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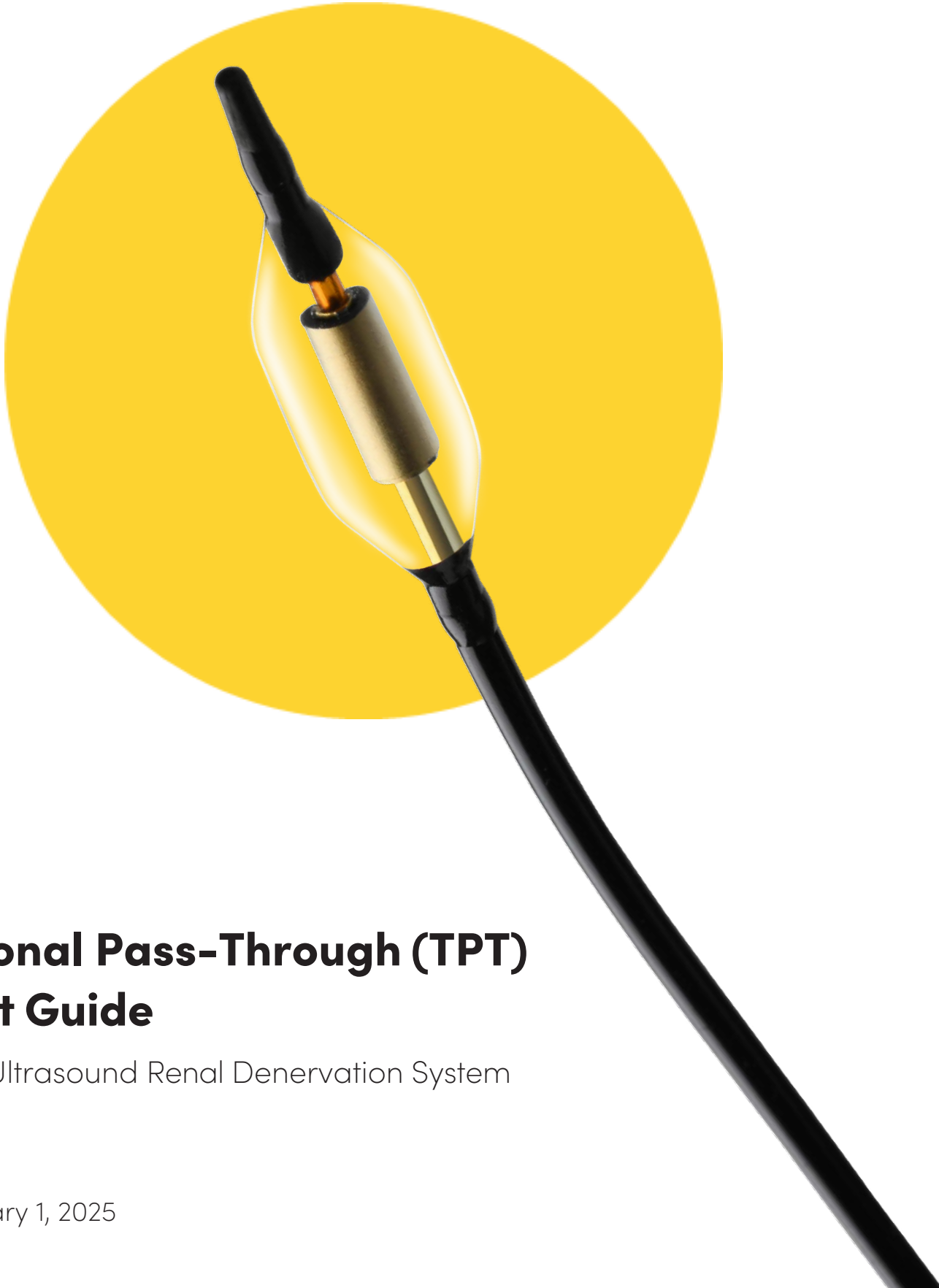


Transitional Pass-Through (TPT) Payment Guide

Paradise® Ultrasound Renal Denervation System

Effective January 1, 2025

Overview

Effective January 1st, 2025, under the Transitional Pass-Through (TPT) Payment granted by CMS, renal denervation cases utilizing the Paradise Ultrasound Renal Denervation System performed in a hospital outpatient or ASC setting are eligible for an incremental payment for Medicare Fee-For-Service beneficiaries to help cover additional costs associated with the Paradise System.[1]

TPT payments provide additional payment for new devices that meet eligibility criteria for a period of up to three years while CMS gathers additional data on the cost of those items. A TPT payment from CMS represents a critical funding mechanism that directly reimburses healthcare centers for the cost of using new and innovative medical devices, beyond the standard OPPS and ASC payment rates.

The New HCPCS C-Code for the Paradise System must be reported on the hospital outpatient claim
C1736: Catheter, Renal Denervation, Ultrasound

In order to secure the incremental payment, hospitals must report the new C-code for uRDN, C1736, along with the relevant procedure code (either 0338T or 0339T). If the uRDN C-Code is not submitted with the claim, Medicare will not map the procedure to the TPT payment and facilities will not be paid appropriately.

2025	Procedure Code	Device Code (C-Code)	C-Code Description	APC Mapping	Total Payment
	0338T or 0339T	C1736	Catheter Renal Denervation, Ultrasound	5192	APC + TPT Payment

TPT amount is dependent on facility-specific reimbursement and acquisition costs reflected in the charges billed to Medicare. Medicare determines the incremental TPT payment amount for Ultrasound RDN based on a case-by-case basis for each hospital; it is not a set payment amount.[2]

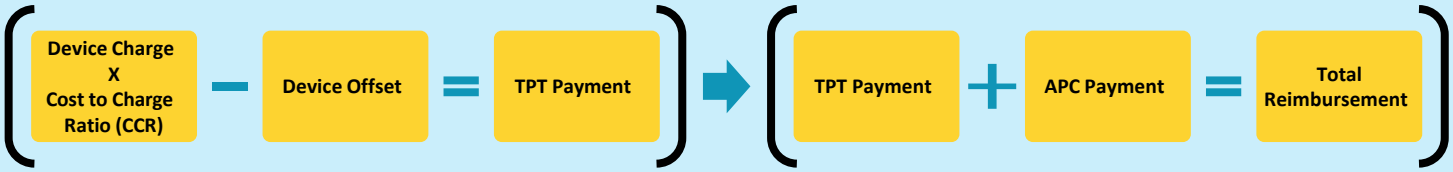
Outpatient Coding & Reimbursement

CPT Code	Description	SI	APC	2025 National Medicare Rate[1]
0338T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral	J1	5192	$5,702
0339T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral	J1	5192	$5,702
C1736	Catheter, Renal Denervation, Ultrasound	H	N/A	Maps to TPT

TPT Payment Calculation Overview[2]

Medicare determines the incremental TPT payment on a case-by-case basis depending on, among other things, the following:

- The amount a hospital charges for the Paradise System.
- Hospital's specific cost-to-charge ratio (CCR) for Medical Devices, which Medicare publishes annually and varies for each specific hospital.
- The device related portion of the relevant HCPCS procedure code, which is also referred to as the device offset. (0338T and 0339T have different HCPCS level device offsets, see calculation examples below)



TPT Payment Calculation Examples[1,2]

Below are examples of procedures that include the use of the Paradise System 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.

Hospital Charges for C1736	x	CCR	=	Cost of Device/Cost Reported to CMS	-	Device Offset for 0339T	=	TPT Payment
$80,000	x	.250	=	$20,000	-	$2,457	=	$17,543

TPT Payment	+	APC 5192 Payment	=	Total Payment
$17,543	+	$5,702	=	$23,245

	Element	Calculation	Amount	
			0338T	0339T
Hospital Charge for C1736	A		$80,000	$80,000
Hospital Implantable Devices CCR	B		0.25	0.25
Reported Cost of C1736	C	A x B	**$20,000**	**$20,000**
Device Related Offset* of CPT Codes 0338T/0339T	D		$1,444	$2,457
Incremental TPT Payment	E	C – D	**$18,556**	**$17,543**
APC Assignment for CPT Codes 0338T/0339T (APC 5192)	F		$5,702	$5,702
Total APC + TPT Payment	G	E + F	**$24,258**	**$23,245**

*Medicare applies the device offset amount to APC 5192 for CPT procedure codes 0338T and 0339T. These codes have different HCPCS level device offsets. The device offset is published by Medicare annually. Therefore, it is subject to change. Please refer to the most current Device Offset Code Pairs file on CMS website at: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/device-offset-code-pairs

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Example UB-04 – For Illustrative Purposes Only

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
0250	PHARMACY GENERAL					
0270	MED/SUR SUPPLIES AND DEVICES					
0301	LAB / CHEMISTRY					
0320	DIAGNOSTIC RADIOLOGY					
0360	OPERATING ROOM	0339T				$XXXXX
0272	MED/SUR SUPPLIES AND DEVICES	C1736				$XXXXX
0710	RECOVERY ROOM					

FOR EXAMPLE ONLY – DO NOT ASSIGN CODES DIRECTLY FROM THIS DOCUMENT

PAGE ____ OF ____ CREATION DATE TOTALS

66 DX: I10 | I1A.0

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC National Uniform Billing Committee LIC9213257 THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

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FAQs

What is a transitional pass-through (TPT) payment and what is it intended to do?

A TPT payment from CMS represents a critical funding mechanism that directly reimburses healthcare centers for the cost of using new and innovative medical devices while claims data is collected. A TPT payment allows an Outpatient facility or ASC to receive additional device cost-based payment for the use of qualified innovative technology.

How long will the TPT last?

Recor Medical anticipates that the Transitional Pass-through Payment (TPT) will be effective for a duration of at least two years but not more than three years.[2]

Is there a specific HCPCS code that I will need to bill under?

Yes, CMS created a new HCPCS Level II code to define this TPT device category, C1736 – Catheter, Renal Denervation, Ultrasound. This code will allow for billing and payment for the Paradise System when medically appropriate and billed with an associated procedure code such as 0338T or 0339T.[1]

Does this TPT only apply to Ultrasound Renal Denervation?

- The TPT and HCPCS Level II code granted by CMS, is unique to "Catheter, Renal Denervation, Ultrasound" and should only be applied when RDN procedures are performed with an ultrasound catheter.
- CMS also approved a separate code for RF-RDN, so it is important to make sure the appropriate code is utilized.

Why did CMS decide to grant separate TPT codes for uRDN and RF-RDN?

CMS created two separate device categories due to them believing "that there are procedural differences and potential resource requirement differences between the two treatment modalities that warrant separate device categories".

Will the TPT payment level be the same for both uRDN and RF-RDN procedures?

CMS has approved a TPT for both Ultrasound RDN and RF-RDN technologies. These payments are directly tied to the charges/acquisition costs of the devices and are intended to offset the device expenses. Variations in the pricing of the devices may result in corresponding and proportional variations in the TPT amounts.[2]

Does the TPT payment apply to uRDN cases performed in other sites of service such as an ambulatory surgery center (ASC) or inpatient facility?

Ambulatory Surgery Centers (ASC)

Renal Denervation procedure codes are listed on CMS's ASC Covered Procedures List (CPL) and the HCPCS Level II code granted has a status indicator of "J7" which means that it is eligible for TPT payments in the ASC setting.[3] It's important to note, however, that the calculation of the additional TPT amount is different from the Outpatient setting (carrier priced) and is defined by the individual Medicare Administrative Contractor (MAC).[4] Your MAC might also require extra documentation to process the claim and to determine the appropriate amount of TPT payment in the ASC context. Should you need clarification or assistance, we encourage you to reach out to your local MAC or the Recor Medical Reimbursement Team via email at reimbursement@recormedical.com.

Hospital Inpatient Setting

TPT payment does not apply to the inpatient setting. The Paradise System was approved for a New Technology Add-on Payment (NTAP) effective October 1, 2024.[5] Please reference our NTAP resources for more information.

Physician's Office / Office Based Lab (OBL)

Renal denervation procedures are not currently payable by Medicare in the OBL setting. TPT payments also only apply to Outpatient and ASC procedures.

FAQs - Continued

Does the TPT payment apply to non-Medicare FFS patients?

No, the TPT payment only applies to Medicare fee-for-service (FFS) beneficiaries when appropriate procedure codes and the C-Code indicating the use of Paradise System are utilized. This payment does not extend to Medicare Advantage or other private payers, whose reimbursement is typically governed by individual contracts with providers.

While these private entities may reference Medicare FFS rates, their coding and payment policies can differ. TPT Payments may provide private payers with insight into changes in market reimbursement updates, however the degree of impact on contract negotiations is uncertain.

Providers are advised to consult with private payers to confirm eligibility for any supplemental reimbursement and to verify accurate coding and billing practices for non-Medicare FFS patients.

Does the Medicare TPT payment have any impact on the physician payment in any setting?

The TPT payment applies to facility payments under the Hospital Outpatient Prospective Payment System, including ASCs. TPT payment status for the Paradise System has no impact on the Medicare Physician Fee Schedule (MPFS) payment to the clinician for the associated procedure.

Do TPT Payments impact coverage policies?

TPT is not directly connected to coverage decisions, rather it affects the payment rate received by facilities for providing Medicare FFS beneficiaries.

How much does my facility receive under the TPT?

TPT amount is dependent on facility-specific reimbursement and acquisition costs. Medicare determines the incremental TPT payment amount for Ultrasound RDN based on a case-by-case basis for each hospital; it is not a set payment amount.

The TPT payment is typically calculated based on:

- A hospital's charges for the Paradise System, which includes a hospital's charge adjustment or markup to account for its operating/capital costs
- A hospital's cost-to-charge ratio (CCR) for Medical Devices, typically reported under Revenue Center 272, which Medicare publishes. Medicare applies this CCR to the charges a hospital submits to determine the cost of the Paradise System to the hospital, and
- The device related portion of the relevant APC payment, also referred to as the device offset.

What is the device offset and why is it removed from the 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.

How much should my hospital charge for the Paradise System?

Each hospital should determine its own charge for the Paradise System. However, it is important to understand that CMS will apply the hospital's cost-to-charge ratio (CCR) to the hospital charge to calculate an estimate of the cost of the device. Therefore, to be consistent with its billing practices, a hospital should submit the charges (accounting for their CCRs), not the invoice amount, to CMS on the claim with HCPCS C1736. Otherwise, CMS will calculate an incorrect payment amount for the Paradise System. CMS also relies on the charges on claims data for setting payment rates for related procedures when the TPT expires.

Where can a hospital find the relevant hospital outpatient operating cost-to-charge-ratio (CCR) used in the TPT payment calculation?

The provider specific CCRs are part of the Outpatient impact files found on CMS's website at FY 2025 Impact File (final rule).[6] Please note that CCRs are published annually. Additionally, you may contact your MAC to find out your hospital's CCR for purposes of new technology payments from CMS.

For any questions or further clarification regarding the TPT or general questions regarding reimbursement, please reach out to the Recor Medical Reimbursement Team at reimbursement@recormedical.com.

References

1. Hospital Outpatient Prospective Payment CY2025- Notice of Final Rulemaking with Comment Period (NFRM) CMS 1809-FC: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1809-fc
2. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-419/subpart-G/section-419.66
3. Ambulatory Surgical Center Payment CY2025- Notice of Final Rulemaking (NFRM) CMS-1809-FC: https://www.cms.gov/node/2097031
4. Medicare Claims Processing Manual Chapter 14 - Ambulatory Surgical Centers: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c14.pdf
5. FY 2025 IPPS Final Rule Home Page 1808-F: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ipps-final-rule-home-page
6. FY 2025 Impact File (final rule): https://www.cms.gov/medicare/payment/prospective-payment-systems/long-term-care-hospital/historical-impact-files/fy-2025-impact-file-final-rule

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