# Medtronic

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# Symplicity<sup>™</sup> blood pressure procedure Sample patient appeal letter

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# **Brief statement**

#### **Important Safety Information**

The Symplicity™ blood pressure procedure (BPP) is a minimally invasive procedure approved to help lower high blood pressure. The procedure is approved as a complement to treatments you may already be trying, such as lifestyle modifications and high blood pressure medications that might not be adequately controlling your blood pressure.

Receiving the Symplicity BPP should be a based on a joint decision between you and your doctor. Consider the benefits and risks of the device and procedure. Please talk to your doctor to decide whether or not the Symplicity BPP is right for you.

If you have a pacemaker or an ICD your doctor will follow-up with steps to take ahead of the procedure if you decide it is right for you.

At the time of your procedure, your doctor may detect certain anatomical conditions (e.g., your blood vessels are too big or too small) that do not allow the blood pressure procedure to continue.

You should not receive the procedure if you cannot tolerate medications that are required for the procedure, like atropine, nitroglycerin, systemic blood thinners, or certain pain medications. These medications are to help you in case your heart rate drops too low, you experience pain, or your blood vessels tighten during the procedure. You should not receive the procedure if you are pregnant.

The Symplicity BPP has not been studied in patients:

- Who are breastfeeding
- Who are under 18 years old
- Who have isolated systolic hypertension (only the "top number" of your blood pressure is high)
- Who have secondary causes of high blood pressure
- Who have had a renal stent placed less than 3 months prior to the procedure
- Who had a prior minimally invasive treatment in their renal arteries (stenting, angioplasty or prior renal denervation)

Potential Risks of the Symplicity BPP: (Note that you may experience other problems that have not been previously observed with this procedure)

- Allergic reaction to the imaging solution
- Damage to your arteries
- Future narrowing of your arteries,
- Arterio-enteric fistula (an abnormal connection between your aorta and your gastrointestinal tract)
- AV fistula (an irregular connection between an artery and a vein)
- Bleeding or blood clots
- Bruising where the device enters your body (mild or severe)
- Cardiac arrest or Heart attack
- Death
- Deep vein thrombosis
- Swelling
- Slow heart rate
- Infection

- Low or high blood pressure
- Damage to your kidneys that may cause one or both to stop working
- Nausea or vomiting
- Peripheral ischemia (lack of blood supply to your limbs),
- Pulmonary embolism (a sudden block in your arteries that send blood to your lungs)
- Pseudoaneurysm (blood collecting on the outside of a vessel wall causing a balloon-like widening),
- Pain or discomfort
- Skin burns from the failure of the equipment during the procedure
- Exposure to radiation
- Stroke

For further information, please call and/or consult Medtronic at 800-633-8766 or the Medtronic website at medtronic.com.

## Overview

An appeal is a request asking your insurance company to reconsider a denial. It can be submitted by you or your healthcare provider. If your provider submits an appeal, you can support it with a personal appeal letter. This sample appeal letter is to assist patients in appealing a denial for the Symplicity blood pressure procedure. It is for your customization and may not include all the information necessary to support your request. Patients are responsible for ensuring accuracy and adequacy of all information provided. Use of this template does not guarantee approval or coverage.

### Instructions

- Please do not include this instruction page.
- Please customize the sections in red text using information pertinent to you and your condition. The remaining letter content can also be edited.
- Please refer to the denial letter from your insurance company for the appeal timeline, submission process, and requirements.
- If you have questions about the denial or appeal process, or to check status of an appeal request, you can contact your insurance company at the phone number on the back of your insurance card.



To open the sample patient appeal letter in Microsoft Word

#### Date

**Insurance Company** 

Attn: Appeals Department

Re: Denial for Symplicity™ Blood Pressure Procedure – Denial Reference Number

Dear Insurance Company,

Please accept this letter in support of the appeal for the Symplicity procedure. My doctor, Doctor's Name, has recommended this procedure to reduce my blood pressure. Based on your letter, dated Denial Letter Date, the procedure has been denied because:

[Quote reason for the denial stated in the denial letter]

I respectfully disagree with the denial and believe the procedure should be covered by my plan. I was diagnosed with hypertension in [insert approximate year of diagnosis] and have been under the care of Doctor's Name for [insert approximate # of months/years]. [Describe your symptoms: when did these begin, how often are you experiencing them, has there been any progression since onset. Are your symptoms impacting your daily life?]

[Detail any treatments you have tried (e.g., weight loss, DASH diet, exercise, blood pressure medications, etc.): how long was each method used for and what was the outcome. Are there any treatments that were recommended but discontinued due to unforeseen or unique circumstances (e.g., medication intolerance, adverse side effects)?]

[Explain any relevant history: family history of high blood pressure, related cardiovascular events (e.g., stroke, heart attack, etc.) and subsequent interventions (e.g., hospitalization including length of stay)]

[Describe possible benefits the Symplicity Spyral system might provide as discussed with your doctor: why you need the procedure and what potentially will happen if you do not receive this]

My doctor has determined the Symplicity blood pressure procedure is the best treatment option for my condition. As a member of Insurance Company, I respectfully ask you to reverse the denial following review of the additional information shared here and provided by Doctor's Name. Allowing coverage for this procedure is necessary for me to comply with the established plan of care for management of my chronic condition.

Thank you for your reconsideration.

Sincerely, Signature

Printed Name ID #: Member ID #

Attachments: [List enclosures (e.g., home blood pressure readings, copy of medication list/medical records from doctor's office, copy of denial letter, any clinical studies/articles that support coverage)]