Corporate Medical Policy

Radiofrequency Ablation of the Renal Nerves as a Treatment of Hypertension

File Name: radiofrequency_ablation_of_the_renal_nerves_as_a_treatment_of_hypertension
Origination: 10/2012
Last Review: 04/2024

Description of Procedure or Service

Uncontrolled 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. 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 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, it is sometimes necessary to address comorbid conditions (ie, 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 side effects 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. The 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 controlled 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.

Regulatory Status

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. There are several devices that have been developed for this purpose and are in various stages of application for FDA approval.

- The Symplicity Spyral™ Renal Denervation System (Medtronic) is a multielectrode RFA catheter system designed to deliver 4-quadrant ablations. On August 23, 2023 the FDA

Advisory Committee for Circulatory System Devices voted that the Symplicity Spyral system met its safety endpoint as well as its efficacy endpoint, but after a tied vote in which the chairperson cast the final vote, the committee determined that the device did not achieve a positive balance of benefits and harms.

- 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 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 a 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 evidence review.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Radiofrequency ablation of the renal sympathetic nerves is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Radiofrequency Ablation of the Renal Nerves is covered

Not applicable.

When is Radiofrequency Ablation of the Renal Nerves not covered

Radiofrequency ablation of the renal sympathetic nerves is considered investigational for the treatment of uncontrolled hypertension.

Policy Guidelines

For individuals who have uncontrolled hypertension, despite the use of anti-hypertensive medications, who receive RFA of the renal sympathetic nerves, the evidence includes several 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0338T

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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Policy Implementation/Update Information

10/30/12 New policy developed. Radiofrequency ablation of the renal sympathetic nerves is considered investigational for treatment of resistant hypertension. Medical Director review 10/2012. (mco)

5/14/13 Specialty Matched Consultant Advisory Panel review 4/2013. Medical Director review 3/2013. New product information added to Description section. References updated. (mco)

12/31/13 Deleted unlisted code 64999 and added CPT codes 0338T and 0339T to Billing/Coding section. (mco)

5/13/14 Description section updated. References updated. Specialty Matched Consultant Advisory Panel review 4/2014. Medical Director review 4/2014. No changes to Policy Statements. (mco)

11/11/14 References updated. No changes to Policy Statements. (td)

5/26/15 Specialty Matched Consultant Advisory Panel review 4/2015. Medical Director review 4/2015. Policy Statements remain unchanged. (td)

10/30/15 Description section: Regulatory Status updated. Policy Guidelines section extensively revised. References updated. (td)

5/31/16 Specialty Matched Consultant Advisory Panel review 4/27/2016. Medical Director review 4/2016. (jd)

5/26/17 References updated. Specialty Matched Consultant Advisory Panel review 4/2017. Medical Director review 4/2017. (jd)

5/11/18 References updated. Specialty Matched Consultant Advisory Panel 4/2018. Medical Director review 4/2018. (jd)

10/12/18 Minor revisions to regulatory status and policy guidelines. No change to policy intent. Reference updated. Medical Director review. 9/2018. (jd)

5/14/19 Specialty Matched Consultant Advisory Panel review 4/2019. Medical Director review 4/2019. (jd)

12/10/19 The following code was removed from the Billing/Coding section effective 10/1/19: 0339T. (jd)

4/28/20 Specialty Matched Consultant Advisory Panel review 4/2020. Medical Director review 4/2020. (jd)

5/4/21 Minor revisions to regulatory status and policy guidelines. References updated. Specialty Matched Consultant Advisory Panel review 4/2021. Medical Director review 4/2021. (jd)

5/3/22 References updated. Specialty Matched Advisory Panel review 4/2022. Medical Director review 4/2021. (jd)

5/16/23 Description, Policy Guidelines and References updated. Specialty Matched Advisory Panel review 4/2023. Medical Director review 4/2023. (tm)

5/1/24 Description, Policy Guidelines and References updated. Not Covered section edited for clarity, replaced “resistant” hypertension with “uncontrolled” hypertension. No change to policy statement. Specialty Matched Advisory Panel review 4/2024. Medical Director review 4/2024. (tm)