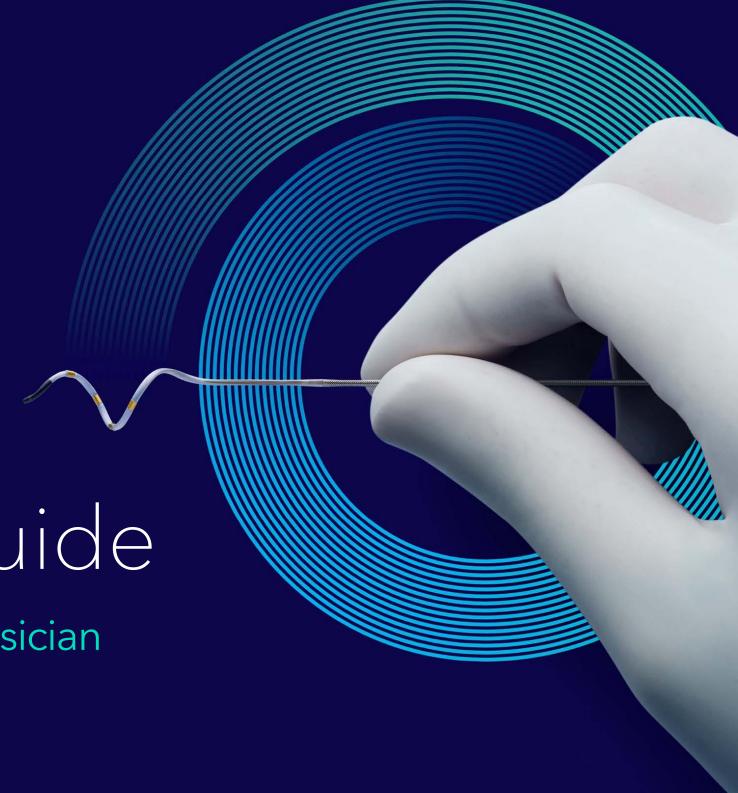
# Medtronic

**Symplicity**<sup>™</sup> blood pressure procedure

Reimbursement guide

Coding, coverage and payment for physician and hospital









#### Indications

## Coverage

- O Medicare
- O Medicare RDN NCD
- O Medicare Advantage/Medicaid
- O Commercial payers

# Coding

- O CPT® codes
- O HCPCS codes (C-code)
- O ICD-10-PCS procedure codes
- O ICD-10-CM diagnosis codes
- O Medicare billing requirements

### **Payment**

- O Physician payment
- O Hospital outpatient payment
- O Transitional pass-through payment
- O Hospital inpatient payment
- O New technology add-on payment
- O Ambulatory surgery center

This guide has been created to help you understand coverage, coding, and reimbursement related to Medicare for percutaneous catheter-based renal denervation procedures. For additional information, please contact the Reimbursement Customer Support team:

Phone: 877-347-9662

Email: rs.cardiovascularhealtheconomics@medtronic.com

Website: www.medtronic.com/en-us/healthcare-professionals/reimbursement/cardiovascular/renal-denervation.html

# 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.









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# Product overview\*

The Symplicity™ blood pressure procedure, also known as renal denervation (RDN), supplies precisely controlled and targeted radiofrequency (RF) energy to the renal nerves, disrupting the overactive sympathetic signaling between the kidneys and brain.¹ Catheter-based RDN is a minimally invasive, device-based percutaneous procedure designed to lower blood pressure by ablating overactive renal artery nerves without permanent implantation. The Symplicity Spyral™ system consists of the following items:

Symplicity Spyral multi-electrode renal denervation catheter provides a single catheter treatment option for patients with uncontrolled hypertension. The Symplicity Spyral catheter denervates the renal artery using RF energy. Each catheter has a distal self-expanding array of four electrodes. It has the deliverability to treat a wide range of anatomy (vessels 3-8 mm in diameter), enabling ablation of the main artery, accessory, and branch vessels to maximize the probability of complete denervation.

Symplicity G3™ renal denervation RF generator works in tandem with the Symplicity Spyral catheter to deliver controlled RF energy during renal denervation treatment.

<sup>\*</sup>Please see the Symplicity Spyral<sup>TM</sup> Multi-Electrode Renal Denervation Catheter, RDN016 Instructions for Use for additional information at https://www.accessdata.fda.gov/cdrh\_docs/pdf22/P220026D.pdf









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# FDA-approved indications

The Symplicity Spyral™ system is FDA approved for the following 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 < 3 mm or > 8 mm
- 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.

<sup>\*</sup>Please see the Symplicity Spyral<sup>TM</sup> Multi-Electrode Renal Denervation Catheter, RDN016 Instructions for Use for additional information at <a href="https://www.accessdata.fda.gov/cdrh\_docs/pdf22/P220026D.pdf">https://www.accessdata.fda.gov/cdrh\_docs/pdf22/P220026D.pdf</a>









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# Coverage for radiofrequency renal denervation

This section addresses coverage by traditional Medicare, Medicare Advantage (MA), and commercial payers. The provider is responsible for determining medical necessity and submitting appropriate codes, charges, and documentation for care provided.

# Coverage policy definitions

**Covered/positive:** Designates RDN as covered; may have associated medical necessity criteria.

**Not covered/negative:** Designates RDN as investigational/experimental or not medically necessary; specifically excluded coverage.

**No medical policy/silent:** There is no designated policy that specifically includes or excluded coverage for RDN; RDN may be covered on a case-by-case basis.









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# Coverage for radiofrequency renal denervation

Medicare – Fee-for-service/Traditional (Parts A/B)

- Generally covers FDA-approved therapies that are deemed reasonable and necessary.
- 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.<sup>2</sup> This NCD, CAG-00470N, applies to Medicare beneficiaries enrolled in either traditional Medicare or Medicare Advantage. To view the full decision memo, please visit: RDN NCD Decision Memo
- 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.







#### **Indications**

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# Medicare National Coverage Determination (NCD) - Summary

# Effective October 28, 2025: For detailed coverage criteria visit RDN NCD Decision Memo

# **Patient Criteria**

- Uncontrolled hypertension
   ≥140 and >90 mmHg
- Diagnosed with ABPM or serial home BP
- Stable doses of maximally tolerated guideline directed medical therapy for ≥ 6 weeks
- Primary clinician managed patient for minimum 6 mo., with at least 3 encounters, no more than 2 virtual
- Secondary HTN evaluated and treated first, including screening 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.\*
- No prior RDN procedure

# **Physician Criteria**

- Referrers must have longitudinal responsibility for HTN management
- Physicians performing RDN must have interventional and endovascular skills to perform effective RDN treatments and must be able to manage potential complications either on their own or with support from institutional colleagues.
- Physicians performing RDN without prior endovascular training or renovascular expertise must complete at least 10 supervised cases of renovascular procedures, half as primary operator, AND at least 5 proctored RDN cases with each device used in their practice.
- Physicians performing RDN with prior endovascular training and active endovascular experience must complete at least 5 proctored RDN cases with each device used in their practice

# **Facility Criteria**

- Facilities must have a
   multidisciplinary
   hypertension program with
   contributions from a
   hypertension clinician with
   longitudinal patient
   management responsibility,
   a hypertension navigator,
   and contributions from
   relevant medical specialties
- Preprocedural imaging capabilities (e.g., ultrasound, Computed Tomography Angiography, etc.)
- An appropriate interventional cardiology or radiology suite

#### **CED**

- RDN is covered in the context of an approved Coverage with Evidence Development (CED) study.
- Medtronic, in collaboration with CMS, has designed the innovative SPYRAL CARE postcoverage study (NCT07174622) to collect important data on Medicarecovered patients. SPYRAL CARE will enable broad patient access with a least burdensome approach for providers.
- SPYRAL CARE features passive enrollment, no site activation, and no patient consent, ensuring seamless integration with existing clinical workflows and zero added burden.

<sup>\*</sup>Per manufacturer IFU. See Symplicity Spyral IFU.







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# Coverage for radiofrequency renal denervation

# Medicare Advantage (MA) (Part C)

- Commercial insurers who administer Medicare Advantage plans are required to provide coverage to their Medicare Advantage beneficiaries according to NCD CAG-00470N.
- Medicare Advantage plans typically require prior authorization. It is important to confirm with the payer whether prior authorization is required and follow the process for the individual payer.
- In some instances, the payer may require extra steps or require additional documentation, so it is important to confirm specific processes and requirements with the specific payer.
- The <u>Medicare Managed Care Manual</u><sup>3</sup> allows the right to request plan approval where there is a question if a service is covered or when PA is not required.

### Medicaid

- Coverage guidelines vary by state contact your state authority for details.
- Requesting prior authorization is strongly recommended and may be required.









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# Coverage for radiofrequency renal denervation

# **Commercial payers**

- Coverage and prior authorization requirements can vary by payer, plan, and individual policy so it is **important to check coverage criteria and requirements with the specific payer.** Medicare NCDs are not applicable to patients with other health plans, such as commercial health plans, exchange plans, or Medicaid.
- Requesting prior authorization is strongly recommended and may be required.
- When prior authorization is not required, requesting a predetermination or medical necessity/pre-service review (terminology may vary by payer) is recommended as it allows for consideration of a patient's unique clinical circumstances despite the coverage policy.

For additional information regarding the prior authorization process, please refer to our coverage and prior authorization information documents shared on our <u>RDN</u> reimbursement website.









#### **Indications**

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## **Coding**

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#### **Payment**

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# Coding for radiofrequency renal denervation

# **CPT**<sup>®</sup> codes

The table below includes the Category III CPT® codes that describe the renal denervation procedure. Currently, there are no Category I CPT® codes for renal denervation.

The following codes may be used by physicians in allowed sites of service, with most RDN procedures expected to be performed in the hospital outpatient setting. It is up to the physician to determine what codes to report. It is important to report the appropriate code(s) based on all procedures performed during the encounter as well as provide all required documentation with the claim.

CPT® code4	CPT® code description	
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.	
0339Т	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.	

#### Note:

According to the parenthetical notes in the current CPT® manual, the following procedure codes **should not be reported** in conjunction with 0338T or 0339T:

- 36251 (Insertion catheter renal artery 1st unilateral),
- 36252 (Insertion catheter renal artery 1st bilateral),
- 36253 (Insertion catheter renal art 2nd + unilateral), or
- 36254 (Insertion catheter renal artery 2nd + bilateral)

Based on this CPT coding instruction, renal angiography should not be separately reported with the RDN procedure code.

CPT° codes, descriptions, and other data only are copyright 2024 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. These CPT° codes have been extended beyond the initial 2024 sunset date by the CPT° Editorial Panel as noted by the CPT° Editorial Summary of Panel Actions, February 2023.









#### **Indications**

# Coverage

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# **Coding**

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#### **Payment**

- O Physician payment
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- O Ambulatory surgery center

# Coding for radiofrequency renal denervation

# **HCPCS** codes (C-code)

Medicare provides device C-codes for hospital use in billing Medicare for medical devices in the outpatient setting. Typically, these codes pertain to Medicare billing but check with your non-Medicare payer for their specific requirements.

The following table includes the new C-code for the Symplicity Spyral™ catheter. There is no C-code that applies to the Symplicity G3™ generator (equipment like generators typically do not have C-codes). There may be applicable C-codes for other items used during this procedure (e.g., guidewires, introducers). It is important to report the appropriate C-codes for items used during this procedure.

Model number	Description	C-code
RDN016	Symplicity Spyral catheter	C1735
RDNG3A	Symplicity G3 generator	N/A
RDN019	Cart for Symplicity G3 generator	N/A
SB6RDND1K	Sherpa NX™ Balanced 6 Fr 55-cm guide catheter with RDND1 curve	C1887
LA6IMAK	Launcher™ 6 Fr 55-cm guide catheter with IMA curve	C1887
SB6IMAK	Sherpa NX Balanced 6 Fr 55-cm guide catheter with IMA curve	C1887
E7507	Valleylab™ REM Polyhesive™ Adult Patient Return Electrode, 9' (2.7 m)	N/A
E7507DB	Valleylab REM Polyhesive Adult Patient Return Electrode, 15' (4.6 m)	N/A
N/A	0.014" Guidewire (non-hydrophilic with a supportive shaft and a floppy tip)	C1769
SpyralStartupCart	Symplicity Spyral System including 5ea RDN016, 1 ea, RDNG3A, 1ea RDN019	N/A
SpyralStartup	Symplicity Spyral System including 5ea RDN016, 1 ea, RDNG3A	N/A









#### **Indications**

# Coverage

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# **Coding**

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# Coding for radiofrequency renal denervation

# **ICD-10-PCS** procedure codes

ICD-10-PCS procedure codes are required when billing for inpatient admissions.

For RDN, the following ICD-10-PCS code describes percutaneous renal denervation by radiofrequency ablation:

X05133A – Destruction of Renal Sympathetic Nerve(s) using Radiofrequency Ablation, Percutaneous Approach









#### **Indications**

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# Coding for radiofrequency renal denervation

# ICD-10-CM diagnosis codes

Hospitals and other providers assign ICD-10-CM codes to indicate a patient's diagnosis or clinical status. The following is a list of examples of possible ICD-10-CM diagnosis codes that may relate to indications associated with renal denervation procedures. This is not an all-inclusive list. Reported diagnosis codes should be based on the appropriate documentation for the individual patient presentation.

ICD-10-CM diagnosis code	ICD-10-CM diagnosis code description
110	Essential (primary) hypertension
I11.0	Hypertensive heart disease with heart failure
111.9	Hypertensive heart disease without heart failure
112.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end-stage renal disease
112.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.10	Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end-stage renal disease
l13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end-stage renal disease
116.0	Hypertensive urgency
116.1	Hypertensive emergency
116.9	Hypertensive crisis, unspecified
I1A.0	Resistant hypertension (Note: When reporting I1A.0, code first specific type of existing hypertension, if known)









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#### **Payment**

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# Medicare renal denervation billing requirements NCD

Under the recently published NCD, RDN is covered in the context of Coverage with Evidence Development (CED). Medicare will publish CED claims instructions via the Medicare Claims Processing Manual in the coming months, which will instruct billing staff on how to properly submit RDN claims under **NCD**, **CAG-00470N**. Until these claims instructions are published, the following information is provided as an overview of what is typically required.

- These instructions apply for both traditional Medicare and Medicare Advantage claims.
- For non-Medicare payers, coverage and specific billing instructions may vary. We recommend contacting each individual plan for information.

Claim Requirement	Identifying information required by RDN NCD
Diagnosis codes	
Primary diagnosis code	Applicable diagnosis code for uncontrolled hypertension (e.g., I10, I11.0, I11.9, I12.0, I12.9, I13.0, I13.1, I13.11, I13.2, I16, I16.1, I16.9, I1A)  When coding I1A.0 for resistant hypertension: code first the specific type of hypertension (e.g., I10 for essential hypertension) before coding I1A.0.
Secondary diagnosis code	Z00.6 Encounter for examination for normal comparison and control in clinical research program
Professional and Facility Claim	n Requirements
National clinical trial (NCT) number	07174622, for claims using Symplicity Spyral device only - the SPYRAL CARE study
CPT procedure code modifier (professional and outpatient facility claims only)	Q0 (zero) Investigational clinical service provided in a clinical research study that is in approved clinical research study
Prior authorization number	For Medicare Advantage claims it is recommended to include prior authorization number if applicable
Additional Facility Claim Requ	uirements
Condition code	30 Qualifying clinical trial
Value code	D4 ("Code") and NCT number ("Amount") (*D4 is not required for electronic billing)









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# Payment for radiofrequency renal denervation

The following information reflects the Medicare national allowable amount published by CMS and does not include Medicare payment reductions resulting from sequestration adjustments to the amount payable to the provider, as mandated by the Budget Control Act of 2011.









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# Payment for radiofrequency renal denervation

# Physician payment

Physicians use CPT<sup>®\*</sup> codes to represent procedures and services performed in all places of service. Under Medicare's methodology for physician payment, each CPT<sup>®</sup> code is assigned a value, known as relative value units (RVUs). RVUs are part of how Medicare determines the physician payment amount. RVUs are converted to a payment amount via a conversion factor. Medicare physician payment rates are effective January 1 through December 31.

The Category III CPT® codes that describe the RDN procedure do not have RVU valuations and thus do not have a national reimbursement rate assigned by Medicare. Instead, they are contractor priced. This means that each individual Medicare contractor sets their reimbursement rate for these codes.

CPT® code <sup>4</sup>	CPT® code description	2025 physician rates <sup>5</sup>
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	Contractor priced
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	Contractor priced

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# Payment for radiofrequency renal denervation

# Physician payment - Crosswalk

In the absence of established RVUs for Category III CPT® codes, providing a comparable Category I CPT® code can assist payers to process claims for procedure codes without established payment. The following CPT® codes are potential Category I CPT® comparator, or "crosswalk," codes for consideration that may be similar to the Symplicity™ procedure; these codes were selected based on discussion with experienced Symplicity proceduralists. It is ultimately the physician's responsibility to choose the most appropriate Category I CPT® crosswalk code that is the best representation of the physician time, work, complexity, and resources required for the Symplicity procedure.

Physicians are encouraged to work with their billing department to determine an appropriate Category I crosswalk for the Symplicity procedure and understand appropriate documentation needs. Physicians should report either 0338T or 0339T on claims forms and provide the crosswalk codes in their claims documentation and cover letter to support appropriate payment.

CPT® code4	Code description	Physician work RVUs <sup>6</sup>	Total RVUs <sup>6</sup>	CY 2025 Medicare PFS facility payment <sup>7</sup> National unadjusted rate	Intra-operative service time <sup>7</sup>
37236	Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery	8.75	12.88	\$420.38	90 minutes
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	10.96	17.21	\$562.80	76 minutes
37246	Transluminal balloon angioplasty (except lower extremity artery(ies) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; initial artery	7.00	10.20	\$331.98	60 minutes
+37247	Transluminal balloon angioplasty (except lower extremity artery(ies) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; each additional artery (List separately in addition to code for primary procedure)	3.50	5.09	\$165.34	+ 30 minutes

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# Payment for radiofrequency renal denervation

# Hospital outpatient payment

The following CPT®\* codes describe procedures associated with radiofrequency renal denervation. These codes may be used by facilities when services are rendered in the outpatient hospital setting. For outpatient hospital billing, CPT®/HCPCS codes are assigned to an Ambulatory Payment Classification (APC) grouping by Medicare.

The table below shows the current national unadjusted payment rates for the assigned APCs related to radiofrequency renal denervation. Medicare hospital outpatient payment rates are effective January 1 through December 31.

CPT® code <sup>3</sup>	CPT® code description	2025 APC	2025 national unadjusted payment rate <sup>8</sup>
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	5192	\$5,702
0339Т	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	5192	\$5,702

<sup>\*</sup>CPT® codes, descriptions, and other data only are copyright 2024 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply.









#### **Indications**

# Coverage

- O Medicare
- O Medicare RDN NCD
- O Medicare Advantage/Medicaid
- O Commercial payers

## Coding

- O CPT® codes
- O HCPCS codes (C-code)
- O ICD-10-PCS procedure codes
- O ICD-10-CM diagnosis codes
- O Medicare billing requirements

### **Payment**

- O Physician payment
- O Hospital outpatient payment
- O Transitional pass-through payment
- O Hospital inpatient payment
- O New technology add-on payment
- O Ambulatory surgery center

# Payment for radiofrequency renal denervation

# Transitional pass-through (TPT) payment for hospital outpatient

In the Calendar Year (CY) 2025 Hospital Outpatient Prospective Payment System (HOPPS) Final Rule, published on November 1, 2024, CMS finalized approval of the Symplicity Spyral™ catheter for the transitional pass-through (TPT) payment program.<sup>8</sup> TPT was established by the Centers for Medicare and Medicaid Services (CMS) to provide an incremental payment to offset qualifying new technology device costs in the hospital **outpatient** setting.

- TPT for Symplicity Spyral will become effective on January 1, 2025
- Only hospital outpatient facilities may qualify for TPT, and TPT has no impact on physician or inpatient reimbursement
- Generally effective for **3** years
- Only applicable to **Medicare fee-for-service** claims (TPT payments do not apply to Medicare Advantage or commercial insurance patients)
- CMS also finalized approval of a new pass-through payment device category (C-code) for Symplicity Spyral, effective January 1, 2025. The new code C1735 (catheter, renal denervation, radiofrequency) must be reported in conjunction with the applicable CPT®\* procedure code for the claim to be eligible for TPT.

<b>EXAMPLE</b> For illustrative purposes only. Does not constitute coding or billing guidance.		
1. HOSPITAL'S CHARGES FOR SYMPLICITY SPYRAL CATHETER (inclusive of mark-up)		\$64,000
2. HOSPITAL'S COST-TO-CHARGE RATIO (CCR) FOR IMPLANTABLE DEVICES		
3. CMS CALCULATED DEVICE COST	(1) X (2)	\$16,000
4. DEVICE OFFSET FOR A BILATERAL RDN PROCEDURE		\$2,457
5. TPT PAYMENT	(3) - (4)	\$13,543
6. APC PAYMENT: APC 5192, CY2025 national unadjusted rate <sup>1</sup>		\$5.702
TOTAL REIMBURSEMENT TPT PAYMENT + APC PAYMENT	(5) + (6)	\$19,245









#### **Indications**

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## Coding

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- O ICD-10-PCS procedure codes
- O ICD-10-CM diagnosis codes
- O Medicare billing requirements

### **Payment**

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# Payment for radiofrequency renal denervation

# Transitional pass-through (TPT) payment for hospital outpatient

# Coding requirements for transitional pass-through payment

What codes should be reported to be considered for the TPT?

For hospital outpatient renal denervation procedures performed with the Symplicity Spyral™ catheter, the following HCPCS Level II C-code and one of the appropriate CPT®\* procedure codes should be reported:

RF RDN HCPCS C-Code	Description
C1735	Catheter, renal denervation, radiofrequency
CPT® procedure codes	Description
0338T	Transcatheter renal sympathetic denervation unilateral
0339T	Transcatheter renal sympathetic denervation bilateral

CPT® codes, descriptions, and other data only are copyright 2024 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply.

## Ensure that:

- The number of Symplicity Spyral catheters used is correctly reported on the claim.
- Include the appropriate revenue code for the device. This may vary by institution and should be reported by your coding/billing specialist on the claim. Devices like the Symplicity catheter may be reported with revenue code 278 (Other Implants) as per CMS and NUBC<sup>9</sup> guidance, there is no permanency requirement.
- The charges for the Symplicity Spyral catheter are correctly reflected on the claim.
- The C-code C1735 is billed with the appropriate RDN CPT® code, 0338T or 0339T.
- For additional information, please refer to our <u>Symplicity Spyral TPT Overview</u> document which can be provided by our reimbursement support team at 877-347-9662.









#### **Indications**

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# Payment for radiofrequency renal denervation

# Hospital inpatient payment

For Medicare, inpatient hospital reimbursement is facilitated through Medicare Severity Diagnosis Related Groups (MS-DRGs). For each admission, the ICD-10 diagnosis and procedure codes are grouped into one of over 750 MS-DRGs. Regardless of the number of codes, only one MS-DRG is assigned to the inpatient hospital admission. Medicare hospital inpatient payment rates are effective October 1 through September 30.

If medical necessity criteria are met to support an inpatient admission for percutaneous radiofrequency ablation of the renal sympathetic nerve(s), the possible MS-DRG assignment may apply:

MS-DRG <sup>†</sup>	Description	FY2026 MS-DRG Medicare national unadjusted payment rate <sup>10</sup>
264	Other circulatory system O.R. procedures	\$24,309

<sup>†</sup> MS-DRG assignment is based on the combination of diagnosis and procedure codes reported and is assigned by the contractor.









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# Payment for radiofrequency renal denervation

# New technology add-on payment (NTAP) for hospital inpatient<sup>11</sup>

New technology add-on payment (NTAP) is a mechanism to provide hospitals with payment in addition to the MS-DRG payment for select inpatient cases that utilize new technologies specifically approved for this temporary payment program. The Symplicity Spyral™ multi-electrode renal denervation catheter has been approved by Medicare for NTAP beginning October 1, 2024. The exact payment amount for individual cases will vary based on costs reported and individual hospital-level factors.

- The following criteria must be met for a case to be eligible for NTAP:
- Patient is a **Medicare fee-for-service beneficiary**
- Procedure using eligible technology performed during an inpatient hospitalization
- The claim includes the appropriate ICD-10-PCS code: X05133A
- Costs of the case exceed the standard MS-DRG payment (i.e., cases with operating loss)

The NTAP amount is not a fixed amount – it is calculated as a case-by-case stop loss. The maximum NTAP amount is 65% of the technology cost as determined by CMS. The payment will vary based on the final DRG assignment of the individual case. The maximum NTAP payment for Symplicity Spyral is \$10,400. For additional information on the NTAP, please refer to our <a href="Symplicity NTAP Overview and FAQ">Symplicity NTAP Overview and FAQ</a>.









## **Indications**

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# Payment for radiofrequency renal denervation

# Ambulatory Surgery Center (ASC) - Medicare national unadjusted rates

CPT® Code/ HCPCS	Description	CY2025 Payment Indicator	CY2025 National Payment <sup>12</sup>
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	G2 - Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight	\$2,630
0339T	Transcatheter renal sympathetic denervation,bilateral	J8 - Device-intensive procedure; paid at adjusted rate	\$3,740

Effective January 1, 2025, device category HCPCS code C1735 was approved for pass-through payment under the OPPS. When reporting the device category code C1735 for radiofrequency renal denervation, it is required that it be reported with one of the above RDN CPT procedure codes.

	mari di i procedure d	
C1735	Catheter, renal denervation radiofrequency	J7 - OPPS pass-through Contractor
		device paid separately Priced
		when provided integral
		to a surgical procedure
		on ASC list; payment
		contractor-priced

\*CMS Manual System Pub 100-04 Medicare Claims Processing, Transmittal 13044, Change Request 13934, January 10, 2025 <a href="https://www.cms.gov/files/document/r13044cp.pdf">https://www.cms.gov/files/document/r13044cp.pdf</a>
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## **Indications**

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- 5. The Medicare Physician Fee Schedule (MPFS) 2025 National payment rates based on information published in the MPFS final rule CMS-1807-F signed on November 1, 2024. PFS Federal Regulation Notices. CMS.gov. Available at: <a href="https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1807-f">https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1807-f</a>. Accessed November 8, 2024.
- 6. <u>PFS Relative Value Files</u>. cms.gov <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files</u> Local physician rates will vary based on location specific factors not reflected in this document. CMS may make adjustments to any or all of the data inputs from time to time.
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- 11. For current requirements regarding the IPPS NTAP, including the NTAP eligibility criteria, see the statute at sections 1886(d)(5)(K) and (L) of the Social Security Act (the "Act"), the regulations at 42 CFR sections 412.87 and 412.88, and the annual IPPS rulemakings. New Medical Services and New Technologies <a href="https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/new-medical-services-and-new-technologies">https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/new-medical-services-and-new-technologies</a>
- 12. 2025 Medicare ASC Final Rule (CMS-1809-FC): <a href="https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices/cms-1809-fc">https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices/cms-1809-fc</a> Updated January 3, 2025, Accessed January 1, 2025.









#### **Indications**

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## Coding

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# Brief statement

#### Indications

The Symplicity Spyral<sup>™</sup> 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 < 3 mm or > 8 mm • 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 SpyralTM 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.

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