Medicare Medical Policy

Renal Denervation for Uncontrolled Hypertension

MEDICARE MEDICAL POLICY NUMBER: 451

Effective Date: 11/1/2025

Last Review Date: 11/2025

Next Annual Review: 11/2026

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Renal Denervation for Uncontrolled Hypertension	CMS Final Decision Memo for Renal Denervation for Uncontrolled Hypertension (CAG-00470N) *(Select I.B in the table of contents to access the criteria quickly)* NOTES: • On October 28, 2025, Medicare published a Final Decision Memo to provide coverage criteria for radiofrequency renal denervation (rfRDN) and ultrasound renal denervation (uRDN) (collectively, RDN) for uncontrolled hypertension. An NCD will be formally developed in the future, and the effective date will be retroactive back to the date of this decision memo; however, **until the NCD is finalized, this decision memo can be used for Medicare coverage decision-making**. • This coverage criteria provides coverage in the context of the coverage with evidence development (CED) studies. Medicare-approved registries and clinical trials can be found on the Medicare CED web page. ***(NOTE: As of the date of the most recent policy review, there is no CED web page specific to RDN. Once CMS updates this CED home page, the user will need to select "renal denervation" from the menu on the left-hand side. As registries and trials are approved by Medicare, they will be added to the appropriate service web page.)*** • According to the CMS Decision Memo, "Nothing in this NCD would preclude coverage of RDN through… the Investigational Device Exemption (IDE) Policy." Therefore, MA plan coverage of these services may also be available if rendered in the context of a Medicare approved IDE study.

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is

uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to review for medical necessity, the following documentation **must** be provided. If any of these items are not submitted, the review may be delayed and the decision outcome could be affected:

- All clinical documentation pertinent to request in order to meet NCD criteria, including:
  - Diagnosis of uncontrolled hypertension; and
  - Documentation the patient meets the FDA market-authorized indications for use, with no contraindications for the device used; and
  - No prior RDN procedure has been performed; and
  - Documentation of lifestyle modifications and stable doses of maximally tolerated guideline-directed medical therapy (GDMT), with assessment of adherence to the prescribed regimen, for at least six weeks before referral for RDN; and
  - If clinically appropriate, documentation that secondary hypertension has been evaluated and treated before determining that blood pressure remains uncontrolled. At a minimum, patients must be screened for primary aldosteronism, obstructive sleep apnea, and drug or alcohol induced hypertension before referral to RDN.
- The name of the device that will be used; and,
- The NCT number for the registry or study the member or provider is enrolled in (enrollment is a requirement under the Medicare criteria).

BACKGROUND

RDN involves ablating nerves in the renal arteries via a catheter-based radiofrequency or ultrasound procedure. Catheter-based radiofrequency ablation is the most commonly used technique, delivering heat to the intended tissue. Alternatively, intraluminal and extracorporeal high-intensity focused ultrasound delivers high-frequency acoustic energy via a transducer to destroy the tissue. *(CAG-00470N)*

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the

availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

Several devices have been developed for renal denervation and are in various stages of application for FDA approval. Examples of RDN devices include, but may not be limited to, the following:

- Paradise® Ultrasound Renal Denervation System (P22023) (Recor Medical) – uRDN device
- Symplicity Spyral™ Renal Denervation System (P220026) (Medtronic) – rfRDN device
    - An earlier version of this device was studied - Symplicity Flex RDN – but while it met its primary safety endpoint, the primary and secondary effectiveness endpoints (a significant reduction in BP compared to sham controls) were not met. Therefore, Medtronic redesigned its RDN device.
- EnligHTN multielectrode renal denervation system by St. Jude Medical
- OneShot Renal Denervation System by Covidien
- Vessix Renal Denervation System by Boston Scientific
- CARTO Thermocool Smarttouch Catheter by Biosense Webster

BILLING GUIDELINES AND CODING

CODES*		
CPT	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
	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
	0935T	Cystourethroscopy with renal pelvic sympathetic denervation, radiofrequency ablation, retrograde ureteral approach, including insertion of guide wire, selective placement of ureteral sheath(s) and multiple conformable electrodes, contrast injection(s), and fluoroscopy, bilateral
HCPCS	C1735	Catheter(s), intravascular for renal denervation, radiofrequency, including all single use system components
	C1736	Catheter(s), intravascular for renal denervation, ultrasound, including all single use system components

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is

submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.

- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
11/2025	New Medicare Advantage medical policy