Transitional Pass-Through (TPT) Payments for the Paradise® Ultrasound Renal Denervation System

Effective Date January 1, 2025¹

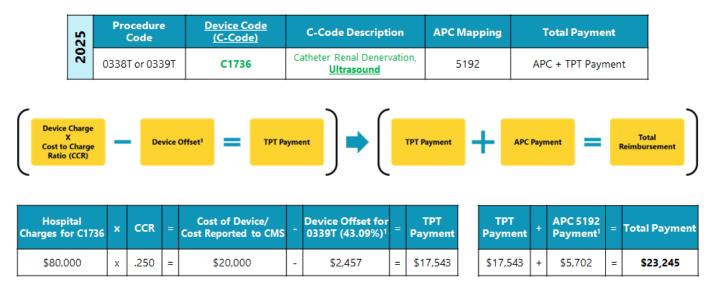
Attention All Hospitals and Healthcare Providers,

Effective January 1, 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.

Why does this matter?

- TPT Payments reduce the financial burden for facilities and patients while expanding uRDN therapy access to Medicare FFS patients.
- Costs associated with the Paradise System are passed through to CMS
- In creating a distinct device category for Ultrasound Renal Denervation, CMS recognizes the differentiated technology and procedure with the Paradise uRDN System.

How will Outpatient Facilities be Reimbursed?²



Actions hospitals can take:

- Make sure all appropriate codes are utilized. Failure to include appropriate C-code will forgo the additional payment.
- Review and update as appropriate your hospital's cost-to-charge ratio (CCR) as Medicare uses this to calculate the cost of the device and procedure

Please review Recor Medical's **Transitional Pass-Through Payment Resource** and the **Paradise System Coding** & **Payment Guide**, available upon request, for additional information.

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.



^{1.} 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

^{2.} https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-419/subpart-G/section-419.66

^{3.} Device Offset is defined as the percentage of the APC that has already been allocated to reimburse the hospital for medical devices used in the procedure

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 Outpatint 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.

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.

Does this TPT only apply to Ultrasound Renal Denervation?

- The TPT and HCPCS Level II code granted by CMS, is unique to "Catheters 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.

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. 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 TPT payment apply to inpatient procedures?

No, TPT payments only apply to Outpatient and ASC procedures. The Paradise was approved for a New Technology Add-on Payment (NTAP) that applies to Medicare FFS inpatient procedures. For more information please reference Recor Medical's NTAP resources or reach out to the Recor Medical Market Access Team at reimbursement@recormedical.com.

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.

What is the impact of the TPT payment on coverage policies?

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



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