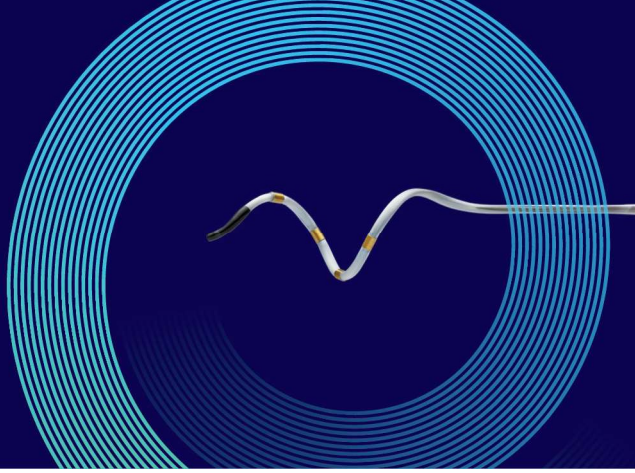
Medtronic

**Symplicity™** blood pressure procedure

# Prior Authorization & Appeal Guide



*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.*

**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.

*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.

# Overview

The information below depicts the general process for requesting prior authorization and appeals from a payer. Prior authorization – sometimes called precertification, preauthorization, prior approval, or predetermination - 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 obtain advance approval that medical necessity and coverage criteria have been met before services are provided. In some circumstances, prior authorization can take up to 2+ weeks to be completed, not including the appeal process. It is recommended providers consider this when scheduling procedures.

Please note: The information provided is based on our understanding of the general prior authorization process and 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 prior authorization requirements and process. Use of this guide does not guarantee authorization or payment.

# Payer Types

## Commercial

- Coverage and prior authorization requirements can vary by plan and within a payer based on an individual's policy type.
- Prior authorization is strongly recommended and may be required.

## Traditional Medicare (Parts A/B)

- There are no national or local coverage determinations (NCDs/LCDs) in place for renal denervation at this time. Generally, traditional Medicare covers FDA approved services 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. A map of the A/B MAC Jurisdictions can be found on the CMS website.[1]

## Medicare Advantage (MA) (Part C)

- Must provide the same coverage as traditional Medicare; however, in the absence of an NCD/LCD, they may create their own coverage criteria or refer to other coverage policies, such as their commercial plan policy, for guidance.[2]
- Prior authorization is strongly recommended and may be required.

## Medicaid

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

# Keys to success in obtaining prior authorization

- **Coordination:** Identify a staff member to coordinate the prior authorization process (e.g., document payer interactions, track outcomes)
- **Clarification:** Determine prior authorization 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*** & ***Sample Prior Authorization Letter***.
- **Attention:** Regularly follow up with the payer to ensure a timely determination.
- **Education:** If prior authorization 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 to address the denial reason. Please refer to the ***Sample Appeal Letter***.

# Steps in the prior authorization process

**Step 1: Collect Information**

- Patient's name, date of birth, and identification number
- Proceduralist's name and NPI
- Name, address, and NPI of facility where procedure will take place (site of service)
- Date of service; requesting a date range allows flexibility in scheduling and may prevent the need to resubmit your prior authorization request should a procedure be rescheduled. Please note: If prior authorization is approved, but the procedure is not performed within the date range requested, your claim may be denied.
- Diagnosis, procedure, and place of service codes and descriptions

**Step 2: Contact Payer**

- Verify patient eligibility and benefits
- Inquire about a coverage policy for the procedure. ***For recently approved therapies, it is not uncommon for payers to be silent (to have no policy that specifically includes or excludes coverage) or to have a noncoverage policy. In these cases, prior authorization is strongly recommended and allows providers to request a one-time patient exception for coverage.***
- Determine payer requirements for prior authorization. If prior authorization is not required, inquire if predetermination or courtesy review is available. If no, document the date of your call, who you spoke with, and call reference number, if available. ***Please note there is a high likelihood of a claim denial if a pre-service review is not performed and the payer has a noncoverage policy.***

**Step 3: Submit Request**

- Determine the payer's prior authorization submission method: fax, payer portal, phone, email, or mail. Track submission method for future prior authorization requests.
- Gather and submit all supporting materials, such as the information in Step 1, any payer required prior authorizations forms, and supporting medical documentation (e.g., prescription, letter of medical necessity, medical records).

**Step 4: Follow-up**

- Call payer to verify receipt of the prior authorization request. If available, obtain the pending prior authorization number. Continue to follow up routinely until a determination has been made. In some circumstances, Prior authorization can take up to 2+ weeks, not including the appeal process.
- Document payer interactions and track outcomes and time to determination.

**Step 5: Verify Outcome & Eligibility**

- If the prior authorization is approved, obtain the prior authorization number and request the approval letter. Reverify the patient's eligibility to ensure they are still covered.
- If the prior authorization is denied, request the denial letter to determine the payer's rationale and appeal process. ***Only continue to the next step if the prior authorization request is denied.***

## Step 6: Peer-to-Peer

- If the prior authorization is denied, the payer may allow a peer-to-peer review. Please contact the payer to inquire about this option.
- ***Generally, a peer-to-peer review must be requested within a few hours to days upon notification of a denied prior authorization and in some cases, could result in approval.***

## Step 7: Appeal

- Review the denial letter for the payer's rationale and information regarding the appeal process. Of note, some payers may offer a reconsideration option prior to a formal appeal.
- Prepare an appeal, addressing the denial reason and including any new supporting medical documentation. If requesting a reconsideration, new information is typically required.
- Submit appeal within the timeframe indicated in the denial letter. Timeframes can vary based on the payer; generally: 180 days for Commercial, 60 days for Medicare Advantage, and 30-45 days for Medicaid. Appeal determinations can take up to 30+ days.
- ***There is only one first level appeal available.*** This can either be submitted by a patient or provider. Patients may contact their employer for assistance.

## Step 8: Subsequent Appeals

- ***The appeal denial letter will provide information on additional appeal rights.***
- Generally, Commercial plans offer a second appeal (within 60 days) followed by an external review (within 120 days). 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, the first appeal 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.[3] If the second appeal is denied, you may request review by the Office of Medicare Hearing and Appeals.[3] This will involve a hearing before an Administrative Law Judge. For additional appeal rights, please contact the payer or the Centers for Medicare & Medicaid Services (CMS).[3]

To facilitate patient access, our Symplicity patient access support team can assist with education on and submission of prior authorizations and appeals for the Symplicity procedure. If you are a healthcare provider and would like additional information or assistance, please contact your regional economic manager (REM) or the patient access support team at rs.symplicitypatientaccesssupport@medtronic.com.

**References**

[1]Centers for Medicare & Medicaid Services. Who are the MACs | CMS. www.cms.gov. Accessed August 30, 2023. https://www.cms.gov/medicare/medicare-contracting/medicare-administrative-contractors/who-are-the-macs#MapsandLists
[2]Medicare IOM Pub. No. 100-16, Ch. 4, §90.5 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs- Items/CMS019326)
[3]Medicare. Medicare.gov: the official U.S. government site for Medicare | Medicare. Medicare.gov. Published 2023. https://www.medicare.gov/

**Symplicity Spyral™ renal denervation system**
**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 707-525-0111or Medtronic's website at medtronic.com