LOUISIANA BLUE

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

Policy # 00465
Original Effective Date: 08/19/2015
Current Effective Date: 05/01/2025

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 uncontrolled hypertension to be **investigational.***

Background/Overview

Uncontrolled Hypertension

Recommendations for blood pressure generally target <130/80 mmHg, although blood pressure goal can vary (e.g., comorbidities, life-expectancy). High blood pressure, or hypertension (HTN) 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. An estimated 1 in 4 adults with hypertension have their hypertension under control, but the remaining 77% (93 million) remain uncontrolled. Uncontrolled hypertension is diagnosed when an individual's blood pressure remains above targeted levels (typically ≥140/90 mmHg) when a patient either is not using, or unable to use, treatments to control blood pressure or when hypertension persists despite antihypertensive therapies. The definition of uncontrolled hypertension is inclusive of resistant hypertension in which blood pressure remains above the targeted range despite the use of 3 or more antihyperensive medications, including a diuretic, with complementary mechanisms of action. A number of factors may contribute to uncontrolled hypertension including 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

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) 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.

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)

One radiofrequency (RF) energy renal denervation device has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of hypertension (FDA product code: QYI):

The Symplicity Spyral™‡ Renal Denervation System (Medtronic, Inc) was approved by the FDA on November 17, 2023. It is indicated to reduce blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure.

No other RF renal denervation devices are currently FDA approved for the treatment of hypertension. Several other devices that were previously in development, such as the EnligHTN™‡ system (St. Jude Medical) and Vessix™‡ system (Boston Scientific), are no longer being marketed for this indication.

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 regulations, other plan medical policies, and accredited national guidelines.

Description

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 uncontrolled hypertension despite the use of anti-hypertensive medications.

Summary of Evidence
For individuals who have uncontrolled hypertension, despite the use of anti-hypertensive medications, who receive radiofrequency ablation (RFA) of the renal sympathetic nerves, the evidence includes several randomized controlled trials (RCTs), numerous systematic reviews of the RCTs, and a multinational registry study. Relevant outcomes are symptoms, change in disease status, morbid events, medication use, and treatment-related morbidity. 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 SBP and -6.6 for office SBP at 3 months. The unpowered SPYRAL HTN-ON MED pilot 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. The SPYRAL HTN-ON MED Expansion study failed to meet its primary efficacy endpoint and found only 0.03 mmHg difference between renal denervation and sham control groups at 6 months follow-up. A significant reduction in office blood pressure was noted at 6 months (-4.1 mmHg). Confounding of these outcome estimates by unbalanced medication changes, missing 24-h SBP outcome data, and timing of antihypertensive medications related to 24-h SBP assessment may explain the discordant results between the pilot and expansion phases of this trial. Study interpretation is also 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. Evidence from systematic reviews and meta-analyses are conflicting, but all available studies included evidence from both first and second-generation Symplicity catheters as well as multiple renal denervation methodologies such as ultrasound. 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 AHA (2024) published a Scientific Statement on renal denervation for the treatment of hypertension. The AHA concluded:

- Although further research is needed, particularly in the realms of patient selection and long-term efficacy, renal denervation is a promising new therapeutic approach for some patients with uncontrolled hypertension, particularly patients with resistant hypertension or who have multiple medication intolerances.
- As with any procedure, safety remains a concern. That said, both short-term and ongoing medium- to longer-term studies have demonstrated reassuring safety profiles.
- A multidisciplinary team approach that includes hypertension specialists and proceduralists is important both for identifying the right candidates for renal denervation and for following them after the procedure.
- Much if not all of our current literature and experience with renal denervation in the United States have been in the context of clinical trials. Therefore, little is currently known about the cost of renal denervation as it compares with conventional treatment options, many of which are now generic and lower-cost pharmacological options.

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.

European Society for Hypertension (ESH)
The European Society of Cardiology (ESC) published guidelines on the management of elevated blood pressure and hypertension in 2024. The following recommendations were issued concerning renal denervation:

- To reduce BP, and if performed at a medium-to-high volume center, catheter-based renal denervation may be considered for resistant hypertension patients who have BP that is uncontrolled despite a three BP-lowering drug combination (including a thiazide or thiazide-like diuretic), and who express a preference to undergo renal denervation after a shared risk-benefit discussion and multidisciplinary assessment. (Class: IIb, Level: B)
- To reduce BP, and if performed at a medium-to-high volume center, catheter-based renal denervation may be considered for patients with both increased CVD risk and uncontrolled hypertension on more than three drugs, if they express a preference to undergo renal denervation after a shared risk-benefit discussion and multidisciplinary assessment. (Class: IIb, Level: A)
- Due to a lack of adequately powered outcomes trials demonstrating its safety and CVD benefits, renal denervation is not recommended as a first-line BP-lowering intervention for hypertension. (Class: III, Level: C)

- Renal denervation is not recommended for treating hypertension in patients with moderate-to-severely impaired renal function (eGFR < 40 mL/min/1.73 m²) or secondary causes of hypertension, until further evidence becomes available. (Class: III, Level: C)

European Society of Hypertension (ESH) and European Association of Percutaneous Cardiovascular Interventions (EAPCI)

In 2023, the ESH, with the EAPCI, issued a clinical consensus statement on the use of renal denervation in the management of adults with hypertension. The following recommendations were issued concerning renal denervation:

- Renal denervation may be used in adult patients with uncontrolled resistant hypertension (office BP ≥140/≥90 mmHg confirmed by 24-hour ambulatory systolic BP ≥130 mmHg or daytime systolic BP ≥135 mmHg) treated with ≥3 antihypertensive drugs and an eGFR ≥40 ml/min/1.73 m^2.
- Renal denervation may be a possible treatment option for patients unable to tolerate antihypertensive drugs in the long term or patients who express a preference to undergo renal denervation in a tailored, shared decision-making process.
- The patient's global CV risk should be evaluated, accounting for hypertension-mediated organ damage and CV complications. High CV risk favors the use of renal denervation.
- The decision-making process should incorporate the preference of a well-informed and educated patient. To optimize the shared decision-making, patients must be fully informed about the benefits/limitations and risks associated with renal denervation.
- Multidisciplinary hypertension teams involving experts on hypertension and percutaneous CV interventions should evaluate the indication and perform renal denervation.
- Standard operating procedures are suggested for each device to achieve the most effective renal nerve ablation in optimal periprocedural patient security conditions.
- At present, there is no validated, easily applicable periprocedural clinical indicator of successful renal nerve ablation.

National Institute for Health and Care Excellence

In 2023, 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.

Society for Cardiovascular Angiography & Interventions

In 2023, the Society for Cardiovascular Angiography & Interventions (SCAI) published a position statement on patient selection, operator competence, training and techniques, and organizational

recommendations for the use of renal denervation for the treatment of hypertension. The following selection criteria were issued concerning renal denervation:

- Patients with resistant hypertension, defined by blood pressure >130/80 mmHg despite being on 3 medications with maximally tolerated doses from classes with outcomes data (angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers, calcium channel blockers, thiazide diuretics, and beta blockers)
- Patients with uncontrolled hypertension despite attempting lifestyle modification and antihypertensive medication but who are either intolerant of additional medication or do not wish to be on additional medications and who are willing to undergo renal denervation after shared decision-making
- Priority may be appropriately given to patients with higher cardiovascular risk (eg, comorbidities of coronary artery disease, diabetes, prior transient ischemic attack/cerebrovascular accident, or chronic kidney disease) who may have the greatest benefit from blood pressure reduction

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			
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	140	Jan 2024 (recruiting)

NCT No.	Trial Name	Planned Enrollment	Completion Date
	to Evaluate the Safety and Efficacy of DENEX, Renal Denervation Therapy, in Patients with Hypertension on no or 1-3 Antihypertensive Medications		
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 Renal Denervation System in Patients With Uncontrolled Hypertension on Standard Medical Therapy (SPYRAL HTN-ON MED)	337	Jul 2026 (ongoing)
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)
NCT05460169[a]	Renal Denervation in ADPKD- RDN-ADPKD Study (RDN-ADPKD)	44	May 2027 (recruiting)
Unpublished			
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 (completed)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04722159	Clinical Outcome of Patients With Resistant Hypertension Undergoing Renal Denervation: A Report From the Swedish Registry for Renal Denervation	300	Aug 2021 (unknown)
NCT05438446[a]	Effect of Renal Denervation on Stress, Hypertension and Anxiety Management (ERSHAM)	60	Dec 2023 (unknown)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

Original Effective Date: 08/19/2015
Current Effective Date: 05/01/2025

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

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

Policy # 00465
Original Effective Date: 08/19/2015
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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.
04/04/2024	Medical Policy Committee review
04/10/2024	Medical Policy Implementation Committee approval. Title changed from "Radiofrequency Ablation of the Renal Sympathetic Nerves as a Treatment for Resistant or Uncontrolled Hypertension" to "Radiofrequency Ablation of the Renal Sympathetic Nerves as a Treatment for Uncontrolled Hypertension". Removed resistant hypertension from the investigational statement.
12/11/2024	Coding update
04/03/2025	Medical Policy Committee review
04/09/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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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	C1735
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.

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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NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.