

Medical Coverage Policy



**Blue Cross
Blue Shield**
of Rhode Island

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

Device/Equipment Drug Medical Surgery Test Other

Effective Date:	04/02/2013	Policy Last Updated:	4/2/2013
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Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

Description:

Radiofrequency ablation (RFA) of the renal sympathetic nerves is a non-pharmacologic treatment for hypertension. This treatment is intended to reduce sympathetic nerve activity in the renal system, thus leading to lower blood pressure. Patients with hypertension that is resistant to treatment with standard medications may derive benefit from this approach.

Resistant hypertension is defined as elevated blood pressure (BP) despite treatment with at least 3 antihypertensive agents at optimal doses. 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 non-adherence 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, 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. 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. This 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.

No RFA devices have been approved 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 U.S. Food and Drug Administration (FDA) approval. The Symplicity™ renal denervation device (Medtronic, Inc.) consists of a flexible catheter that is specifically intended for use in the renal arteries, and an external power generator. Other devices under development for this purpose include the Biosense Webster Thermocouple Catheter™, which has been used for cardiac electrophysiology procedures, and the St. Jude Medical EnligHTN™ multi-electrode renal denervation system.

At this time, there is no evidence that reports improvements in health outcomes as a result of treatment with RFA of the renal sympathetic nerves. Potential complications of this procedure include vascular access problems, perforation of the renal artery, and renal artery stenosis, but rates of complications have not been well-established. This evidence is insufficient to determine whether health outcomes are improved, and therefore radiofrequency ablation of the renal sympathetic nerves is considered not medically necessary.

Medical Criteria:

None

Policy:

Radiofrequency ablation of the renal sympathetic nerves is considered not medically necessary for the treatment of resistant hypertension as there is insufficient peer-reviewed scientific literature to demonstrate that the procedure is effective.

Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for the applicable benefit/coverage for services not medically necessary.

Codes:

There are no specific code(s) for radiofrequency ablation of the renal sympathetic nerves. The radiofrequency ablation may be reported using the unlisted nervous system procedure code: 64999

Note: The procedure is considered not medically necessary when coded with 36521-36254 codes for the renal artery catheter placement which include the fluoroscopic guidance for the catheter placement.

Related Topics:

None

Published:

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References:

Blue Cross and Blue Shield Association. Medical Policy Reference Manual/**7.01.136 Radiofrequency Ablation of the Renal Sympathetic Nerves as a Treatment for Resistant Hypertension**. Accessed 3/6/2013

Simonetti G, Spinelli A, Gandini R et al. Endovascular radiofrequency renal denervation in treating refractory arterial hypertension: a preliminary experience. Radiol Med 2012; 117(3):426-44. Accessed 3/6/2013

Mabin T, Sapoval M, Cabane V et al. First experience with endovascular ultrasound renal denervation for the treatment of resistant hypertension. EuroIntervention 2012; 8(1):57-61. Accessed 3/6/2013

http://www.resistanthypertensioncourse.com/sites/default/files/documents/48th_issue-article_10.pdf

Review History:

4/2/2013: Policy approved at the Payment and Medical Review Committee.

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