CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 13695	**Date: March 19, 2026**
	Change Request 14302

Transmittal 13640 issued February 13, 2026, is being rescinded and replaced by Transmittal 13695, dated March 19, 2026, to update the Pub.100-04 NCD excel spreadsheet, the IOM, and business requirements 14302 - 04.5, 14302 - 04.6, and 14302 - 04.13 to include POS 24. There are no changes to publication 100-03. All other information remains the same.

SUBJECT: NCD 20.40- Renal Denervation (RDN) for Uncontrolled Hypertension

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to make contractors aware of coverage for Renal Denervation on October 28, 2025.

EFFECTIVE DATE: October 28, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 6, 2026

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
N	1/20/40/-Renal Denervation (RDN) for Uncontrolled Hypertension

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-03	Transmittal: 13695	Date: March 19, 2026	Change Request: 14302

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SUBJECT: NCD 20.40- Renal Denervation (RDN) for Uncontrolled Hypertension

EFFECTIVE DATE: October 28, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 6, 2026

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to make contractors aware of coverage for Renal Denervation on October 28, 2025.

II. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to make contractors aware of coverage for radiofrequency renal denervation (rfRDN) and ultrasound renal denervation (uRDN) (collectively, RDN) for uncontrolled hypertension.

B. Policy: Effective October 28, 2025, the Centers for Medicare & Medicaid Services (CMS) covers radiofrequency renal denervation (rfRDN) and ultrasound renal denervation (uRDN) (collectively, RDN) for uncontrolled hypertension under Coverage with Evidence Development (CED) according to the criteria outlined in NCD manual, chapter 1, section 20.40.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet all the criteria and standards identified above.

Renal denervation (RDN) for uncontrolled hypertension) is not covered for patients outside of a CMS-approved study.

Nothing in this NCD would preclude coverage of RDN through NCD 310.1 (Clinical Trial Policy) or through the Investigational Device Exemption (IDE) Policy.

III. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
14302 - 03.1	Effective October 28, 2025, contractors shall allow claims for radiofrequency renal denervation (rfRDN) and	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	ultrasound renal denervation (uRDN) (collectively, RDN) for uncontrolled hypertension, under Coverage with Evidence Development (CED) according to the criteria outlined in NCD manual referenced above. Please refer to the NCD Manual, Pub. 100-03, section 20.40 and Pub. 100-04 Chapter 32, Section 415 for claims processing instructions.									

IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

Impacted Contractors: A/B MAC Part A, A/B MAC Part B

V. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

VI. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VII. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual
Chapter 1 - Coverage Determinations

Table of Contents
(Rev. 13695; Issued: 03-19-26)

NCD-20.40 – Renal Denervation for Uncontrolled Hypertension

(Rev. 13695; Issued: 03-19-26; Effective:10-28-25; Implementation: 04-06-26)

A. General

Renal Denervation (RDN) is used in the treatment of uncontrolled hypertension.

B. Coverage Criteria

The Centers for Medicare & Medicaid Services (CMS) covers radiofrequency renal denervation (rfRDN) and ultrasound renal denervation (uRDN) (collectively RDN) for uncontrolled hypertension when furnished according to a Food and Drug Administration (FDA) market-authorized indication and all the following conditions are met:

1. Patient Criteria

The patient meets all the following criteria:

(a) Diagnosis of uncontrolled hypertension (≥ 140 mm Hg systolic blood pressure and > 90 mm Hg diastolic blood pressure) despite active management by a clinician with primary responsibility for blood pressure management.

(b) Uncontrolled hypertension diagnosed using either ambulatory blood pressure monitoring or serial home blood pressure readings.

(c) On 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.

(d) As clinically appropriate, secondary hypertension must be 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.

(e) The patient has no contraindications to RDN, consistent with the FDA labeling of the device used.

(f) The primary clinicians must coordinate management of the patient for a minimum of six months before referral for RDN, during which the patient had at least three encounters, with no more than two of the three encounters being virtual.

(g) No prior RDN procedure.

2. Physician Criteria

RDN is furnished by clinicians who meet the following criteria, as applicable:

(a) Clinicians referring Medicare beneficiaries must have longitudinal responsibility for hypertension management.

(b) Physicians performing RDN must have interventional and endovascular skills to perform effective RDN treatments. Additionally, they must be able to manage potential complications either themselves or with institutional support from colleagues who are immediately available to assist in emergency management.

(c) Physicians performing RDN without prior endovascular training or renovascular expertise must complete at least ten supervised cases of diagnostic/therapeutic renovascular procedures, half as primary operator. Additionally, they must complete at least five proctored RDN cases with each approved device used in their practice.

(d) Physicians performing RDN with prior endovascular training and active endovascular experience must complete at least five proctored RDN cases with each approved device used in their practice.

3. Facility Criteria

The RDN device and related items and services are furnished at facilities meeting the following criteria:

(a) 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.

(b) Preprocedural imaging capabilities (e.g., ultrasound, Computed Tomography Angiography, Magnetic Resonance Angiography).

(c) An appropriate interventional cardiology or radiology suite.

4. CED Study Criteria

The RDN device and related items and services are furnished in the context of a CMS-approved CED study. CMS-approved CED study protocols must: include only those patients who meet the criteria in section B.1; furnish items and services only through practitioners who meet the criteria in section B.2; furnish items and services at facilities meeting the criteria in section B.3; and include all of the following:
(a) One or more primary outcomes of ambulatory systolic blood pressure (ASBP), ambulatory diastolic blood pressure (ADBP), home systolic blood pressure (HSBP), home diastolic blood pressure (HDBP), office systolic blood pressure (OSBP), office diastolic blood pressure (ODBP), worsening renal function, cerebrovascular accident, acute myocardial infarction, incidence of new-onset heart failure, cardiovascular mortality, all-cause mortality, or a composite of these, through a minimum of 24 months. Each component of a composite outcome must be individually reported.

(b) An active comparator.

(c) Design sufficient for subgroup analyses by:

- *Age (Stratify <65, 65-74, 75+);*
- *Other clinically important patient demographic factors;*
- *Chronic kidney disease (Stratify by CKD Stages);*
- *Progression of CKD;*
- *Hypertension phenotype (e.g., resistant hypertension vs. uncontrolled for any reason);*
- *Medication adherence.*

(d) In addition, CMS-approved CED studies must adhere to the scientific standards (criteria 1-17 below) that have been identified by the Agency for Healthcare Research and Quality (AHRQ) as set forth in Section VI. of CMS' Coverage with Evidence Development Guidance Document, published August 7, 2024 (the "CED Guidance Document").

1. *Sponsor/Investigator: The study is conducted by sponsors/investigators with the resources and skills to complete it successfully.*
2. *Milestones: A written plan is in place that describes a detailed schedule for completion of key study milestones, including study initiation, enrollment progress, interim results reporting, and results reporting, to ensure timely completion of the CED process.*
3. *Study Protocol: The CED study is registered with ClinicalTrials.gov and a complete final protocol, including the statistical analysis plan, is delivered to CMS prior to study initiation. The published protocol includes sufficient detail to allow a judgment of whether the study is fit-for-purpose and*

whether reasonable efforts will be taken to minimize the risk of bias. Any changes to approved study protocols should be explained and publicly reported.

4. *Study Context: The rationale for the study is supported by scientific evidence and study results are expected to fill the specified CMS-identified evidence deficiency and provide evidence sufficient to assess health outcomes.*

5. *Study Design: The study design is selected to safely and efficiently generate valid evidence of health outcomes. The sponsors/investigators minimize the impact of confounding and biases on inferences through rigorous design and appropriate statistical techniques. If a contemporaneous comparison group is not included, this choice should be justified, and the sponsors/investigators discuss in detail how the design contributes useful information on issues such as durability or adverse event frequency that are not clearly answered in comparative studies.*

6. *Study Population: The study population reflects the demographic and clinical diversity among the Medicare beneficiaries who are the intended population of the intervention, particularly when there is good clinical or scientific reason to expect that the results observed in premarket studies might not be observed in older adults or subpopulations identified by other clinical or demographic factors.*

7. *Subgroup Analyses: The study protocol explicitly discusses beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion requirements effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. In the protocol, the sponsors/investigators describe plans for analyzing demographic subpopulations as well as clinically-relevant subgroups as identified in existing evidence. Description of plans for exploratory analyses, as relevant subgroups emerge, are also included.*

8. *Care Setting: When feasible and appropriate for answering the CED question, data for the study should come from beneficiaries in their expected sites of care.*

9. *Health Outcomes: The primary health outcome(s) for the study are those important to patients and their caregivers and that are clinically meaningful. A validated surrogate outcome that reliably predicts these outcomes may be appropriate for some questions. Generally, when study sponsors propose using surrogate endpoints to measure outcomes, they should cite validation studies published in peer-reviewed journals to provide a rationale for assuming these endpoints predict the health outcomes of interest. The cited validation studies should be longitudinal and demonstrate a statistical association between the surrogate endpoint and the health outcomes it is thought to predict.*

10. *Objective Success Criteria: In consultation with CMS and AHRQ, sponsors/investigators establish an evidentiary threshold for the primary health outcome(s) so as to demonstrate clinically meaningful differences with sufficient precision.*

11. *Data Quality: The data are generated or selected with attention to provenance, bias, completeness, accuracy, sufficiency of duration of observation to demonstrate durability of health outcomes, and sufficiency of sample size as required by the question.*

12. *Construct Validity: Sponsors/investigators provide information about the validity of drawing warranted conclusions about the study population, primary exposure(s) (intervention, control), health outcome measures, and core covariates when using either primary data collected for the study about individuals or proxies of the variables of interest, or existing (secondary) data about individuals or proxies of the variables of interest.*

13. *Sensitivity Analyses: Sponsors/investigators will demonstrate robustness of results by conducting pre-specified sensitivity testing using alternative variable or model specifications as appropriate.*

14. *Reporting: Final results are provided to CMS and submitted for publication or reported in a publicly accessible manner within 12 months of the study's primary completion date. Wherever possible, the study is submitted for peer review with the goal of publication using a reporting guideline appropriate for the study design and structured to enable replication. If peer-reviewed publication is not possible, results may also be published in an online publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with incomplete results).*

15. *Sharing: The sponsors/investigators commit to making study data publicly available by sharing data, methods, analytic code, and analytical output with CMS or with a CMS-approved third party. The study should comply with all applicable laws regarding subject privacy, including 45 CFR § 164.514 within the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient Records.*

16. *Governance: The protocol describes the information governance and data security provisions that have been established to satisfy Federal security regulations issued pursuant to HIPAA and codified at 45 CFR Parts 160 and 164 (Subparts A & C), United States Department of Health and Human Services (HHS) regulations at 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient and HHS regulations at 45 CFR Part 46, regarding informed consent for clinical study involving human subjects. In addition to the requirements under 42 CFR and 45 CFR, studies that are subject to FDA regulation must also comply with regulations at 21 CFR Parts 50 and 56 regarding the protection of human subjects and institutional review boards, respectively.*

17. *Legal: The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals, although it is acceptable for a study to test a reduction in toxicity of a product relative to standard of care or an appropriate comparator. For studies that involve researching the safety and effectiveness of new drugs and biological products aimed at treating life-threatening or severely-debilitating diseases, refer to additional requirements set forth in 21 CFR § 312.81(a).*

Consistent with section 1142 of the Act, AHRQ supports clinical research studies that CMS determines meet all the criteria and standards identified above.

C. National Non-Covered Indications

RDN is not covered for patients outside of a CMS-approved study.

D. Other

Nothing in this NCD would preclude coverage of RDN through NCD 310.1 (Clinical Trial Policy) or through the Investigational Device Exemption (IDE) Policy.

(This NCD last reviewed October 28, 2025)