



APC Reassignment Request for CPT 0620T

Transcatheter Arterialization
of the Deep Veins (TADV)

Advisory Panel on Hospital Outpatient Payment
August 21-22, 2023

Request Summary

Presenters:

- John McInnes, Arnold & Porter
- Dr. Miguel Montero-Baker, Vascular Surgeon, LimFlow Pivotal Study Investigator

We request the Panel recommend that CMS temporarily reassign CPT code 0620T from APC 5194 to New Tech APC 1579 for CY 2024 to more accurately reflect the resources used.

- 0620T describes transcatheter arterialization of the deep veins (TADV) with the LimFlow System, a new implant procedure for patients with chronic limb-threatening ischemia (CLTI) who have no suitable surgical or endovascular options and are at risk of major amputation.
- Current assignment of 0620T to APC 5194 results in significant underpayment based on the reported cost from claims during the LimFlow Pivotal Study. PMA approval expected by end of August 2023.
- Not providing payment commensurate with the costs to hospitals limits beneficiary access to this critical therapy and risks further exacerbating disparities in an already vulnerable patient population.

Unmet Need Addressed by TADV LimFlow Therapy

No-Option Chronic Limb Threatening Ischemia (CLTI)

>50%

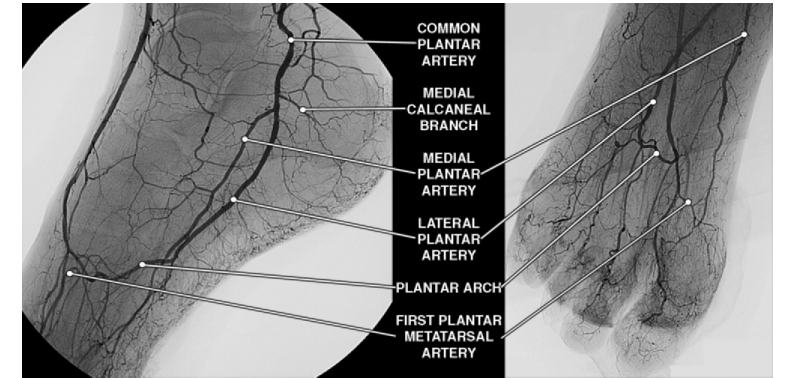
of no-option patients die
or require major
amputation within 6 mos²



4 X

Greater risk of major
amputation for Black
Americans³

NORMAL FOOT



SEVERE ISCHEMIA

No acceptable **arterial**
target for standard
revascularization



CHRONIC WOUNDS

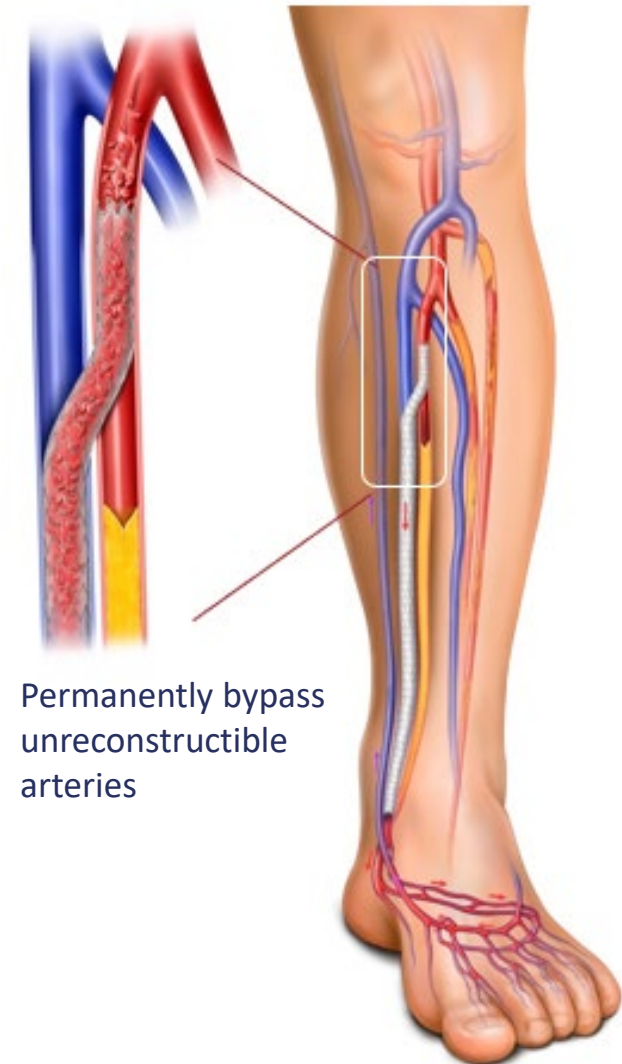
Typically do not heal
without successful
reperfusion



Images courtesy of Dr. Roberto Ferraresi

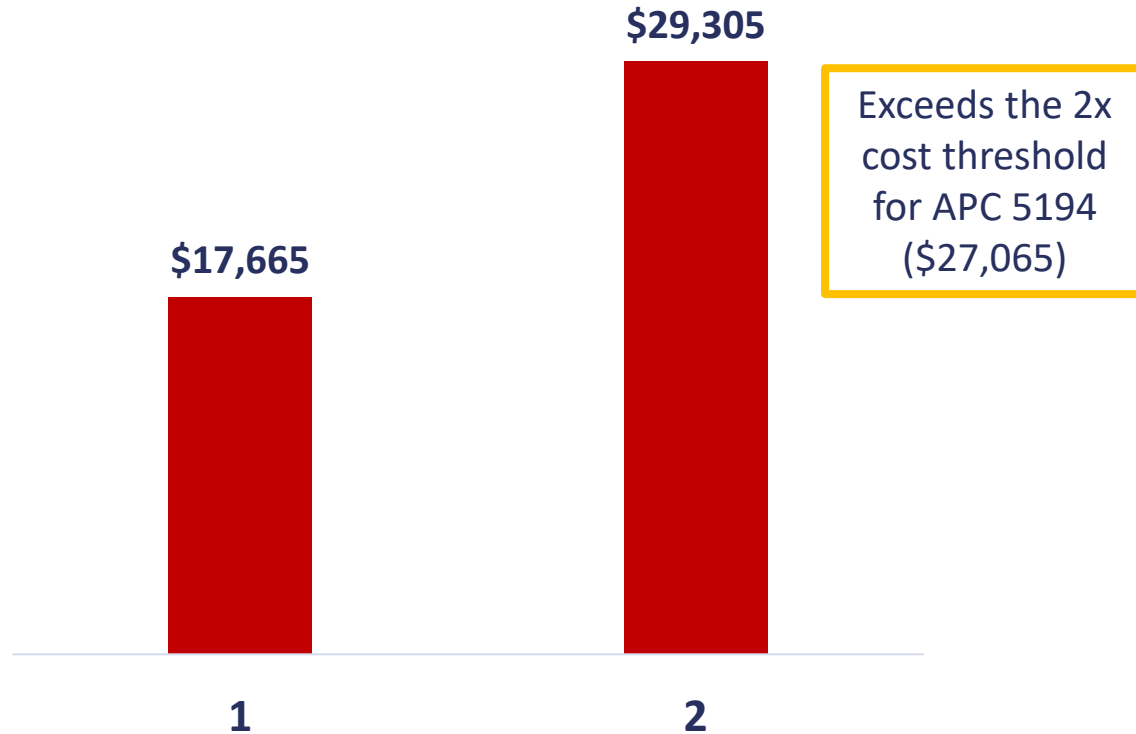
Transcatheter Arterialization of the Deep Veins (TADV) with the LimFlow System

- Creates new routes to deliver oxygenated blood to the ischemic foot to avoid amputation
- *New England Journal of Medicine* publication of positive clinical outcomes after TADV with the LimFlow System⁴
 - 76% functional limb preservation in patients who otherwise faced amputation
- U.S. FDA PMA approval of the LimFlow System for TADV is expected by end of August 2023
 - Currently available to patients in Medicare-covered Category B IDE Continued Access Study (PROMISE III)
 - Expect to be first FDA-approved TADV system



2022 Hospital Outpatient Claims Indicate Costs of CPT 0620T Are Well Above the Costs of Procedures in Existing Clinical APC 5194

Geometric Mean Costs (GMC, 2022)



CPT 0620T Claims (2022)

- Arithmetic Mean = \$31,057
- Median = \$32,774
- GMC = \$29,305

This claims data provides a conservative estimate of total hospital cost of the procedure following FDA approval because these claims were during the LimFlow Pivotal IDE trial when hospitals were not incurring the full cost of the LimFlow System.

Total Estimated Cost for LimFlow TADV Case Supports Reassignment to New Tech APC 1579

Estimated Procedure Costs to Hospital		LimFlow System Cost Per Case to Hospital		Estimated Total Cost for LimFlow TADV Case
\$6,000 to \$8,000	+	\$25,000	=	\$31,000 to \$33,000

Calculation Detail:

Deduct the device offset for 0620T from the GMC of 0620T to estimate TADV procedure costs of TADV *excluding* the LimFlow Device System cost

- \$6,142 for 2022 claims (CY24 NPRM)
- \$7,780 for 2021 claims (CY23 NFRM)

LimFlow System:

- LimFlow Arterial Catheter
- LimFlow Venous Catheter
- LimFlow Valvulotome
- LimFlow Conical Stent Graft and Cylindrical Stent Grafts

*Sold as an integrated system.
Components are single use.*

Recommend temporary assignment to New Tech APC 1579 (\$30,001 - \$40,000)

- APC 5194 is the highest paying endovascular APC with a proposed payment of \$17,195 in CY 2024
- No other clinical APC to which 0620T could be appropriately assigned

CPT 0620T went into effect January 1, 2021.
5 claims in 2022 and 9 claims in 2021 for 0620T.

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References

1. M. Imran Ghare, MD et al, Outcomes Among Patients With Chronic Critical Limb Ischemia With No Revascularization Option: Systematic Review and Meta-Analysis J CRIT LIMB ISCHEM 2021;1(3):E85-E92. Epub 2021 August 18.
2. Norgren, L, Hiatt, WR, Dormandy, JA, Nehler, MR, Harris, KA, & Fowkes, FGR. Inter-society consensus for the management of peripheral arterial disease (TASC II). J Vasc Surg, 2007; 45(1), S5–S67. [https://www.jvascsurg.org/article/S0741-5214\(06\)02296-8/fulltext](https://www.jvascsurg.org/article/S0741-5214(06)02296-8/fulltext).
3. Creager et al. Reducing Nontraumatic Lower-Extremity Amputations by 20% by 2030: Time to Get to Our Feet: A Policy Statement From the American Heart Association. Circulation 2021
4. Shishehbor MH, Powell RJ, Montero-Baker MF, Dua A, Martínez-Trabal JL, Bunte MC, Lee AC, Mugglin AS, Mills JL, Farber A, Clair DG; PROMISE II Investigators. Transcatheter Arterialization of Deep Veins in Chronic Limb-Threatening Ischemia. N Engl J Med. 2023 Mar 30;388(13):1171-1180.