

Renal Denervation for Uncontrolled Hypertension

Policy # 00465

Original Effective Date: 08/19/2015

Current Effective Date: 09/01/2026

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.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

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) and ultrasound ablation 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 $\geq 140/90$ 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 antihypertensive 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.

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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 radiofrequency (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.

Ultrasound Denervation of the Renal Sympathetic Nerves

Ultrasound renal denervation (usRDN) is a minimally invasive procedure designed to treat hypertension by disrupting renal sympathetic nerves. The procedure targets the same physiological mechanism as radiofrequency ablation, aiming to decrease both afferent and efferent sympathetic signaling between the kidneys and the brain. This reduction in sympathetic activation is thought to decrease vasoconstriction and inhibit the renin-angiotensin system, ultimately leading to blood pressure reduction. The usRDN procedure is typically performed under local anesthesia with conscious sedation. Access is obtained through the femoral artery, and the catheter is advanced to the renal artery under fluoroscopic guidance. Once positioned, the catheter's balloon is inflated with cooling fluid, and ultrasound energy is delivered. Usually, 2 to 3 ultrasound emissions are delivered per renal artery, with the ability to treat both main renal arteries and accessory renal arteries when present.

Contraindications to denervation include: pregnancy, fibromuscular dysplasia, stented renal artery, renal artery aneurysm, significant renal artery stenosis, known kidney or secreting adrenal tumors, and unaddressed causes of secondary HTN. There is very limited data to support use for stage 1 HTN, isolated systolic HTN, stage 4 or 5 chronic kidney disease, single kidney, kidney transplant recipients, or redo renal denervation in individuals who fail to respond to initial renal denervation.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Two renal denervation devices have been approved by the U.S. Food and Drug Administration (FDA) for the treatment of hypertension (FDA product code: QYI):

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The Paradise[®]† Ultrasound Renal Denervation System (ReCor Medical, Inc) was approved by the FDA on November 7, 2023 and the Symplicity Spyral[™]‡ Renal Denervation System (Medtronic, Inc) was approved by the FDA on November 17, 2023. Both systems are 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 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 individuals with uncontrolled hypertension despite the use of anti-hypertensive medications.

Summary of Evidence

In the data submitted to the FDA, the decrease in systolic blood pressure after 2 months was < 5 mm Hg compared with sham, after 6 months it was 3 mm Hg. Long-term durability remains uncertain because in the pivotal trials, physicians were at liberty to change medications. Up to one-third of patients do not respond to ablation procedures and efforts to identify reasons have not been successful. No biomarker can adequately predict response. Optimal patients need to be defined. A key to a successful response is the adequacy of denervation, which currently cannot be assessed in real time. Combined systolic/diastolic hypertension appears more responsive than isolated systolic hypertension. It remains uncertain whether patients with comorbidities associated with higher adrenergic tone should be targeted, e.g., obesity, diabetes, sleep apnea, and chronic kidney disease. Concern remains that ablated renal nerves may regenerate. Closer scrutiny of the computed tomography angiography/magnetic resonance angiography data set in the FDA executive summary revealed 3 patients with a 31-50% occlusion and 2 patients with a 51% to 70% occlusion of renal arteries, corresponding to 2.7% and 1.8% of the patient population, respectively. These figures are of concern for a procedure poised to be used in a prevalent condition such as treatment-resistant hypertension (reported prevalence with rates from 3% to 30% of hypertensive patients). Although

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modest reductions in surrogate endpoints (ambulatory and office blood pressure) have been demonstrated, evidence remains insufficient to establish that renal denervation improves patient-centered health outcomes including cardiovascular events, kidney outcomes, mortality, or quality of life.

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 systolic blood pressure (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. Twenty-four month results demonstrated significant decreases in 24-hour ABPM and office SBP in the renal denervation group compared to sham controls, with no additional safety signals. A pooled patient-level analysis of 4 RCTs with 3-year follow-up demonstrated a sustained and statistically significant reduction in both office SBP (-4.7 mmHg) and 24-h SBP (-3.6 mmHg) in the renal denervation group compared to sham, with a low incidence of adverse events. 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.

For individuals who have uncontrolled hypertension, despite the use of anti-hypertensive medications, who receive ultrasound renal denervation (usRDN), the evidence includes 4 randomized sham-controlled trials, 1 RCT comparing usRDN to radiofrequency-based renal denervation, and a pooled analysis of 3 sham-controlled RCTs. Relevant outcomes are changes in blood pressure, medication use, and treatment-related morbidity. Two trials, RADIANCE-HTN SOLO and RADIANCE II evaluated usRDN in patients with no antihypertensive medication usage for 2 months post-intervention. The RADIANCE-HTN SOLO trial demonstrated that usRDN was superior to sham, with a between-group difference of -6.3 mmHg for daytime ambulatory at 2

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months. The RADIANCE II trial showed similar results, also showing a -6.3 mmHg difference in daytime ambulatory SBP at 2 months. The RADIANCE-HTN TRIO trial, focusing on resistant hypertension in patients with a standardized triple combination antihypertensive treatment, found a -4.5 mmHg difference in daytime ambulatory SBP at 2 months. The durability of this effect was confirmed over 36 months of open-label follow-up, with significant reductions in office SBP from baseline levels in the usRDN group. The REQUIRE trial, conducted in Asian populations, did not show a significant difference between usRDN and sham control, possibly due to study design limitations. Long-term data from these trials show mixed results: while studies suggest that blood pressure reductions with usRDN are sustained over time, the differences between usRDN and sham control groups diminished at 6 or 12 months after medication titration in some trials. However, the U.S. Food and Drug Administration's summary of safety and effectiveness data for the RADIANCE-HTN TRIO and SOLO trials demonstrated superior office systolic blood pressure reductions with usRDN compared to sham control at 24 and 36 months. Notably, these improved outcomes in the usRDN group were achieved despite patients using fewer antihypertensive medications than the sham control group. A meta-analysis of the sham-controlled RADIANCE trials showed that fewer usRDN patients required additional antihypertensive medications and demonstrated significant reductions in ambulatory, home, and office SBP at 6 months. Adverse events were infrequent and similar between usRDN and sham groups across studies. The RADIOSOUND-HTN trial compared 3 renal denervation techniques in patients with resistant hypertension who were on a stable regimen of antihypertensive medications. The trial found that usRDN showed superiority over RFA of main renal arteries in reducing daytime ambulatory SBP at 3 months, while RFA of main arteries plus branches did not significantly differ from the other groups. While these results are promising, there was high variability in patient responses suggesting that further research may be needed to identify who is most likely to benefit from usRDN. Additionally, there is currently no practical method to verify nerve destruction following ablation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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

In August 2025, AHA/ACC/AANP/AAPA/ABC/ACCP/ACPM/AGS/AMA/ASPC/NMA/PCNA/SGIM Guideline for the Prevention, Detection, Evaluation and Management of High Blood Pressure in Adults: A report of the American College of Cardiology/ American Heart Association Joint Committee on Clinical Practice Guidelines gave renal artery denervation a 2b recommendation

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(weak recommendation, may or might be reasonable or considered, usefulness/ effectiveness is unknown/ unclear/ uncertain/ not well established): In carefully selected patients with systolic and diastolic hypertension (office SBP 140-180 mm Hg and DBP $\geq$ 90 mm Hg) and eGFR $\geq$ 40 mL/min/1.73 m² who have resistant hypertension despite optimal treatment, or intolerable side effects to additional antihypertensive drug therapy, renal denervation (RDN) may be reasonable as an adjunct treatment to BP medications and lifestyle modification to reduce BP. Guideline noted that all patients with hypertension who are being considered for RDN should be evaluated by a multidisciplinary team with expertise in resistant hypertension and RDN. For patients with hypertension for whom RDN is contemplated, the benefits of lowering BP and potential procedural risks compared with continuing medical therapy should be discussed as part of a shared decision-making process to ensure patients choose the therapy that meets their expectations.

The Guideline summarized that while some trials showed a small but significant reduction in 24-hour ambulatory SBP by 3 to 5 mm Hg over the sham arm, others failed to reach their primary endpoint. Although broader indications are approved for the RDN devices by the FDA, given the relatively short duration of follow-up in clinical trials with modest BP-lowering effects and the absence of CVD outcome trials, RDN should not be considered as a curative therapy for hypertension or full replacement for antihypertensive drugs. The benefit for isolated systolic HTN or advanced CKD remains uncertain. Only patients with suitable renal anatomy with artery diameters between 3 and 8 mm were included. The magnitude of SBP reduction was shown to be inferior to or similar to the addition of spironolactone as the fourth agent in 2 RCTs (between 10% and 40% of patients in the trials could not tolerate spironolactone). RDN should be reserved for adults with HTN who develop intolerable side effects to optimal antihypertensive regimens and patient selection should be made in the same manner as used in clinical trials to maximize outcomes and minimize potential complications. Secondary hypertension that may be directly treated, white-coat hypertension, and the presence of supine hypertension with orthostatic hypotension were exclusion criteria in most RDN trials; therefore, evaluation should include measurement of 24-hour ambulatory BP and orthostatic vital signs in addition to screening for secondary hypertension. The presence of renal artery disease (stenosis, dissection, renal stenting) is considered a contraindication to the procedure. After RDN, it is estimated that the risk of renal artery stenosis requiring intervention is approximately 0.2% per year, with the highest risk within the first 6 months. Thus, surveillance for renal artery stenosis or dissection using noninvasive imaging studies (e.g., duplex Doppler, computed tomography angiogram, or magnetic resonance angiography) is suggested after RDN. Only 60% to 70% of patients undergoing RDN experienced a meaningful reduction in ambulatory SBP of at least 5 mm Hg in clinical trials. Predictors of BP response to RDN have not been consistently demonstrated among clinical trials.

Recommendations related to renal denervation are summarized in Table 1.

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Table 1. AHA/ACC 2025 Hypertension Guidelines

Recommendation	CORa	LOEb
In carefully selected patients with systolic and diastolic hypertension (office SBP 140-180 mmHg and DBP $\geq$ 90 mmHg) and eGFR $\geq$ 40 mL/min/1.73 m ² who have resistant hypertension despite optimal treatment, or intolerable side effects on additional antihypertensive drug therapy, RDN may be reasonable as an adjunct treatment to BP medications and lifestyle modification to reduce BP.	2b	B-R
All patients with hypertension who are being considered for RDN should be evaluated by a multidisciplinary team with expertise in resistant hypertension and RDN.	1	B-NR
For patients with hypertension for whom is RDN is contemplated, the benefits of lowering BP and potential procedural risks compared with continuing medical therapy should be discussed as part of a shared decision-making process to ensure patients choose the therapy that meets their expectations.	1	C-EO

ACC: American College of Cardiology; AHA: American Heart Association; BP: blood pressure; COR: class of recommendation; DBP: diastolic blood pressure; eGFR: estimated glomerular filtration rate; LOE: level of evidence; SPB: systolic blood pressure; RDN: renal denervation. aCOR: 1=strong (benefit $\gg$ risk); 2a=moderate (benefit $\gg$ risk); 2b=weak (benefit $\geq$ risk)

bLOE: A=high-quality evidence from more than 1 RCT or meta-analyses of high-quality RCTs, or 1 or more RCTs corroborated by high-quality registry studies; B-R=moderate-quality evidence from 1 or more RCTs or meta-analyses of moderate-quality RCTs; B-NR=moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies or meta-analyses of such studies; C-LD=limited data; C-EO=consensus of expert opinion based on clinical experience.

The American Heart Association (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."

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European Society of Cardiology

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 [blood pressure], 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 [cardiovascular disease] 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 [estimated glomerular filtration rate] < 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 $\geq 140/\geq 90$ 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 m².
- 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.

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- At present, there is no validated, easily applicable periprocedural clinical indicator of successful renal nerve ablation."

European Society for Hypertension (ESH)

The ESH, with endorsement by the European Renal Association and the International Society of Hypertension, issued guidance on the management of arterial hypertension in 2023. The following recommendations were issued concerning renal denervation:

- Renal denervation can be considered as a treatment option in patients with an eGFR of > 40 ml/min/1.73m² who have uncontrolled blood pressure despite the use of anti-hypertensive drug combination therapy or if drug treatment elicits serious side effects. (Class of Recommendation: II, Level of Evidence: B)
- Renal denervation can be considered as an additional treatment option in patients with resistant hypertension if eGFR is > 40 ml/min/1.73m². (Class of Recommendation: II, Level of Evidence: B)
- Selection of patients to whom renal denervation is offered should be done in a shared decision-making process after objective and complete patient information is collected. (Class of Recommendation: I, Level of Evidence: C)
- Renal denervation should only be performed in experienced specialized centers to guarantee appropriate selection of eligible patients and completeness of the denervation procedure. (Class of Recommendation: I, Level of Evidence: C)

A class of recommendation I indicates a general consensus that the measure is useful, and a class II recommendation reflects that there is no general consensus and that only doubtful evidence exists. An 'A' level of evidence indicates that randomized controlled trials (RCTs) or meta-analyses with cardiovascular disease outcomes are available for this recommendation, a level 'B' suggests RCTs with surrogate measures, observational studies with cardiovascular disease outcomes or meta-analyses are available, and a C recommendation reflects either expert opinion or only observational or lower quality experimental evidence.

ESH recommendations did not discuss the specific use of radiofrequency renal denervation and included evidence from other modalities, such as ultrasound, in their evidence appraisal.

National Institute for Health and Care Excellence

In 2023, the National Institute for Health and Care Excellence (NICE) published 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. The guidance is scheduled for its next review in 2026.

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:

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- "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 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT04307836a	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	Apr 2024 (unknown)
NCT04535050a	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	Apr 2026 (unknown)

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NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT05198674a	The SPYRAL AFFIRM Global Clinical Study of Renal Denervation With the Symplcity Spyral Renal Denervation System in Subjects With Uncontrolled Hypertension (SPYRAL AFFIRM)	1899	Nov 2029 (active, not recruiting)
NCT05563337	Renal Denervation in Hypertensive Women Planning to Become Pregnant (WHY-RDN)	80	Nov 2028 (recruiting)
NCT01534299a	Global SYMPPLICITY Registry (GSR) Denervation Findings in Real World (DEFINE)	5000	Dec 2031 (recruiting)
NCT05703620a	REducing Sympathetic Activity Through Ultrasound-based Renal deneRvation in Excessive Cardiovascular Risk populaTions. (RESURRECT)	75	May 2026 (recruiting)
NCT02649426a	A Study of the ReCor Medical Paradise System in Clinical Hypertension (RADIANCE-HTN)	282	May 2027 (active, not recruiting)
NCT05460169a	Renal Denervation in ADPKD- RDN-ADPKD Study (RDN-ADPKD)	44	Mar 2028 (active, not recruiting)
NCT05326230a	A Clinical Study of the Paradise™‡ Renal Denervation System in Patients With Hypertension (RADIANCE-HTN DUO)	154	Dec 2032 (active, not recruiting)
NCT03614260a	The RADIANCE II Pivotal Study: A Study of the ReCor Medical Paradise System in Stage II Hypertension (RADIANCE-II)	225	Jul 2027 (active, not recruiting)
NCT06297291a	Global Paradise System US Post Approval Study (US GPS)	1000	Jul 2031 (recruiting)
NCT05017935a	RADIANCE Continued Access Protocol (RADIANCE CAP)	300	Dec 2028 (active, not recruiting)
NCT05027685a	The "Global Paradise System" Registry (GPS Registry)	3000	Dec 2031 (recruiting)
NCT05934383a	Safety and Efficacy of Ultrasound Renal Denervation in Kidney Transplantation Patients With Uncontrolled Hypertension (RESTART)	40	Sep 2030 (not yet)

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NCT No.	Trial Name	Planned Enrollment	Completion Date
			recruiting) (recruiting)
NCT04182620a	Ultrasound-Based Renal Sympathetic Denervation as Adjunctive Upstream Therapy During Atrial Fibrillation Ablation (ULTRA-HFIB)	160	Feb 2025 (completed)
NCT05988411a	ULTRA-HFIB-Redo: Ultrasound-based Renal Sympathetic Denervation vs Control in Redo Ablation Patients	250	Dec 2027 (recruiting)
Unpublished			
NCT04307836a	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	Apr 2024 (unknown)
NCT04535050a	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) Apr 2026 (unknown)
NCT04182620a	Ultrasound-Based Renal Sympathetic Denervation as Adjunctive Upstream Therapy During Atrial Fibrillation Ablation (ULTRA-HFIB)	160	Feb 2025 (completed)
NCT04311086 ^a	Global Clinical Study of Renal Denervation in the Distal Main and First Order Branch Renal Arteries Using the Symplicity Spyral ^{TM‡} Multi-electrode Renal Denervation System (SPYRAL DYSTAL)	128	Dec 2022 (completed)
NCT04722159	Clinical Outcome of Patients With Resistant Hypertension Undergoing Renal Denervation: A Report From the Swedish Registry for Renal Denervation	300	Aug 2021 (unknown)

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NCT No.	Trial Name	Planned Enrollment	Completion Date
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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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

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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.
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.
08/07/2025	Medical Policy Committee review
08/13/2025	Medical Policy Implementation Committee approval. Title changed from "Radiofrequency Ablation of the Renal Sympathetic Nerves as a Treatment for Uncontrolled Hypertension" to "Renal Denervation for Uncontrolled Hypertension". Added ultrasound ablation to the investigational statement.
08/06/2026	Medical Policy Committee review
08/12/2026	Medical Policy Implementation Committee review
08/20/2026	Medical Quality Management Committee approval. Coverage eligibility unchanged.
10/01/2026	Coding update

Next Scheduled Review Date: 08/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 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.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA

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disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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	C1735 Add code effective 10/01/2026: C1736
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.

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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.

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.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.