



## MASSACHUSETTS

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### Medical Policy

## Radiofrequency Ablation of the Renal Sympathetic Nerves as a Treatment for Resistant or Uncontrolled Hypertension

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### Policy Number: 919

BCBSA Reference Number: 7.01.136 (For Plan internal use only)

### Related Policies

Baroreflex Stimulation Devices, #[595](#)

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Radiofrequency ablation of the renal sympathetic nerves for the treatment of resistant or uncontrolled hypertension is considered [INVESTIGATIONAL](#).

### Prior Authorization Information

#### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

#### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is <b>not</b> a covered service.
Commercial PPO and Indemnity	This is <b>not</b> a covered service.
Medicare HMO Blue <sup>SM</sup>	This is <b>not</b> a covered service.
Medicare PPO Blue <sup>SM</sup>	This is <b>not</b> a covered service.

### CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

## **CPT Codes**

There is no specific CPT code for this service.

## **Diagnosis Codes**

Investigational for the diagnoses described in the medical policy statement.

## **Description**

### **Resistant Hypertension**

Hypertension is estimated to affect approximately 30% of the population in the U.S.<sup>1</sup> It accounts for a high burden of morbidity related to strokes, ischemic heart disease, kidney disease, and peripheral arterial disease. Resistant hypertension is defined as elevated blood pressure, despite treatment with at least 3 antihypertensive agents at optimal doses. Resistant hypertension is also a relatively common condition, given a large number of individuals with hypertension. In large clinical trials of hypertension treatment, 20% to 30% of participants meet the definition for resistant hypertension, and in tertiary care hypertension clinics, the prevalence is estimated at 11% to 18%.<sup>1</sup> Resistant hypertension is associated with a higher risk for adverse outcomes such as stroke, myocardial infarction, heart failure, and kidney failure.

A number of factors may contribute to uncontrolled hypertension, and they should be considered and addressed in all patients with hypertension before labeling a patient resistant. They include nonadherence to medications, excessive salt intake, inadequate doses of medications, excess alcohol intake, volume overload, drug-induced hypertension, and other forms of secondary hypertension.<sup>2</sup> Also, sometimes it is necessary to address comorbid conditions (ie, obstructive sleep apnea) to control blood pressure adequately.

### **Treatment**

Treatment for resistant hypertension is mainly intensified drug therapy, sometimes with the use of nontraditional antihypertensive medications such as spironolactone and/or minoxidil. However, control of resistant hypertension with additional medications is often challenging and can lead to high costs and frequent adverse events of treatment. As a result, there is a large unmet need for additional treatments that can control resistant hypertension. Nonpharmacologic interventions for resistant hypertension include modulation of the baroreflex receptor and/or radiofrequency (RF) denervation of the renal nerves.

### **Radiofrequency Denervation of the Renal Sympathetic Nerves**

Increased sympathetic nervous system activity has been linked to essential hypertension. Surgical sympathectomy has been shown to be effective in reducing blood pressure but is limited by the adverse events of surgery and was largely abandoned after effective medications for hypertension became available. The renal sympathetic nerves arise from the thoracic nerve roots and innervate the renal artery, the renal pelvis, and the renal parenchyma. Radiofrequency ablation (RFA) is thought to decrease both the afferent sympathetic signals from the kidney to the brain and the efferent signals from the brain to the kidney. This procedure decreases sympathetic activation, decreases vasoconstriction, and decreases activation of the renin-angiotensin system.<sup>3</sup>

The procedure is performed percutaneously with access at the femoral artery. A flexible catheter is threaded into the renal artery, and a controlled energy source, most commonly low-power RF energy, is delivered to the arterial walls where the renal sympathetic nerves are located. Once adequate RF energy has been delivered to ablate the sympathetic nerves, the catheter is removed.

## **Summary**

Radiofrequency ablation (RFA) of the renal sympathetic nerves is thought to decrease both the afferent sympathetic signals from the kidney to the brain and the efferent signals from the brain to the kidney. This procedure decreases sympathetic activation, decreases vasoconstriction, and decreases activation of the renin-angiotensin system. RFA of the renal sympathetic nerves may act as a nonpharmacologic treatment for hypertension and has been proposed as a treatment option for patients with resistant or uncontrolled hypertension.

For individuals who have hypertension resistant to standard medical management or uncontrolled hypertension who receive RFA of the renal sympathetic nerves, the evidence includes numerous RCTs, numerous systematic reviews of the RCTs, as well as multiple nonrandomized comparative studies and case series. Relevant outcomes are symptoms, change in disease status, morbid events, medication use, and treatment-related morbidity. The Symplicity HTN-3 trial, used a sham-controlled design to reduce the likelihood of placebo effect and demonstrated no significant differences between single-electrode renal denervation and sham control patients in office-based or ambulatory blood pressure at 6-month follow-up. The Symplicity HTN-3 results were in contrast to other studies not using a sham control design but were supported by a number of early smaller sham-controlled trials. Meta-analyses of the RCTs have also reported inconsistent findings, with most analyses showing no significant benefit in blood pressure measurements following single-electrode RFA. Recent evidence focuses on the use of next generation multielectrode RFA catheters. The proof of principle SPYRAL HTN-OFF MED study found that multielectrode renal denervation was superior to sham in the absence of background antihypertensive medication therapy, with between-group differences of -4.0 mmHg for 24-h systolic blood pressure (SBP) and -6.6 for office SBP at 3 months. The unpowered SPYRAL HTN-ON MED study also found significant between-group differences of -7.4 mmHg for 24-h SBP and -6.8 mmHg for office SBP at 6 months; however, results were only significant for the subgroup of patients non-adherent to medications. Long-term data from the SPYRAL HTN-ON MED study suggest that blood pressure reductions with multielectrode renal denervation are progressive and sustained over time. However, study interpretation is complicated by short-term blinded follow-up and imputation of excluded crossover patient data. It is unclear which patients are most likely to derive benefit, and currently, there is no practical method to verify nerve destruction following ablation. The powered SPYRAL HTN-ON MED Expansion study is ongoing. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## Policy History

Date	Action
12/2022	Annual policy review. Minor editorial refinement to policy statement to include patients with uncontrolled hypertension; intent unchanged. Title updated to: "Radiofrequency Ablation of the Renal Sympathetic Nerves as a Treatment for Resistant or Uncontrolled Hypertension." Description, summary, and references updated.
10/2021	Annual policy review. Policy statements unchanged.
2/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
11/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2016	Annual policy review. New references added.
11/2015	Annual policy review. New references added.
12/2013	Annual policy review. New references added.
3/2013	New policy describing non-coverage. Effective 3/1/2013.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)  
[Managed Care Guidelines](#)  
[Indemnity/PPO Guidelines](#)  
[Clinical Exception Process](#)  
[Medical Technology Assessment Guidelines](#)

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