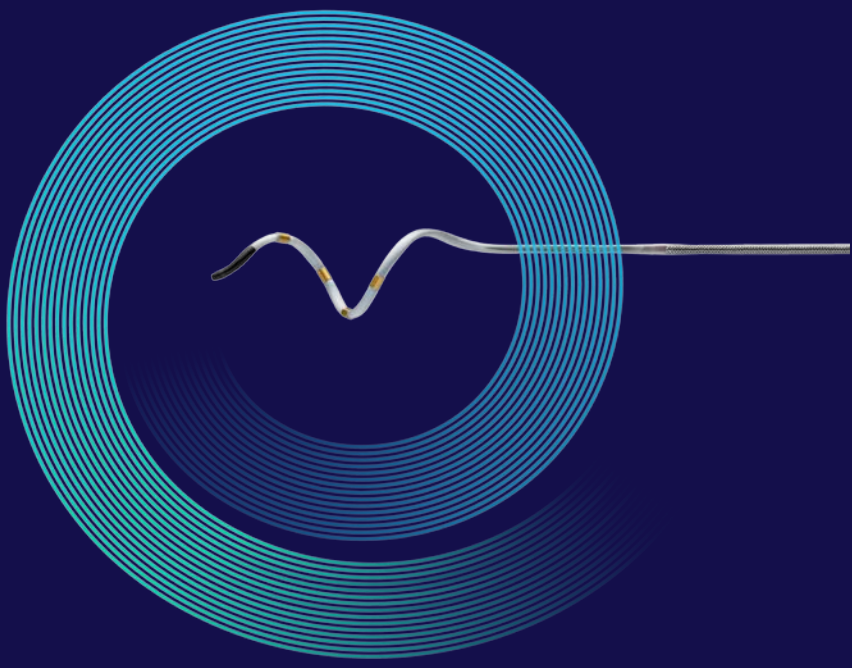
Medtronic

Engineering the extraordinary

Symplicity™ blood pressure procedure

Prior authorization & appeal resources



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US-SE-2500449v2

Resource table of contents

Overview

This document outlines resources available to support your efforts in obtaining prior authorization (PA) for the Symplicity blood pressure procedure, also known as renal denervation. Click on the blue buttons below to access resources within this document as well as links to external resources.

Prior authorization & appeal resources

Additional resources

Symplicity Reimbursement Homepage

Additional resources available from RDN Reimbursement website include: product brochure, reimbursement guide, transitional pass-through payment (TPT) overview, new technology add-on payment (NTAP) overview & FAQ, and more.

Contact

For additional information, please contact the Reimbursement Customer Support team at rs.cardiovascularhealtheconomics@medtronic.com or 877-347-9662 or your local sales rep to be connected to your Regional Economic Manager (REM).

Prior authorization process flow chart

Initial request — 14+ days

The following are verified for each patient:
- Eligibility & benefits
- Prior authorization (PA) requirements
- Coverage policy

PA request is submitted
- If PA is not an option, inquire if predetermination, courtesy or medical necessity review is available

Approved

Denied

Appeal options — 1-2 days after denial

Appeal process initiated
- Review denial letter for rationale and next steps

Peer-to-peer review
- Should occur promptly after denial
- May not be available for all plans

1st level written appeal
- Refer to denial letter for appeal instructions

2nd level written appeal
- Refer to level 1 appeal denial letter

30+ days per appeal

3rd level written appeal
- External appeal reviewed by an independent review entity

The process outlined is generally for non-traditional Medicare payers (e.g., Commercial/Private and Medicare Advantage). Each payer has its own process. Please contact the patient's payer for exact prior authorization steps.

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Claim process flow chart

Procedure performed

If PA is approved, but the procedure is not performed within the date range requested, your claim may be denied.

Claim submitted

Time frames for claims submissions and payer processing can vary. If PA was obtained, it may be helpful to include the approval number or letter when submitting the claim.

Approved

Claim paid

Denied

Claim appeal process initiated

- Review EOB/remittance advice for denial rationale
- Can dispute coverage decision or payment rate

Contact payer promptly for next steps

- Some payers may reprocess the claim before written appeal

1st level appeal

- Follow payer appeal instructions
- Including an appeal letter and supportive clinical documentation is recommended

Subsequent appeals

- Some payers offer multiple claim appeals
- Refer to appeal denial letter or contact the payer for next steps

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Prior authorization & appeal guide

Overview

The information below depicts the general process for obtaining prior authorization from a payer. Prior authorization (PA) – sometimes called predetermination, preauthorization, precertification, clinical review, prior approval, preservice review, or advanced benefit notification – is a utilization management process used by payers to evaluate medical necessity and determine if certain products or services will be covered. This process requires providers to obtain advanced approval that medical necessity and coverage criteria have been met before services are provided. Prior authorization may take over two weeks, not including the appeal process. It is recommended providers consider this when scheduling the procedure.

Note: The information provided is for consideration only. The provider is responsible for determining medical necessity and submitting appropriate codes and charges for care provided. Please contact the payer for its PA requirements and process. Use of this guide does not guarantee authorization or payment.

Considerations for obtaining a prior authorization

- **Coordination:** Identify a staff member to coordinate the PA process (e.g., document payer interactions, track outcomes)
- **Clarification:** Determine PA and coverage requirements before providing the service
- **Accuracy:** Ensure appropriate documentation is submitted and supports medical necessity and coverage criteria. Please refer to the Documentation Best Practices.
- **Attention:** Regularly follow up with the payer to ensure a timely determination
- **Education:** If the PA is denied, request the denial letter to determine the payer's rationale and appeal process
- **Escalation:** Inquire about a peer-to-peer review. Please refer to the Physician Peer-to-Peer Guide.
- **Preparation:** If appealing, be prepared with documentation addressing the denial reason. Please refer to the Sample Appeal Letters.

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

Payer coverage overview

Commercial

- Coverage and PA requirements can vary by payer, plan, and individual policy.
- Requesting PA is strongly recommended and may be required.*

Medicare (Fee-For Service/Traditional) (Parts A/B)

- Generally, covers FDA approved therapies that are deemed reasonable & necessary.
- Effective October 28th, 2025, RDN for uncontrolled hypertension is covered by Medicare. See the RDN NCD for details.

Medicare Advantage (MA) (Part C)

- MA plans are required to provide the same coverage as traditional Medicare under the RDN NCD. However, it is important to confirm prior authorization and documentation requirements with the plan administrator.
- Requesting PA is strongly recommended and may be required.*
- The Medicare Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance[1] 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 PA is strongly recommended and may be required.*

When PA 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.

Steps in the prior authorization process:

Step 1: Collect information

- Patient name, date of birth, identification number
- Proceduralist name, address, NPI, Tax ID (TIN)
- Site of service for procedure: Facility name, address, NPI
- Date of service
    - Requesting a date range allows flexibility in scheduling and may prevent the need to resubmit your PA request if a procedure is rescheduled
    - If PA is approved, but the procedure is not performed within the date range requested, your claim may be denied
- Diagnosis, procedure, place of service codes and descriptions

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Step 2: Contact payer

- Verify patient eligibility, benefits, network status
- Inquire about a coverage policy for the procedure
    - It is not uncommon for payers to be silent or have a negative policy
- Determine payer requirements for PA
    - PA is strongly recommended and may be required
    - If PA is not required, inquire if a predetermination or medical necessity/pre-service review is available
    - Please note the likelihood of a claim denial if a pre-service review is not performed and there is a negative policy
- Document the date of each call, who you spoke with, and call reference number if available

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Step 3: Submit request

- Determine the payer's PA submission method: fax, phone, payer provider portal, email, mail
    - Note submission method for future PA requests
- Gather and submit all supporting materials:
    - Information in Step 1
    - Payer required prior authorization form(s)
    - Medical documentation (e.g., prescription, medical records)
    - Letter of medical necessity (optional)
    - Relevant literature
- If payer provider portal rejects request, call payer to initiate predetermination or medical necessity/pre-service review via fax

Step 4: Follow-up

- Contact the payer within a few days of submission to verify receipt of the PA request
  - If available, obtain the pending PA number
- PA may take over two weeks for an initial decision
- Document payer interactions and call reference numbers
- Continue to follow up routinely until a determination is made

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Step 5: Verify outcome

- If PA is approved:
  - Obtain PA number and approved dates of service
  - Request approval letter
  - Re-verify eligibility to ensure patient is still covered prior to scheduling procedure
- If PA is denied:
  - Inquire about a peer-to-peer option (please note this may not be available with all payers or plans)
  - Request denial letter to determine the payer's rationale and next steps for appeal
  - Continue to Step 6

Step 6: Peer-to-peer

- If there is a peer-to-peer option available, generally this must be requested and scheduled within a few hours to days upon notification of a denied PA
  - Payer may request dates and times of provider availability and their contact information
  - In some cases, a peer-to-peer may result in approval

Step 7: Appeal

- Review denial letter for payer's rationale and appeal process
  - Some payers may offer a reconsideration option prior to first level appeal. New information may be required, and timeframes may vary.
- Write appeal letter addressing:
  - Denial reason and why you disagree
  - Indication for and clinical benefits of procedure
  - Potential risks if the patient does not receive this treatment
- Attach new and previously submitted supporting materials:
  - Medical documentation
  - Relevant literature
- Submit appeal within timeframe listed in denial letter. Timeframes can vary based on the payer.
- Follow up with the payer until a determination is made. Appeal determinations can take up to 30+ days.
- Appeal options may also be available for the patient/member
  - Patients may contact Member Services at the phone number on the back of their insurance card or their employer for assistance.

Step 8: Subsequent appeals

- The first appeal denial letter will provide information on subsequent appeal rights.
- Generally, Commercial payers offer a second appeal followed by an external review (timeframes can vary based on the payer). An external review, also referred to as an independent medical review, is a final appeal submitted to a third-party review organization.
- For Medicare Advantage plans, if the first appeal is denied, it will automatically be sent to an Independent Review Entity (IRE) for a second appeal.
  - Providers can submit additional information to the IRE within 10 days.[2]
  - If the second appeal is denied by IRE, you may request review by the Office of Medicare Hearing and Appeals.[2] This will involve a hearing before an Administrative Law Judge.

Documentation best practices

Overview

Medical record documentation should support why the Symplicity blood pressure procedure is medically necessary to treat the patient's condition. This guide is to assist providers in documenting support for renal denervation. The payer policy, when available, or Medicare NCD should also be referenced.

Please note: This is provided for consideration only. It does not constitute legal advice or a recommendation regarding clinical practice. The provider is responsible for determining medical necessity and submitted appropriate documentation for care being provided. Use of this guide does not guarantee authorization or payment.

Medicare NCD Patient Criteria

- ✓ BP >140/90 mm Hg, confirmed with ambulatory or home BP
- ✓ Stable on guideline directed medical therapy (GDMT) for >3 months
- ✓ At least 3 encounters with primary clinician in past 6 months, with no more than 1 being virtual
- ✓ No contraindications
- ✓ No prior RDN procedure

Patient documentation checklist

The following is a list of information payers commonly look for when reviewing for medical necessity:

- How a patient's care pathway has followed the Clinical Practice Guidelines for hypertension
- Hypertension diagnosis e.g., essential/primary, resistant
- Onset, symptoms, severity
  - Status of related conditions e.g., CV disease, diabetes, obesity, kidney disease
- Blood pressure readings/logs e.g., ambulatory, office, home
- Related cardiovascular events, interventions, hospitalizations
- 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)
- Lifestyle modifications e.g., diet, weight, exercise, limiting alcohol, smoking cessation
- Screening to rule out secondary causes of hypertension
- Suitable renal anatomy and function e.g., eGFR, renal artery imaging to rule out possible exclusions or contraindications.
- Reason/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
- Clinical studies that substantiate the clinical benefit your patient may achieve with this therapy

Physician peer-to-peer guide

Overview

A peer-to-peer (P2P) review provides physicians the opportunity to discuss a denied PA with the insurance company's Medical Director. This guide is intended to support P2P discussions for the Symplicity blood pressure procedure, also known as renal denervation. Use of this guide does not guarantee authorization or payment.

Considerations:

- A P2P review is a scheduled phone call, typically brief, that must be arranged by the requesting physician or designated person from the requesting physician's office within the timeframe set by the payer. **Many payers require the call to be completed within a few hours to days upon notification of a denied PA.**
- A P2P review is optional and occurs prior to submitting a written appeal (or in accordance with the payer's P2P guidelines).
- There may be an option to request the P2P discussion be with a physician with similar medical specialty.
- A determination is usually made at the conclusion of the call. In some cases, a P2P review may result in an approved PA.
- A P2P may not be available for all health plans.
- For a list of supplemental resources that are available to support your P2P discussion, please refer to the Resource Table of Contents.

Talking points

Before the call, take time to review the denial reason, payer's coverage policy, and patient documentation. The information provided below is for your consideration as you prepare for a P2P review of the Symplicity blood pressure procedure.

State your request and why you disagree with the denial

- Even if the denial is a result of a payer's non-coverage policy, the goal of the P2P review is to request a coverage exception for the Symplicity blood pressure procedure based on the patient's medical necessity.

Describe the Symplicity Spyral system

- The Symplicity Spyral system was granted premarket approval by the U.S. Food and Drug Administration (FDA) on November 17, 2023.
- The Symplicity Spyral system, which is used during the Symplicity blood pressure procedure, supplies precisely controlled and targeted radiofrequency (RF) energy to the renal nerves, safely disrupting the overactive sympathetic signaling between the kidneys and brain[3] resulting in (or delivering) clinically significant, safe, and sustained blood pressure reductions.[4-9]
- The Symplicity Spyral 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.[10]

Explain the medical necessity of this therapy for your patient

- Patient's relevant medical history:
  - Diagnosis, onset, symptoms, severity
  - Clinical presentation e.g., blood pressure readings, eGFR rate, impact on quality of life & activities of daily living
  - Risk factors e.g., family history, past cardiovascular event(s), organ damage, comorbidities, related hospitalization(s)
- Treatment history
  - Antihypertensive medications
  - Lifestyle modifications
- Reason/Indication for procedure
  - Clinical benefits
  - Potential risks
  - Patient preference for treatment

Share your experience with renal denervation

- Procedure volume
- Clinical outcomes for patients who receive this therapy

Describe any other key facts to support your request

- Clinical evidence to substantiate the clinical benefit your patient may achieve with this therapy. Focus on guidelines, safety, efficacy, and patient selection. Please refer to the Bibliography.
- Payers that have covered the Symplicity blood pressure procedure for your other patients.

Bibliography

Overview

This bibliography includes articles that support the approved U.S. FDA indication for use of the Symplicity Spyral™ renal denervation (RDN) system for uncontrolled hypertension and therefore deemed to be relevant to aid in the payer decision-making process. This includes randomized controlled trials, real-world evidence, clinical practice guidelines, society recommendations, and systematic reviews. This list is current as of August 14, 2025, and is not exhaustive of all articles on the Symplicity system.

Randomized Controlled Trials (RCTs)

Study: SPYRAL HTN-ON MED

Kandzari DE, Mahfoud F, Townsend RR, et al. Long-Term Safety and Efficacy of Renal Denervation: 24-Month Results From the SPYRAL HTN-ON MED Trial. Circ Cardiovasc Interv. Published online May 20, 2025. doi: 10.1161/circinterventions.125.015194 Full text: https://pmc.ncbi.nlm.nih.gov/articles/PMC12244969/

Kandzari DE, Cao, KC, Ryschon AM, Catheter-Based Radiofrequency Renal Denervation in the United States: A Cost- Effectiveness Analysis Based on Contemporary Evidence. *Journal of the Society of Cardiovascular Angiography & Interventions*. 2024 Aug 13. doi: https://doi.org/10.1016/j.jscai.2024.102234Full text: https://www.sciencedirect.com/science/article/pii/S2772930324016144

Townsend RR, Ferdinand KC, Kandzari DE, et al. Impact of Antihypertensive Medication Changes after Renal Denervation among Different Patient Groups: SPYRAL HTN-ON MED. *Hypertension*. 2024 Feb 5. doi: 10.1161/HYPERTENSIONAHA.123.22251Full text: https://www.ahajournals.org/doi/10.1161/HYPERTENSIONAHA.123.22251

Kandzari DE, Townsend RR, Kario K, et al. SPYRAL HTN-ON MED Investigators. Safety and Efficacy of Renal Denervation in Patients Taking Antihypertensive Medications. *J Am Coll Cardiol*. 2023 Nov 7;82(19):1809-1823. doi: 10.1016/j.jacc.2023.08.045. PMID: 37914510.Full text: https://www.sciencedirect.com/science/article/pii/S0735109723066512?via%3Dihub

Kario K, Mahfoud F, Kandzari DE, et al. Long-term reduction in morning and nighttime blood pressure after renal denervation: 36-month results from SPYRAL HTN-ON MED trial. Hypertens Res. 2023;46(1):280-288. doi:10.1038/s41440-022-01042-8Full text: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9747613/

Mahfoud F, Kandzari DE, Kario K, et al. Long-term efficacy and safety of renal denervation in the presence of antihypertensive drugs (SPYRAL HTN-ON MED): a randomised, sham-controlled trial. *Lancet*. 2022 Apr 9;399(10333):1401-1410. doi: 10.1016/S0140-6736(22)00455-X. Epub 2022 Apr 4. PMID: 35390320. PubMed Abstract: https://pubmed.ncbi.nlm.nih.gov/35390320/

Kandzari DE, Hickey GL, Pocock SJ, et al. Prioritised endpoints for device-based hypertension trials: the win ratio methodology. EuroIntervention. 2021 Apr 2;16(18):e1496-e1502. doi: 10.4244/EIJ-D-20-01090. PMID: 33226002; PMCID: PMC9724872.

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PubMed Abstract: https://pubmed.ncbi.nlm.nih.gov/29803589/

Study: SPYRAL HTN-OFF MED

Böhm M, Kario K, Kandzari DE, et al. SPYRAL HTN-OFF MED Pivotal Investigators. Efficacy of catheter-based renal denervation in the absence of antihypertensive medications (SPYRAL HTN-OFF MED Pivotal): a multicentre, randomised, sham-controlled trial. *Lancet.* 2020 May 2;395(10234):1444-1451. doi: 10.1016/S0140-6736(20)30554-7. Epub 2020 Mar 29. PMID: 32234534.

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Townsend RR, Mahfoud F, Kandzari DE, et al. SPYRAL HTN-OFF MED trial investigators*. Catheter-based renal denervation in patients with uncontrolled hypertension in the absence of antihypertensive medications (SPYRAL HTN- OFF MED): a randomised, sham-controlled, proof-of-concept trial. *Lancet.* 2017 Nov 11;390(10108):2160-2170. doi: 10.1016/S0140-6736(17)32281-X. Epub 2017 Aug 28. PMID: 28859944.

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Non-Randomized Studies

Study: GLOBAL SYMPLICITY REGISTRY (GSR)

Schmieder RE, Mahfoud F, Mancia G, et al. Clinical event reductions in high-risk patients after renal denervation projected from the global SYMPLICITY registry. *Eur Heart J Qual Care Clin Outcomes.* 2023 Sep 12;9(6):575-582. doi: 10.1093/ehjqcco/qcac056. PMID: 36057838; PMCID: PMC10495746.

Full text: https://academic.oup.com/ehjqcco/article/9/6/575/6691720?login=false

Mahfoud F, Mancia G, Schmieder RE, et al. Outcomes Following Radiofrequency Renal Denervation According to Antihypertensive Medications: Subgroup Analysis of the Global SYMPLICITY Registry DEFINE. *Hypertension.* 2023 Aug;80(8):1759-1770. doi: 10.1161/HYPERTENSIONAHA.123.21283. Epub 2023 Jun 15. PMID: 37317866; PMCID: PMC10355804.

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Brief Statement

Indication

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

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Contact

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Or visit our reimbursement website at
https://www.medtronic.com/us-en/healthcare-professionals/reimbursement/cardiovascular-coding-coverage-resources.html

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