Baroreflex Stimulation Devices

Baroreflex stimulation devices provide 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 various physiologic changes, including slowed heart rate and decreased blood pressure. A device for baroreflex stimulation has been developed, but has not received U.S. Food and Drug Administration (FDA) approval other than a humanitarian device exemption for patients who had previously participated in a clinical trial.

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.

The use of baroreflex stimulation devices (also known as baroreflex activation therapy) is a potential alternative treatment for resistant hypertension and heart failure. Both hypertension and heart failure are relatively common conditions, and are initially treated with medications and lifestyle changes. A substantial portion of patients are unresponsive to conventional therapy and treating these patients is often challenging, expensive, and can lead to adverse effects. As a result, there is a large unmet need for additional treatments.

One device is approved for sale in Europe for hypertension and heart failure patients. This second-generation system consists of a unilateral electrode and lead that is attached to the carotid sinus and a pulse generator that is implanted subcutaneously in the chest wall. Programming is performed via radiofrequency telemetry using an external laptop computer and software. The first-generation system had bilateral leads attached to each carotid sinus and a larger pulse generator.

Regulatory Status

In 2014, the Barostim neo® Legacy System (CVRx, Minneapolis, MN) received a humanitarian device exemption from the FDA, for use in patients with treatment-resistant hypertension who received Rheos® Carotid Sinus leads as part of the Rheos pivotal trial and were considered responders in that trial.
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In November 2015, CVRx received expedited access pathway (EAP) designation from the FDA for Barostim Therapy® to treat heart failure. EAP designation does not guarantee that an application to the FDA will ultimately be approved.

In August 2019, the FDA granted premarket approval for Barostim Neo System (CVRx) device for use in patients with advanced heart failure who are unable to undergo treatment with other heart failure devices, such as cardiac resynchronization.

***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

Baroreflex stimulation devices are considered investigational for all applications. 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 Baroreflex Stimulation Devices are covered

Not Applicable.

When Baroreflex Stimulation Devices are not covered

Baroreflex stimulation devices are considered investigational for all applications, including treatment of hypertension and heart failure.

Policy Guidelines

The evidence on baroreflex stimulation therapy for individuals with treatment-resistant hypertension, includes 1 randomized controlled trial and several small uncontrolled studies. Relevant outcomes are overall survival, quality of life, functional outcomes, hospitalizations, medication use, and treatment-resistant morbidity. The uncontrolled studies report short-term reductions in blood pressure in patients treated with baroreflex stimulation devices, as well as adverse events such as infection, hypoglossal nerve injury, and wound complications. The RCT comparing baroreflex stimulation with continued medical management met some efficacy end points but not others, and 2 of the 3 predefined safety end points. Additional RCTs are needed assess conclusions about efficacy and safety. In addition, baroreflex stimulation currently has a very narrow FDA approval (ie, for patients who previously participated in a pivotal trial) and broader approval or clearance is needed for wider application. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence on baroreflex stimulation therapy for individuals with treatment-resistant heart failure, includes 1 RCT. Relevant outcomes are overall survival, quality of life, functional outcomes, hospitalizations, medication use and treatment-resistant morbidity. The RCT met all 3 efficacy end points but had some methodologic limitations, including lack of blinding, relatively small sample size for a common condition and relatively short intervention periods. A second, larger RCT designed to assess the effects of the intervention on mortality, safety, functional and quality of life outcomes, is underway. In addition, the one baroreflex stimulation device with humanitarian device exemption approval currently has only a very narrow FDA approval (ie, for patients who previously participated in
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a pivotal trial) and broader approval or clearance is needed for wider application. 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: 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


Specialty Matched Consultant Advisory Panel review 4/2013

Medical Director review 4/2013


Medical Director review 4/2014


Specialty Matched Consultant Advisory Panel review 4/2015

Medical Director review 4/2015
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Medical Director review 4/2016
Specialty Matched Consultant Advisory Panel review 4/2017
Medical Director review 4/2017
Medical Director review 5/2017
Specialty Matched Consultant Advisory Panel review 4/2018
Medical Director review 4/2018
Specialty Matched Consultant Advisory Panel review 10/2019
Medical Director review 10/2019


Policy Implementation/Update Information

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<tr>
<th>Date</th>
<th>Description</th>
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<td>9/30/11</td>
<td>New policy developed. Baroreflex stimulation devices are considered investigational for all applications, including treatment of resistant hypertension. Medical Director review 9/2011. (mco)</td>
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<tr>
<td>10/16/12</td>
<td>Description section updated. References updated. No changes to Policy Statement. (mco)</td>
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<td>When Not Covered section updated to include heart failure as an example in the investigational statement. Policy Guidelines section updated. References updated. (td)</td>
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6/3017  Description section, regulatory status and policy guidelines updated. References updated. Medical Director review 5/2017. (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.