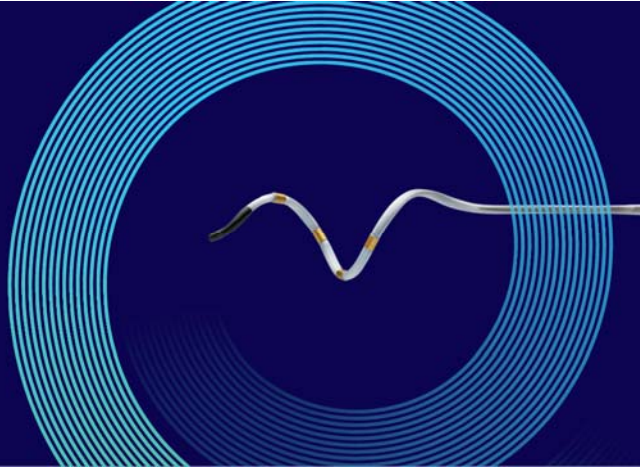
Medtronic

Symplicity™ blood pressure procedure

Reimbursement Summary



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 you with accurate billing, leading to appropriate and timely reimbursement of the Symplicity blood pressure procedure for indicated patients.*

This document reflects commonly billed codes for Symplicity blood pressure procedure and the associated Medicare national reimbursement rates. The 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.

Your Medtronic Regional Economic Managers (REM) can provide site-specific information upon request.

Physician Reimbursement

CY 2024 National Unadjusted Medicare Rates

CPT®	Description	CY 2024 Facility Payment	CY 2024 Non-Facility Payment
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	Carrier Priced	Carrier Priced
0339T	Transcatheter renal sympathetic denervation, …bilateral	Carrier Priced	Carrier Priced

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.

Hospital Outpatient (OPPS) Reimbursement

CY 2024 National Unadjusted Medicare Rates

CPT®	Description	APC	CY2024 Outpatient Payment
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, …bilateral	5192	$5,452

HCPCS Codes (C-codes)

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). 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
RDN016	Symplicity Spyral™ catheter	N/A*
RDNG3A	Symplicity G3™ generator	N/A
RDN019	Cart for Symplicity G3 generator	N/A
SB6RDND1K	Sherpa™ NX Balanced 6Fr 55-cm guide catheter with RDND1 curve	C1887
LA6IMAK	Launcher™ 6Fr 55-cm guide catheter with IMA curve	C1887
SB6IMAK	Sherpa™ NX Blanaced 6Fr 55-cm guide catheter with IMA curve	C1887
E7507	Valleylab™ REM Polyhesive™ Adult Patient Return Electrode, 9' (2.7 m)	
E7507DB	Valleylab™ REM Polyhesive™ Adult Patient Return Electrode, 15' (4.6 m)	
N/A	0.014" Guidewire (non-hydrophilic with a supportive shaft & 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

**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.*

Hospital Inpatient (IPPS) Reimbursement

FY 2024 National Unadjusted Medicare Rates

ICD-10-PCS	ICD-10-PCS Description	MS-DRG	MS-DRG Description	FY 2024 Inpatient Payment
015M3ZZ	Destruction of Abdominal Sympathetic Nerve, Percutaneous Approach	264	Other circulatory system O.R.	$22,867

Sources

- PFS Relative Value Files: https://www.cms.gov/medicare/payment/fee-schedules/physician/pfs-relative-value-files
- 2024 Medicare IPPS Final Rule (CMS-1785-F): https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2024-ipps-final-rule-home-page
- 2024 Medicare OPPS Final Rule (CMS-1772-FC): https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1786-fc
- 2024 Medicare Physician Final Rule (CMS-1784-F): https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1784-f

For additional information, please contact the Medtronic Reimbursement Customer Support team:

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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.

Brief Statement

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