



ENSURING MEDICARE BENEFICIARY ACCESS TO PERIPHERAL INTRAVASCULAR LITHOTRIPSY (IVL)

ADVISORY PANEL ON HOSPITAL OUTPATIENT PAYMENT | 31 AUGUST 2020

Summary of Shockwave Medical Presentation

Presenters

Robert Fletcher
John Argiro
Mark Domyahn

VP Marketing & Market Access, Shockwave Medical
Sr Director Reimbursement, Shockwave Medical
Partner, JD Lymon

CPT / HCPCS codes involved

C9764, C9765, C9766, C9767

APCs affected

APC 5192, 5193, 5194

Description of the issue(s)

The current APC assignments for IVL create a significant financial disincentive to use or code IVL therapy in tibial and peroneal arteries, impeding Medicare beneficiary access to care as well as the collection of appropriate data for future rate-setting.

Clinical description of service

IVL treatment utilizes lithotripsy (sound waves) to fracture arterial calcium, leading to safer, more effective treatment heavily calcified lower extremity arteries

Recommendation & Rationale for Change

CMS should: 1) reassign HCPCS code C9764 to APC 5193 and 2) reassign HCPCS codes C9765 and C9766 to APC 5194. These reassignments would remove the financial disincentive to report the IVL C-codes and more appropriately align with the hospital resources needed to complete the procedures, helping to ensure Medicare beneficiary access to this important advancement in care.

Potential Consequence of Not Making Change

If the change is not made, Medicare beneficiaries will not have adequate access to IVL in below-the-knee procedures. Moreover, CMS is unlikely to be able to collect the data necessary for appropriate rate-setting for IVL procedures in the future.

IVL = Intravascular Lithotripsy

Goal of Vascular Intervention

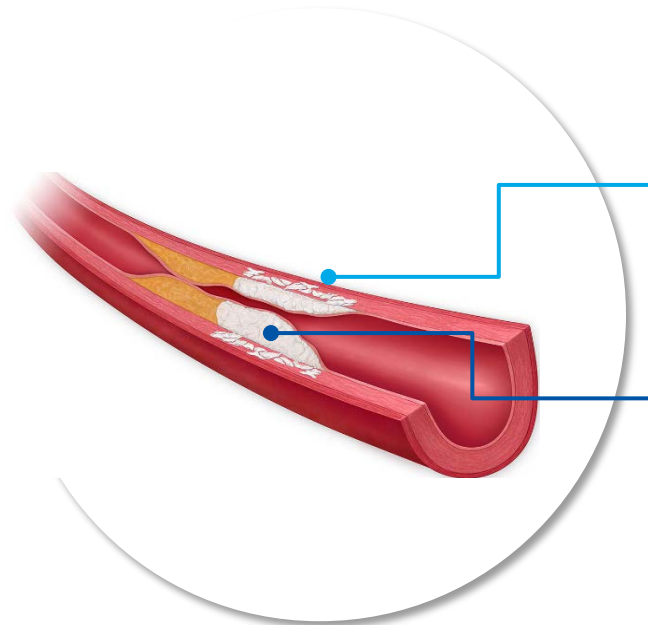
Restore Vessel Lumen and Blood Flow

Atherosclerosis

Disease of aging in which arteries become narrowed (“stenotic”) by the progressive growth of plaque.

Calcium in atherosclerotic plaque can prevent therapies from opening the stenotic artery.

Peripheral Artery Disease (PAD):



US
Prevalence¹

8.5
Million

Interventional
Procedures²

750
Thousand

Complex, Calcified
Lesions³

10-20%

Medial (“Deep”) Calcium

Calcification in middle layer
(associated with stiffening)

Intimal (“Superficial”) Calcium

Calcification close to the inner
surface of the artery (associated
with obstruction and embolization)

Calcified Arteries Resist Expansion Resulting in More Complications and Vessel Damage

¹<https://www.cdc.gov/heartdisease/PAD.htm>

²Decision Resources Group | Peripheral Vascular Disease 2018

³J Vasc Surg . 2015 October ; 62(4): 998–1002. [10.1016/j.jvs.2015.04.450](https://doi.org/10.1016/j.jvs.2015.04.450)

Intravascular Lithotripsy (IVL)

Lithotripsy Has A History of Safely Cracking Calcium

Lithotripsy

Method has 30 years of success for safe elimination of kidney stones

Sonic pressure waves preferentially crack calcium without harming soft tissue

Shockwave's Intravascular Lithotripsy

Miniaturized, localized treatment

Sound waves pass through soft tissue to crack calcium

Vessel then expands under low pressure balloon dilation



Coding considerations

- IVL can be used as a standalone or in conjunction with other therapies.
- IVL is additive to procedure costs and does not replace any devices or supplies when performing procedures.

IVL = Intravascular Lithotripsy

Description of Issue: IVL Payment Assignment

- Currently, 16 CPT® Codes describe Lower Extremity Revascularization (LER) procedures and are differentiated by:
 - Anatomical location of procedure (i.e. iliac, femoral/popliteal or tibial/peroneal)
 - Procedural device(s) utilized (i.e. balloon angioplasty, stent and/or atherectomy)
 - APC assignment varies by anatomical location in a non-uniform matter
 - Current CPT codes do not appropriately describe IVL as it represents a distinct therapy
- In 2019, Shockwave requested C-codes that mirror current 16 CPT code structure to initiate claims data collection and payment in the hospital outpatient setting
- On July 1, CMS created 4 C-codes for IVL and assigned them to clinical APCs
 - Unlike the LER CPT structure (16-codes), the 4 IVL C-codes do not distinguished by anatomical location of procedure (e.g. iliac, femoral/popliteal or tibial/peroneal)
 - The current APC assignments creates payment disparity for the most severe PAD patients

Current Procedural Terminology or CPT® is a registered trademark of the American Medical Association

LER = Lower Extremity Revascularization. Refers to the basket of CPT codes that currently describe lower extremity revascularization procedures.

IVL is Additive To Resources Required to Perform Lower Extremity Revascularization Procedures

Methodology: Recalculated 2021 Procedure GMCs Including Cost of IVL Catheters¹

| Vessel | CPT Code | Procedure | Proposed 2021 Geometric Mean Cost (GMC) ² | APC Assignment | 2021 APC Payment | Revised 2021 GMC <u>with</u> IVL Cost |
|---------------------|----------|---------------------------------|--|----------------|------------------|---------------------------------------|
| Iliac | 37220 | Transluminal angioplasty | \$6,619.26 | 5192 | \$5,049 | \$10,193.01 |
| | 37221 | Stent placement | \$10,308.02 | 5193 | \$10,222 | \$13,871.08 |
| Femoral / Popliteal | 37224 | Transluminal angioplasty | \$7,151.20 | 5192 | \$5,049 | \$10,700.40 |
| | 37225 | Atherectomy | \$13,587.83 | 5193 | \$10,222 | \$17,100.54 |
| | 37226 | Stent placement | \$11,646.01 | 5193 | \$10,222 | \$15,223.66 |
| | 37227 | Atherectomy and Stent placement | \$20,054.79 | 5194 | \$16,349 | \$23,580.84 |
| Tibial / Peroneal | 37228 | Transluminal angioplasty | \$8,690.31 | 5193 | \$10,222 | \$12,258.39 |
| | 37229 | Atherectomy | \$15,804.84 | 5194 | \$16,349 | \$19,393.29 |
| | 37230 | Stent placement | \$14,994.38 | 5194 | \$16,349 | \$18,678.42 |
| | 37231 | Atherectomy and Stent placement | \$22,305.36 | 5194 | \$16,349 | \$25,887.72 |

¹IVL Average Procedure Cost equals catheter average sales price (\$2,800) multiplied by average catheters per case (1.2). Madhaven, M, et al . CCI. 2019; DOI: 10.1002/ccd.28729

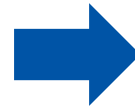
²Geometric Mean Cost (GMC) – CMS-1736-P, 2021 NPRM CPT Cost Stats.07242020.xls

Current APC Assignments for IVL C-Codes Reduce Payment Levels

Creates a Significant Financial Disincentive For IVL Therapy in Tibial And Peroneal Arteries

Proposed 2021 Payment Without IVL¹

| CPT® Code ² | | Tibial / Peroneal |
|------------------------|-----------------------|----------------------|
| 37228 | PTA ³ | APC 5193 \$10,222 |
| 37230 | PTA+Stent | APC 5194 \$16,349 |
| 37229 | PTA+Atherectomy | |
| 37231 | PTA+Stent+Atherectomy | |



Proposed 2021 Payment With IVL¹

| C-Code | | Tibial / Peroneal |
|--------|---------------------------|----------------------|
| C9764 | IVL+PTA | APC 5192 \$5,049 |
| C9765 | IVL+PTA+Stent | APC 5193 \$10,222 |
| C9766 | IVL+PTA+Atherectomy | |
| C9767 | IVL+PTA+Stent+Atherectomy | APC 5194 \$16,349 |

Lower

- For CY 2021, the IVL C-Codes reimburse ~\$5,000-\$6,000 **less** than three of four similar tibial peroneal procedures when IVL is not performed, despite IVL not replacing any current hospital resources to complete these procedures
- We believe that this mapping is not consistent with CMS's goals of facilitating patient access and accurate cost data collection

¹CMS-1736-P, Addendum B

²CPT® is a registered trademark of the American Medical Association

³PTA = Percutaneous Transluminal Angioplasty

CMS Should Reassign Three of the IVL C-Codes to More Appropriate APCs

APC reassignment will reduce financial disincentives to use and report IVL C-codes and more appropriately aligns with the hospital resources to complete the procedures

| HCPCS | Description | Current APC Assignment ¹ | | Proposed APC Assignment | |
|--------------|---|-------------------------------------|----------|-------------------------|-----------------|
| | | APC | Payment | APC | Payment |
| C9764 | Revascularization, endovascular, open or percutaneous, <u>any vessel(s)</u> ; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed | 5192 | \$5,049 | 5193 | \$10,222 |
| C9765 | Revascularization, endovascular, open or percutaneous, <u>any vessel(s)</u> ; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed | 5193 | \$10,222 | 5194 | \$16,348 |
| C9766 | Revascularization, endovascular, open or percutaneous, <u>any vessel(s)</u> ; with intravascular lithotripsy, and atherectomy, includes angioplasty within the same vessel(s), when performed | 5193 | \$10,222 | 5194 | \$16,348 |
| C9767 | Revascularization, endovascular, open or percutaneous, <u>any vessel(s)</u> ; with intravascular lithotripsy, and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed | 5194 | \$16,348 | 5194 | \$16,348 |

¹ CMS-1736-P, Addendum B

Changing APC Assignment Better Aligns with Hospital Resources Required to Perform IVL and Reduces Disincentives

Assign IVL C-Codes to APCs 5193 and 5194

| Vessel | IVL HCPCS Code | Procedure | Revised 2021 GMC <u>with</u> IVL Cost | Current APC Assignment | Appropriate APC Assignment with IVL | 2021 APC Payment |
|---------------------|----------------|-----------------------------|---------------------------------------|------------------------|-------------------------------------|------------------|
| Iliac | C9764 | IVL + PTA | \$10,193 | 5192 | 5193 | \$10,222 |
| | C9765 | IVL + Stent | \$13,871 | 5193 | 5194 | \$16,349 |
| Femoral / Popliteal | C9764 | IVL + PTA | \$10,700 | 5192 | 5193 | \$10,222 |
| | C9766 | IVL + Atherectomy | \$17,101 | 5193 | 5194 | \$16,349 |
| | C9765 | Stent placement | \$15,224 | 5193 | 5193 | \$16,349 |
| | C9767 | IVL + Atherectomy and Stent | \$23,581 | 5194 | 5194 | \$16,349 |
| Tibial / Peroneal | C9764 | IVL + PTA | \$12,258 | 5192 | 5193 | \$10,222 |
| | C9766 | IVL + Atherectomy | \$19,393 | 5193 | 5194 | \$16,349 |
| | C9765 | Stent placement | \$18,678 | 5193 | 5194 | \$16,349 |
| | C9767 | IVL + Atherectomy and Stent | \$25,888 | 5194 | 5194 | \$16,349 |

Shockwave asks the HOP Panel to recommend that CMS:

- Reassign HCPCS code C9764 to APC 5193 and
- Reassign HCPCS codes C9765 and C9766 to APC 5194.

