MEDICAL POLICY

POLICY TITLE	**RENAL DENERVATION FOR UNCONTROLLED HYPERTENSION**
POLICY NUMBER	**MP 1.166**

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**4/1/2026**

POLICY

Radiofrequency ablation of the renal sympathetic nerves is considered **medically necessary** for individuals whose blood pressure remains above >130/80 mmHg despite use of 3 or more antihypertensive medications from 3 classes (angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, calcium channel blockers, thiazide diuretics, and beta blockers) at maximally tolerated doses or with intolerance to antihypertensive medications whose blood pressure remains uncontrolled despite attempting lifestyle modifications (see Policy Guidelines).

Ultrasound ablation of the renal sympathetic nerves is considered **medically necessary** for individuals whose blood pressure remains above >130/80 mmHg despite use of 3 or more antihypertensive medications from 3 classes (angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, calcium channel blockers, thiazide diuretics, and beta blockers) at maximally tolerated doses or with intolerance to antihypertensive medications whose blood pressure remains uncontrolled despite attempting lifestyle modifications (see Policy Guidelines).

Policy Guidelines

Priority for renal denervation of the renal sympathetic nerves may be appropriately given to patients with higher cardiovascular risk (e.g., 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.

The procedure should only be performed in experienced, specialized centers with multidisciplinary hypertension teams involving experts in hypertension and percutaneous cardiovascular interventions after shared decision-making about the risks and benefits of treatment with the individual.

There is too little data to support the use of renal denervation for the following: 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.

Contraindications 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 hypertension.

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PRODUCT VARIATIONS
This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

DESCRIPTION/BACKGROUND

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 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 (i.e., obstructive sleep apnea) to control blood pressure adequately.

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.

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, 2-3 ultrasound emissions are delivered per renal artery, with the ability to treat both main renal arteries and accessory renal arteries when present.

Regulatory Status

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):

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

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. 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 systolic blood pressure (SBP) at 2 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 BP 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 FDA'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 radiofrequency ablation (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. Despite these limitations, the overall evidence suggests that usRDN may result in an improvement in net health outcomes for patients with uncontrolled hypertension despite the use of anti-hypertensive medications. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

DEFINITIONS/BACKGROUND

N/A

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These polices are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes							
0338T	0339T	C1735	C1736				

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POLICY HISTORY

MP 1.166	**10/30/2025** New policy adoption.

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