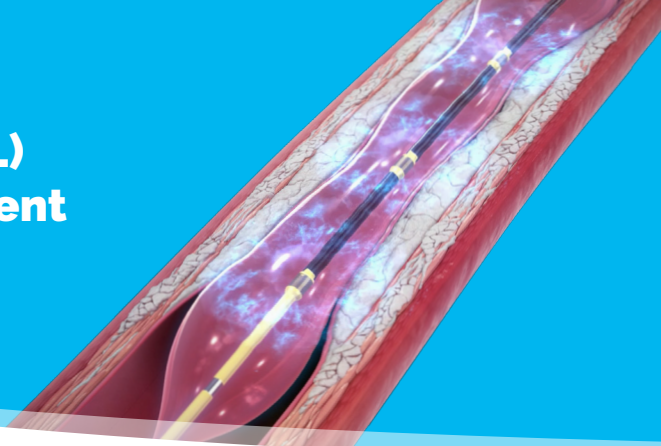


# Coronary Intravascular Lithotripsy (IVL) Transitional Pass-Through (TPT) Payment Overview, Examples, and FAQs



## Overview

Effective July 1, 2021 Medicare approved a Transitional Pass-Through (TPT) payment when the Shockwave C<sup>2</sup> Coronary IVL catheter is utilized in procedures performed in the hospital outpatient setting. The TPT provides incremental payment in addition to the applicable Ambulatory Payment Classifications (APC) payment to recognize the additional cost of Shockwave C<sup>2</sup> Coronary IVL device(s).<sup>1</sup>

**The New HCPCS C-Code for the Shockwave C<sup>2</sup> IVL Catheter must be reported on the hospital outpatient claim:**  
**C1761** = Catheter, transluminal intravascular lithotripsy, coronary

In order to secure the incremental payment, hospitals must report the new C-code for IVL, C1761, **along with** the relevant HCPCS code (procedure code).

The device(s) in the category described by HCPCS code C1761 should always be billed with one of the following Current Procedural Terminology (CPT) codes:

- CPT code 92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch), which is assigned to APC 5193 for Calendar Year (CY) 2021
- CPT code C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch), which is assigned to APC 5193 for Calendar Year (CY) 2021

If hospitals do not report C1761, they will **not** receive the incremental TPT payment for the Shockwave C<sup>2</sup> catheter. Additionally, Medicare will not have adequate claims and cost information to determine the appropriate APC payment rate for procedures that include the Shockwave C<sup>2</sup> Coronary IVL catheter.

**Medicare determines the incremental TPT payment amount for Coronary IVL on a case-by-case basis for each hospital;** it is not a set payment amount. The TPT payment amount is typically calculated based on:

- **A hospital's charges for the Shockwave C<sup>2</sup> Catheter**, which includes a hospital's charge adjustment or markup to account for its operating and capital costs
- **A hospital's cost-to-charge ratio (CCR) for Implantable Medical Devices**, typically reported under Revenue Center 278, which Medicare publishes. Medicare applies this CCR to the charges a hospital submits to determine the cost of the IVL to the hospital, and
- **The device related portion of the relevant HCPCS procedure code**, which is also referred to as the device offset.

**CMS has determined that the costs associated with HCPCS code C1761 (Catheter, transluminal intravascular lithotripsy, coronary) are not already reflected in APC 5193. Therefore, no device offset to C1761 is applied.**

1. <https://www.cms.gov/files/document/r10825cp.pdf>

## Medicare’s Formula for Calculating a Hospital’s Total Payment Amount for a Coronary IVL Case

**CY 2021 National APC Payment Amount** + **Hospital-Specific TPT Payment Amount** = **Total Hospital Amount for an IVL Case**



See below for hypothetical examples illustrating how Medicare calculates the TPT payment for an IVL case and frequently asked questions (FAQs).

### ***TPT Calculation Examples for IVL***

Below are three examples of procedures that include the use of Coronary IVL in the outpatient setting for a fictitious outpatient hospital to help illustrate how Medicare calculates the incremental TPT payment amount. These are hypothetical examples and should not be construed as reimbursement advice or guidance.

Example	Clinical Case	HCPCS	APC
1	One Shockwave C <sup>2</sup> IVL catheter is utilized in a Percutaneous Coronary Intervention (PCI) with a Drug Eluting Stent (DES)	C9600	5193
2	Two Shockwave C <sup>2</sup> IVL catheters are utilized in a PCI with DES	C9600	5193
3	One Shockwave C <sup>2</sup> IVL catheter is utilized in a PCI with a Bare Metal Stent (BMS)	92928	5193

**Example 1:**

One Shockwave C<sup>2</sup> IVL catheter is utilized in a PCI with a DES Procedure; the incremental TPT payment calculation shown below with three different charge adjustments.

APC Payment Amount												
HCPCS C9600; APC 5193 \$10,043	+	(	Acquisition Cost for Shockwave C <sup>2</sup> IVL Catheters	x	Hospital Charge Adjustment	=	Total IVL Charges C1761	x	Hospital Specific Implantable Devices Charged to Patients (Rev Ctr 278) CCR	) =	Medicare Calculated IVL Costs/ Incremental TPT Payment	Total Hospital Payment <sup>2</sup>
\$10,043	+	(	\$4,700	x	200% (or 2x)	=	\$9,400	x	.293	) =	\$2,754	\$12,797
\$10,043	+	(	\$4,700	x	300% (or 3x)	=	\$14,100	x	.293	) =	\$4,131	\$14,174
\$10,043	+	(	\$4,700	x	400% (or 4x)	=	\$18,800	x	.293	) =	\$5,508	\$15,551

**Example 2:**

Two Shockwave C<sup>2</sup> IVL catheters are utilized in a PCI with a DES; the incremental TPT payment calculation shown below with three different charge adjustments.

APC Payment Amount												
HCPCS C9600; APC 5193 \$10,043	+	(	Acquisition Cost for Shockwave C <sup>2</sup> IVL Catheters	x	Hospital Charge Adjustment	=	Total IVL Charges C1761	x	Hospital Specific Implantable Devices Charged to Patients (Rev Ctr 278) CCR	) =	Medicare Calculated IVL Costs/ Incremental TPT Payment	Total Hospital Payment <sup>2</sup>
\$10,043	+	(	\$9,400	x	200% (or 2x)	=	\$18,800	x	.293	) =	\$5,508	\$15,551
\$10,043	+	(	\$9,400	x	300% (or 3x)	=	\$28,200	x	.293	) =	\$8,263	\$18,306
\$10,043	+	(	\$9,400	x	400% (or 4x)	=	\$37,600	x	.293	) =	\$11,017	\$21,060

2. In accordance with CMS' payment policies, Total Hospital Payments may be adjusted geographically

**Example 3:**

One Shockwave C<sup>2</sup> IVL catheter is utilized in a PCI with a BMS; the incremental TPT payment calculation shown below with three different charge adjustments.

APC Payment Amount												
HCPCS C9600; APC 5193 \$10,043	+	(	Acquisition Cost for Shockwave C <sup>2</sup> IVL Catheters	x	Hospital Charge Adjustment	=	Total IVL Charges C1761	x	Hospital Specific Implantable Devices Charged to Patients (Rev Ctr 278) CCR	) =	Medicare Calculated IVL Costs/ Incremental TPT Payment	Total Hospital Payment <sup>2</sup>
\$10,043	+	(	\$4,700	x	200% (or 2x)	=	\$9,400	x	.293	) =	\$2,754	\$12,797
\$10,043	+	(	\$4,700	x	300% (or 3x)	=	\$14,100	x	.293	) =	\$4,131	\$14,174
\$10,043	+	(	\$4,700	x	400% (or 4x)	=	\$18,800	x	.293	) =	\$5,508	\$15,551

**FAQs****1. Why did IVL qualify for TPT payment?**

The FDA granted the Shockwave C<sup>2</sup> Coronary IVL system its Breakthrough Devices Designation (BDD) in 2019 based on its potential to provide for a more effective treatment for life-threatening or irreversibly debilitating conditions. Since 2020, CMS has provided an alternative pathway for innovative technologies that have received FDA Premarket Approval (PMA) and BDD to qualify for device pass-through payment. The Shockwave C<sup>2</sup> Coronary IVL system met the criteria for this pathway.

TPT payment allows Medicare to support patient access to a new technology while evaluating costs and appropriate clinical APC assignment.

**2. How long is the TPT in place for the Shockwave C<sup>2</sup> Coronary IVL?**

Medicare published that the effective date of the TPT for Coronary IVL is July 1, 2021. Medicare allows for TPT payments for a full three-year term. As such, it is expected the incremental TPT payment will be effective through June 30, 2024.

**3. Does the TPT apply to peripheral IVL?**

No, the approved TPT is specific to the Shockwave C<sup>2</sup> Coronary Catheter. Reimbursement questions regarding peripheral can be addressed by contacting the Reimbursement Hotline at (877) 273-4628 or at [reimbursement@shockwavemedical.com](mailto:reimbursement@shockwavemedical.com). The reimbursement guide for peripheral IVL can be found using the following link <https://shockwavemedical.com/reimbursement>.

**FAQs** (continued)**Hospital Outpatient Reimbursement for IVL****4. What procedure codes are eligible for TPT in the hospital outpatient setting?**

The TPT was awarded to Coronary IVL, and the incremental payment calculation is applicable when HCPCS code C1761 is included on the hospital claim. As Coronary IVL is indicated for use prior to the placement of a coronary stent, the most appropriate procedure codes that should be billed are typically those that include the placement of a coronary stent (e.g., CPT 92928, HCPCS C9600):

CPT Code and Description	APC Assignment & Description	CY 2021 Average Payment
92928 - Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	5193 - Level 3 Endovascular Procedures	\$10,043
C9600 - Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	5193 - Level 3 Endovascular Procedures	\$10,043

**5. Where can a hospital find its hospital specific cost-to-charge-ratio (CCR) used in the TPT payment calculation?**

The Provider specific CCRs are part of the Outpatient Rate Setting Files at CMS. Hospital specific CY 2021 CCRs are available by calling the Shockwave Reimbursement Hotline at (877) 273-4628. Please have your Medicare provider number available. If you do not know your Medicare provider number, please contact us via email at [reimbursement@shockwavemedical.com](mailto:reimbursement@shockwavemedical.com) with the name and location of your hospital and we can look it up for you.

**6. What is the device offset and why is it not part of the IVL TPT calculations?**

The device offset is mandated by CMS as part of the program payment calculations. CMS applies a fixed device offset to account for device costs already captured in the base APC payment. The device offset is intended to remove payment already included in the base APC amount.

As part of the application for incremental payment, Shockwave requested the removal of the device offset because the Shockwave C<sup>2</sup> is a new technology that is entirely additive to the procedure and whose costs are not previously accounted for in the APC payment. CMS has determined that the costs associated with HCPCS code C1761 (Catheter, transluminal intravascular lithotripsy, coronary) are not already reflected in APC 5193. Therefore, no device offset to C1761 is applied.

**FAQs** (continued)**7. What if a hospital encounters claims edits/issues requiring resubmission of the claim or other issues with claims using the C1761 code (including denial)?**

The best source of information regarding claims processing issues is the payer – either the patient’s private insurance company or the Medicare Administrative Contractor (for traditional Medicare Fee-For -Service (FFS) patients). Providers should contact the appropriate payer to seek clarification about the issue.

Please also contact us at the Shockwave Medical Reimbursement Hotline (877-273-4628) or send us an email at [reimbursement@shockwavemedical.com](mailto:reimbursement@shockwavemedical.com) with the details of the issue for additional support and guidance.

**8. How should a hospital bill procedures that include the use of Coronary IVL in the outpatient setting?**

We offer the following suggested best practices for billing a PCI procedure that utilizes coronary IVL and includes the placement of a coronary stent in the hospital outpatient setting to Medicare:

- Ensure that the correct CPT/HCPCS procedure code(s) for the procedure performed is submitted with C1761, as well as the appropriate device codes for other devices used (e.g., C1874, Stent, coated/covered, with delivery system).
- Specify the number of units of Coronary IVL catheters used
- Include the appropriate revenue code from the 027X series
- Ensure the charges reflect the number of Coronary IVL catheters used in the procedure

**Physician Reimbursement****9. How are physician payments impacted by the C-Code for Coronary IVL?**

Physicians do not bill C1761 when utilizing Coronary IVL catheters in procedures. C1761 is specifically designated for use in the hospital outpatient setting for the purposes of providing incremental payment.

**Reimbursement for IVL Cases performed in the inpatient or ambulatory surgery center (ASC)****10. Does the TPT payment apply to IVL cases performed in the inpatient setting or an ambulatory surgery center (ASC)?*****Hospital Inpatient Setting***

TPT payment does not apply to the inpatient setting. However, Shockwave Medical has submitted an application for a New Technology Add-on Payment (NTAP) for IVL. Medicare has recently published the CY2022 Hospital Inpatient Proposed Rule and recommended approval of the NTAP. We are currently in the public comment period and CMS will issue its final determination likely in early September. The effective date is expected to be October 1, 2021. Once approved, hospital inpatient cases using a coronary IVL catheter will receive an additional payment above the applicable MS-DRG payment.

**FAQs** (continued)***Ambulatory Surgery Centers (ASC)***

Providers in the ASC setting of care are typically eligible for TPT payments. However, the formula in calculating the incremental TPT payment amount is different, and is set by each Medicare Administrative Contractor (MAC). Additional information may be required by the MAC to support the claim and determine the appropriate amount of TPT payment in the ASC setting. Please contact your local MAC, or please contact the Shockwave Medical Reimbursement Hotline at (877) 273-4628 or [reimbursement@shockwavemedical.com](mailto:reimbursement@shockwavemedical.com)

**Reimbursement for Non-Medicare IVL Cases****11. Does the TPT apply to non-Medicare patients?**

TPT payment only applies to Medicare FFS claims that include the C-Code identifying that Coronary IVL was utilized. While commercial and Medicare Advantage plans often use Medicare FFS payment rates as a reference when establishing their own payment rates, the coding and payment policies of commercial payers may vary. Providers should contact these payers to ensure appropriate coding and billing for non-Medicare FFS patients.

The coding, coverage, and payment information contained herein is gathered from various resources and is subject to change without notice. Shockwave Medical cannot guarantee success in obtaining third-party insurance payments. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine and submit appropriate codes, charges, and modifiers for services that are rendered. Providers should contact their third-party payers for specific information on their coding, coverage, and payment policies.

Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events available at <https://shockwavemedical.com/important-safety-information/>

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