SHOCKWAVE | IVL

CORONARY INTRAVASCULAR LITHOTRIPSY (IVL)

TRANSITIONAL PASS-THROUGH (TPT) PAYMENT

OVERVIEW, EXAMPLES, AND FAQ's

OVERVIEW

Effective July 1, 2021 Medicare approved a Transitional Pass-Through (TPT) payment when the Shockwave C^2 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^2 Coronary IVL device(s).[1]

[1] www.cms.gov/files/document/r10825cp.pdf and www.cms.gov/files/document/r10997cp.pdf

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The New HCPCS C-Code for the Shockwave C^2 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[2] 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)[3] 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) 2022
- CPT code 92933 (Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch), which is assigned to APC 5194 for Calendar Year (CY) 2022
- CPT code 92943 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel), which is assigned to APC 5193 for Calendar Year (CY) 2022
- 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) 2022
- CPT code C9602 (Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch), which is assigned to APC 5194 for Calendar Year (CY) 2022
- CPT code C9607 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluding intracoronary stent, atherectomy and angioplasty; single vessel), which is assigned to APC 5194 for Calendar Year (CY) 2022

If hospitals do not report C1761, they will **not** receive the incremental TPT payment for the Shockwave C^2 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^2 Coronary IVL catheter.

Effective July 1, 2022, Category III add-on CPT®[1] code +0715T *(Percutaneous transluminal coronary lithotripsy) (List separately in addition to code for primary procedure)* has been established for Shockwave Coronary Intravascular Lithotripsy. Physicians are required to use the Coronary add-on code +0715T in conjunction with the primary procedure code in all procedures where coronary IVL is used. Hospitals should continue coding C1761 for all Coronary IVL procedures for TPT and NTAP payments.

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[1] www.cms.gov/files/document/r10825cp.pdf and https://www.cms.gov/files/document/r10997cp.pdf;
[2] Healthcare Common Procedure Coding System (HCPCS);
[3] All rights reserved. CPT® is a registered trademark of the American Medical Association. Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

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 C² 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.

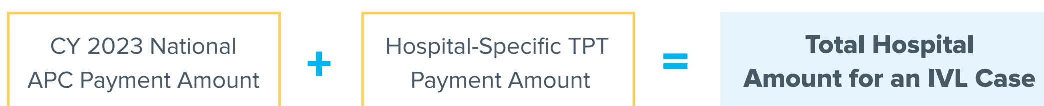
CMS has determined that the costs associated with HCPCS code C1761 (Catheter, transluminal intravascular lithotripsy, coronary) are not already reflected in APC 5193 when combined with CPT codes 92928 and C9600. Therefore, no device offset to C1761 is applied when billed in combination with codes 92928 and C9600.

When C1761 is combined with codes 92933, 92943, C9602, or C9607, a device offset amount will be applied to the TPT portion of the payment calculation.

MEDICARE'S FORMULA FOR CALCULATING A HOSPITAL'S TOTAL PAYMENT AMOUNT FOR A CORONARY IVL CASE

TPT CALCULATION

TOTAL HOSPITAL PAYMENT



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

OVERVIEW OF THE TPT CALCULATION

1. Determine the APC Payment amount for the procedure performed.
2. Multiply the IVL Catheter(s) acquisition costs by your hospital mark-up. Bill this amount using C1761.
3. Determine your hospital specific implantable devices cost to charge ratio. (See FAQ #5).
4. Determine the device offset amount published for your CPT procedure code. (See FAQ #6).
5. Calculate your TPT payment amount by multiply your IVL charges times the CCR.
   Subtract the device offset from step 4. No amounts less than zero.
6. Calculate the Total Hospital Payment by adding your APC amount (step 1) plus the calculated TPT payment (step 5).

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^2 IVL catheter is utilized in a Percutaneous Coronary Intervention (PCI) with a Drug Eluting Stent (DES)	C9600	5193
2	Two Shockwave C^2 IVL catheters are utilized in a PCI with DES	C9600	5193
3	One Shockwave C^2 IVL catheter is utilized in a PCI with Atherectomy and DES	C9602	5194

EXAMPLE 1:

One Shockwave C^2 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	+ ((	Acquisition Cost for Shockwave C^2 IVL Catheter	X	Hospital Charge Adjustment	=	Total IVL Charges C1761	X	Hospital Specific Implantable Devices Charged to Patients (Rev Ctr 278) CCR	) -	Device Offset	) +	Medicare Calculated IVL Costs/ Incremental TPT Payment	=	Total Hospital Payment [4]
1						2		3		4		5		6
$10,615	+ ((	$4,700	x	200% (or 2x)	=	$9,400	x	.293	) -	$0	) +	$2,754	=	$13,369
$10,615	+ ((	$4,700	x	300% (or 3x)	=	$14,100	x	.293	) -	$0	) +	$4,131	=	$14,746
$10,615	+ ((	$4,700	x	400% (or 4x)	=	$18,800	x	.293	) -	$0	) +	$5,508	=	$16,123

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

EXAMPLE 2:

Two Shockwave C² 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	+ ((	Acquisition Cost for Shockwave C² IVL Catheter	X	Hospital Charge Adjustment	=	Total IVL Charges C1761	X	Hospital Specific Implantable Devices Charged to Patients (Rev Ctr 278) CCR	) -	Device Offset	) +	Medicare Calculated IVL Costs/ Incremental TPT Payment	=	Total Hospital Payment [4]
1						2		3		4		5		6
$10,615	+ ((	$9,400	x	200% (or 2x)	=	$18,800	x	.293	) -	$0	) +	$5,508	=	$16,123
$10,615	+ ((	$9,400	x	300% (or 3x)	=	$28,200	x	.293	) -	$0	) +	$8,263	=	$18,878
$10,615	+ ((	$9,400	x	400% (or 4x)	=	$37,600	x	.293	) -	$0	) +	$11,017	=	$21,632

EXAMPLE 3:

One Shockwave C² IVL catheter is utilized in a PCI with Atherectomy and a DES; the incremental TPT payment calculation shown below with three different charge adjustments.

APC Payment Amount														
HCPCS C9602; APC 5194	+ ((	Acquisition Cost for Shockwave C² IVL Catheter	X	Hospital Charge Adjustment	=	Total IVL Charges C1761	X	Hospital Specific Implantable Devices Charged to Patients (Rev Ctr 278) CCR	) -	Device Offset	) +	Medicare Calculated IVL Costs/ Incremental TPT Payment	=	Total Hospital Payment [4]
1						2		3		4		5		6
$17,178	+ ((	$4,700	x	200% (or 2x)	=	$9,400	x	.293	) -	$9,563	) +	$0	=	$17,178
$17,178	+ ((	$4,700	x	300% (or 3x)	=	$14,100	x	.293	) -	$9,563	) +	$0	=	$17,178
$17,178	+ ((	$4,700	x	400% (or 4x)	=	$18,800	x	.293	) -	$9,563	) +	$0	=	$17,178

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

FREQUENTLY ASKED QUESTIONS

Question	Answer
Why did IVL qualify for TPT payment?	The FDA granted the Shockwave C^2 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 quality for device pass-through payment. The Shockwave C^2 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.
How long is the TPT in place for the Shockwave C^2 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.
Does the TPT apply to peripheral IVL?	No, the approved TPT is specific to the Shockwave C^2 Coronary Catheter. Reimbursement questions regarding peripheral can be addressed by contacting the Reimbursement Hotline at (877) 273-4628 or at reimbursement@shockwavemedical.com. The reimbursement guide for peripheral IVL can be found using the following link: https://shockwavemedical.com/reimbursement/coronary/

FAQ's - HOSPITAL OUTPATIENT REIMBURSEMENT FOR IVL

Question	Answer
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, 92933, 92943, HCPSC C9600, C9602, C9607).

CPT Code and Description	APC Assignment & Description	CY 2023 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	$10,615
92933 - Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	5194 – Level 4 Endovascular Procedures	$17,178
92943 - Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel	5193 – Level 3 Endovascular Procedures	$10,615
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	$10,615
C9602 - Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	5194 – Level 4 Endovascular Procedures	$17,178
C9607 - Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluding intracoronary stent, atherectomy and angioplasty; single vessel	5194 – Level 4 Endovascular Procedures	$17,178

FAQ's - HOSPITAL OUTPATIENT REIMBURSEMENT FOR IVL

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 2022 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 with the name and location of your hospital and we can look it up for you.

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^2 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 when used for procedures 92928 and C9600. Therefore, no device offset to C1761 is applied.

When C1761 is combined with the other combination codes (92933, 92943, C9602, or C9607), a device offset is applied. The device offset amounts for each of the codes are listed in the table below.

CPT Code	Descriptor	Device Offset
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	$0
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	$8,831.00
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel	$4,536.98
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	$0
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	$9,562.77
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluding intracoronary stent, atherectomy and angioplasty; single vessel	$8,853.34

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 with the details of the issue for additional support and guidance.
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.

FAQ's - PHYSICIAN REIMBURSEMENT

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.

FAQ's - REIMBURSEMENT FOR IVL CASES PERFORMED IN THE INPATIENT OR AMBULATORY SURGERY CENTER (ASC)

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 submitted an application for a New Technology Add-on Payment (NTAP) for IVL. Medicare has recently published the CY2023 Hospital Inpatient Final Rule and recommended continuation of the NTAP. Hospital inpatient cases using a coronary IVL catheter will receive an additional payment above the applicable MS-DRG payment. **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

FAQ's - REIMBURSEMENT FOR NON-MEDICARE IVL CASES

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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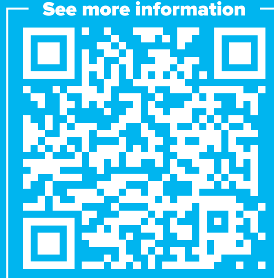

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