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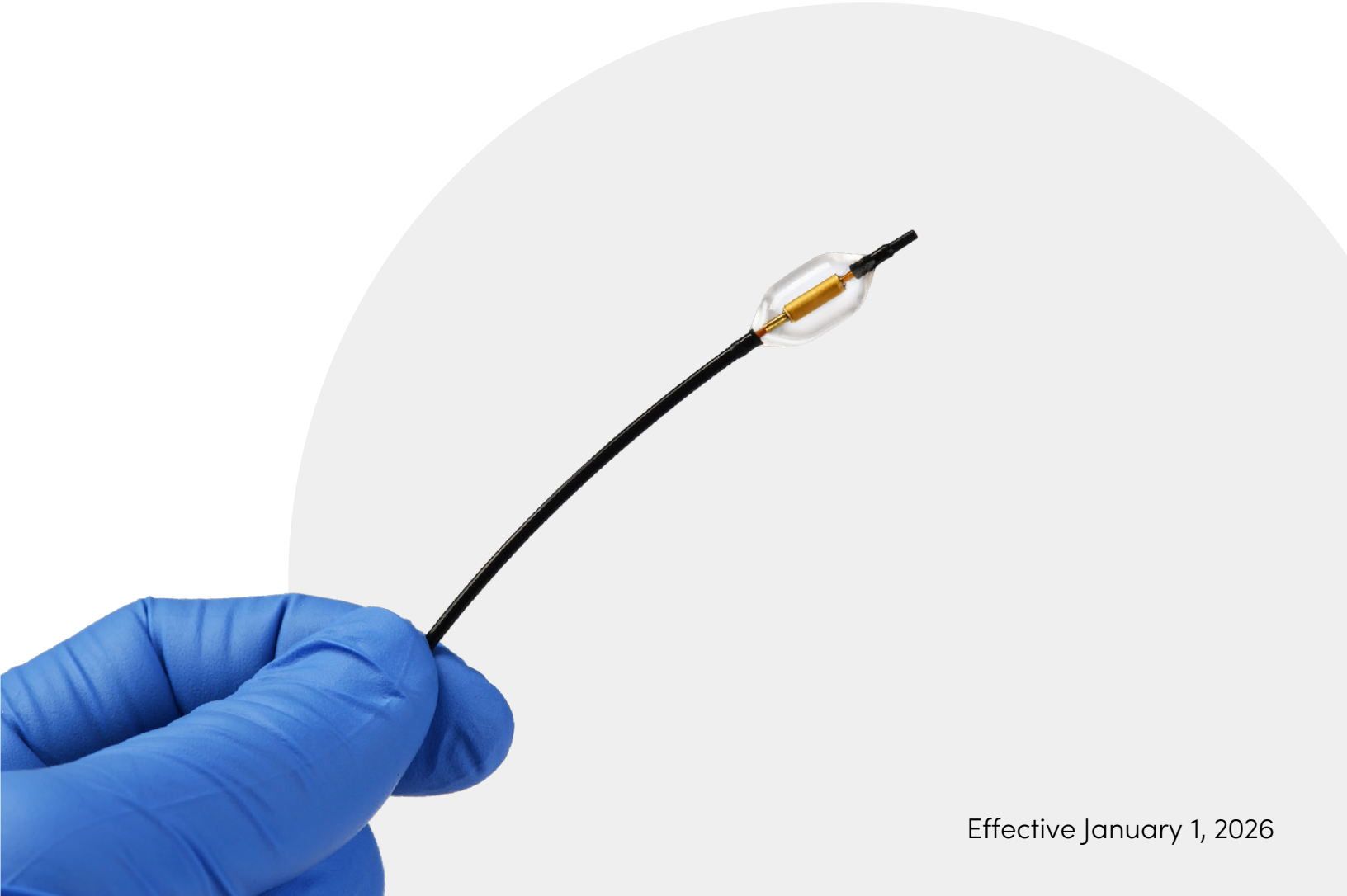
Coding & Payment Guide

Paradise® Ultrasound Renal Denervation System



Effective January 1, 2026

Table of Contents

Indications for Use

The Paradise Ultrasound Renal Denervation System (Paradise System) is indicated to reduce blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure.

Please refer to the last page for Important Safety Information for the Paradise® Ultrasound Renal Denervation System.

Also consult the specific guidelines provided in the IFU for the Paradise Ultrasound Renal Denervation System to ensure that the patient's condition aligns with the approved uses of the system.

https://www.accessdata.fda.gov/cdrh_docs/pdf22/P220023A.pdf

Important Definitions* and Standard Measures

Essential or Primary hypertension is high blood pressure that doesn't have a known secondary cause (90-95% of all HTN patients)

Secondary hypertension is high blood pressure that is caused by a known disease or condition (5-10% of all HTN patients)

Uncontrolled hypertensive patients are those with clinic blood pressure of 140/90 mmHg or higher despite undergoing anti-hypertensive treatment[1]

Resistant hypertension is a condition where the blood pressure (BP) of a patient with hypertension remains above goal in spite of the concurrent use of at least three antihypertensive medications of different pharmacologic classes, commonly including a long-acting calcium channel blocker, a blocker of the renin-angiotensin system (angiotensin converting enzyme inhibitor or angiotensin receptor blocker) and a diuretic.[2]

Refractory hypertensive patients are a subset of resistant defined as continued HTN despite treatment with 5+ medications[3]

Blood Pressure Measurements

- **Office or Clinic Blood Pressure Measurement:** Blood pressure reading taken in a healthcare provider's office or a clinical setting. It's typically performed by a nurse or doctor using a standard or digital sphygmomanometer, a device that includes a blood pressure cuff and a pressure-measuring gauge.
- **Home Blood Pressure Monitoring (HBPM):** Process of measuring blood pressure at home using a home blood pressure monitor. It's often done to monitor one's blood pressure on a regular basis outside of a health-care setting.
- **Ambulatory Blood Pressure Monitoring (ABPM):** Method where your blood pressure is being measured as the patient moves around, living their normal daily life. A device known as an ambulatory blood pressure monitor is worn for a 24-hour period to take readings at regular intervals throughout the day and night. This method can provide a more accurate picture of a person's blood pressure as it captures variations that can occur throughout the day.

Classification of BP According to the 2017 ACC/AHA BP Guideline[4]

Office BP Levels			2017 ACC/AHA Guideline Classification
SBP, mm Hg		DBP, mm Hg	
<120	and	<80	Normal BP
120–129	and	<80	Elevated BP
130–139	or	80–89	Stage 1 hypertension
≥140	or	≥90	Stage 2 hypertension

BP Thresholds for Home and ABPM That Correspond to Office BP Levels in the 2017 ACC/AHA BP Guideline[4]

Office BP	HBPM	Awake ABPM	Asleep ABPM	24-h ABPM
120/80	120/80	120/80	100/65	115/75
130/80	130/80	130/80	110/65	125/75
140/90	135/85	135/85	120/70	130/80
160/100	145/90	145/90	140/85	145/90

Treatment related SBP reduction magnitude varies based on BP measurement setting[5]

*Definitions leverage previous definitions of HTN ≥ 140/90. Newer categorization may lead to differing definitions. **1.** Calhoun et al. Circulation. 2008 Jun;117:e510–e526 **2.** Carey et al. Hypertension. 2018;72:e55–e90. **3.** Acelajado et al. Circulation Research. 2019 Mar; 124(7):1061-1070**4.** Mutner et al. Hypertension. 2018 Nov; 73(1):33–38 **5.** Ishikawa et al. Hypertension. 2008 Nov; 52(5): 856–864.

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Payer Coverage

Medicare Beneficiaries

On October 28, 2025, the Centers for Medicare and Medicaid Services (CMS) posted the final decision memo for Renal Denervation (RDN) for Uncontrolled Hypertension (NCD 20.40).[1] This NCD establishes coverage, under specific criteria including coverage with evidence development (CED)[2], for FDA-approved indications of the Paradise® Ultrasound Renal Denervation System. This policy applies to all Medicare Fee-For-Service and Medicare Advantage beneficiaries. Specifically, criteria are as follows:

Patient Criteria:

- Uncontrolled Hypertension SBP ≥ 140 mmHg and DBP ≥ 90 despite active clinical management by a clinician with primary responsibility for HTN management
- Diagnosis confirmed via ambulatory BP monitoring or serial home BP readings
- On stable, maximally tolerated GDMT (+ lifestyle changes), w/ assessment of adherence, for ≥ 6 weeks
- Secondary hypertension evaluated and treated if appropriate. Must be screened for primary aldosteronism, obstructive sleep apnea, and drug or alcohol induced HTN
- No RDN contraindications, consistent with the FDA labeling of the device used
- Coordination managed by primary clinician ≥ 6 months with ≥ 3 encounters, of which 2 can be virtual
- No prior RDN procedure

Physician Criteria:

- **Referring Physicians** must have longitudinal responsibility for managing the patient's HTN
- **Treating Physicians** must have interventional and endovascular skills to perform effective RDN treatments. Additionally, they must be able to manage potential complications in case of emergency management
- If **Treating Physicians** do not have prior endovascular training or renovascular expertise, they must complete at least 10 supervised cases of diagnostic / therapeutic renovascular procedures, half as primary operator. Additionally, they must complete at least 5 proctored RDN cases w/ each device used in their practice

Physician Criteria Continued...

- If **Treating Physicians** have prior endovascular training and active endovascular experience, they must complete at least 5 proctored RDN cases w/ each device used in their practice

Facility Criteria

- Facilities performing RDN must have a hypertension program with contributions from a hypertension clinician with longitudinal patient management responsibility, a hypertension navigator, and access to relevant medical specialties (e.g., internal medicine, endocrinology, sleep medicine, cardiology, and nephrology) as appropriate
- Preprocedural imaging capabilities
- An appropriate interventional cardiology or radiology suite

To access the full NCD released on October 28, 2025, and the associated CMS analysis, please click **here**.

Medicare Advantage

The NCD for RDN issued by CMS applies to all Medicare beneficiaries, including those enrolled in Medicare Part C (Medicare Advantage). However, many Medicare Advantage plans still require prior authorization. When submitting these requests, provide comprehensive documentation to confirm the patient meets all NCD coverage criteria.

Commercial/Private

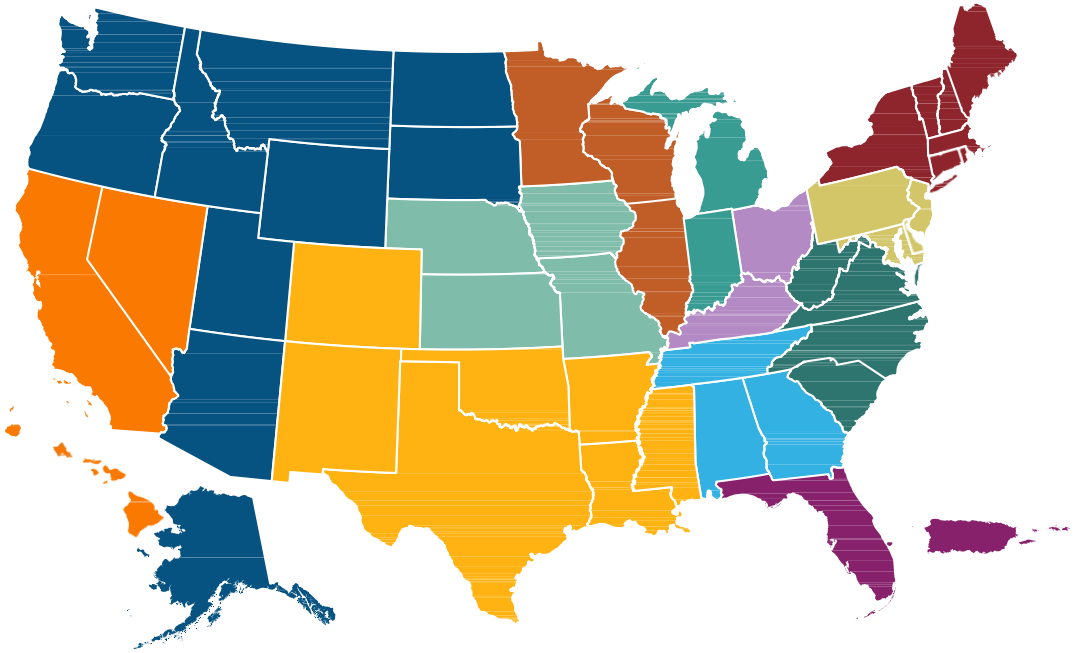
Several private payers have begun adopting favorable coverage policies for uRDN, signaling growing acceptance of this innovative technology. However, coverage remains inconsistent, and some plans still classify these procedures as non-covered or apply restrictive criteria. To navigate this variability, it's essential to confirm each payer's requirements and any local policies. Submitting a prior authorization request enables individualized review and supports demonstrating medical necessity and can help secure coverage even when general policy appears unfavorable.

1. Centers for Medicare & Medicaid Services. NCA Tracking Sheet – Renal Denervation for Uncontrolled Hypertension. Available at: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=318. Accessed October 28, 2025.
2. ClinicalTrials.gov. The RADIANCE CED Study (NCT07231757). Available at: https://clinicaltrials.gov/study/NCT07231757?term=NCT07231757&rank=1. Accessed November 17, 2025.

Medicare Administrative Contractors (MACs)

Medicare

Medicare Administrative Contractors (MACs) are private healthcare insurers that have been awarded contracts by the Centers for Medicare & Medicaid Services (CMS) to administer the Medicare Part A and Part B (A/B) and Durable Medical Equipment (DME) benefit programs. These MACs are responsible for processing Medicare claims, enrolling healthcare providers in the Medicare program, assisting with Medicare billing questions and issues, handling Medicare appeals, and educating healthcare providers about changes in Medicare billing regulations and procedures.



Original source: https://www.cms.gov/files/document/ab-jurisdiction-map-03282023pdf.pdf

CGS J15 | FCSO JN | NGS JK | NGS J6 | Noridian JF | Noridian JE | Novitas JL | Novitas JH | Palmetto JM | Palmetto JJ | WPS j5 | WPS J8

Medicare Administrative Contractor (MAC)	Jurisdiction(s)	uRDN LCD?	Website
National Govt. Services (NGS)	J6 / JK	N	NGS Homepage
Noridian	JF / JE	N	Noridian Homepage
CGS	J15	N	CGS Homepage
Wisconsin Physicians Service (WPS)	J5 / J8	N	WPS Homepage
First Coast Service Options (FCSO)	JN	N	FCSO Homepage
Palmetto	JJ / JM	N	Palmetto Homepage
Novitas Solutions	JL / JH	N	Novitas Homepage

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Documentation and Prior Auth Considerations

Reimbursement is driven by several key factors that include proper documentation to support clinical decision making and medical necessity based on appropriate level of care concepts. It is the foundation that all payers use, both governmental and commercial, to ensure appropriate spend of healthcare dollars. Below are some recommended critical education points to ensure prior authorization gatekeeping decisions, reimbursement rates, and claims payment decisions are based on provider care decisions that align both the ordering/referring provider assessment of uRDN patients and the performing providers. It's important to note that documentation satisfying some or all of these elements does not assure coverage, and each payer may require additional medical documentation outside of these recommendations.

Referring/Ordering Physician/Care Team Documentation Considerations (Include in Referral Packet)

May be documented across multiple visit notes

- Most recently documented BP readings
  - Office and if available serialized home readings or ambulatory BP measurements (ABPM)
- Medication history with maximally tolerated GDMT and validation of adherence with any relevant annotations
- Documentation of lifestyle modifications
- HTN management visit dates during last 6 months (include visit notes)
  - The primary clinicians must coordinate management of the patient for a minimum of six months before referral for RDN for Medicare and Medicare Advantage patients. It is recommended your referral documentation include visit notes spanning a 6-month period demonstrating management of HTN disease.
- Screening for secondary causes of HTN (i.e., obstructive sleep apnea, alcohol/and or drugs, endocrine disorders)
- Appropriate lab work
- Primary referral diagnosis of hypertension as documentation supports

Performing Provider Documentation Considerations

Documentation in H&P and/or Operative Note

- Summary of patient clinical history to include:
  - Primary referral diagnosis of hypertension as documentation supports
  - Office BP and an out of office BP measurement such as serial home BP readings and/or ABPM
  - Problem pertinent review of cardiovascular and gastrointestinal systems
  - Medication management history (current medications, previous regimen, intolerances if any)
  - Screening for secondary causes of HTN (i.e., obstructive sleep apnea, alcohol/and or drugs, endocrine disorders)
  - Suitable renal anatomy and function (e.g., eGFR, renal artery imaging to rule out exclusions/contraindications)
  - Relevant personal clinical history:
    - History of ER and/or hospitalizations related to HTN care
    - Diabetes mellitus
    - Obesity (BMI)
    - Smoking history
    - Atrial fibrillation
    - Peripheral Artery Disease
    - Other:_____

Additional Supportive Documentation Considerations for Prior Authorization

- Reason for procedure, including clinical benefits, risks if not performed, and patient preference
- Your experience with renal denervation
- Clinical studies supporting potential benefit of this therapy

Reimbursement and Prior Authorization Support

Recor Reimbursement Team

For questions related to Paradise Ultrasound RDN System reimbursement, the Recor Medical Reimbursement Team is here to assist you. Please reach out to us directly by emailing us at: Reimbursement@recormedical.com. Our dedicated professionals are committed to providing timely responses and informative insights to meet your needs.

You can also reach us through our official website.

- www.recormedical.com/reimbursement
- reimbursement@recormedical.com

To assist providers, Recor's Reimbursement team offers comprehensive resources designed to support and guide you through the reimbursement process, including:

- **Coding and Billing Handbooks**
  General coding and payment for RDN, Crosswalk guides, reimbursement FAQs, and hospital reimbursement presentations
- **Policy Informational Discussions**
  Transitional-Passthrough (TPT) Payments, New Technology Add-On (NTAP) Payments, National Coverage Determinations (NCD)
- **In-person or Virtual Training and Education**
  One-on-one support for navigating billing requirements and coverage policies

Prior Authorization Support

Recor Medical is dedicated to supporting patients and healthcare professionals through the complex process of prior authorization (PA) and appeals. To assist we've developed a set of comprehensive PA materials including PA and appeals templates. These resources are designed to provide education on the process as well as a structured framework for communicating the necessary information to insurance providers.

Recor Patient Access Program

Recor Medical offers patient therapy access support via Prior Authorization resources and **The Recor Patient Access Program (PAP)** to assist patients in navigating the prior authorization process for the Paradise Ultrasound RDN System.

The Recor Patient Access Program will support patient access to the Paradise System through submission of thorough and well-documented patient requests for prior authorization and patient-based appeals.

Paradise System candidates whose health benefits are provided through commercial/private health plans will generally require prior authorization for coverage.

The Recor Patient Access Program can support the following:

- Comprehensive Benefits Verification
- Prior Authorization, Level 1 and Level 2 Authorization Appeal Submissions
- External Reviews/Independent Review Organization (IRO)

These services are offered via a secure online portal for prior authorization and appeal requests with real-time case updates and streamlined communications.

Please contact your local Recor Medical Reimbursement Representative or email reimbursement@recormedical.com for more information or to enroll.

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Hospital Inpatient Coding

Effective October 1, 2025 - September 30, 2026

ICD 10-PCS Code[1]	Description	MDC Assignment for HTN	Typical MS-DRG Assignment	Weight	2026 National Medicare Rate[2]
X051329	Destruction of Renal Sympathetic Nerve(s) using Ultrasound Ablation, Percutaneous Approach	05	MS-DRG 264	3.3406	$24,309

CMS granted a unique ICD-10 PCS code to represent renal denervation via catheter-based ultrasound ablation. This code became effective October 1st, 2023. (CMS FY2024)

Hypertension diagnosis codes are assigned to Major Diagnostic Category (MDC) 05 for MS-DRG Grouper logic. Within this MDC, the Paradise Ultrasound RDN System maps to MS-DRG 264: Other Circulatory System O.R. Procedures.

New Technology Add-on Payment (NTAP)

Effective October 1, 2024, renal denervation cases utilizing the Paradise Ultrasound Renal Denervation System performed in a hospital inpatient setting are eligible for an incremental payment from Medicare (in addition to the MS-DRG payment) to help cover the additional costs of performing uRDN procedures. The uRDN NTAP provides additional payment of up to $14,950 for FY 2025, based on the hospital's reported cost of each case.

The incremental NTAP is based on the total covered cost to hospitals for a uRDN procedure. If the total covered costs of a discharge (derived by multiplying the hospital's inpatient operating cost-to-charge ratio (CCR) to the total covered charges for the case) exceed the full MS-DRG payment (including payments for indirect medical education and disproportionate share hospitals, but excluding outlier payments), Medicare will provide the NTAP add-on payment equal to 65% of the difference between the full MS-DRG payment and hospital's reported cost for the discharge up to $14,950. **See next page for an overview of the NTAP calculation.**

For FAQs related to the NTAP, please see the Paradise System Reimbursement FAQ resource.

1. CMS 2024 ICD-10-PCS (Downloads). https://www.cms.gov/medicare/icd-10/2024-icd-10-pcs
2. FY 2026 IPPS Final Rule Home Page 1833-F: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-final-rule-home-page

Hospital Inpatient - NTAP Calculation Overview[1]

Effective October 1, 2025 - September 30, 2026

1. Determine total covered charges for the entire hospital stay involving uRDN
2. Determine the Hospital-Specific Operating cost-to-charge ratio (CCR)
3. Derive total covered costs of the case = Total charges * CCR
4. Determine the hospital specific MS-DRG payment
5. Subtract the MS-DRG payment from the total covered costs of the case
6. If the difference is > $0, NTAP equals the lesser of 65% of that difference or $14,950
7. Total Case Payment. NTAP + MS-DRG

Total Hospital Reimbursement if Charges/Covered Cost is more than the DRG Reimbursement but less than the maximum NTAP amount

Hospital Charges for Admission	x	Hospital CCR	=	Covered Cost	-	MS-DRG 264 Reimbursement	=	Costs over DRG
$120,000	x	0.25	=	$30,000	-	$24,309	=	$5,691

NTAP Reimbursement (lesser of $14,950 or 65% of the cost over DRG)	+	MS-DRG 264 Payment	=	Payment
$5,127 x 65% = $3,699	+	$24,309	=	**$28,008**

Total Hospital Reimbursement if Charges/Covered Cost is more than the DRG Reimbursement and more than the maximum NTAP amount

Hospital Charges for Admission	x	Hospital CCR	=	Covered Cost	-	MS-DRG 264 Reimbursement	=	Costs over DRG
$200,000	x	0.25	=	$50,000	-	$24,309	=	$25,691

NTAP Reimbursement (lesser of $14,950 or 65% of the cost over DRG)	+	MS-DRG 264 Payment	=	Payment
$14,950	+	$24,309	=	**$39,259**

1. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-F/subject-group-ECFR5703923263fedba/section-412.88
2. FY 2026 IPPS Final Rule Home Page 1833-F: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-final-rule-home-page

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Hospital Outpatient Coding

Effective January 1, 2026 - December 31, 2026

Code	Description	SI	APC	2026 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	$5,815
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	$5,815
C1736	**Catheter(s), intravascular for renal denervation, ultrasound, including all single use system components**	**H**	**N/A**	**Packaged** (Maps Procedure to TPT Payment)

APC 5192 - Level 2 Endovascular Procedures
Status Indicator "J1" - Hospital part B services paid through a comprehensive APC (C-APC)
Status Indicator "H" - Separate cost-based pass-through payment, not subject to copayment.

** On claims for Medicare beneficiaries, hospitals should report not only the appropriate CPT® Code, but also HCPCS II device category C-Code C1736

Transitional Pass-Through (TPT) Payment

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.

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.

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]

1. CY 2026 NFRM OPPS CMS 1834-FC: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1834-fc
2. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-419/subpart-G/section-419.66

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Hospital Outpatient Billing – TPT Payment Calculation

Effective January 1, 2026 - December 31, 2026

Medicare calculates incremental TPT payments on a case-by-case, considering factors such as the following:

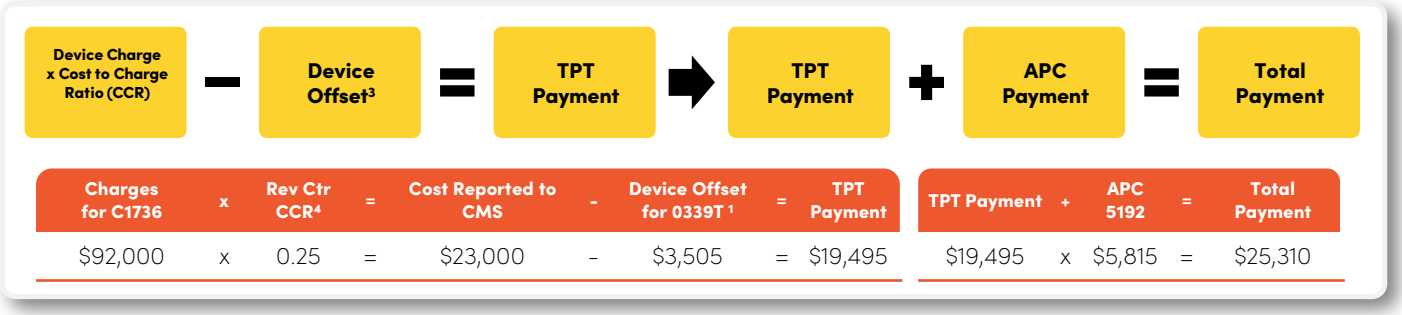
- Device Cost/Invoice
- Device Offset for the CPT code (0338T or 0339T)
- Charges for HCPCS C1736: Catheter(s), Renal Denervation, Ultrasound
- Revenue Center/Code the hospital charges C1736 against
- CMS's Calculation of the cost-to-charge ratio (CCR) for the Revenue Center/Code

Key Considerations:

- Revenue Center/Code CCRs often differ from the overall Outpatient CCR that hospitals typically track
- Medical device Revenue Centers generally fall within the "27(x)" range, with the most commonly used being:
  - Rev Code 272: Med/Surg Supplies, Sterile Supply
  - Rev Code 278: Med/Surg Supplies, Other Implants

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.



Charges for C1736	x	Rev Ctr CCR[4]	=	Cost Reported to CMS	-	Device Offset for 0339T [1]	=	TPT Payment
$92,000	x	0.25	=	$23,000	-	$3,505	=	$19,495

TPT Payment	+	APC 5192	=	Total Payment
$19,495	x	$5,815	=	$25,310

	Element	Calculation	Amount	
			0338T	0339T
Hospital Charge for C1736	A		$92,000	$92,000
Hospital Implantable Devices CCR	B		0.25	0.25
Reported Cost of C1736	C	A x B	**$23,000**	**$23,000**
Device Related Offset* of CPT Codes 0338T/0339T	D		$4,244	$3,505
Incremental TPT Payment	E	C – D	**$18,756**	**$19,495**
APC Assignment for CPT Codes 0338T/0339T (APC 5192)	F		$5,815	$5,815
Total APC + TPT Payment	G	E + F	**$24,571**	**$25,310**

*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

1. CY 2026 NFRM OPPS CMS 1834-FC: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1834-fc
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.
4. Revenue Center CCR is provided as an example only, individual hospital's CCR will depend on which Revenue Center the hospital deems as appropriate and differs from hospital to hospital.

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Ambulatory Surgery Center (ASC) Coding

Effective January 1, 2026 - December 31, 2026

Code	Description	PI	2026 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	J8	$4,441
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	J8	$4,175
C1736[2]	**Catheter(s), intravascular for renal denervation, ultrasound, including all single use system components**	**J7**	**Contractor Priced** (Maps Procedure to TPT Payment)

Payment Indicator "J8" - Device-intensive procedure; paid at adjusted rate.
Payment Indicator "J7" - OPPS pass-through device paid separately when provided integral to a surgical procedure on ASC list; payment contractor-priced

** On claims for Medicare beneficiaries, hospitals should report not only the appropriate CPT® Code, but also HCPCS II device category C-Code C1736

Transitional Pass-Through (TPT) Payment

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.

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.

TPT payments in ASCs are generally based on actual device cost, which is typically verified through manufacturer invoices or hospital purchase documentation.[3,4]

1. CY 2026 NFRM ASC CMS 1834-FC: https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices/cms-1834-fc
2. CMS Manual System Pub 100-04 Medicare Claims Processing, Transmittal 13044, Change Request 13934. https://www.cms.gov/files/document/r13044cp.pdf
3. Medicare Claims Processing Manual Chapter 14 - Ambulatory Surgical Centers https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c14.pdf
4. Novitas Solutions: Ambulatory surgical center (ASC) pass-through devices. https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00261904

Physician Coding

Effective January 1, 2026 - December 31, 2026

CPT ® Code	Description	MUE	RVUs	2026 National Medicare Rate[1]	
				Facility	Non-Facility
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	1	0.00	Contractor Priced	Contractor Priced
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	1	0.00	Contractor Priced	Contractor Priced

Unlike standard CPT I (Current Procedural Terminology) codes, Category III CPT codes do not have nationally established wRVUs or payment. MACs may have fee schedules associated with "T" codes. Please verify with your local MAC if there is payment established for the RDN procedure.

In situations where RVUs aren't established, payers may utilize a "crosswalk" or comparator code to set an RVU rate for codes lacking a defined payment.

The following CPT codes are examples of potential crosswalk codes that may be comparable to uRDN. It is ultimately the physician's responsibility to choose the most appropriate CPT code comparator that is best representative of the work and complexity associated with the uRDN procedure. Physicians report the either the 0338T or 0339T code on their claims submission forms and document the crosswalk or comparable CPT I code in their documentation and cover letter to ensure payment is commensurate with comparable procedures they currently perform. Note: Do not report/bill the CPT crosswalk code on the claim form.

CPT® Code	Brief Description	wRVUs	Total RVUs	2026 National Medicare Rate (Facility)[2]	Practitioner Labor Est			
					Pre – Service	Intra-Service	Post-Service	Total Time[3]
37236	Transcatheter placement of an intravascular stent(s), open or percutaneous	8.53	11.68	$390	31	90	30	151 min
36252	Selective catheter placement (first-order), main renal artery and any accessory renal artery(s) for renal angiography	6.57	9.27	$310	31	53	30	114 min
37246	Transluminal balloon angioplasty, open or percutaneous, initial artery	6.83	9.23	$308	31	60	28	119 min
+37247	Transluminal balloon angioplasty, open or percutaneous, additional artery	3.41	4.55	$152	0	30	0	30 min

1. CY 2026 Physician Prospective Payment CMS-1832-F: https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1832-f
2. Rates associated w/ the conversion factor ($33.40) for nonqualifying alternative payment model (APM) participants
3. Total Time may be greater than the displayed components

Diagnosis Codes[1]

Effective October 1, 2025 - September 30, 2026

The following ICD-10-CM (International Classification of Diseases, 10th Revision, Clinical Modification) diagnosis codes are examples which might be associated with indications relevant to ultrasound renal denervation (uRDN) procedures performed using the Paradise Ultrasound RDN System. It's important to note that this list is not exhaustive, and the reported codes should reflect accurate documentation corresponding to the patient's specific condition(s). The task of selecting and reporting these codes ultimately rests with the discretion of the treating provider.

	ICD-10 CM	Description
Potential Primary Diagnosis Codes	I10	Essential (primary) hypertension, includes hypertension (arterial) (benign) (essential) (malignant) (primary) (systemic)
	I11.0	Hypertensive heart disease with heart failure
	I11.9	Hypertensive heart disease without heart failure
OR		
*Other Potential Primary Diagnosis Codes**	I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 CKD, or unspecified CKD
	I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 CKD, or unspecified CKD
	I13.10	Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 CKD, or unspecified CKD

+ If Applicable

	ICD 10-CM	Description
Potential Secondary Diagnosis, Should Not Be Primary Diagnosis	I1A.0**	Resistant Hypertension

	ICD 10-CM	Description
Other Potentially Relevant Codes	I16.0	Hypertensive urgency
	I16.1	Hypertensive emergency
	I16.9	Hypertensive crisis, unspecified

*If qualifying your patient with one of the "Other Potential Primary Diagnosis Codes", consult the specific guidelines provided in the IFU for the Paradise Ultrasound Renal Denervation System to ensure that the patient's condition aligns with the approved uses of the system.

**I1A.0: Resistant Hypertension diagnosis code effective October 1st, 2023. (CMS FY2024)

- Applicable for "Apparent treatment resistant hypertension", "Treatment resistant hypertension", and "True resistant hypertension"
- Code first specific type of existing hypertension, if known, such as: essential hypertension (I10)

1. FY 2026 IPPS Final Rule Home Page 1833-F: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-final-rule-home-page

Recor Medical®

Hospital & Physician Billing – NCD CED Requirements

Effective October 28, 2025

Attention All Hospitals and Healthcare Providers,

On October 28, 2025, the Centers for Medicare and Medicare Services (CMS) posted the final decision memo for Renal Denervation (RDN) for Uncontrolled Hypertension (HTN).[1] This NCD establishes coverage, under specific criteria including coverage with evidence development (CED), for FDA-approved indications of the Paradise® System.

RDN Devices and related items and services furnished by this NCD require following CMS-approved CED study protocols. To meet the criteria of the CED study protocol CMS publishes specific RDN claims processing instructions. Please check with your coding department on appropriate coding requirements. The following codes may apply to RDN claims covered under this NCD.

<table>
<tr><th rowspan="2"></th><th rowspan="2">Physician Claims</th><th colspan="2">Facility Claims</th></tr>
<tr><th>Outpatient</th><th>Inpatient</th></tr>
<tr><td rowspan="2">Procedure</td><td colspan="2">CPT® 0338T or 0339T</td><td rowspan="2">X051329</td></tr>
<tr><td colspan="2">Modifier -Q0: Investigational clinical service provided in a clinical research study that is in an approved clinical research study</td></tr>
<tr><td rowspan="2">Diagnosis</td><td colspan="3">Applicable Primary Diagnosis Code (e.g. . I10, I11.0, I11.9, I12.9, I13.0, I13.10, etc.)</td></tr>
<tr><td colspan="3">Secondary Diagnosis Code: Z00.6
Encounter for examination for normal comparison and control in clinical research program</td></tr>
<tr><td>Condition Code</td><td>N/A</td><td colspan="2">Condition Code 30: Qualified Clinical Trial</td></tr>
<tr><td>NCT[2]</td><td>“CT07231757” reported on Item 19 on CMS-1500 forms</td><td colspan="2">NCT# “07231757” reported with Value Code D4</td></tr>
</table>

For more detailed information related to the NCD and CED billing, please refer to Recor Medical’s Paradise System NCD Overview & FAQs and NCD Billing Guide resources.

1. Centers for Medicare & Medicaid Services. NCA Tracking Sheet – Renal Denervation for Uncontrolled Hypertension. Available at: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=318. Accessed October 28, 2025.
2. ClinicalTrials.gov. The RADIANCE CED Study (NCT07231757). Available at: https://clinicaltrials.gov/study/NCT07231757?term=NCT07231757&rank=1. Accessed November 17, 2025.

Recor Medical®

Rx Only. Brief Summary - Prior to use, please reference the Instructions for Use

Indications for Use

The Paradise Ultrasound Renal Denervation System (Paradise System) is indicated to reduce blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure.

Contraindications

The Paradise Catheter is contraindicated in any of the following:

- Renal arteries diameter <3 mm and >8mm
- Renal artery Fibromuscular disease (FMD)
- Stented renal artery
- Renal artery aneurysm
- Renal artery diameter stenosis >30%
- Pregnancy
- Presence of abnormal kidney (or secreting adrenal) tumors
- Iliac/femoral artery stenosis precluding insertion of the catheter

Warnings

- Failure to use the recommended balloon size may result in renal artery stenosis, dissection, perforation, aneurysm, significant vasospasm requiring intervention, ablation of unintended tissues or structures, and/or no ablation of target tissue achieved.
- Energy emission in an unintended location may result in unintended tissue damage.
- Do not move the Paradise Catheter during sonication.
- Do not sonicate in renal artery at locations with visible plaque.
- Do not deliver sonications in an overlapping arterial target zone.

Precautions

- Patients with known allergy to contrast medium may be at increased risk of hypersensitivity reactions.
- Only use specified coolant (Sterile water) for fluid supply. DO NOT USE SALINE.
- Avoid multiple balloon inflations to achieve apposition of the balloon to the renal artery wall; multiple balloon inflations may result in increased vessel trauma.
- The Paradise Catheter is for single use only. Do not resterilize or reuse. Reuse, reprocessing, or resterilization will compromise device integrity which may result in patient injury, illness, or death.
- Do not touch the Paradise Catheter balloon during sonication, as it may result in serious injury.
- The Paradise System may interfere with or adversely affect the operation of cardiac pacemakers or other active implants, unless proper precautions have been taken or managed per the manufacturer's instructions. When in doubt regarding possible hazards, seek qualified advice and/or consult with the manufacturer(s) prior to initiating a procedure. The Paradise Catheter is a Type CF, defibrillation-proof Applied Part.

Potential risks of renal denervation procedure/response to treatment

Ablation or thermal injury to vessel, adjacent tissue or other structures, Acute kidney injury, Angina, Anxiety, Arrhythmia, Atrial tachycardia, Bradycardia, Gastrointestinal complications (diarrhea, nausea, vomiting), Hypotension/ Dizziness and/or Headaches, Hypertension, Hyperhidrosis, Pain (transient abdominal, lower back), Renal failure or renal insufficiency, Renal artery aneurysm or pseudoaneurysm, Renal infarction, Renal artery dissection, or perforation, Renal artery stenosis, Vasospasm, Vasovagal response, Stroke or transient ischemic event

Potential risks of arterial catheterization procedure

Allergic reaction to contrast, Arterio-enteric fistula, Arterio-venous fistula, Bleeding, Cardiopulmonary arrest, Complications related to pain and anti-anxiety medications, Death, Deep vein thrombosis, Edema, Embolism (pulmonary, renal, peripheral vasculature, plaque), Hematuria, Infection, Myocardial infarction, Pain, Vascular access site complications (pseudoaneurysm, pain, swelling, hematoma)

Recor Medical®

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