Corporate Medical Policy

Baroreflex Stimulation Devices

File Name:	baroreflex_stimulation_devices
Origination:	9/2011
Last CAP Review:	10/2021
Next CAP Review:	10/2022
Last Review:	10/2021

Description of Procedure or Service

Baroreflex stimulation devices provide electrical stimulation of the baroreceptors in the carotid arteries by means of an implanted device. Activation of the baroreflex inhibits 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.

Regulatory Status

In 2014, the Barostim Neo® Legacy System received a humanitarian device exemption from the U.S. Food and Drug Administration (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.

In 2019, Barostim Neo ™ was granted premarket approved (PMA P180050) and is indicated for the improvement of symptoms of heart failure, quality of life, six-minute hall walk, and functional status, for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are NYHA Class III or Class II (who have a history of Class III), have a left ventricular ejection fraction ≤ 35%, a NT-proBNP < 1600pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines.
It was the first device to be granted via the Expedited Access Pathway (EAP). EAP will hasten the approval of novel therapies that target life-threatening conditions.

Baroreflex Stimulation Devices

******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 for individuals with treatment-resistant hypertension who receive baroreflex stimulation therapy, 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 endpoints. Additional RCTs are needed to assess conclusions about efficacy and safety. 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 for individuals with treatment-resistant heart failure who receive baroreflex stimulation therapy, includes 2 RCTs and a post hoc subgroup analysis of an RCT. Relevant outcomes are overall survival, quality of life, functional outcomes, hospitalizations, medication use and treatment-resistant morbidity. The expedited phase of the 2019 RCT was used by the U.S. Food and Drug administration to approve the Barostim Neo System. The trial demonstrated that they system is safe and effective for its intended use population in the short term; however, the extended trial is still underway, and longer-term outcomes have not been determined. A 2018 RCT met all 3 efficacy endpoints but had methodologic limitations, incomplete blinding, a relatively small sample size for a common condition, and a short intervention period. A second larger RCT, designed to assess the effects of the intervention on mortality, safety, functional and quality of life outcomes, is underway. 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

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

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Specialty Matched Consultant Advisory Panel review 4/2017

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Specialty Matched Consultant Advisory Panel review 10/2019

Medical Director review 10/2019

Food and Drug Administration: FDA approves new device to improve symptoms in patients with advanced heart failure. August 16, 2019, reviewed via: https://www.fda.gov/news-events/press-announcements/fda-approves-new-device-improve-symptoms-patients-advanced-heart-failure

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.57, 6/2020

Specialty Matched Consultant Advisory Panel review 10/2020

Medical Director review 10/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.57, 6/2021

Specialty Matched Consultant Advisory Panel review 10/2021

Medical Director review 10/2021

Policy Implementation/Update Information

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)

10/16/12 Description section updated. References updated. No changes to Policy Statement. (mco)

4/30/13 Specialty Matched Consultant Advisory Panel review 4/2013. Medical Director review 4/2013. No changes to Policy Statement. (mco)

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

10/14/14 References updated. No changes to Policy Statement. (td)

5/26/15 Policy Statements remain unchanged. References updated. Specialty Matched Consultant Advisory Panel review 4/29/2015. Medical Director review 4/2015. (td)

10/30/15 When Not Covered section updated to include heart failure as an example in the investigational statement. Policy Guidelines section updated. References updated. (td)

5/31/16 Description section updated. Reference section updated. Specialty Matched Consultant Advisory Panel review 4/27/2016. Medical Director review 4/2016.

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

6/3017 Description section, regulatory status and policy guidelines updated. References updated. Medical Director review 5/2017. (jd)

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

10/29/19 Regulatory status updated with recent approval by FDA for Barostim Neo System. Specialty Matched Consultant Advisory Panel review 10/2019. Medical Director review 10/2019. (jd)

11/10/20 Minor updates to the background, regulatory status and policy guidelines. References updated. Specialty Matched Consultant Advisory Panel review 10/2020. Medical Director review 10/2020. (jd)

11/2/21 References updated. Specialty Matched Consultant Advisory Panel review 10/2021. Medical Director review 10/2021. (jd)