



**ENSURING MEDICARE BENEFICIARY ACCESS TO
PERIPHERAL INTRAVASCULAR LITHOTRIPSY (IVL)**
ADVISORY PANEL ON HOSPITAL OUTPATIENT PAYMENT | 23 AUGUST 2021

Summary of Shockwave Medical Presentation

Presenters

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CPT / HCPCS codes involved

C9764, C9765, C9766

APCs affected

APC 5192, 5193, 5194

Description of the issue(s)

The current APC assignments for IVL impede Medicare beneficiary access to care by creating a significant financial disincentive to utilize IVL therapy in various procedures

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 more appropriately align with the reported hospital resources needed to complete the procedures, helping to ensure Medicare beneficiary access to this important advancement in care. Medicare claims available demonstrate the resources required for these procedures and support APC reassignment.

Potential Consequence of Not Making Change

If the change is not made, Medicare beneficiaries will not have adequate access to IVL in various procedures

IVL = Intravascular Lithotripsy

Goal of Vascular Intervention

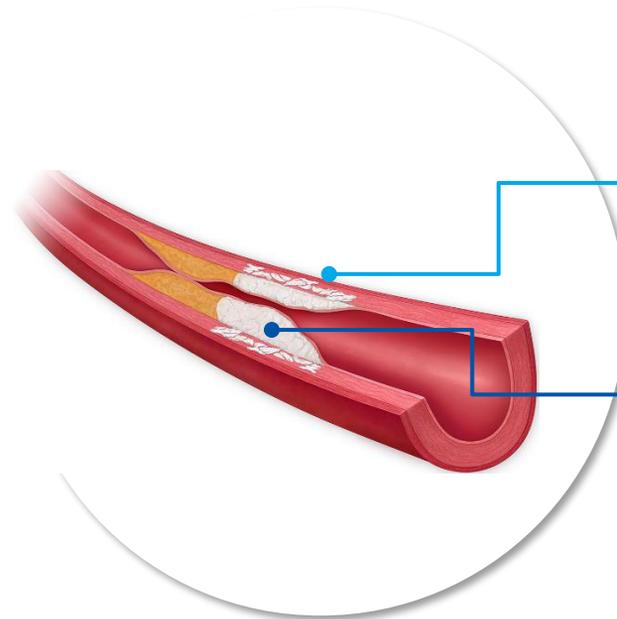
Restore Vessel Lumen and Blood Flow

Atherosclerosis

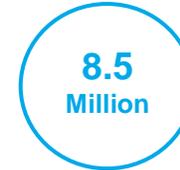
Disease of aging in which arteries become narrowed (“stenotic”) by the progressive growth of plaque.

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

Peripheral Artery Disease (PAD):



US Prevalence¹



Interventional Procedures²



Complex, Calcified Lesions³



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
 - 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
- Effective July 1, 2019, CMS created four HCPCS codes (C9764-C9767) for IVL and assigned them to clinical APCs
 - Unlike the LER CPT structure (16-codes), the 4 IVL C-codes do not distinguish by anatomical location of procedure (e.g., iliac, femoral/popliteal or tibial/peroneal)
- Effective January 1, 2020, CMS created four additional HCPCS codes for IVL (C9772-C9775) to distinguish procedures performed in the tibial and peroneal arteries (aka below-the-knee (BTK))

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.

CMS Coding for IVL Procedures

July 1, 2020

	HCPCS
IVL + PTA	C9764
IVL + PTA + Stent	C9765
IVL + PTA + Atherectomy	C9766
IVL + PTA + Stent + Atherectomy	C9767

- 4 IVL Codes created
- No anatomical differentiation
- Unlike LER procedures, BTK was not paid higher than ATK

August 31st, 2020

Hospital Outpatient Advisory Panel

- Panel recommends APC reassignment
- Condition: IVL cost is within 10% of other LER therapies (atherectomy)

LER = Lower Extremity Revascularization procedures
 PTA = Percutaneous Transluminal Angioplasty
 ATK = Above the Knee; Iliac or Femoral Popliteal Arteries
 BTK = Below the Knee; Tibial Peroneal Arteries

January 1, 2021

	HCPCS – ATK	HCPCS – BTK
IVL + PTA	C9764	C9772
IVL + PTA + Stent	C9765	C9773
IVL + PTA + Atherectomy	C9766	C9774
IVL + PTA + Stent + Atherectomy	C9767	C9775

- 8 IVL codes, 4 New BTK codes
- Updated ATK descriptors
- More appropriate APC assignment for BTK
- IVL added to ASC procedure list

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

Methodology: Recalculated 2022 Procedure GMCs Including Cost of IVL Catheters¹

Vessel	CPT Code	Procedure	Proposed 2022 Geometric Mean Cost (GMC) ²	APC Assignment	Proposed 2022 APC Payment	Revised 2022 GMC <u>with</u> IVL Cost
Iliac	37220	Transluminal angioplasty	\$6,354.67	5192	\$5,086	\$9,889
	37221	Stent placement	\$10,217.55	5193	\$10,309	\$13,765
Femoral / Popliteal	37224	Transluminal angioplasty	\$7,117.31	5192	\$5,086	\$10,657
	37225	Atherectomy	\$13,507.00	5193	\$10,309	\$16,997
	37226	Stent placement	\$11,561.24	5193	\$10,309	\$15,127
	37227	Atherectomy and Stent placement	\$20,031.54	5194	\$16,484	\$23,514
Tibial / Peroneal	37228	Transluminal angioplasty	\$8,657.90	5193	\$10,309	\$12,212
	37229	Atherectomy	\$15,612.54	5194	\$16,484	\$19,168
	37230	Stent placement	\$14,753.98	5194	\$16,484	\$18,410
	37231	Atherectomy and Stent placement	\$20,114.50	5194	\$16,484	\$23,555

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

²Geometric Mean Cost (GMC) – CMS-1753-P, 2022 NPRM CPT Cost Stats.07092021.xls

CMS Claims Data

- CMS claims data for C9764-C9767 is available in the CY 2020 hospital outpatient claims
- The GMC of these claims are consistent with prior analyses estimating the total procedure costs including IVL
- These claims data further support APC reclassification based on resource utilization for these procedures

HCPCS	Description (Above the Knee Vessels)	2022 APC	2022 Payment	Single Claims (2020)	GMC ¹ (2020 Claims)	Difference
C9764	IVL + PTA	5192	\$5,086	205	\$11,056	\$5,970
C9765	IVL + PTA + Stent	5193	\$10,309	151	\$17,041	\$6,732
C9766	IVL + PTA + Atherectomy	5193	\$10,309	87	\$19,009	\$8,700
C9767	IVL + PTA + Stent + Atherectomy	5194	\$16,484	38	\$24,000	\$7,516

¹ Alternative 2022 NPRM OPSS CPT Cost Stats_2020 based.07092021.xls

2020 HOP Panel Recommendations

Reassign C9764, C9765 and C9766 to APCs 5193 and 5194 Respectively

- Panel Recommendations¹
 - Reassign C9764 to APC 5193
 - Reassign C9765 and C9766 to APC 5194 consistent with the CMS staff confirming the cost of intravascular lithotripsy device is within 10% of other devices currently available (atherectomy was specifically discussed during the panel meeting)
- CMS Response (CMS-1736-FC): “We are unable to identify devices that are similar to IVL and cannot complete the analysis”
- In the context of the HOP Panel discussion, we contend an appropriate “similar” device to IVL is atherectomy as they both address calcium albeit with different mechanisms of action
- Analysis provided by Shockwave supports HOP Panel recommendation
 - 2018 StrategyGen report commissioned by CMS determined that the cost of an atherectomy catheter (CMS Code SD253) is \$3,083.88
 - This is within 10% of the cost of an IVL catheter (\$2,800) as well as the average per case costs of IVL (\$3,360)

¹ CMS HOP Panel Recommendations, August 31, 2020

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

APC reassignment will reduce financial disincentives to utilize IVL and more appropriately aligns with the hospital resources to complete the procedures

HCPCS	Description	2020 Single Claims GMC ¹	Current 2022 APC Assignment ²		Requested 2022 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	\$11,056	5192	\$5,086	5193	\$10,309
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	\$17,040	5193	\$10,309	5194	\$16,484
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	\$19,009	5193	\$10,309	5194	\$16,484
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	\$24,000	5194	\$16,484	5194	\$16,484

¹ 2022 NPRM CPT Cost Stats.07092021.xls

² CMS-1753-P, Addendum B

Shockwave asks the HOP Panel to recommend that CMS:

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

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Appendix – Comparison of Estimated GMC to 2020 IVL Claims

- To account for the potential impact of the vessel treated, we estimated the GMC of IVL procedures by grouping existing procedures regardless of vessel treated
 - Calculated the GMC for each group and the GMC when the cost of IVL were added
- Even when accounting for potential differences in the vessels treated, the reported cost IVL in 2020 claims is typically greater than the estimated GMC after IVL is added

Description	CPT Code Grouping	GMC of Procedure Group	Estimated GMC with IVL	IVL HCPCS (2020)	GMC ¹ (2020 Claims)	Difference
PTA	37220 + 37224+ 37228	\$7,678	\$11,247	C9764	\$11,056	(\$191)
PTA + Stent	37221 + 37226 + 37230	\$11,140	\$14,720	C9765	\$17,041	\$2,131
PTA + Atherectomy	37225 + 37229	\$14,324	\$17,863	C9766	\$19,009	\$1,146
PTA + Stent + Atherectomy	37227 + 37231	\$20,031	\$23,516	C9767	\$24,000	\$484