

## Corporate Medical Policy

### Baroreflex Stimulation Devices

**File Name:** baroreflex\_stimulation\_devices  
**Origination:** 9/2011  
**Last CAP Review:** 4/2012  
**Next CAP Review:** 4/2013  
**Last Review:** 4/2012

#### Description of Procedure or Service

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Baroreflex stimulation devices are used to provide baroreflex activation therapy® (BAT®) which refers to electrical stimulation of the baroreceptors in the carotid arteries by means of an implanted device. Activation of the baroreflex causes inhibition of the sympathetic nervous system, resulting in a variety of physiologic changes including slowed heart rate and decreased blood pressure. Use of baroreflex stimulation devices has therefore been proposed as a treatment for hypertension that is resistant to standard medications, as well as related conditions which are associated with high sympathetic tone.

##### Background

The baroreceptors are pressure sensors contained within the walls of the carotid arteries. They are part of the autonomic nervous system that regulates basic physiologic functions such as heart rate and blood pressure. When these receptors are stretched, as occurs with increases in blood pressure, the baroreflex is activated. Activation of the baroreflex sends signals to the brain, which responds by inhibiting sympathetic nervous system output and increasing parasympathetic nervous system output. The effect of this activation is to reduce heart rate and blood pressure, thereby helping to maintain homeostasis of the circulatory system.

##### Resistant Hypertension

Hypertension is a widely prevalent condition, which is estimated to affect approximately 30% of the population in the United States, and 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 despite treatment with at least three anti-hypertensive agents at optimal doses. Resistant hypertension is a relatively common condition. 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, MI, heart failure and kidney failure. 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. Surgical treatment has been tried but is not widely accepted at the present time. Besides baroreflex stimulation, another non-pharmacologic option is sympathectomy of the renal sympathetic nerves via surgery or radiofrequency ablation.

# Baroreflex Stimulation Devices

## Baroreflex activation devices.

Devices that activate the baroreflex are implantable devices that provide electrical stimulation to the baroreceptors. The Rheos® Hypertension system has been developed for this purpose. It consists of three components:

- 1) Implantable pulse generator, which controls and delivers the electrical energy. It is implanted subcutaneously beneath the collarbone by minimally invasive surgery.
- 2) Carotid sinus leads, which are thin wires with electrical contacts that are placed in contact with the carotid baroreceptors. They conduct the electrical energy from the pulse generator to the baroreceptors.
- 3) The programmer system, which is an external device that allows clinicians to turn the system on and off and regulate the electrical signal delivered to the baroreceptors.

## Regulatory Status

There are no baroreflex activation therapy devices that have received FDA approval.

**\*\*\*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

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**Baroreflex stimulation devices are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.**

## Benefits Application

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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 Baroreflex Stimulation Devices are covered

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Not Applicable.

## When Baroreflex Stimulation Devices are not covered

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Baroreflex stimulation devices are considered investigational for all applications, including treatment of resistant hypertension.

## Policy Guidelines

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The use of baroreflex stimulation devices is a potential alternative treatment for resistant hypertension. At least one device is in the development stages but has not received FDA approval for any indications. Small, uncontrolled feasibility studies report short-term reductions in blood pressure, together with adverse events such as infection, hypoglossal nerve injury, and wound complications. Results of an RCT comparing baroreflex stimulation with continued medical therapy were published in 2011. This trial met some efficacy endpoints but not others. There was not a significant increase in the percent of patients achieving at least a 10 mm Hg decrease in SBP at 6 months, but more patients in the treatment group did reach a target systolic BP of 140 mm Hg or less at 6 months. The trial met 2 of 3 predefined safety

## Baroreflex Stimulation Devices

endpoints. Further research from RCTs is needed to determine whether baroreflex activation therapy is effective in reducing blood pressure for patients with resistant hypertension. Because of limited evidence showing benefit, and the lack of FDA approval, this treatment is considered investigational.

### Billing/Coding/Physician Documentation Information

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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](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 0266T, 0267T, 0268T, 0269T, 0270T, 0271T, 0272T, 0273T*

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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BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.57, 8/11/11

National Institutes of Health (NIH). Rheos® Pivotal Trial. Clinical Trial #NCT00442286. Retrieved on August 12, 2011 from <http://clinicaltrials.gov/ct2/show/NCT00442286?term=NCT00442286&rank=1>

National Institutes of Health (NIH). Rheos® Feasibility Trial. Clinical trial #NCT01077180. Retrieved on August 12, 2011 from <http://clinicaltrials.gov/ct2/show/NCT01077180?term=NCT01077180&rank=1>

National Institutes of Health (NIH). Rheos HOPE4HF Trial. Clinical Trial # NCT00957073. Retrieved on August 12, 2011 from <http://clinicaltrials.gov/ct2/show/NCT00957073?term=NCT00957073&rank=1>

Papademetriou V, Doumas M, Faselis C, et.al. Carotid Baroreceptor Stimulation for the Treatment of Resistant Hypertension. *Int J Hypertens*. 2011; 2011:964394. Retrieved on August 12, 2011 from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3124753/?tool=pubmed>

Specialty Matched Consultant Advisory Panel review 4/2012.

### Policy Implementation/Update Information

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9/30/11 New policy developed. Baroreflex stimulation devices are considered investigational for all applications, including treatment of resistant hypertension. Medical Director review 9/2011.(mco)

5/15/12 Specialty Matched Consultant Advisory Panel review 4/2012. Policy Guidelines updated.(mco)

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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.

