

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 CAP Review: 4/2018
Next CAP Review: 4/2019
Last Review: 9/2018

Description of Procedure or Service

Resistant Hypertension.

Hypertension is a widely prevalent condition, which is estimated to affect approximately 30% of the population in the United States. It accounts for a high burden of morbidity related to strokes, ischemic heart disease, kidney disease, and peripheral arterial disease. Resistant hypertension is defined as elevated blood pressure (BP) despite treatment with at least 3 antihypertensive agents at optimal doses. Resistant hypertension is also a relatively common condition, given the large number of individuals with hypertension. In large clinical trials of hypertension treatment, up to 20-30% of participants meet the definition for resistant hypertension, and in tertiary care hypertension clinics, the prevalence has been estimated to be 11-18%. Resistant hypertension is associated with a higher risk for adverse outcomes such as stroke, myocardial infarction (MI), heart failure, and kidney failure.

There are a number of factors that may contribute to uncontrolled hypertension, and these should be considered and addressed in all patients with hypertension prior to labeling a patient resistant. These include nonadherence to medications, excessive salt intake, inadequate doses of medications, excess alcohol intake, volume overload, drug-induced hypertension, and other forms of secondary hypertension. Also, sometimes it is necessary to address comorbid conditions, i.e., obstructive sleep apnea, in order to adequately control BP.

Treatment for resistant hypertension is mainly intensified drug therapy, sometimes with the use of non-traditional antihypertensive medications such as spironolactone and/or minoxidil. However, control of resistant hypertension with additional medications is often challenging and can lead to high costs and frequent adverse effects of treatment. As a result, there is a large unmet need for additional treatments that can control resistant hypertension. Non-pharmacologic interventions for resistant hypertension include modulation of the baroreflex receptor, and/or radiofrequency (RF) denervation of the renal nerves.

Radiofrequency Denervation of the Renal Sympathetic Nerves.

Increased sympathetic nervous system activity has been linked to essential hypertension. Surgical sympathectomy has been shown to be effective in reducing blood pressure but is limited by the adverse 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) 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.

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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.

- Symplicity™ Renal Denervation System (Medtronic). In April 2018, FDA approved an investigational device exemption (IDE) pivotal trial, SPYRAL HTN. The trial will be randomized and sham-controlled.
- 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 One-Shot™ Renal Denervation System (Covidien) is an irrigated RFA balloon catheter, consisting of a spiral shaped electrode surrounding a balloon. In 2014, Covidien abandoned development of its OneShot™ Renal Denervation.
- 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.

****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 treatment of resistant hypertension.

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Policy Guidelines

The evidence for the use of radiofrequency ablation (RFA) of the renal sympathetic nerves for individuals with hypertension resistant to standard medical management, includes at least 10 randomized controlled trials (RCTs), numerous systematic reviews of the RCTs, along with multiple nonrandomized comparative studies and case series. Relevant outcomes are symptoms, change in disease status, morbid events, medication use, and treatment-related morbidity. The largest trial, the Symplicity HTN-3 trial, which used a sham-controlled design to reduce the likelihood of placebo effect, demonstrated no significant differences between renal denervation and sham-control patients in office based or ambulatory blood pressure at 6-month follow-up. The Symplicity HTN-3 results are supported by a subsequent sham-controlled trial. The Symplicity HTN-3 results were in contrast to additional studies, including Symplicity HTN-2 and Renal Denervation for Hypertension (DENERHTN) trial, which reported efficacy in reducing blood pressure over a 6-month time period compared with a control group. Additional smaller RCTs, some of which were stopped early after results of the Symplicity HTN-3 trial became available, did not demonstrate significantly improved outcomes with renal denervation. Single-arm studies with overlapping populations report improvements in blood pressure and related physiologic parameters, such as echocardiographic measures of left ventricular hypertrophy, that appear to be durable up to 24 months of follow-up. The strongest evidence comes from sham-controlled trials, the largest of which found no significant benefits with renal denervation. Meta-analyses of the systematic reviews have also reported inconsistent findings, with most analyses showing no significant benefit in blood pressure measurements following RFA. The evidence is insufficient to determine the effects of the technology on health outcomes.

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, 0339T

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.136, 8/9/12

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National Institutes of Health (NIH). Clinical trial #NCT01438229. Safety and Efficacy Study of Renal Artery Ablation in Resistant Hypertension Patients (EnligHTN I). Retrieved from <http://clinicaltrials.gov/ct2/show/NCT01438229>

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Ott C, Mahfoud F, Schmid A et al. Renal denervation in moderate treatment resistant hypertension. *J Am Coll Cardiol* 2013.

Schlaich MP1, Schmieder RE, Bakris G. International expert consensus statement: Percutaneous transluminal renal denervation for the treatment of resistant hypertension. *J Am Coll Cardiol.* 2013 Dec 3;62(22):2031-45.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.136, 9/12/13

Medical Director review 4/2014

Specialty Matched Consultant Advisory Panel review 4/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.136, 9/11/14

Specialty Matched Consultant Advisory Panel review 4/2015

Medical Director review 4/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.136, 9/10/15

Specialty Matched Consultant Advisory Panel review 4/2016

Medical Director review 4/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.136, 9/2016

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Medical Director review 4/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.136, 9/2018

Medical Director review 9/2018

Policy Implementation/Update Information

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| 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) |

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.