LimFlow
Transforming CLTI

LimFlow PROMISE III Category B IDE Study Reimbursement Guide

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Note: Please contact **reimbursement@limflow.com** with any reimbursement questions and to receive your hospital's locally adjusted Medicare payment rates for this procedure. This guide only includes national unadjusted Medicare payment rates.

PROMISE III CATEGORY B IDE STUDY

Thank you for participating in LimFlow's PROMISE III clinical study. The purpose of this guide is to provide PROMISE III sites with information to support Medicare reimbursement efforts related to the study.

The PROMISE III study received Category B Investigation Device Exemption (IDE) designation by the FDA. The PROMISE III study was approved for coverage by the Centers for Medicare & Medicaid Services on July 28, 2022. CMS' Approval Letter can be found at the link below.

https://www.cms.gov/medicarecoverageideapproved-ide-studies/g160156-nct05313165

IDE #: G160156

NCT #: NCT05313165

This approval means that Medicare (including Medicare Advantage plans) will cover the Category B IDE device, associated procedure, and routine care items and services furnished in the PROMISE III study. As detailed in this guide, providers must ensure that their clinical trial claims contain the proper components when billing Medicare.

While study sites are not required to obtain separate approval from local Medicare Administrative Contractors (MACs), MACs may require additional documentation to facilitate claims processing.

Non-Medicare payors are not required to provide coverage for IDE trials. Many non-Medicare payors generally determine coverage for procedures based on prior authorization. The process of seeking coverage and payment from non-Medicare payors can be challenging during an IDE trial. Not obtaining prior authorization may result in unpaid/denied claims. In the event of an unpaid/denied claim, the patient will be responsible for charges not covered by their insurance payor. LimFlow is committed to supporting you in complying with applicable requirements for coding, coverage and payment for the PROMISE III clinical study. For help with obtaining a prior authorization, please contact our Prior Authorization and Reimbursement Support Services at **limflow@pacifictherapyaccess.com**. If you choose to submit coverage requests to non-Medicare payors, please contact us for additional materials.

Finally, note that this guide includes the national unadjusted Medicare payment rates for PROMISE III LimFlow cases. To receive your hospital's local Medicare payment rates, which may be different from the national average due to adjustments Medicare makes for a hospital's geographic location, IME, DSH, outliers, etc., please contact LimFlow's reimbursement team at **reimbursement@limflow.com**. The team is also available to answer any other coding and billing questions about this study.

Thank you for your participation!

OVERVIEW OF MEDICARE PAYMENT POLICIES

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. Payment varies by geographic region.

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.

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.

CODING FOR PROMISE III CATEGORY B IDE STUDY

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.

In PROMISE III, the LimFlow transcatheter arterialization of the deep veins (TADV) procedure is intended for patients with chronic limb-threatening ischemia (CLTI) staged at Rutherford class 5 for ischemic ulceration or Rutherford class 6 for severe ischemic ulceration or gangrene with no suitable endovascular or surgical revascularization options.

The following table lists commonly used principal diagnosis codes for patients being treated with LimFlow TADV for CLTI*.

ICD-10-CM Code	Description
	Atherosclerosis of native arteries of right leg with ulceration:
I70.231	Thigh
I70.232	Calf
I70.233	Ankle
I70.234	Heel and midfoot
I70.235	Other part of foot
I70.238	Other part of lower leg
I70.239	Unspecified site
	Atherosclerosis of native arteries of left leg with ulceration:
I70.241	Thigh
I70.242	Calf
I70.243	Ankle
I70.244	Heel and midfoot
I70.245	Other part of foot
I70.248	Other part of lower leg
I70.249	Unspecified site
	Atherosclerosis of native arteries of extremities with gangrene:
I70.261	Right leg
I70.262	Left leg
I70.263	Bilateral legs
	The following diagnosis code must also be submitted on the claim in the primary or secondary position, along with any other relevant secondary diagnosis codes.
Z00.6	Encounter for examination for normal comparison and control in clinical research program

*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

SECONDARY DIAGNOSIS CODES COMMON WITH TADV PROCEDURES[1]

ICD-10-CM Code	Description
I70.92	Other and unspecified atherosclerosis Chronic total occlusion of artery of the extremities
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
N18.5	Chronic kidney disease, stage 5
I42.9	Cardiomyopathy, unspecified
D62	Acute posthemorrhagic anemia

*Codes shown are examples. 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.

CATEGORY III CPT CODE

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.

CPT Code	Description
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

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 code C1889.

HCPCS Code	Description
C1889	Implantable/insertable device, not otherwise classified

ICD-10-PCS PROCEDURE CODES

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

The following table lists ICD-10-PCS codes that uniquely describe the LimFlow TADV procedure.

ICD-10-PCS Code	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

REIMBURSEMENT FOR PROMISE III CATEGORY B IDE STUDY

CATEGORY III CODE & 2023 MEDICARE NATIONAL PAYMENT RATES

Category III codes are not nationally valued and therefore payors use different payment methodologies to determine physician reimbursement associated with the code. For Medicare claims, associated relative value units (RVUs) and payment rates for Category III codes are established by the Medicare Administrative Contractors (MACs). Each local MAC establishes its own payment rates for Category III CPT codes and may or may not make these public.

For example, the MAC, First Coast Services Options has established a public carrier price of $1414.22 for 0620T in the facility for all localities in their jurisdictions for 2023.[2]

For facilities in regions governed by other MACs, we recommend that you check with **reimbursement@limflow.com** and your local MAC to see if they have specific guidelines for pricing and billing of Category III CPT Codes.

Physician Payment

		Physician Payment[3] (POS 21 or 22)	
CPT Code[4]	Description	RVUs	Physician Payment (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 road mapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed	N/A	Carrier-Priced

Hospital Outpatient Payment

		Facility Payment[5] (POS 22)		
CPT Code	Description	APC	Description	Medicare National Average 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	5194	Level 4 Endovascular Procedures	$17,178

MEDICARE-SEVERITY DIAGNOSIS RELATED GROUPS (MS-DRGS)

Medicare assigns a hospital inpatient stay to a Medicare Severity-Diagnosis Related Group (MS-DRG) based on the reported ICD-10 diagnoses and procedure codes. Using the ICD-10-CM diagnosis codes and ICD-10-PCS procedures codes shown, patients are typically assigned to the following DRGs depending on the presence or absence of qualifying complications or comorbidities.

Hospital Inpatient Payment

DRG	Description	2023 Medicare National Unadjusted Average Rate[6]
252	Other Vascular Procedures w/ MCC	$22,933
253	Other Vascular Procedures w/ CC	$18,342
254	Other Vascular Procedures w/o CC/ MCC	$12,543

*Note that another DRG payment rate may be triggered if other procedures are performed during the same hospitalization.

Disclaimer: The LimFlow System is currently limited by Federal law to investigational use. LimFlow is providing this information to help your site adequately code claims in the PROMISE III clinical study. However, these coding suggestions do not replace seeking coding advice from the payor and/or your own coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payor for interpretation of the appropriate codes to use for specific procedures. LimFlow makes no guarantee that the use of this information will prevent differences of opinion or dispute with Medicare or other third-party payors as to the correct form of billing or the amount that will be paid to providers of service.

MEDICARE BILLING OF CATEGORY B IDE STUDIES

FACILITY BILLING

Providers must ensure that their clinical trial claims contain the proper components when billing Medicare:

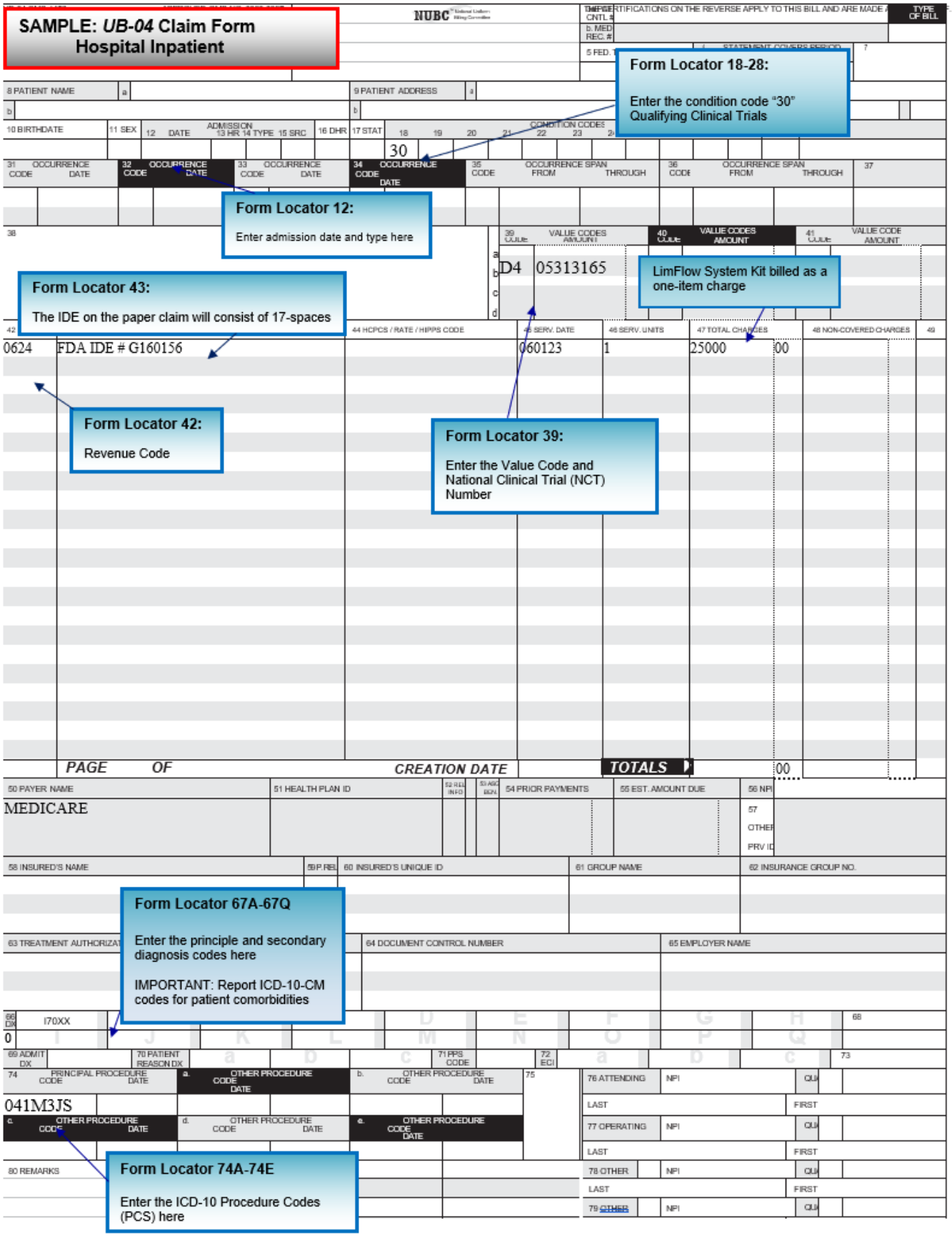
- Condition code 30 in field 18-28 of the UB-04 to denote participation in a clinical trial
- Clinical study identifier: NCT05313165
- Diagnosis code Z00.6 must be reported on all claims
- Category B IDE device HCPCS code, if applicable
- Modifiers Q0 and Q1 (Hospital Outpatient Only) (numeral 0 versus the letter O)
- Category B IDE number: G160156
- Report the device charge on the UB-04 claim form with the charges in the covered charges field:
  - For Inpatient claims: Use revenue code 0624. Report the IDE # in the Device Exempt Field in the 837I.
  - For Outpatient claims: Use revenue code 0624, HCPCS code C1889, Modifier Q0. Report the IDE # in the Device Exempt Field in the 837I. Include the LimFlow system as one line-item charge

It is the provider's responsibility to ensure that a patient meets inpatient or outpatient criteria per standard clinical practice.

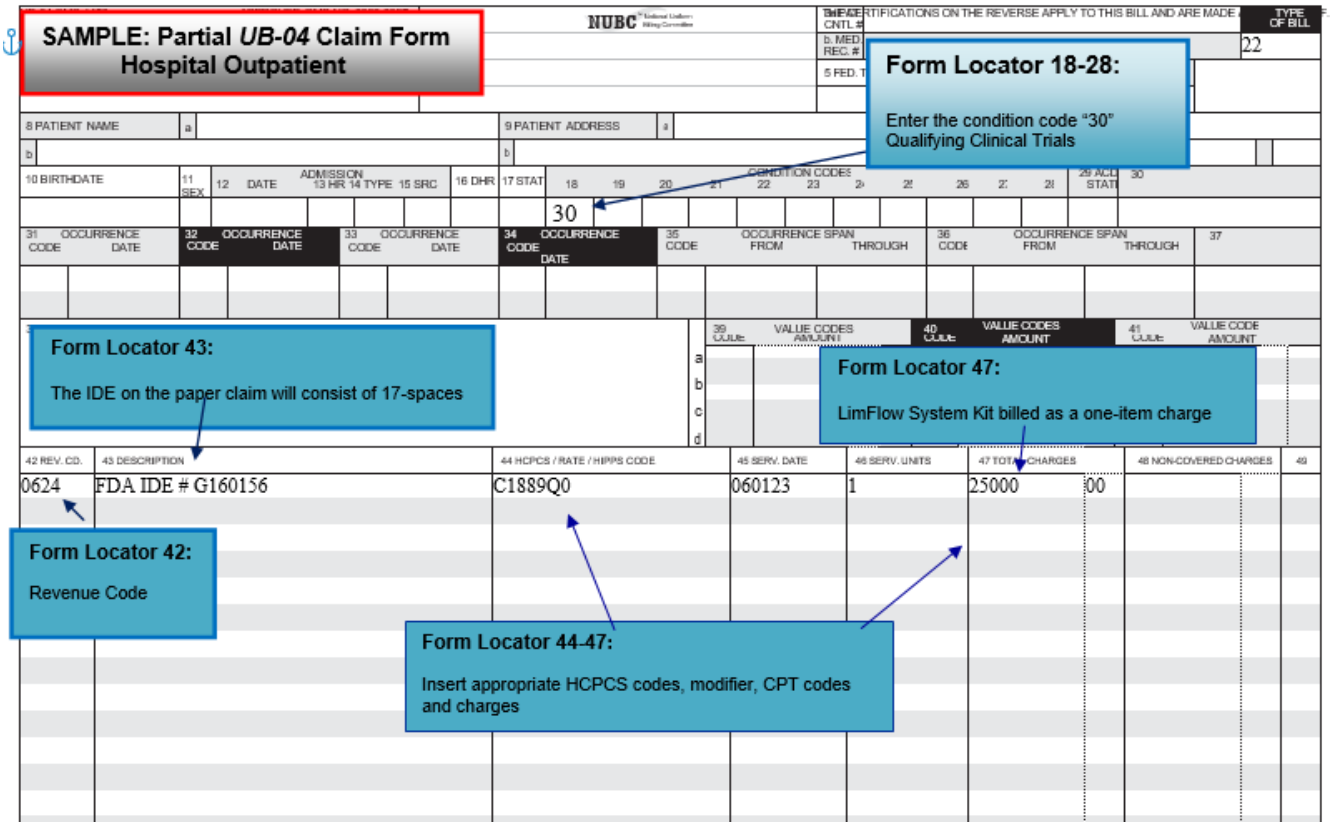
Table 2: Facility Claims Billing and Coding Requirement

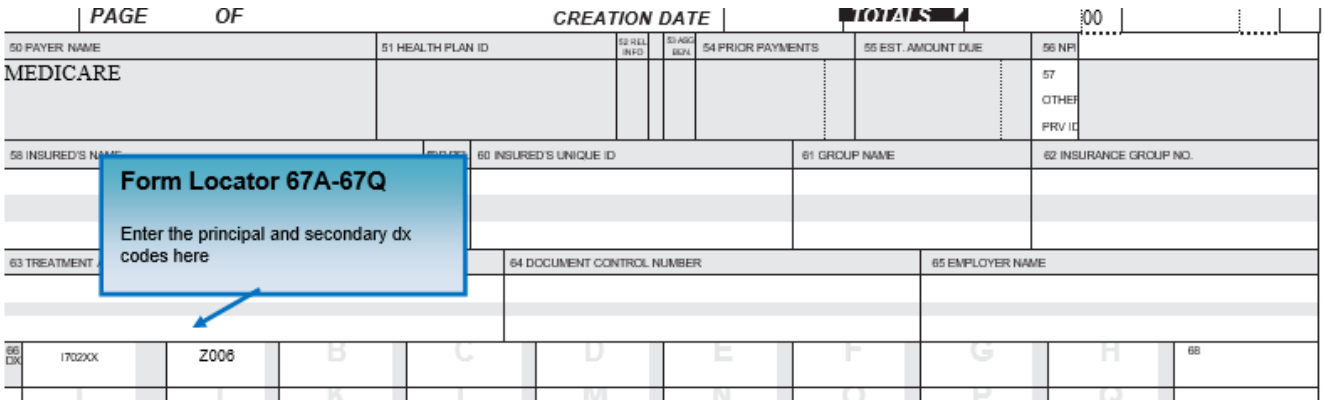
Principal Diagnosis Code	One of the following ICD-10 diagnosis codes for atherosclerosis with ulceration or gangrene: I70.231-I70.239: Atherosclerosis of native arteries of right leg with ulceration I70.241-I70.249: Atherosclerosis of native arteries of left leg with ulceration I70.261-I70.263: Atherosclerosis of native arteries of legs with gangrene
Secondary Diagnosis Code(s)	Z00.6: Encounter for examination for normal comparison and control in clinical research program (primary or secondary position) I70.92: Chronic total occlusion of artery of the extremities (if applicable) **Plus:** the ICD-10-CM code(s) for any comorbidities
Bill Type	11X: Hospital Inpatient 13X: Hospital Outpatient 85X: Critical Access Hospital
Condition Code	30 – Qualifying Clinical Trial (UB-04 - Field 18-28)
Clinical Study Identifier	For a paper UB-04, hospital bills D4 plus the NCT # in FL 39-41 (numeric only) For electronic billing with the 837I, the NCT # is entered with P4 in the equivalent field in the 2300 Loop (Demonstration Project ID) **NCT #: 05313165**
Clinical Study Device	Field 42 - Revenue 0624 Field 43 – FDA investigational devices Field 44 – HCPCS Code C1889 (outpatient only), Q0 modifier (outpatient only) Field 46 – Unit of 1 Field 47 – Device charge/cost (Include the LimFlow System Kit as one line-item charge) For electronic billing with the 837I, the IDE # is entered in the equivalent field in the 2300 Loop (IDE# only e.g., G160156)

SAMPLE UB-04/CMS-1450: HOSPITAL INPATIENT DEPARTMENT



SAMPLE UB-04/CMS-1450: HOSPITAL OUTPATIENT DEPARTMENT





PHYSICIAN BILLING

The billing provider must include in the medical record the following information: trial name, sponsor and sponsor-assigned protocol number. This information does not need to be submitted with the claim but must be provided if requested for medical review.

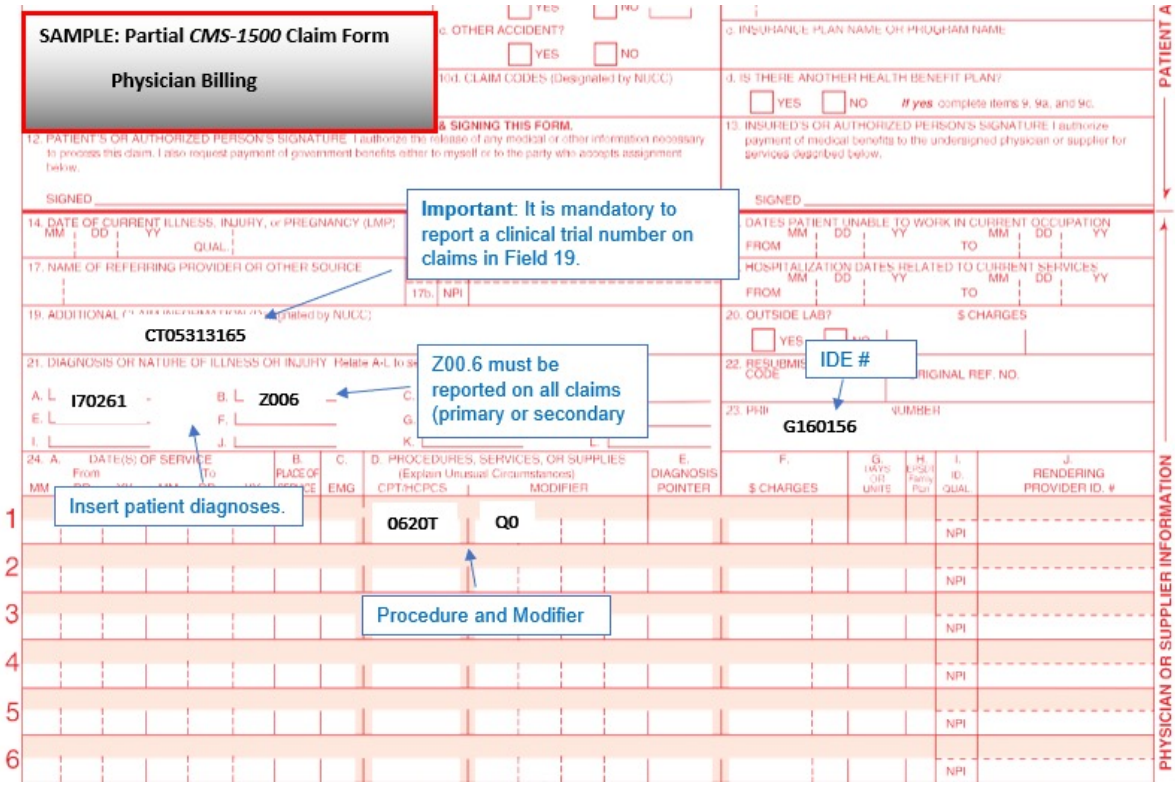
Providers must ensure that their clinical trial claims contain the proper components when billing Medicare:

- Clinical study identifier: NCT05313165
- Diagnosis code Z00.6 must be reported on all claims
- Required modifiers on all CPT codes to indicate the services were provided as part of an IDE study
- CPT procedure code: 0620T

Table 1: Physician Claim Billing and Coding Requirements

Clinical study identifier	For a paper CMS-1500: physician bills "CT" plus the numeric NCT # in Item 19 (i.e., CT05313165) For electronic billing with the 837P, the NCT # (numeric only) is entered with code P4 in the equivalent field in the 2300 Loop (Demonstration Project ID). Do not use 'CT' on electronic claim. **NCT #: 05313165**
Principal Diagnosis Code	One of the following ICD-10 diagnosis codes for atherosclerosis with ulceration or gangrene: 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
Secondary Diagnosis Code	Z00.6: Encounter for examination for normal comparison and control in clinical research program (primary or secondary position) I70.92: Chronic total occlusion of artery of the extremities (if applicable) **Plus:** the ICD-10-CM code(s) for any comorbidities
Place of Service	21: Inpatient hospital 22: Outpatient hospital (on-campus)
CPT Procedure 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 road mapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed
Modifiers	Q0: Identifies the investigational Category B device (i.e., LimFlow System) provided in the approved clinical study Q1: Identifies item/services that constitute medically necessary routine patient care or treatment of complications in an approved clinical research study

SAMPLE CMS 1500: PHYSICIAN



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.

Recommended items to support your Category III claims submissions include:

- CMS' Coverage Approval Letter for PROMISE III (attached)
- Copy of operative or procedure report (Note: Enter the Investigational Device Exemption (IDE) number (G160156) when an investigational device is used in an FDA-approved clinical trial. The NCT number should also be placed here (NCT #05313165)
- Clinical notes (severity of calcification)
- Relevant crosswalk Category I CPT code with anticipated payment indicated
- Document any differences in work for the service associated with the LimFlow procedure as a percentage increase or decrease of the work for the comparison service
- Include a statement on Box 19 of the paper 1500 form or in the NTE 2400 Field (line note) of an electronic claim form indicating "0620T is comparable to reference code XXXXX, payment of $Y expected." (Note: this narrative field is limited to 80 characters)

The following CPT codes for lower extremity surgical bypass procedures are potential examples of Category I CPT procedure codes that LimFlow Study investigators have identified as most similar to 0620T in terms of physician time and intensity needed for treatment planning, the procedure itself and post-procedure care. They did not feel there was a comparable lower extremity endovascular procedure. 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 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)	2023 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	48.47	$1,643	306
35556	Bypass graft, with vein; femoral-popliteal	26.75	40.66	$1,378	251
35666	Bypass graft, with other than vein; femoral-anterior tibial, posterior tibial, or peroneal artery	23.66	37.65	$1,276	150

Notes

- **Source for crosswalk RVU and payment information:** Medicare 2023 Physician Facility Payment and RVUs, 2023 Medicare Physician Fee Schedule, Addendum B. CMS CY2023 PFS Final Rule Physician Time File; Available at https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1770-f
- **Disclaimer:** It is ultimately the physician's responsibility to choose the most appropriate CPT code comparator that is best representative of the work and complexity associated with Category III CPT Code 0620T.

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

Pacific Therapy Access

On Behalf Of:

LimFlow
Transforming CLTI

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.

REFERENCES

[1]Results from Promise II Study published in The New England Journal of Medicine.
[2]FCSO Part B Fee Schedule. Record Effective 01/01/2023.
[3]2023 CMS PFS Final Rule, CMS 1770-F, Addendum B (JAN. 30, 2023) (available on CMS website).
[4]Current Procedural Terminology (CPT®) is a registered trademark of the American Medical Association (AMA). Copyright 2022. AMA. All rights reserved.
[5]2023 CMS OPPS/ASC Final Rule, CMS 1772-FC, Addendum B (Nov. 1, 2022) (available on CMS website).
[6]Rates effective October 1, 2022, through September 30, 2023. Source: FY 2023 Hospital Inpatient Prospective Payment System Final Rule, CMS- 1771-FC, Centers for Medicare & Medicaid Services