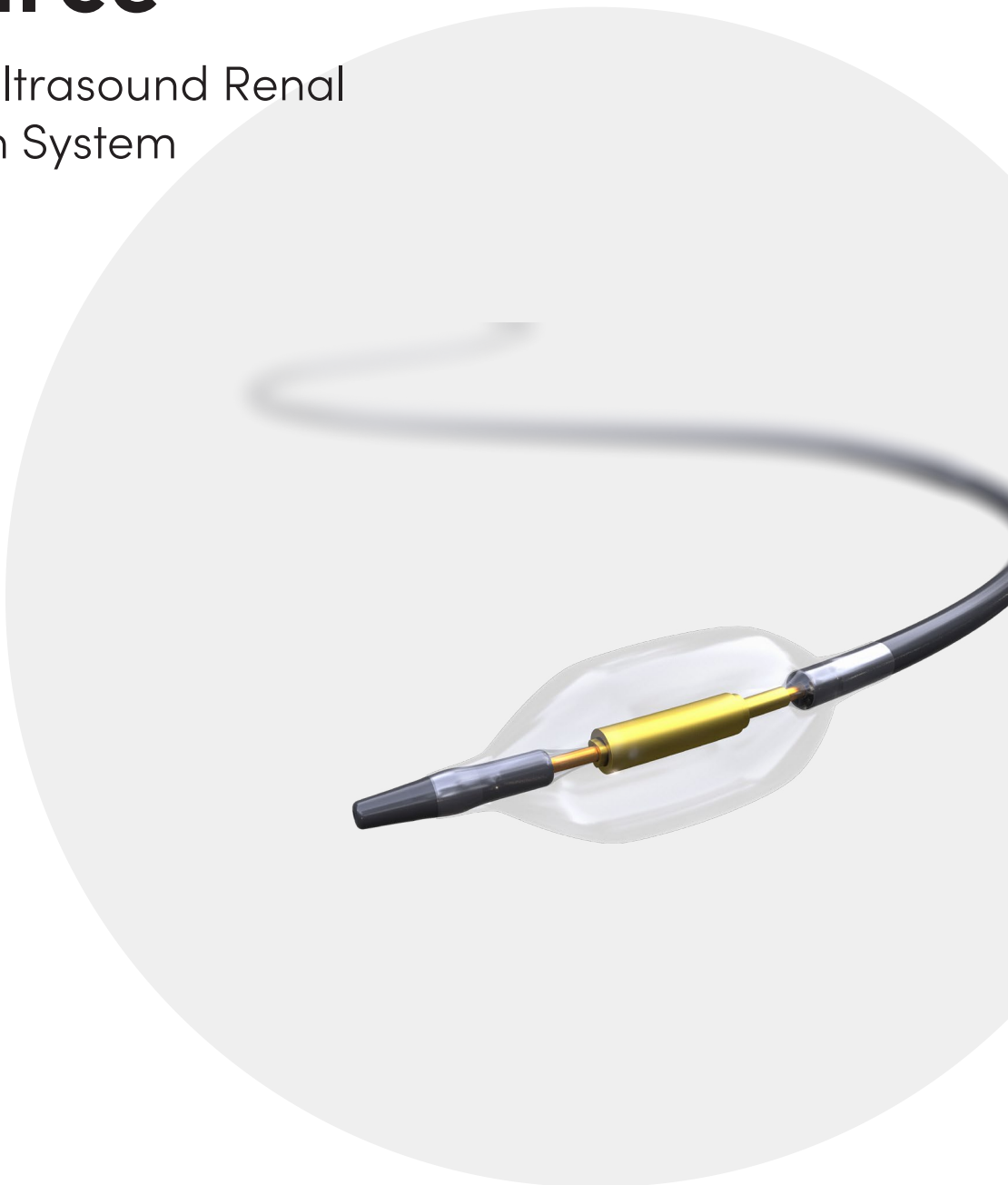
Recor Medical®

Crosswalk Resource

Paradise® Ultrasound Renal Denervation System



Effective January 1, 2026

CROSSWALK RESOURCE

On November 7th, 2023, the U.S. Food and Drug Administration (FDA) issued a Premarket Approval (PMA) for the Paradise® Ultrasound Renal Denervation System. This critical milestone symbolizes a considerable advancement in the management and treatment of hypertension with ultrasound renal denervation (uRDN).

The authorization states:
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.

As with numerous cutting-edge technologies at the initial stages of regulatory approval, there currently exists no defined Category I Current Procedural Terminology (CPT) codes that adequately represents the skill, time, and resources required to perform these services.

It is in these situations where the role of Category III (emerging technology) CPT codes or "T" codes become paramount. Category III codes serve as placeholders for procedures that don't yet have an assigned Category I code, allowing the reporting of innovative services, treatments, or technologies for which there is not yet widespread adoption. Utilizing Category III codes ensures that novel procedures are tracked, which can help with data collection and assessment of efficacy and safety. Over time, as the use of these innovative technologies becomes more prevalent and their value is demonstrated, they may be assigned a permanent Category I CPT code, facilitating consistent documentation and billing across healthcare providers.

Unlike standard CPT Category I codes, Category III CPT codes do not have nationally established RVUs or payment. MACs may have fee schedules associated with "T" codes. Please verify with your local MAC if there is payment established for the uRDN procedure. Work that is integral to the procedure such as renal angiography or selective catheter placement is bundled into the uRDN procedure. The existing CPT codes associated with those components of the uRDN procedure are not separately billed on the CMS Form 1500 claim form.

CPT® Code	Description	RVUs	2026 National Medicare Rate[1] (Facility)	Intraoperative Time
0338T	Transcatheter renal sympathetic denervation, percutaneous approach, unilateral Transcatheter renal sympathetic denervation, percutaneous approach, unilateral	0.00	Contractor Priced	n/a
0339T	Transcatheter renal sympathetic denervation, percutaneous approach, unilateral Transcatheter renal sympathetic denervation, percutaneous approach, bilateral	0.00	Contractor Priced	n/a

Importantly, the utilization of Category III codes does not guarantee coverage by third party health payers or set a national or local payment level for physician services. In fact, payers may not immediately update their claims processing systems to include new Category III codes.

1. CY 2026 Physician Prospective Payment CMS-1832-F: https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1832-f

REPORTING CATEGORY III CODES

Category III codes lack national valuation, leading payers to employ various methodologies to determine physician reimbursement related to the code. For Medicare claims, Relative Value Units (RVUs) and corresponding payment rates for Category III codes are set by Medicare Administrative Contractors (MACs), each establishing unique payment rates and coverage policies for these codes. Providers are advised to consult their specific MAC for additional details regarding payment levels for Category III CPT codes 0338T/0339T.

Private payers independently determine coverage and payment for procedures delineated by Category III CPT codes, which may be based on a percentage of physician charges, a percentage of the Medicare fee schedule amounts, or alternative methodologies. We suggest reviewing your payer contracts for any specific guidelines concerning the pricing and billing of Category III codes.

In situations where RVUs aren't established as is with Category III codes such as 0338T/0339T, payers utilize a "crosswalk" or comparator code to set an RVU rate for codes lacking a defined payment. These payers will require supporting evidence to assign payment, necessitating thorough documentation of the services provided, including resources used and time spent. These reimbursement decisions are payer specific and may require a prior authorization per payer guidelines.

Physician work value typically focuses on:

- Time (pre-, intra-, and post-operative time in the hospital)
- Mental effort,
- Professional judgment,
- Technical skill,
- Physical effort,
- Stress due to risk,
- Number and complexity of follow up visits.

The crosswalk first identifies a reference procedure with an established payment level. Next, the physician suggests that payment for the Category III code should be at the same rate as the reference procedure rate because both procedures require similar physician time, effort, and complexity. The payer may accept the "comparability" of the procedures and crosswalk payment from the reference procedure to the uRDN procedure.

Recommended documentation to support your Category III code claims submissions include:

- Copy of operative or procedure report
- Letter of medical necessity
- Clinical notes
- Relevant crosswalk CPT code with anticipated payment indicated
- Copy of relevant published clinical literature or uRDN bibliography
- Copy of the FDA approval letter

CROSSWALK EXAMPLES

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)[1,2]	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

*Total Time may be greater than the displayed components.

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

EXAMPLE – CLAIM SUBMITTAL LETTER – CATEGORY III PROCEDURE PARADISE RENAL DENERVATION SYSTEM

When a provider establishes that a Category III code is appropriate, they should submit a specialized report to the payer. This report outlines the procedure for the consideration of coverage and reimbursement.

Here is an example of a 'special report' format, which includes a recommendation for describing the Paradise Renal Denervation System and establishing a clinical 'crosswalk' code for reimbursement valuation, based on the payer's contract-specific guidelines. The provided sample letter is not intended for direct case prior authorization submission, but it offers a practical structure commonly found useful when securing prior authorizations for procedures represented by Category III codes.

Clinicians ought to bear in mind the crucial importance of avoiding over-reliance on generic template documents. Instead, the focus should be on providing case-specific descriptions and details of the actual procedures performed. This sample letter illustrates a possible format for submissions, aiming to present a clear and concise explanation of the actual procedure and the specific details needed to highlight the use of the technology. This should correspond to the individual medical necessity of the procedure for the patient, corroborated by relevant clinical data and case documentation.

[SITE LETTERHEAD]

[DATE]
Health Plan Administrator
[HEALTH PLAN NAME]
[ADDRESS / PO BOX]
[CITY], [STATE] [ZIP CODE]

RE: [PATIENT NAME]
[INSURANCE IDENTIFICATION NUMBER]

Special Report for ultrasound renal denervation procedure, Category III CPT codes 0338T/0339T for Paradise Renal Denervation System

On behalf of my patient, [INSERT PATIENT NAME], this letter provides clinical information on this patient's condition, and a formal explanation of the Paradise Renal Denervation System procedure for medically necessary health care services. [INSERT PATIENT NAME] is a [INSERT AGE AND GENDER] who presented to me with [INSERT DIAGNOSIS].

Description:
0338T: Transcatheter renal sympathetic denervation, percutaneous approach, unilateral
0339T: Transcatheter renal sympathetic denervation, percutaneous approach, bilateral

Reason for use: No CPT I code exists to precisely represent the ultrasound renal denervation procedure medically necessary for my patient [INSERT PATIENT NAME]. The proposed technique utilizing the Paradise Renal Denervation System is described below.

Description of Procedure: [SURGEON INSERTS DETAILED PROCEDURE DESCRIPTION INCLUDING THE USE OF THE PARADISE RENAL DENERVATION SYSTEM & TECHNOLOGY. FOLLOWING IS FOR EXAMPLE PURPOSES ONLY]

[Using the Seldinger technique, the vessel is punctured, a guide wire is passed, a sheath is placed over the guidewire, and a flush catheter and guide wire are manipulated into the aorta. After forming the catheter, a small amount of contrast is injected to confirm appropriate positioning. A non-selective DSA imaging of the aorta and renal ostia is performed, with potential imaging of the kidneys bilaterally as well. Images are reviewed to confirm that the anatomy is suitable for ultrasound ablation. If suitable anatomy is confirmed, the introducer is upsized and an appropriate selective 7Fr guide is chosen. The guide catheter is passed over a guidewire into the ostium of one renal artery, the position is checked with test injections, and the appropriately sized ultrasound catheter is passed into the distal portion of the main renal artery. The generator then inflates the balloon with water at the first ablation site. A small amount of contrast is injected through the guide catheter to ensure it does not pass the balloon, confirming good wall apposition. The generator is used to deliver an ultrasound emission lasting 7 seconds. The balloon automatically deflates, and the catheter is moved proximally to the next ablation site, and the process is repeated. Treatment of the main renal artery is performed from distal to proximal with care given to not recross previously treated vascular sites. Typically, 2-3 focal treatments are performed to ablate the renal nerves and the procedure may require a different size balloon catheter to be advanced dependent on arterial diameter variability and if treatable accessory arteries are present. Additional sedation and analgesia are provided as needed during these treatments. After treating, the ultrasound catheter is withdrawn and a final DSA arteriogram is performed to document that the artery has not been damaged. The procedure is then repeated on the contralateral side including treatable accessory arteries which may require advancing a different size balloon catheter dependent on arterial diameter. Once a satisfactory result has been documented in the absence of extravasation or embolization, the catheter and sheath are removed, and hemostasis obtained with manual compression or closure device. Sterile dressings are applied, and the patient is moved out of the room.]

Device Description: The Paradise Renal Denervation System uses ultrasound renal denervation to treat hypertension. The newly-approved system is catheter-based and designed to use ultrasound energy to thermally ablate the afferent and efferent nerves surrounding the renal artery and innervating the kidney. This ablation is designed to reduce the activity of the renal sympathetic afferent and efferent nerves, which has been shown to decrease renal and central sympathetic activity subsequently leading to a reduction in arterial BP. uRDN offers focal sympathetic denervation at the renal artery level, thus mitigating the systemic side effects.

The Paradise System is made up of the following two main components which deliver ablation to the renal artery:

- The Paradise catheter consists of a sterile, single use, multi-lumen catheter with an ultrasound generating cylindrical transducer inside an inflatable balloon (available in six sizes) at the distal end of the catheter. The catheter delivers a uniform, circumferential (360 degree) ultrasound emission with each ablation taking 7 seconds. Ablation is per formed 2–3 times along each main renal artery

- The Paradise generator controls the energy delivery and fluid management of the Paradise System. The generator delivers electrical energy through the catheter, where it is converted to ultrasound energy via the transducer, and the ultrasound heats tissue which ablates the renal artery nerves. Cold water is circulated through the catheter balloon, and this provides protective cooling to help avoid ablating the renal artery wall. The target ablation zone is located approximately 1–6 mm from the arterial lumen where the thermal dose is sufficient to achieve denervation

Per the FDA PMA the Paradise Renal Denervation 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.

Patient's Clinical Need for the Paradise Renal Denervation System Procedure: [PATIENT NAME] is a [AGE] [GENDER] who presented to me with [DESCRIBE SYMPTOMS WITH SPECIFICITY]. Prior treatments and medication regimen have included [TYPE OF PREVIOUS THERAPY]. The impact hypertension has had on my patient may be described as [DESCRIBE].

This letter provides a depiction of this patient's clinical history and description of the work involved in the Paradise Renal Denervation System procedure. It is my sincere hope that this additional information will assist in your valuation of the use of the ultrasound renal denervation procedure represented by the Category III codes 0338T/0339T and explain the "crosswalk" CPT code [INSERT "CROSSWALK" CODE] used to value the uRDN procedure.

"Crosswalk" Code for Valuation: [INSERT "CROSSWALK" CODE]

Valuation: The appropriate level of physician reimbursement for this procedure, based on relevant [INSERT YEAR] fee schedules for the crosswalk code, is that which is provided for CPT [INSERT "CROSSWALK" CODE]. [PHYSICIAN INSERTS DETAILED SUMMARY OF WORK, TIME AND EXPERTISE THAT IS SIMILAR TO THE "CROSSWALK" CODE (may be from another anatomy)]

Documentation: Attached are operational [OR CLINICAL] notes detailing the procedure as [OR TO BE] performed on [DATE] on [PATIENT NAME].

Summary: Use of Category III codes 0338T/0339T are necessary as an established CPT Category 1 code does not represent the ultrasound renal denervation to be performed. A "crosswalk" to CPT Code [INSERT "CROSSWALK" CODE], including detailed procedure documentation, is presented for valuation and reimbursement justification.

Given the nature of the patient's response to medication, additional or escalation of pharmacological treatment would not be the best course of care for this case. I believe that the proposed procedure would provide the best result to reduce [PATIENT'S NAME] blood pressure. For additional reference, I have attached a copy of the FDA approval letter for the Paradise Ultrasound Renal Denervation System. Should you have further questions or concerns, please do not hesitate to call me at [INSERT PHYSICIAN TELEPHONE NUMBER].

Thank you for your immediate attention and anticipated reimbursement of these services for your insured.

Sincerely,
[PHYSICIAN NAME], [DEGREE]
[PRACTICE NAME]

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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)

DISCLAIMER

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