

Reimbursement Update for Medicare Fee-for-Service Patients with HTN

Overview

Effective January 1st, 2025, under the Transitional Pass-Through (TPT) Payment by CMS, Paradise® Ultrasound Renal Denervation (RDN) procedures performed in a hospital outpatient or ASC setting are eligible for full device reimbursement for Medicare Fee-For-Service beneficiaries.¹

Highlights

1. Applies only to Medicare Fee-for-Service (FFS) patients
2. Available to hospital outpatient and ASC facilities
3. Helps offset Paradise System costs beyond standard outpatient procedure payments
4. Covers costs beyond standard OPPIs and ASC payment rates
5. No fixed payment amount (determined on a case-by-case basis); Medicare adjusts reimbursement according to submitted charges

If your Medicare Fee-for-Service patients need another treatment option to manage high blood pressure, you can now refer them for Ultrasound RDN procedures with added reimbursement support—reducing financial barriers for both your hospital and patients.

FAQs

Does the TPT Payment only apply to Ultrasound Renal Denervation?

The TPT Payment and HCPCS Level II code (C1736) granted by CMS, is unique to "Catheter, Renal Denervation, Ultrasound" and should only be utilized when RDN procedures are performed with a Paradise Ultrasound RDN Catheter.

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

TPT payments apply only to Medicare FFS beneficiaries with the correct procedure code (either 0338T: RDN, unilateral or 0339T: RDN, bilateral) and the Paradise System HCPCS Level II Code (C1736). They do not extend to Medicare Advantage or private payers, which typically reimburse under individual contracts.

Private payers may reference Medicare FFS rates but often have different coding and payment policies.

Do TPT Payments impact coverage policies?

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

Do my patients need a prior authorization to qualify for the TPT payment?

Prior authorizations are not required for Medicare FFS beneficiaries and TPT payments are not contingent on a prior authorization.

It is highly encouraged to seek prior authorization for any Medicare Advantage or private payer beneficiary, however these patients are not eligible for TPT Payments.

How does the TPT Payment impact patient's out of pocket expenses for the procedure?

Patient responsibility is based on the outpatient payment associated with APC 5192 and standard out of pocket policies related to outpatient procedures. For more information, please reference Medicare's policies for Part B costs.²

The HCPCS Level II code established for the Paradise System is designated with a payment indicator of "H" and is a "separate cost-based pass-through payment, not subject to copayment". This means that the additional reimbursement provided via the TPT Payment is not applied to the patient's responsibility.

¹ RecorMedical.com

References

1. Hospital Outpatient Prospective Payment CY2025- Notice of Final Rulemaking with Comment Period (NFRM) CMS 1809-FC: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice/cms-1809-fc>
2. <https://www.medicare.gov/basics/costs/medicare-costs>

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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