LimFlow's Prior Authorization and Reimbursement Support Services can also provide assistance for prior authorization denials and post claim service denials on an as needed basis.

IMPORTANT SAFETY INFORMATION (United States)

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.