



# Louisiana

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

**Policy #** 00465

**Original Effective Date:** 08/19/2015

**Current Effective Date:** 05/11/2020

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Baroreflex Stimulation Devices is addressed separately in medical policy 00315.*

### **Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers radiofrequency ablation (RFA) of the renal sympathetic nerves for the treatment of resistant hypertension to be **investigational**.\*

### **Background/Overview**

#### **Resistant Hypertension**

Hypertension is estimated to affect approximately 30% of the population in the U.S. 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 three 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%. 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.

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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.

### **RF 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.

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.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

No RFA devices have been approved by the U.S. Food and Drug Administration (FDA) for ablation of the renal sympathetic nerves as a treatment for hypertension. Several devices have been developed

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for this purpose and are in various stages of application for the FDA approval (FDA product code: DQY):

- Symplicity™‡ Renal Denervation System (Medtronic). In April 2018, the FDA approved an investigational device exemption pivotal trial, SPYRAL HTN. The trial will be randomized and sham-controlled.
- The EnligHTN™‡ Multi-Electrode Renal Denervation System (St. Jude Medical) is an RFA catheter using a 4-point multiablation basket design. In January 2014, the EnligHTN™‡ Renal Guiding Catheter was cleared for marketing by the FDA through the 510(k) process, based on substantial equivalence to predicate devices for the following indication: percutaneous use through an introducer sheath to facilitate a pathway to introduce interventional and diagnostic devices into the renal arterial vasculature.
- The OneShot™‡ Renal Denervation System (Covidien) is an irrigated RFA balloon catheter, consisting of a spiral-shaped electrode surrounding a balloon. (In 2014, Covidien abandoned development of its OneShot Renal Denervation program.)
- The Vessix™‡ Renal Denervation System (Boston Scientific; formerly the V2 renal denervation system, Vessix Vascular) is a combination of an RF balloon catheter and bipolar RF generator technologies, intended to permit a lower voltage intervention.

Other RFA catheters (eg, Thermocouple Catheter™‡ [Biosense Webster]) used for other types of ablation procedures (eg, cardiac electrophysiology procedures) have been used off-label for RFA of the renal arteries.

### **Rationale/Source**

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 hypertension.

For individuals who have hypertension resistant to standard medical management who receive RFA of the renal sympathetic nerves, the evidence includes at least ten randomized controlled trials,

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numerous systematic reviews of the randomized controlled trials, as well as multiple nonrandomized comparative studies and case series. The relevant outcomes are symptoms, change in disease status, morbid events, medication use, and treatment-related morbidity. The largest trial, the Symplicity HTN-3 trial, used a sham-controlled design to reduce the likelihood of placebo effect and demonstrated no significant differences between renal denervation and sham control patients in office-based or ambulatory blood pressure at six-month follow-up. Results from Symplicity HTN-3 have been supported by a subsequent sham-controlled trial. The Symplicity HTN-3 results were in contrast to other studies, including Symplicity HTN-2 and the Renal Denervation for Hypertension (DENERHTN) trial, which reported efficacy in reducing blood pressure over a six-month period compared with a control group. Additional smaller randomized controlled trials, some of which were stopped early after results of the Symplicity HTN-3 trial became available, did not demonstrate significantly improved outcomes with renal denervation. Single-arm studies with overlapping populations have reported improvements in blood pressure and related physiologic parameters, such as echocardiographic measures of left ventricular hypertrophy, that appear to be durable up to 24 months of follow-up. The strongest evidence comes from sham-controlled trials, the largest of which found no significant benefits with renal denervation. Meta-analyses of the systematic reviews have also reported inconsistent findings, with most analyses showing no significant benefit in blood pressure measurements following RFA. The evidence is insufficient to determine the effects of the technology on health outcomes.

## **Supplemental Information**

### **Practice Guidelines and Position Statements**

#### **American Heart Association et al**

The American Heart Association, American College of Cardiology, and American Society of Hypertension (2015) issued joint guidelines on the treatment of hypertension in patients with coronary artery disease. The guidelines noted the Symplicity HTN-3 trial did not find a significant benefit from renal denervation and stated that additional randomized controlled trials would be needed.

The American Heart Association, American College of Cardiology, and 9 additional specialty societies (2018) published joint guidelines on the prevention, detection, evaluation, and management

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of high blood pressure in adults. In discussing resistant hypertension, the guidelines indicated that studies using catheter ablation of renal sympathetic nerves "have not provided sufficient evidence to recommend the use of these devices."

### **Eighth Joint National Committee**

The Eighth Joint National Committee (2014), which was appointed to provide recommendations on hypertension treatment, published an evidence-based guideline on the management of hypertension in adults. These recommendations did not discuss the use of renal denervation.

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

### **Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### **Ongoing and Unpublished Clinical Trials**

Some currently ongoing and unpublished trials that might influence this review are listed in Table 4.

**Table 4. Summary of Key Trials**

<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date</b>
<i>Ongoing</i>			
NCT02439775	Global Clinical Study of Renal Denervation With the Symplicity Spyral™ Multi-electrode Renal Denervation System in Patients With Uncontrolled Hypertension on Standard Medical Therapy (SPYRAL HTN-ON MED)	106	Feb 2024
NCT01673516	Effect of Renal Sympathetic Denervation on Resistant Hypertension and Cardiovascular	60	Aug 2022

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NCT No.	Trial Name	Planned Enrollment	Completion Date
	Hemodynamic in Comparison to Intensive Medical Therapy Utilizing Impedance Cardiography		
NCT02439749	Global Clinical Study of Renal Denervation With the Symplicity Spyral™ Multi-electrode Renal Denervation System in Patients With Uncontrolled Hypertension in the Absence of Antihypertensive Medications (SPYRAL HTN-OFF MED)	433	Dec 2022
NCT02021019	Renal Denervation to Improve Outcomes in Patients With End-stage Renal	100	Dec 2022 (unknown)
<i>Unpublished</i>			
NCT02029885a	Wave IV Study: Phase II Randomized Sham Controlled Study of Renal Denervation for Subjects With Uncontrolled Hypertension	132	Mar 2018 (unknown)
NCT01911078	Renal Sympathetic Denervation in Metabolic Syndrome (Metabolic Syndrome Study)	20	Jun 2016 (completed)
NCT01901549	Renal Denervation in Patients After Acute Coronary Syndrome	80	Jun 2016 (unknown)
NCT02041130	Renal Sympathectomy in Heart Failure (the RESPECT-HF Study) - a Study of Renal Denervation for Heart Failure With Preserved Ejection Fraction	144	Dec 2016 (unknown)
NCT01522430	Denervation of Renal Sympathetic Activity and Hypertension Study	120	Dec 2016 (unknown)
NCT01932450	A Randomized, Open-label Study Investigating the Effect of Bilateral Renal Artery Sympathetic Denervation by Catheter-based Radiofrequency Ablation on Blood Pressure and Disease Progression in Autosomal Dominant Polycystic Kidney Disease	100	Jul 2015 (unknown)

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NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01628172 <sup>a</sup>	Renal Sympathetic Denervation for the Management of Chronic Hypertension	96	Mar 2014 (completed)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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- |            |   |
|------------|---|
| 08/06/2015 | Medical Policy Committee review   |
| 08/19/2015 | Medical Policy Implementation Committee approval. New Policy                      |
| 08/04/2016 | Medical Policy Committee review   |
| 08/17/2016 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes                                     |
| 11/02/2017 | Medical Policy Committee review   |

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11/15/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

11/08/2018 Medical Policy Committee review

11/21/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

11/07/2019 Medical Policy Committee review

11/13/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

04/02/2020 Medical Policy Committee review

04/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2021

### **Coding**

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# Louisiana

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

Policy # 00465

Original Effective Date: 08/19/2015

Current Effective Date: 05/11/2020

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0338T, 0339T
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.

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**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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