National Coverage Determination
Renal Denervation for Uncontrolled Hypertension

Effective Date 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® Ultrasound Renal Denervation System.

Link to Renal Denervation NCD

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
- 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

Criteria Clarifications

What is an HTN Clinician?
CMS confirmed that an HTN clinician does not need to be a specialist. "Could be a primary care provider with an interest and additional training in hypertension management, or it could be a cardiologist or nephrologist without further training."

Is coverage limited to "resistant hypertension"?
CMS clarified that coverage is not limited to resistant hypertension: "Coverage of RDN is not limited to patients with resistant hypertension. Rather, coverage is available for patients who remain uncontrolled despite attempted lifestyle changes and maximally tolerated doses of GDMT."

What is meant by "maximally tolerated GDMT"?
CMS is not imposing strict numeric thresholds for medications or doses. Instead, "CMS is not mandating a minimum number of medications or that medication doses be at the top of the maximum dosing range before referral for RDN but expects that patients and clinicians make a concerted and sustained effort to achieve control with maximally tolerated doses of medications and lifestyle changes before considering RDN."

Do all three encounters need to be with the primary HTN clinician?
No. CMS detailed that while the primary clinician must coordinate management, other team members can conduct some visits. "CMS does not require that a single clinician conduct all visits."

Is formal accreditation required, and what constitutes an HTN program?
CMS does not require formal accreditation for facilities providing RDN. "CMS does not intend for RDN access to be limited to tertiary academic medical centers or large, multidisciplinary practices; therefore, we are not requiring formal accreditation."

Recognizing potential concerns about feasibility, CMS stressed that: "While not all facilities will have access to a formal multidisciplinary program, we do not believe that requiring a hypertension clinician with longitudinal care responsibility, supported by a hypertension navigator, is excessively burdensome."

Does the facility need a dedicated HTN Navigator?
Not exclusively. CMS highlighted, "CMS does not mandate that the hypertension navigator exclusively perform this function, but rather that a hypertension program have a person responsible for care coordination of hypertension management under the supervision of a hypertension clinician as defined above."

How should physicians assess patient adherence to prescribed regimens?
CMS explains that: "Medication adherence assessment involves frank and nonjudgmental clinician-patient discussions, monitoring of prescription refills and pill counts, and, if available, biochemical assays of drugs or their metabolites in urine or plasma."

How should physicians and programs demonstrate that all first-line treatments have been exhausted prior to RDN referral?
CMS emphasizes a good-faith effort: "CMS is looking for practices and physicians to put in 'good-faith effort to control blood pressure w/ lifestyle changes and maximally tolerated doses of AHMs' before referring them for RDN."

FAQs

What documentation do I need to prove that a patient meets the criteria in the NCD?
Appropriate documentation that patients, physicians and facilities where RDN is being performed meet the NCD criteria should be available in medical records and ready to be provided to CMS if requested.

What about Medicare Advantage? Does this NCD apply to those patients as well?
Yes, these coverage criteria will impact both Medicare Fee-for-Service and Medicare Advantage patients.

Will there be Prior Authorization required for these patients?
For Medicare Fee-for-Service, there is no prior authorization required. However, for Medicare Advantage patients, it is likely that prior authorization is required and that the appropriate patient criteria are met in the clinical documentation provided. Additionally, the NCT number of the CED study (NCT07231757)[2] will likely be requested in the prior authorization request.

If my patient's Prior Authorization was previously denied by their Medicare Advantage plan, can I resubmit?
Practices can review the updated NCD criteria to determine if previously denied patients may now qualify for the Paradise System under the new coverage criteria. Please note that some insurers may have mandatory waiting periods before they can be resubmitted after a denied prior authorization.

Does this NCD have any impact on commercial payer policies?
While commercial payers independently assess the medical necessity of a therapy, many look to CMS for direction. Over time, the private payers may adopt similar criteria. Please check with your local payers for updates on coverage policies.

How does this change Medicare Payment or Transitional Pass-Through Payments for C1736?
This NCD is only related to coverage – there are no changes or impacts it will have on Medicare fee schedules or additional payment mechanisms such as Transitional Pass-Through.

What is a CED and what does it mean?
Coverage with Evidence Development (CED) is a policy used by CMS to establish coverage for a medical technology conditionally, while additional evidence is being gathered to confirm outstanding research questions. The vast majority of new NCDs have a CED component to them.

How does my facility qualify for the CED study?
Your facility does not need to enroll or pay registry fees to participate in the CED study. The RADIANCE CED Study, managed by Recor Medical, uses large EMR datasets instead of traditional trials or registries, reducing administrative burden for facilities and clinicians. This approach is consistent with other recent CED studies, such as T-TEER and IPAPS, under their respective NCDs.

To ensure CMS recognizes patients under the NCD, specific billing requirements must be met. For details, refer to the Paradise System NCD Billing Guide.

Do other Renal Denervation devices require their own specific CED study?
Yes, all other RDN devices will need to manage their own approved CED study for coverage.

Will participation in this CED study impact a patient's ability to participate in the GPS Study?
No. Patients who are part of the RADIANCE CED Study could also be enrolled in the GPS Study.

References

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.

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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