Paradise® Ultrasound Renal Denervation System

Frequently Asked Questions (FAQs) Guide

This guide provides coverage and reimbursement information for the Paradise System procedure. Recor Medical offers reimbursement support via email at **reimbursement@recormedical.com**. Customer reimbursement assistance is provided subject to the disclaimers set forth in this guide.

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Clinical

My patient is: intolerant to "X" drug class, or intolerant to escalating drug dosage and remains uncontrolled above target blood pressure". Does my patient meet the indication, and will they meet coverage criteria?

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.[1]

*Refer to last page for Important Safety Information

The patient referenced above may meet the FDA indication, however it is important to understand that individual insurance plans may have coverage criteria that are more restrictive to indicated patients. It is important to verify with the insurance provider if they have a uRDN coverage policy and if so what their patient criteria for coverage are.

While the FDA approves treatments based on their safety and efficacy, insurance providers consider other factors, like medical necessity and the need for the treatment compared to alternatives, which can sometimes lead to more restrictive coverage.

It's essential to confirm with individual insurance providers if they have a coverage policy for uRDN, and if so, what their specific patient coverage criteria are. Prior Authorizations are highly encouraged to verify patient eligibility.

Do I need to verify an office Systolic blood pressure (SBP) w/ an out-out-office measurement?

SBP measured in a clinical or office environment is often subjected to bias stemming from the 'white coat' effect. This phenomenon can compromise the accuracy of the assessment and may lead to misdiagnoses. As such, the American College of Cardiology (ACC) and the American Heart Association (AHA) advise measuring blood pressure outside of the clinical setting as a confirmatory process for diagnosing hypertension or resistant HTN.[2] It is recommended that physicians follow ACC/AHA guidelines for the most appropriate blood pressure measurement.

Additionally, per the CMS National Coverage Determination (NCD) for Renal Denervation for HTN,[3] either serial at home BP readings or ambulatory BP measurements (ABPM) confirming the patient's uncontrolled HTN are required.

Please validate the necessary clinical documentation with the patient's insurance provider to determine eligibility for coverage.

Coding

There are long standing codes previously used for modality agnostic RDN, do these codes apply to uRDN?

Inpatient Coding:

No, the Centers for Medicare & Medicaid Services (CMS) granted an ICD-10 PCS code to represent renal denervation via catheter-based ultrasound ablation. ICD-10-PCS code X051329 (Destruction of Renal Sympathetic Nerve(s) using Ultrasound Ablation, Percutaneous Approach) is effective October 1st, 2023.[4] Once effective, other ICD-10 PCS codes describing RDN should not be utilized for Inpatient billing for uRDN procedures.

Outpatient/Physician Coding:

Yes, the American Medical Association (AMA) via a September 2023 CPT Editorial Panel meeting deemed that the previous Category III (emerging technology) codes describing RDN do apply to uRDN.[5] Please see the Paradise Ultrasound RDN System Coding Guide for more information regarding utilizing these codes.

CMS created a new ICD-10-CM code for resistant hypertension I1A.0, is there any coding guidance around utilizing this code?

ICD-10-CM code "I1A.0: Resistant Hypertension" became effective October 1st 2023.[4] This code is applicable for "apparent treatment resistant hypertension", "treatment resistant hypertension", and "true resistant hypertension". Code first the specific type of existing hypertension, if known, such as: essential hypertension (I10) or secondary hypertension (I15.-).

Coding

What is the definition of *Resistant Hypertension* when utilizing ICD-10 CM code I1A.0?

Consistent with the 2018 AHA Scientific Statement presented at the ICD-10 Coordination and Maintenance Committee Meeting,[4,6] resistant hypertension (RH) is defined as above-goal elevated blood pressure (BP) in a patient despite the concurrent use of 3 anti-hypertensive drug 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. When a physician documents a patient as having "resistant hypertension", that medical terminology would conclude the patient meets the accepted "clinical" guideline definition (above) for a diagnosis of resistant HTN.

Is there a device supply code to report hospital charges for the Paradise Ultrasound RDN System?

Yes, CMS created a new HCPCS Level II code to define a new device category for the Paradise System, *C1736 – Catheter(s), intravascular for renal denervation, ultrasound, including all single use system components*. 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.[7]

HCPCS C-Codes are tracking codes established by CMS to assist Medicare in establishing future APC payment rates. C-Codes are required for billing device charges within Medicare hospital outpatient claims (e.g., Form UB-04) and may also be used for other payers. Use of this code as appropriate is required to trigger the additional transitional pass-through (TPT) payment.

For more information, please go to the "**Payment**" section of this FAQ.

Coverage

Are there any National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), or other national policies regarding RDN?

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).[3] This NCD establishes coverage, under specific criteria including coverage with evidence development (CED), for FDA-approved indications of the Paradise® Ultrasound Renal Denervation System.

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.

Specifically, the patient criteria are as follows:

- 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

To access the full NCD released on October 28, 2025, along with physician and facility requirements, please click **here**.

For any service reported to Medicare, it is expected that the medical documentation clearly demonstrates that the service meets all of the above criteria. All documentation must be maintained in the patient's medical record and be available to the contractor upon request.

Coverage

What workup should I perform before submitting a prior authorization?

While coverage requirements may differ among various insurance providers, certain key elements may serve to demonstrate medical necessity for prior authorizations. These integral aspects are partly drawn from the Paradise Ultrasound RDN System indication[1], inclusion/exclusion criteria seen in Paradise Ultrasound RDN System clinical trials8 or guidance from the Society for Cardiovascular Angiography & Interventions (SCAI).[9]

- Out-of-office BP measurement to confirm HTN diagnosis
- Documentation that the patient is currently being prescribed anti-HTN medications (class and dos-ages)
- Documentation of any intolerance to additional anti-HTN medications
- Renal Imaging to exclude secondary causes of HTN that are anatomically ineligible for RDN, for example, renal artery stenosis or fibromuscular dysplasia
- eGFR Measurement

It is important to note that satisfying some or all of these elements does not assure coverage. These criteria are non-exhaustive, and each payer may require additional medical documentation.

Note: Traditional Medicare FFS (Part A/B) does not require prior authorizations (PA) for this therapy currently. However, most Medicare Advantage (MA) plans have PA requirements that must be followed.

Recor Medical offers Prior Authorization educational resources as well as patient therapy access support via the Recor Patient Access Program 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.

If you would like more information about the Recor Patient Access Program or how to enroll, please contact your local Recor Medical Reimbursement Representative or email reimbursement@recormedical.com

How long is a Prior Authorization valid for?

Prior Authorization policies vary from payer to payer and state to state. Some states have explicit legislation that prior authorizations are to be valid for no less than 60 days. Certain states also have policies which define the length a prior authorization is valid for even when a patient changes their insurance. Please verify your state's specific policies and check with the insurance provider on any policy specific timelines.[10]

Will longstanding private payer policies regarding Radiofrequency-RDN apply to uRDN?

Many current private payer policies regarding RDN were developed before there were FDA approved devices and many of these policies have not yet taken into consideration the latest evidence from the newest generation of renal denervation technologies.

Over the last year, 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.

It is highly encouraged providers seek Prior Authorization to facilitate individual case considerations for appropriate patients.

Can this procedure be performed in the ASC setting?

Yes, at least with respect to Medicare cases. The Paradise Ultrasound RDN System procedure represented by CPT Category III codes 0338T/0339T is currently on the CMS ASC Covered Procedures List[11] and there are no ASC exclusions in the NCD.[3] It is important to note that private payers may have different policies regarding the appropriateness of the ASC site of service for uRDN procedures.

It is highly encouraged to verify or seek prior authorization if the payer will allow procedures to be done in this setting.

NTAP

When is the NTAP for the Paradise System effective?
CMS approved the NTAP for the Paradise System effective October 1st, 2024 (the start of Federal FY 2025). Ultrasound Renal Denervation procedures will be eligible for NTAP for at least two years but not more than three years from the effective date.

Are there any special coding or billing requirements related to the NTAP?
There are no special billing requirements placed on the hospital for processing the NTAP, other than using the appropriate uRDN ICD-10-PCS code, X051329. Using this code on your inpatient claim will trigger a calculation of the NTAP by your Medicare Administrator Contractor's (MAC) claims processing system.

What is the maximum additional reimbursement provided by the NTAP?
While the NTAP amount is not a fixed amount and can vary for each case, hospitals are eligible for up to $14,950 in additional reimbursement (plus the hospital's full DRG payment).

It is important to note that the NTAP is calculated on a case-by-case basis.[15] The exact payment amount per case is not fixed and depends on the total cost of the admission. Should the hospital specific calculation of 65% of the hospital costs minus the DRG payment be less than $14,950, then the lower amount is paid.

Please see the "Paradise System Coding & Payment Guide" for example NTAP calculations.

Does the NTAP apply to Medicare Advantage or private insurance inpatient procedures?
No, NTAPs only apply to Medicare FFS discharges. Medicare Advantage plans and private insurance reimbursement is based on private contracts with these providers. If you would like more insight into what your contracted rates are with these providers, contact your contracting team for more information.

How is the actual cost of the discharge determined?
CMS derives the total covered cost of the discharge based on the total covered hospital charges for each case, and the hospital's inpatient operating cost to charge ratio determined from its cost report.

Where can a hospital find the hospital inpatient operating cost-to-charge-ratio (CCR) used in the NTAP calculation?
The CCRs by provider number are available at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-final-rule-home-page#DataFiles

Download the FY2026 Impact File and search the excel file by Medicare provider number. The CCR is listed in Column AG (Operating CCR). If you do not know your Medicare provider number, please us via email at reimbursement@recormedical.com with the name and location of your hospital and we can look it up for you.

TPT Payment

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

A TPT payment from CMS represents a critical fundi-ng 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 payment be effective?

Recor Medical anticipates that the TPT payment will be effective for a duration of at least two years but not more than three years.[15]

Does this TPT payment only apply to Ultrasound Renal Denervation?

The TPT payment and HCPCS Level II code granted by CMS, is unique to "Catheter(s), intravascular for renal denervation, ultrasound, including all single use system components" 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.

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 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)

RDN 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.[16] It's important to note, however, that the calculation of the TPT payment amount is different from the Outpatient setting (carrier priced) and is defined by the individual Medicare Administrative Contractor (MAC).[17] 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 an NTAP effective October 1, 2024. Please reference our NTAP resources for more information.

Physician's Office / Office Based Lab (OBL)

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

Why did CMS decide to grant separate 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 payment 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 in the TPT payment amounts.[15]

TPT Payment

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 payment 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 with the TPT payment?

The TPT payment 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.

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

What is the device offset and why is it removed from the TPT payment 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 Revenue Center 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 payment expires.

Where can a hospital find the relevant hospital CCRs used in the TPT payment calculation?

The provider specific Revenue Center CCRs are part of the Outpatient impact files found on CMS's website at FY 2026 Impact File (final rule).[18] Please note that this information in published and updated annually.

You can contact the Recor Medical Reimbursement team for your hospital's different CCRs for the relevant Revenue Centers.

Additionally, you may contact your MAC to find out your hospital's CCR for purposes of new technology payments from CMS.

References

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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)

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