

Medtronic

Symplicity™ blood pressure procedure

# Reimbursement guide

Physician and hospital coding, coverage, and payment



# Medtronic

## Product overview

## Indications

## Coverage

- Traditional Medicare
- Medicare Advantage
- Commercial payers

## Coding

- CPT\*\* codes
- HCPCS codes (C-code)
- ICD-10-PCS procedure codes
- ICD-10-CM diagnosis codes

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In support of the Medtronic Mission, we aim to help reduce economic barriers for our products and related therapies/procedures to ensure access to patients who need them. We are hopeful that our work will help with accurate billing, leading to appropriate and timely reimbursement of the Symplicity blood pressure procedure for indicated patients.

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:

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**Email:** [rs.cardiovascularhealththeconomics@medtronic.com](mailto:rs.cardiovascularhealththeconomics@medtronic.com)

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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.

**Please note:** For emerging therapies like the Symplicity Spyral™ renal denervation system, which is used during the Symplicity blood pressure procedure, it can take time to establish reimbursement.

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The Symplicity blood pressure procedure, also known as renal denervation, supplies precisely controlled and targeted radiofrequency (RF) energy to the renal nerves, disrupting the overactive sympathetic signaling between the kidneys and brain.<sup>1</sup> Catheter-based renal denervation (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 patient 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.

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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.

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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.

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### Traditional Medicare

There are no national or local coverage determinations (NCDs/LCDs) in place for renal denervation at this time. Generally, traditional (fee-for-service) Medicare covers FDA-approved therapies that are deemed reasonable and necessary for the diagnosis or treatment of an illness or injury. Please contact your local Medicare Administrative Contractor (MAC) for pre-procedure guidance and additional information.

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# Medicare Advantage

Medicare Advantage plans must provide the same coverage as traditional Medicare. In the absence of an NCD/LCD, they may refer to their commercial coverage policy for guidance. Prior authorization is often required. Please contact the payer for their prior authorization requirements and process.

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# Commercial payers

Coverage and prior authorization requirements can vary by plan and within a payer based on an individual's commercial policy. For new therapies, it is not uncommon for a payer to be silent (for example, no policy which includes or excludes coverage) or have a noncoverage policy. Prior authorization is strongly recommended and allows providers to request a one-time patient exception for coverage. Providers are encouraged to contact the payer for their prior authorization requirements and process. Please note the likelihood of a claim denial if a pre-procedure review is not performed and there is a noncoverage policy.

For additional information regarding the prior authorization process, please refer to our **coverage and prior authorization information** documents.



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### CPT codes

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

The following codes may be used by physicians in allowed sites of service. We expect most of these procedures will be performed in the hospital outpatient setting. It is the physician's discretion as to 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 code <sup>2</sup>	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.
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.

**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)

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### 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.

Currently, there is no C-code that describes the Symplicity Spyral catheter nor is there a C-code that applies to the Symplicity G3 generator (equipment like generators typically do not have C-codes). However, there may be applicable C-codes for other items that may be 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
<b>RDN016</b>	Symplicity Spyral™ catheter	N/A†
<b>RDNG3A</b>	Symplicity G3™ generator	N/A
<b>RDN019</b>	Cart for Symplicity G3 generator	N/A
<b>SB6RDND1K</b>	Sherpa™ NX Balanced 6 Fr 55-cm guide catheter with RDND1 curve	C1887
<b>LA6IMAK</b>	Launcher™ 6 Fr 55-cm guide catheter with IMA curve	C1887
<b>SB6IMAK</b>	Sherpa NX Blanaced 6 Fr 55-cm guide catheter with IMA curve	C1887
<b>E7507</b>	Valleylab™ REM Polyhesive™ Adult Patient Return Electrode, 9' (2.7 m)	
<b>E7507DB</b>	Valleylab REM Polyhesive Adult Patient Return Electrode, 15' (4.6 m)	
<b>N/A</b>	0.014" Guidewire (non-hydrophilic with a supportive shaft and a floppy tip)	C1769
<b>SpyralStartupCart</b>	Symplicity Spyral System including 5ea RDN016, 1 ea, RDNG3A, 1ea RDN019	N/A
<b>SpyralStartup</b>	Symplicity Spyral System including 5ea RDN016, 1 ea, RDNG3A	N/A

†There is currently no specific C-code that describes the Symplicity Spyral catheter. It is the provider's discretion as to what codes to report. May consider the unlisted device code C1889: Implantable/insertable device, not otherwise specified.

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# ICD-10-PCS procedure codes

ICD-10-PCS codes are required when billing for inpatient admissions. For RDN, the following ICD-10-PCS code describes percutaneous renal denervation:

015M3ZZ – Destruction of Abdominal Sympathetic Nerve, Percutaneous Approach

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# 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
I10	Essential (primary) hypertension
I11.0	Hypertensive heart disease with heart failure
I11.9	Hypertensive heart disease without heart failure
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end-stage renal disease
I12.9	Hypertensive chronic kidney disease with 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
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end-stage renal disease
I16.0	Hypertensive urgency
I16.1	Hypertensive emergency
I16.9	Hypertensive crisis, unspecified
I1A.0	Resistant hypertension

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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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### Physician reimbursement

Physicians use CPT codes to represent procedures and services performed in all places of service. Under Medicare's methodology for physician payment, each CPT 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>3</sup>	CPT code description	2024 physician rates <sup>4</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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# Hospital outpatient reimbursement

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>5</sup>	CPT code description	2024 APC	2024 national unadjusted payment rate <sup>6</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	\$5,452
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	5192	\$5,452

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

Currently, a Medicare transitional pass-through payment is not available for renal denervation. Medtronic will provide updated information should a pass-through payment be approved and becomes available.



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# Hospital inpatient reimbursement

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	FY2024 MS-DRG Medicare national unadjusted payment rate
264	Other circulatory system O.R. procedures	\$22,867

<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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### New technology add-on payment (NTAP) for hospital inpatient

Currently, a Medicare new technology add-on payment (NTAP) is not available for renal denervation. Medtronic will provide updated information should an NTAP for RDN be approved and becomes available.

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<sup>1</sup> Coates P, Tunev S, Trudel J, Hettrick DA. Time, temperature, power, and impedance considerations for radiofrequency catheter renal denervation. *Cardiovasc Revasc Med*. September 2022;42:171-177.

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<sup>3</sup> The Medicare Physician Fee Schedule (MPFS) 2024 National payment rates based on information published in the MPFS final rule CMS-1784-F signed on November 2, 2023. PFS Federal Regulation Notices. CMS.gov. <https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices>. Accessed January 26, 2024. PFS Relative Value Files. CMS.gov. <https://www.cms.gov/medicare/payment/fee-schedules/physician/pfs-relative-value-files>. Accessed January 26, 2024. 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.

<sup>4</sup> CPT® only copyright 2022 American Medical Association. All rights reserved.

<sup>5</sup> The OPPS 2024 National payment rates based on information published in the OPPS/ASC final rule CMS-1786-FC and corresponding Addendum B table which was released on November 2, 2023. Hospital Outpatient Regulations and Notices. CMS.gov. <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1786-fc>. Accessed January 26, 2024. Hospital-specific rates will vary based on various hospital-specific factors not reflected in this document and CMS may make adjustments to any or all of the data inputs from time to time.

<sup>6</sup> FY 2024 IPPS Final Rule Home Page. CMS.gov. Available at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2024-ippf-final-rule-home-page>. Accessed on January 26, 2024. Hospital-specific rates will vary based on various hospital-specific factors not reflected in this document and CMS may make adjustments to any or all of the data inputs from time to time.

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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 Spyral<sup>™</sup> 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-spasmodic 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](http://medtronic.com).

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