Medtronic

Symplicity Spyral™ renal denervation system

Medicare National Coverage Determination (NCD) Overview

Effective October 28th, 2025, the Centers for Medicare and Medicaid Services (CMS) released a National Coverage Determination (NCD) for renal denervation (RDN) for uncontrolled hypertension, including the Symplicity Spyral™ blood pressure procedure.[1] This NCD applies to Medicare beneficiaries enrolled in either traditional Medicare or Medicare Advantage. The following document contains a summary of the coverage criteria along with frequently asked questions. To view the full decision memo, please visit: RDN NCD Decision Memo

RDN NCD Coverage Criteria

For Medicare patients, RDN is covered for uncontrolled hypertension when furnished according to a Food and Drug Administration (FDA) market-authorized indication and all the following conditions are met:

I. Patient Criteria

The patient meets all the following criteria, which must be documented in the patient record:

- Diagnosis of uncontrolled hypertension (≥140 mmHg systolic blood pressure (SBP) and >90 mmHg diastolic blood pressure (DBP)) despite active management by a clinician with primary responsibility for blood pressure management.
- Uncontrolled hypertension diagnosed using either ambulatory blood pressure monitoring or serial home blood pressure readings.
- 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.
- 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.
- The patient has no contraindications to RDN, consistent with the FDA labeling of the device used.
- 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.
- No prior RDN procedure.

II. **Physician Criteria**

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

- Clinicians referring Medicare beneficiaries must have longitudinal responsibility for hypertension management.
- 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.
- 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.
- 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.

III. **Facility Criteria**

The RDN device and related items and services are furnished at facilities meeting the following 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 (e.g., ultrasound, Computed Tomography Angiography, Magnetic Resonance Angiography).
- An appropriate interventional cardiology or radiology suite.

IV. **CED Study Criteria**

The RDN device and related items and services are furnished in the context of a CMS-approved Coverage with Evidence Development (CED) study.

Medtronic, working collaboratively with CMS, has designed the innovative SPYRAL CARE post-coverage study. SPYRAL CARE will enable Medicare patient access with a least burdensome approach for providers. Participation is automatic through the usual capture of patient encounter data and submission of claims to CMS. SPYRAL CARE features passive enrollment, no site activation, and no patient consent necessary, ensuring seamless integration with existing clinical workflows and zero added burden. Information on SPYRAL CARE can be found at https://clinicaltrials.gov/, National Clinical Trial (NCT) #07174622.[2]

The SPYRAL CARE NCT only applies to Symplicity RDN claims.

Coding and Billing Considerations

NCD specific coding information will be available when CMS publishes RDN NCD claims processing instructions. Check with your coding department on appropriate coding requirements.

Claim Requirements		
Procedure Codes		
Professional: All places of service Facility: Hospital Outpatient and ASC	**CPT® procedure codes** 0338T - Transcatheter renal sympathetic denervation, …; unilateral 0339T - Transcatheter renal sympathetic denervation, …; bilateral	**HCPCS device code** (only reported by facilities) C1735 – Catheter(s), renal denervation, radiofrequency
Facility: Inpatient Hospital	**ICD-10-PCS procedure code:** X05133A - Destruction of Renal Sympathetic Nerve(s) using Radiofrequency Ablation, Percutaneous Approach	
Diagnosis Codes		
Primary diagnosis code	Applicable hypertension diagnosis code (I10, I11.0, I11.9, I12.0, I12.9, I13.0, I13.10, I13.11, I13.2, I16.0, I16.1, I16.9, I1A.0)	
Secondary diagnosis code	Z00.6 Encounter for examination for normal comparison and control in clinical research program	
Professional and Facility Claim Requirements		
National clinical trial (NCT) #	07174622 for claims using Symplicity Spyral device only – the SPYRAL CARE study	
Modifier to CPT® procedure code	Q0 (zero) Investigational clinical service provided in a clinical research study that is in approved clinical research study	
Prior authorization number	(Medicare Advantage claims only) Include prior authorization number	
Additional Facility Claim Requirements		
Condition code	30 Qualifying clinical trial	
Value code	D4 ("Code") and NCT number ("Amount") (*D4 is not required for electronic billing)	

Procedure Coding for Medicare Temporary Add-On Payments

Note: these add-on payments for facilities only apply to traditional fee-for-service (FFS) Medicare claims.

- **Transitional pass-through payment (TPT)** in the hospital outpatient or ASC setting - report both the CPT code (0338T or 0339T) and HCPCS device code C1735.
- **New technology add-on payment (NTAP)** in the inpatient setting – report the ICD-10-PCS procedure code (X05133A).

Patient Documentation

It is up to the provider to ensure that the NCD coverage criteria are documented in the patient record for Medicare patients.

Medicare Advantage patients are also subject to the NCD criteria, but it is important to confirm any prior authorization and documentation requirements with the plan administrator.

The following is provided for consideration only and does not guarantee authorization or payment. This does not constitute legal advice or a recommendation regarding clinical practice.

Medicare NCD Key Patient Criteria

- ✓ BP ≥140/90 mmHg
- ✓ Uncontrolled BP confirmed with ambulatory (ABPM) or serial home BP measurements
- ✓ On lifestyle modifications and stable maximally tolerated guideline-directed medical therapy (GDMT) for ≥6 weeks
- ✓ At least 3 encounters with primary clinician in past 6 months, with no more than 2 being virtual
- ✓ Secondary hypertension must be evaluated & treated
- ✓ No contraindications to RDN, consistent with the FDA labeling of the device used
- ✓ No prior RDN procedure

Some information payers commonly look for when reviewing for medical necessity:

- Hypertension diagnosis, e.g., essential/primary, resistant, uncontrolled
- Onset, symptoms, severity and status of related conditions, e.g., CV disease, diabetes, obesity
- Blood pressure readings/logs, e.g., ambulatory (ABPM), office, home an/or remote
- Related cardiovascular events, interventions, hospitalizations
- Lifestyle modifications, e.g., diet, weight, exercise, limiting alcohol, smoking cessation
- Antihypertensive medications (drug name, class, dose, duration of use, patient compliance)
    - Currently prescribed
    - History of medications tried and failed
    - Any intolerances/allergy to medications (please specify)
    - Assessment of adherence
- Recent relevant visit history
- Screening and treatment of secondary causes of hypertension prior to RDN referral
- Screening to rule out possible exclusions or contraindications, per Symplicity Spyral Instructions for Use (IFU) and any others specified by the payer
- Reasons/indication for procedure
    - Clinical benefits of the procedure for this patient
    - Potential risks if the patient does not receive the procedure
    - Patient preference for treatment options
- Your experience with renal denervation and hypertension management

Frequently Asked Questions

Does the NCD impact Medicare coverage immediately?	Coverage under the NCD is provided with an effective date of October 28, 2025. Claims submitted with dates of service on or after this date will be subject to the criteria described in the NCD. CMS will issue a transmittal in the coming months to further outline billing instructions related to the NCD. Medicare Administrative Contractors (MACs) and Medicare Advantage plans may take some time to update their systems, so it is important to communicate closely with the payer to ensure coverage is provided.
What is the implementation date and how is it different from the effective date?	The *effective date* is the date on which the NCD is considered active and applies to claims with dates of service on or after this date. It is typically the date the NCD is published or announced by CMS and is the point from which the policy is considered enforceable for coverage and payment purposes. Any service that occurs on or after the effective date is subject to the NCD, regardless of whether local systems have been updated for automated processing. The *implementation date* refers to the date by which MACs must have their systems and processes updated to comply with the new NCD. There is typically a gap between the effective date and the implementation date to allow technical and administrative changes—like system updates, edits, and training—to be completed so claims can be processed according to the new policy. Until the implementation date, MACs may need to hold claims or process them through manual procedures to ensure claims are paid (or denied) correctly according to the NCD. Providers should document services normally, but understand payments may be delayed, or denied. If an appropriate claim is denied, the provider should appeal to the MAC and notify them it is subject to the new NCD. MACs may be instructed by CMS to process and pay claims retroactively in accordance with the effective date once systems are updated.
Does this NCD impact commercial payers?	No. NCDs are applicable to all Medicare beneficiaries nationally, including those with traditional Medicare, and those enrolled in Medicare Advantage plans. Medicare NCDs are not applicable to patients with other health plans, such as commercial health plans, exchange plans, or Medicaid. Commercial insurers and non-Medicare payers establish their own coverage policies for their beneficiaries. It is always important to check with the payer for individual coverage criteria. Medicare Advantage (MA): Insurers who administer Medicare Advantage plans are required to provide coverage to their MA beneficiaries according to the NCD. MA plans typically require prior authorization. In some instances, the payer may require extra steps, require additional documentation, or provide clarification to certain NCD criteria, so it is important to confirm specific processes and requirements with the specific payer.

Will prior authorization be required for RDN?	Traditional fee-for-service Medicare: FFS Medicare does not typically require prior authorization for most services, and this is true for RDN. For traditional Medicare patients, coverage is determined at the time the claim is filed, so it is critical that all information relevant to the NCD coverage criteria are reflected in the patient's record, and that the claim form includes all necessary information for billing under the CED. Medicare Advantage (MA): These plans must provide coverage subject to the criteria outlined in the NCD, but they typically require prior authorization. It is important to confirm with the MA plan whether prior authorization is required, and follow the process for the individual payer. Good documentation to ensure the beneficiary meets all coverage criteria is critical to ensure a smooth prior authorization process.
Does the NCD impact Medicare payment for facilities or physicians?	This process does not impact Medicare payment amounts for physicians or facilities. Payment and coverage are managed separately by CMS. For information on Medicare payment rates and policies, see The Medtronic Symplicity Reimbursement Guide.
Does the NCD impact coding?	Providers and hospitals should continue to use the appropriate CPT, HCPCS, ICD-10-CM, and/or ICD-10-PCS codes for the Symplicity procedure. The Medtronic Symplicity Reimbursement Guide provides information and guidance on coding. Note: under the NCD, there are additional codes to include on the Medicare claim form to ensure coverage is provided, including the NCT # for the Medtronic post-coverage study, SPYRAL CARE.
What is Coverage with Evidence Development (CED)?	CED studies are common with Medicare NCDs, as they provide a mechanism for CMS to collect additional evidence specific to the covered Medicare population. The coverage outlined in the NCD would be provided as part of a CMS-approved study meeting the criteria as described in the NCD. SPYRAL CARE, NCT07174622, is Medtronic's approved post-coverage study for RDN.[2] *Use the SPYRAL CARE NCT number, NCT07174622, for Symplicity RDN claims only.*
How does the SPYRAL CARE post-coverage study work? Will my facility need to do extra work?	SPYRAL CARE is an innovative claims-based post-coverage study designed to meet the CED requirements outlined in the NCD with a least burdensome approach for providers. "Enrollment" is passive and automatic through the usual submissions of claims and patient encounter data to CMS. Aside from ensuring the claim form has necessary information, no additional work is required for facilities.
How does CMS track or confirm the facility and physician requirements?	Medicare typically monitors these criteria through audits using contractors such as the Recovery Audit Contractors (RACs) . There is no specific documentation that needs to be submitted *proactively* to CMS or the MACs to confirm eligibility. RACs may request manual attestation or additional supporting documents from providers to confirm that all conditions of the NCD (such as physician/facility credentials) were satisfied at the time of service. It is up to providers and facilities to ensure their programs meet the criteria as outlined in the NCD, and that documentation is available to confirm such eligibility.

For additional information, please contact our Reimbursement Customer Support:

Website: https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/renal-denervation/reimbursement.html
Phone: 877-347-9662
Email: rs.cardiovascularhealtheconomics@medtronic.com

References

1. CMS NCA Tracking Sheet – Renal Denervation for Uncontrolled Hypertension. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=318 ; Accessed 10/28/25.
2. SPYRAL CARE Study at Clinicaltrials.gov; https://clinicaltrials.gov/study/NCT07174622 Accessed 10/22/25.

Disclaimer

Medtronic provides this information for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules, and regulations. As a result, Medtronic does not represent or guarantee that this information is complete, accurate, or applicable to any particular patient or third-party payer or guarantees payment.

The provider has the responsibility to determine medical necessity and to submit appropriate documentation, codes and charges for care provided. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers as to the correct form of billing or the amount that will be paid to providers of service.

Please contact your Medicare contractor, other payers, reimbursement specialists and/or legal counsel for interpretation of coding, coverage and payment policies and any applicable laws or regulations that may apply.

This document provides assistance for FDA approved or cleared indications. Where reimbursement is sought for use of a product that may be inconsistent with, or not expressly specified in, the FDA cleared or approved labeling (e.g., instructions for use, operator's manual or package insert), consult with your billing advisors or payers on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related service.

Indications

The Symplicity Spyral™ renal denervation system is indicated to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure.

Contraindications

The Symplicity Spyral system is contraindicated in patients with any of the following conditions: • Renal artery diameter < 3mm or > 8mm • Renal artery fibromuscular dysplasia (FMD) • Stented renal artery (<3 months prior to RDN procedure) • Renal artery aneurysm • Renal artery diameter stenosis >50% • Pregnancy • Presence of abnormal kidney (or secreting adrenal) tumor • Iliac/femoral artery stenosis precluding insertion of the catheter.

Warnings and Precautions

A thorough understanding of the technical principles, clinical applications, and risks associated with vascular access techniques and percutaneous transluminal catheterization in renal arteries is necessary before using this device.

The safety and efficacy of the Symplicity Spyral system has not been established in patients with isolated systolic hypertension or in patients with prior renal artery interventions including renal stents, renal angioplasty, or prior renal denervation. The Symplicity Spyral system has not yet been studied in patients who are breastfeeding, under the age of 18, or with secondary hypertension • Avoid treatment with the Symplicity Spyral™ catheter within 5 mm of any diseased area or stent. • Implantable pacemakers (IPGs) and implantable cardioverter defibrillators (ICDs) or other active implants may be adversely affected by RF ablation. Refer to the implantable device's Instructions for Use. • The patient's heart rate may drop during the ablation procedure. • Proper pain medication should be administered at least 10 min before ablating renal nerves.

Potential Adverse Events

Potential adverse events associated with use of the renal denervation device or the interventional procedures include, but are not limited to, the following conditions: • Allergic reaction to contrast • Arterial damage, including injury from energy application, dissection, or perforation, • Arterial spasm, or stenosis • Arterio-enteric fistula • AV fistula • Bleeding • Blood clots or embolism • Bruising • Cardiopulmonary arrest • Complications associated with medications commonly utilized during the procedure, such as narcotics, anxiolytics, or other pain or anti-vasospasm medications • Death • Deep vein thrombosis • Edema Electrolyte imbalance • Heart rhythm disturbances, including bradycardia • Hematoma • Hematoma – retroperitoneal • Hematuria • Hypertension • Hypotension (may cause end organ hypoperfusion) • Infection• Kidney damage including renal failure or perforation • Myocardial infarction • Nausea or vomiting • Pain or discomfort • Peripheral ischemia • Pulmonary embolism • Proteinuria • Pseudoaneurysm • Radiocontrast nephropathy • Renal artery aneurysm •Skin burns from failure of the dispersive electrode pad • Stroke • Other potential adverse events that are unforeseen at this time.

Please reference appropriate product *Instructions for Use* and *User Manual* for more information regarding indications, contraindications, warnings, precautions, and potential adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
For further information, please call and/or consult Medtronic at 800-633-8766 or the Medtronic website at medtronic.com

