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

Policy # 00465
Original Effective Date: 08/19/2015
Current Effective Date: 05/08/2023

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 or uncontrolled 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 stroke, ischemic heart disease, kidney disease, and peripheral arterial disease. Resistant hypertension is defined as an elevated blood pressure, despite treatment with at least 3 antihypertensive agents at optimal doses. Resistant hypertension is also a relatively common condition, given the 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 these should be considered and addressed in all patients with hypertension before labeling a patient resistant. These factors 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. 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.

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

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

- The Symplicity™‡ Renal Denervation System (Medtronic) is a single-electrode RFA catheter system. The next generation Symplicity Spyral™‡ Renal Denervation System (Medtronic) is a multielectrode RFA catheter system designed to deliver 4-quadrant ablations.
- 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 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.

In 2020, the FDA granted breakthrough therapy designation to 2 renal artery denervation systems - SoniVie's Therapeutic Intra-Vascular Ultrasound (TIVUS) System and Recor's Paradise Renal Denervation System - for the treatment of patients with persistently elevated blood pressure. However, ultrasound-based renal denervation systems are outside of the scope of this medical policy.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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. Radiofrequency ablation 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.

Summary of Evidence

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.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association et al

The American Heart Association (AHA), American College of Cardiology (AHA), and American Society of Hypertension (ASH; 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 AHA, ACC, and 9 additional specialty societies (2018) published joint guidelines on the prevention, detection, evaluation, and management 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."

The AHA (2018) published a Scientific Statement on the detection, evaluation, and management of resistant hypertension. The AHA Statement discussed the lack of benefit found in the Symplicity HTN-3 trial, as well as its methodological limitations. The statement also referred to the more recent positive data from the SPYRAL HTN-OFF MED trial, but noted that because the enrolled patients did not have resistant hypertension, "at best, this represents a proof-of-principle study demonstrating the role of the renal sympathetic nervous system in hypertension." The statement concluded that "the role of device-based sympatholytic treatments, as with renal denervation and baroreceptor stimulation, awaits clarification."

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.

National Institute for Health and Care Excellence
In 2012, the National Institute for Health and Care Excellence (NICE) published an interventional procedures guidance on the use of percutaneous transluminal radiofrequency sympathetic denervation of the renal artery for resistant hypertension, recommending that the procedure should only be used with special arrangements for clinical governance, consent, and audit or research due to limited evidence. This guidance is currently being updated with expected publication in March 2023.

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 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04722159	Clinical Outcome of Patients With Resistant Hypertension Undergoing Renal	300	Aug 2021 (recruiting)

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Denervation: A Report From the Swedish Registry for Renal Denervation		
NCT04311086[a]	Global Clinical Study of Renal Denervation in the Distal Main and First Order Branch Renal Arteries Using the Symplicity Spyral™‡ Multi-electrode Renal Denervation System (SPYRAL DYSTAL)	56	Jan 2023 (ongoing)
NCT02439749[a]	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)	366	Dec 2023 (ongoing)
NCT04307836[a]	A Prospective, Multicenter, No-treatment Controlled, Randomized, Open-label, Pivotal Study to Evaluate the Safety and Efficacy of DENEX, Renal Denervation Therapy, in Patients with Hypertension on no or 1-3 Antihypertensive Medications	140	Jan 2024(recruiting)
NCT04535050[a]	A Prospective, Multicenter, Sham-controlled, Single-blinded, Randomized, Pilot Study to Evaluate the Safety and Effectiveness of DENEX Renal Denervation System in Patients With Uncontrolled Hypertension Not Treated With Antihypertensive Medication	100	Mar 2026 (not yet recruiting)
NCT02439775[a]	Global Clinical Study of Renal Denervation With the Symplicity Spyral™‡ Multi-electrode	337	Jul 2026 (ongoing)

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Renal Denervation System in Patients With Uncontrolled Hypertension on Standard Medical Therapy (SPYRAL HTN-ON MED)		
NCT05198674[a]	The SPYRAL AFFIRM Global Clinical Study of Renal Denervation With the Symplicity Spyral Renal Denervation System in Subjects With Uncontrolled Hypertension (SPYRAL AFFIRM)	1200	Jun 2027 (recruiting)
NCT05563337	Renal Denervation in Hypertensive Women Planning to Become Pregnant (WHY-RDN)	80	Aug 2027 (not yet recruiting)
NCT01534299[a]	Global SYMPLICITY Registry (GSR) Denervation Findings in Real World (DEFINE)	5000	Oct 2027 (recruiting)

NCT: national clinical trial.
[a] 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
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.
04/01/2021	Medical Policy Committee review
04/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/07/2022	Medical Policy Committee review
04/13/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/06/2023	Medical Policy Committee review
04/12/2023	Medical Policy Implementation Committee approval. Title changed from “Radiofrequency Ablation of the Renal Sympathetic Nerves as a Treatment for Resistant Hypertension” to “Radiofrequency Ablation of the Renal Sympathetic Nerves as a Treatment for Resistant or Uncontrolled Hypertension." Revised investigational statement to include patients with uncontrolled hypertension. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2024

Coding

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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 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.