



Symplicity Spyral™ renal denervation system

Transitional Pass-Through (TPT) Payment

Overview and Frequently Asked Questions

Transitional Pass-Through Payment Overview

The Centers for Medicare and Medicaid Services (CMS) finalized approval of the Symplicity Spyral catheter for the transitional pass-through (TPT) payment program, effective January 1, 2025.¹ TPT was established by CMS to provide an incremental payment for new technologies in the hospital outpatient setting.

- **TPT for Symplicity Spyral is effective starting January 1, 2025**
- Effective for up to **3 years**
- Provides a temporary payment mechanism designed to offset new technology device cost, added to the **outpatient** payment amount the hospital receives for the procedure
- Only hospital outpatient facilities may qualify for TPT. TPT has no impact on physician or inpatient payment.
- Only applicable to **Medicare fee-for-service** claims (TPT payments do not apply to Medicare Advantage or commercial insurance patients)
- CMS also finalized approval of a new pass-through payment device category (C-code) for Symplicity Spyral, effective January 1, 2025. The new HCPCS² code **C1735 (Catheter, renal denervation, radiofrequency)** must be reported in conjunction with the applicable CPT[®] procedure code for the claim to be eligible for TPT.

Coding & Billing Requirements

For hospital outpatient procedures performed with the Symplicity Spyral catheter, the following HCPCS Level II C-code and one of the appropriate CPT[®] procedure codes must be reported:

HCPCS C-Code	Description
C1735	Catheter, renal denervation, radiofrequency

CPT [®] Procedure Codes	Description
0338T	Transcatheter renal sympathetic denervation, unilateral
0339T	Transcatheter renal sympathetic denervation, bilateral

CPT[®] codes, descriptions, and other data only are copyright 2023 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. These CPT[®] codes have been extended beyond the initial 2024 sunset date by the CPT[®] Editorial Panel as noted by the CPT[®] Editorial Summary of Panel Actions, February 2023.

Ensure that:

- The number of Symplicity Spyral catheters used is correctly reported on the claim.
- Include the appropriate revenue code for the device. This may vary by institution and should be reported by your coding/billing specialist on the claim. Devices like the Symplicity catheter may be reported with revenue code 278 (Other Implants) as per CMS and NUBC guidance, there is no permanency requirement.^{3,4}
- The charges for the Symplicity Spyral catheter are correctly reflected on the claim.
- The C-code C1735 is billed with the appropriate RDN CPT^{®i} code, 0338T or 0339T.

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Transitional Pass-Through Payment Calculations

Hospital payment is determined at the claim level. TPT payment is not a set amount. The Medicare Administrative Contractor (MAC) will calculate the TPT payment amount on a claim-by-claim basis for each hospital.

Total Hospital Outpatient Payment



TPT Calculation Methodology:



1. Hospital's charges for the new technology

This is determined by the hospital's acquisition costs for the device(s), multiplied by the hospital's charge adjustment, or mark-up, to account for its operating and capital costs.

2. Hospital's cost-to-charge ratio (CCR) for implantable devices

CMS calculates and applies a cost-to-charge ratio (CCR) for implantable devices that is specific to each hospital. The hospital-specific amount is determined by Medicare and published annually. For the TPT, Medicare applies the CCR to the submitted charges to determine the estimated costs of items and services on the claim form.

3. The device offset

If CMS determines there are costs associated with the TPT already reflected in the APC payment, then an offset amount is deducted from the TPT calculation. This offset amount is subtracted from the TPT payment.⁵

- The device offset for a bilateral RDN procedure with Symplicity Spyrals is \$2,457 (CPT® code 0339T reported with C1735)
- The device offset for a unilateral RDN procedure with Symplicity Spyrals is \$1,444 (CPT® code 0338T reported with C1735)

EXAMPLE <i>For illustrative purposes only. Does not constitute coding or billing guidance.</i>		
1. HOSPITAL'S CHARGES FOR SYMPLICITY SPYRAL CATHETER (inclusive of mark-up)		\$64,000
2. HOSPITAL'S COST-TO-CHARGE RATIO (CCR) FOR IMPLANTABLE DEVICES		0.25
3. CMS CALCULATED DEVICE COST	(1) X (2)	\$16,000
4. DEVICE OFFSET FOR A BILATERAL RDN PROCEDURE		\$2,457
5. TPT PAYMENT	(3) - (4)	\$13,543
6. APC PAYMENT: APC 5192, CY2025 national unadjusted rate ¹		\$5,702
TOTAL REIMBURSEMENT TPT PAYMENT + APC PAYMENT	(5) + (6)	\$19,245

Frequently Asked Questions

When is the TPT payment effective?	The TPT for Symplicity Spyral for TPT is effective on January 1, 2025.
How long will TPT payment for Symplicity Spyral last?	Hospitals will be eligible to receive TPT payments for Symplicity Spyral beginning January 1, 2025, for a period of up to 3 years.
How did Symplicity Spyral attain approval to qualify for TPT payment?	CMS determines which technologies qualify for TPT payment. Technologies with Breakthrough Device Designation from the FDA are eligible to qualify for the TPT payment through an alternative pathway. As a Breakthrough Device, the Symplicity Spyral catheter qualified for this alternative pathway, as well as meeting other criteria and received TPT approval.
What codes must be reported for TPT?	The newly approved pass-through payment HCPCS C-code C1735 (Catheter, renal denervation, radiofrequency) must be reported in conjunction with one of the applicable procedure codes - CPT ^{®i} code 0338T or 0339T.
Does TPT payment apply for other renal denervation devices?	HCPCS C-code C1735 applies <u>only</u> to Symplicity Spyral at this time, as it is the only currently FDA-approved radiofrequency RDN device. Other RDN devices may have TPT approval under their own device categories.
Does the TPT payment affect physician payment? Should physicians bill C1735?	TPT payment is not applicable to physician billing, and physicians do not report the C-code when they bill for RDN services rendered.
Will reimbursement for the Symplicity[™] procedure cover the costs of the procedure?	The Medicare temporary add-on payments for hospitals are intended to help offset the costs of adopting new technologies. Overall, many variables factor into the actual reimbursement that individual facilities receive on a claim (for example, hospital geographic adjustments). Please contact us for more information.
Are TPT payments applicable to Ambulatory Surgical Centers (ASCs)?	Providers in the ASC setting may be eligible for TPT payments. However, the formula in calculating the incremental TPT payment amount is different in this setting and is determined by each Medicare Administrative Contractor (MAC). Please contact your local MAC for more information.
Are TPT payments applicable to the hospital inpatient setting?	TPT does not apply to the inpatient hospital setting. However, Symplicity is eligible for the New Technology Add-On Payment (NTAP), which is applicable to the inpatient setting. Please contact the Medtronic reimbursement team for more information on NTAP.
Are there any special steps required when billing to receive TPT payment?	No special steps are required, other than hospitals need to ensure that the appropriate C-code and CPT [®] code are reported on the claim.

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<p>Are procedures for patients with non-Medicare coverage eligible for TPT payment?</p>	<p>TPT payments only apply to traditional Medicare Fee-For-Service claims. Medicare Advantage plans and other commercial payers set their payment rates contractually with facilities. Please consult with the payer to determine appropriate coding, billing, payment rates for the procedure.</p>
<p>What is the device offset? Is it part of the Symplicity Spyril TPT calculations?</p>	<p>The device offset is a deduction from the TPT payment and is determined by CMS. It reduces TPT payment by the amount of the device portion already included in the APC payment. At this time, CMS has established a device offset of \$2,457 when C1735 is reported with 0339T. When C1735 is reported with 0338T, the offset is \$1,444. Device offsets are subject to change. The most up to date figures can be found in the CMS Device Offsets Code Pairs file.⁵</p>
<p>What revenue code should the Symplicity catheter be reported under? Does it matter for TPT calculation?</p>	<p>Pass-through payment calculation assumes implant revenue codes are being used to report TPT devices. Catheters such as Symplicity may be reported under revenue code 278 (Other Implants). Note, per CMS and NUBC guidance, there is no permanency requirement for revenue code 278 (Other Implants).^{3,4} Hospital billing practices may vary so it is always recommended to confirm with your billing department.</p>

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We provide



- Help understanding the TPT payment program
- Staff education on billing and coding best practices
- Help finding your hospital-specific CCR or understanding the payment calculation
- Support and guidance with claims issues

Connect with us



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References

1. 2025 Medicare OPPS Final Rule (CMS-1809-FC): <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice/cms-1809-fc> Updated 11/1/2024; Accessed 11/1/2024
2. Healthcare Common Procedure Coding System (HCPCS) 2023 Level II Professional Edition. American Medical Association; 2023.
3. NUBC Guidance: <https://www.nubc.org/updated-guidance-other-implant-revenue-code-0278-effective-july-1-2020> ; Accessed 9/5/2025
4. 2009 Medicare IPPS Final Rule (CMS-1390-F): <https://www.govinfo.gov/content/pkg/FR-2008-08-19/pdf/E8-17914.pdf> ; Accessed 9/5/2025
5. CMS Device Offset Code Pairs Files: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/device-offset-code-pairs> ; Accessed 1/17/2025

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Indications

The Symplicity Spyral™ renal denervation system is indicated to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure.

Contraindications

The Symplicity Spyral system is contraindicated in patients with any of the following conditions: • Renal artery diameter < 3mm or > 8mm • Renal artery fibromuscular dysplasia (FMD) • Stented renal artery (<3 months prior to RDN procedure) • Renal artery aneurysm • Renal artery diameter stenosis >50% • Pregnancy • Presence of abnormal kidney (or secreting adrenal) tumor • Iliac/femoral artery stenosis precluding insertion of the catheter.

Warnings and Precautions

A thorough understanding of the technical principles, clinical applications, and risks associated with vascular access techniques and percutaneous transluminal catheterization in renal arteries is necessary before using this device. The safety and efficacy of the Symplicity Spyral system has not been established in patients with isolated systolic hypertension or in patients with prior renal artery interventions including renal stents, renal angioplasty, or prior renal denervation. The Symplicity Spyral system has not yet been studied in patients who are breastfeeding, under the age of 18, or with secondary hypertension • Avoid treatment with the Symplicity Spyral™ catheter within 5 mm of any diseased area or stent. • Implantable pacemakers (IPGs) and implantable cardioverter defibrillators (ICDs) or other active implants may be adversely affected by RF ablation. Refer to the implantable device's Instructions for Use. • The patient's heart rate may drop during the ablation procedure. • Proper pain medication should be administered at least 10 min before ablating renal nerves.

Potential Adverse Events

Potential adverse events associated with use of the renal denervation device or the interventional procedures include, but are not limited to, the following conditions: • Allergic reaction to contrast • Arterial damage, including injury from energy application, dissection, or perforation, • Arterial spasm, or stenosis • Arterio-enteric fistula • AV fistula • Bleeding • Blood clots or embolism • Bruising • Cardiopulmonary arrest • Complications associated with medications commonly utilized during the procedure, such as narcotics, anxiolytics, or other pain or anti-vasospasm medications • Death • Deep vein thrombosis • Edema • Electrolyte imbalance • Heart rhythm disturbances, including bradycardia • Hematoma • Hematoma - retroperitoneal • Hematuria • Hypertension • Hypotension (may cause end organ hypoperfusion) • Infection • Kidney damage including renal failure or perforation • Myocardial infarction • Nausea or vomiting • Pain or discomfort • Peripheral ischemia • Pulmonary embolism • Proteinuria • Pseudoaneurysm • Radiocontrast nephropathy • Renal artery aneurysm • Skin burns from failure of the dispersive electrode pad • Stroke • Other potential adverse events that are unforeseen at this time.

Please reference appropriate product *Instructions for Use* and *User Manual* for more information regarding indications, contraindications, warnings, precautions, and potential adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

For further information, please call and/or consult Medtronic at 800-633-8766 or the Medtronic website at medtronic.com

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