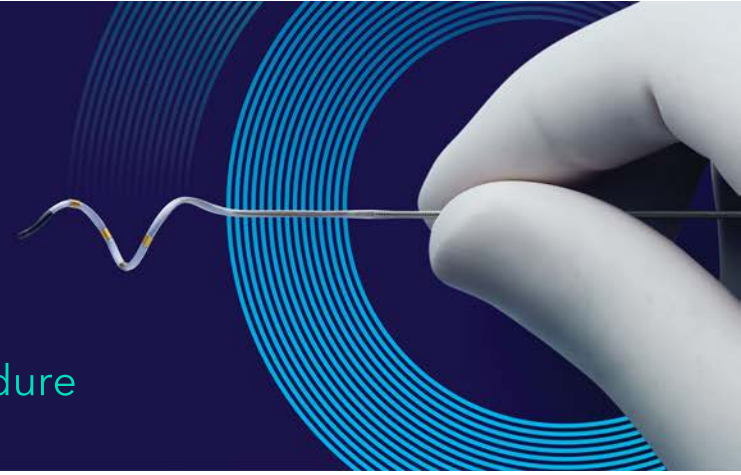
Medtronic

Symplicity Spyral™ renal denervation system

Medicare Billing and Coding Instructions

For the Symplicity blood pressure procedure



Effective October 28, 2025, Medicare has published a National Coverage Determination (NCD) for renal denervation for uncontrolled hypertension, including the Symplicity™ blood pressure procedure.[1] Subject to the 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 the 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.
- Additional coverage, coding, and payment information, along with frequently asked questions, is available in the Symplicity reimbursement guide found here.

Procedure Coding for Renal Denervation

Codes and Descriptions	
Professional – All Places of Service **Facility – Hospital Outpatient and Ambulatory Surgical Centers (ASCs)**	
CPT® Procedure Codes 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, …bilateral	**HCPCS Device Code** (Facilities only) C1735 - Catheter, renal denervation, radiofrequency
Facility – Hospital Inpatient	
ICD-10-PCS Procedure Code X05133A - Destruction of Renal Sympathetic Nerve(s) using Radiofrequency Ablation, Percutaneous Approach	

1 US-SE-2500517 v3

Procedure Coding for Facility 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).

Medicare Renal Denervation Billing Requirements

(All elements are required for claims submission – See Appendix for example claims)

Claim Requirements	Identifying Information Required by RDN NCD
Diagnosis Codes	
Primary diagnosis code	Applicable primary diagnosis code for uncontrolled hypertension (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) *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 Requirements	
National clinical trial (NCT) number	07174622 for claims using Symplicity Spyral device only – the SPYRAL CARE study
Modifier to CPT® procedure code (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 Requirements	
Condition code	30 Qualifying clinical trial
Value code	D4 ("Code") and NCT number ("Amount") (*D4 is not required for electronic billing)

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 NCD – Renal Denervation for Uncontrolled Hypertension. https://www.cms.gov/medicare-coverage-database/view/nca.aspx?ncaid=318; Accessed 10/28/25.

Appendix: Example Medicare Claim Forms

Example claim forms illustrate appropriate additional billing information.

These are provided for your information only and does not guarantee authorization or payment.

Outpatient hospital claim form

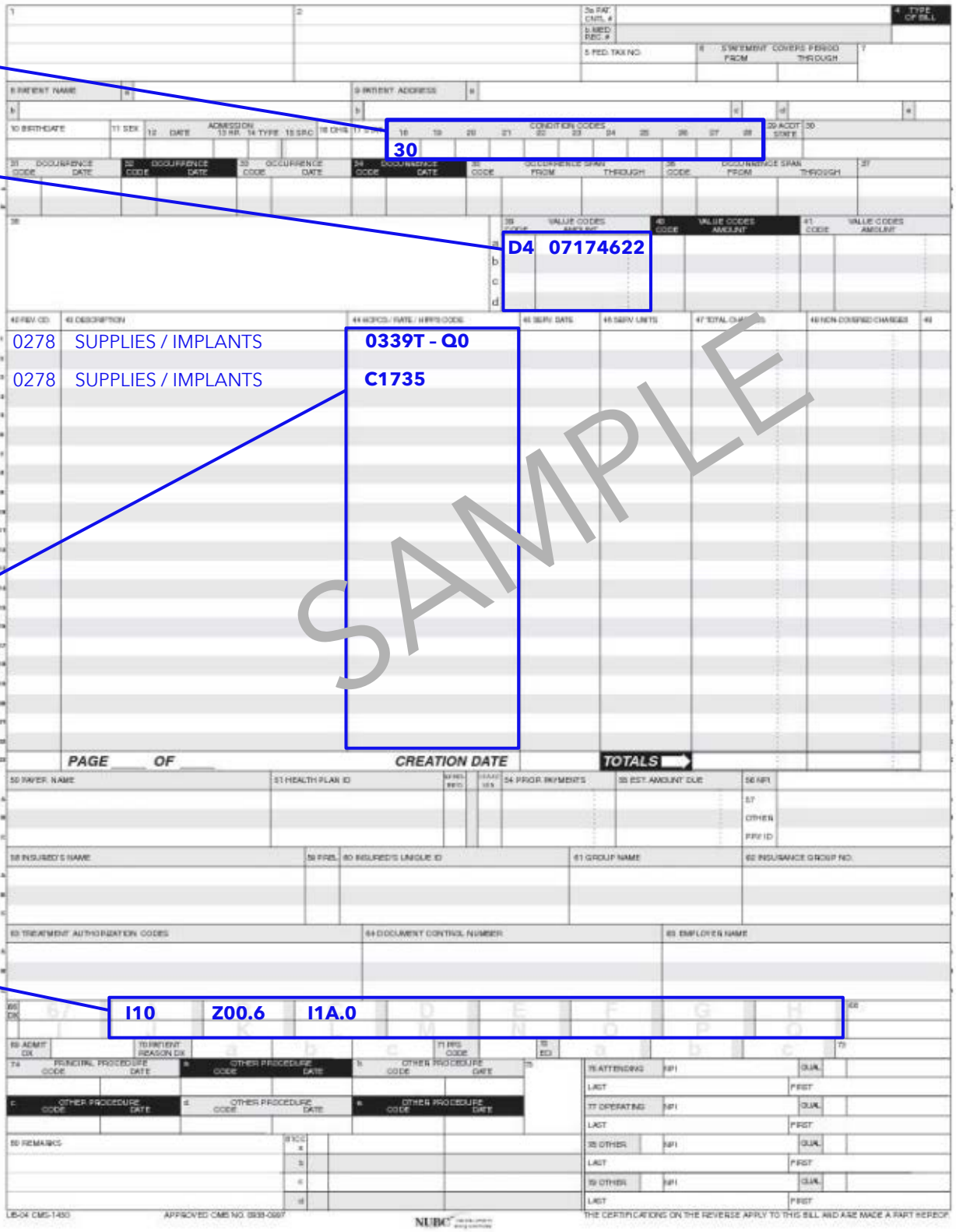
Form Locator 18: Condition Code 30 identifies a study.

Form Locator 39: Value code has two parts: D4 goes under "Code" (not used for electronic claims) The SPYRAL CARE NCT # 07174622 goes under "amount."

Symplicity claims should use this NCT number.

Form Locator 44: The Q0 modifier is appended to the CPT® procedure code 0339T.

Form Locator 67 A-Q: Z00.6 is a secondary diagnosis code identifying a clinical trial participant. The primary diagnosis (hypertension) goes in form locator 67.



Inpatient hospital claim form

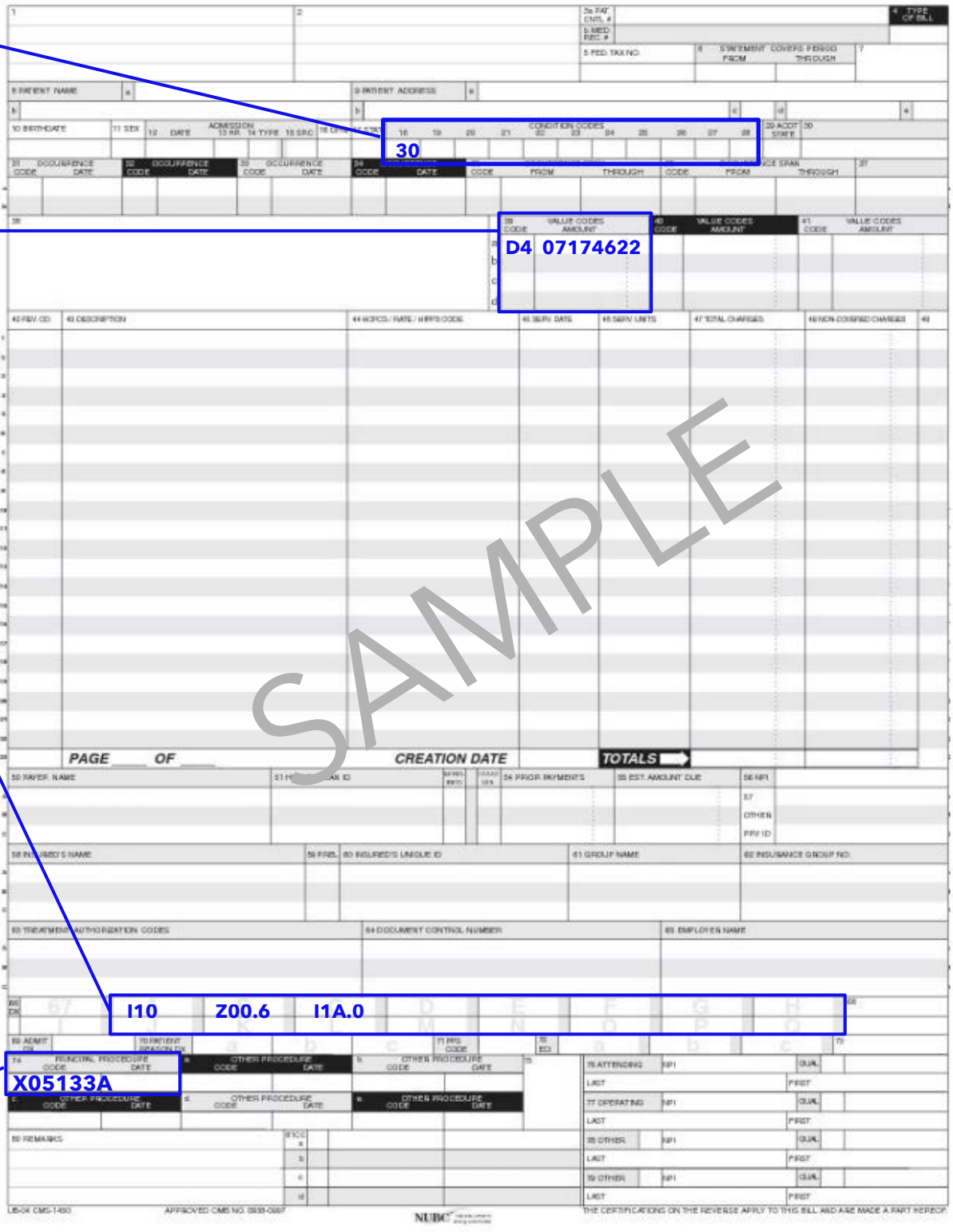
Form Locator 18: Condition Code 30 identifies a study.

Form Locator 39: Value code has two parts: D4 goes under "Code" (not used for electronic claims) The SPYRAL CARE NCT # 07174622 goes under "amount."

Symplicity claims should use this NCT number.

Form Locator 67 A-Q: Z00.6 is a secondary diagnosis code identifying a clinical trial participant. The primary diagnosis (hypertension) goes in form locator 67.

Form Locator 74: X05133A identifies the ICD-10-PCS procedure code.



Professional claim form

Item 19:
For the NCT number: include the number only, not the "NCT" prefix. *[CT prefix required for paper CMS-1500 forms]*

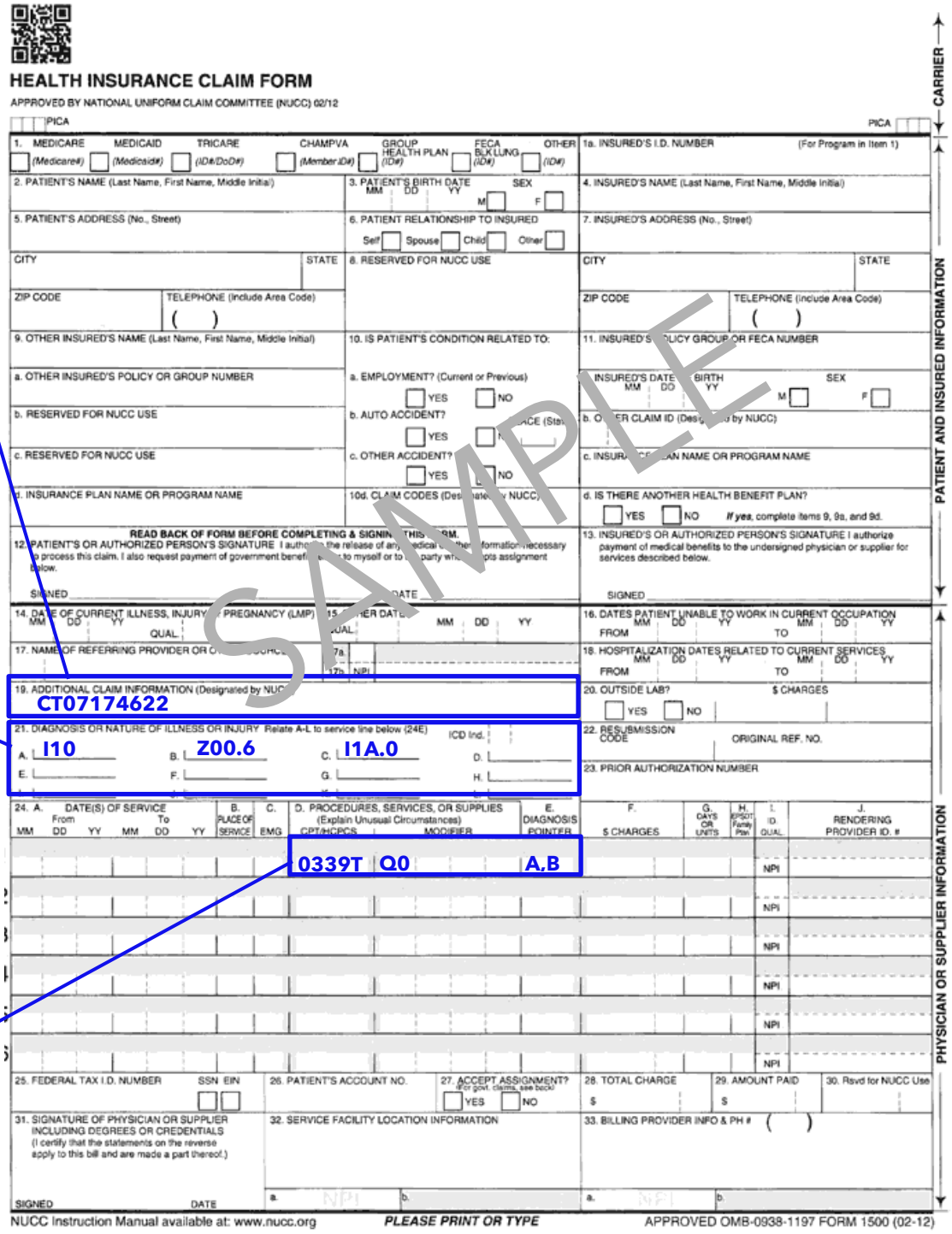
Symplicity claims should only use the SPYRAL CARE NCT number: 07174622

You may also include the comparator crosswalk code in this box.

Item 21B:
Z00.6 is a secondary diagnosis code identifying a clinical trial participant. The primary diagnosis (hypertension) goes in item 21A.

Item 24D:
The Q0 modifier is required is appended to the CPT® procedure code 0339T.

Item 24E: The A,B diagnosis pointer is required. This links the CPT code to the primary and secondary diagnoses.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
CT07174622

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.
A. **I10** B. **Z00.6** C. **I1A.0** D.
E. F. G. H.
I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
				0339T	**Q0**	**A,B**				NPI	
										NPI	
										NPI	
										NPI	
										NPI	
										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

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

