MEDICAL POLICY

POLICY TITLE	BAROREFLEX STIMULATION DEVICE
POLICY NUMBER	MP-1.142

Original Issue Date (Created):	**4/1/2014**
Most Recent Review Date (Revised):	**7/16/2018**
Effective Date:	**9/1/2018**

POLICY
RATIONALE
DISCLAIMER
POLICY HISTORY
PRODUCT VARIATIONS
DEFINITIONS
CODING INFORMATION
DESCRIPTION/BACKGROUND
BENEFIT VARIATIONS
REFERENCES

I. POLICY

Use of baroreflex stimulation implanted devices is considered **investigational** in all situations including but not limited to treatment of hypertension and heart failure as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

III. DESCRIPTION/BACKGROUND

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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 (BP). When these receptors are stretched, as occurs with increases in BP, 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 BP, thereby helping to maintain homeostasis of the circulatory system.

The use of baroreflex stimulation devices (also known as baroreflex activation therapy [BAT]) 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 and can lead to high costs and 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 attached to the carotid sinus and a pulse generator implanted subcutaneously in the chest wall. Programming is performed using radiofrequency telemetry with 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 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.[1]

In November 2015, CVRx received expedited access pathway (EAP) designation from FDA for Barostim Therapy® to treat heart failure.[2] EAP designation does not guarantee that an application to FDA will ultimately be approved.

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have treatment-resistant hypertension who receive baroreflex stimulation therapy, the evidence includes an RCT and several small uncontrolled studies. Relevant outcomes are overall survival, functional outcomes, quality of life, hospitalizations, medication use, and treatment-resistant morbidity. The uncontrolled studies have reported 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 as well as 2 of its 3 predefined safety end points. Additional RCTs are needed to permit conclusions on the efficacy and safety. In addition, baroreflex stimulation currently has a very narrow Food and Drug Administration 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.

For individuals who have treatment-resistant heart failure who receive baroreflex stimulation therapy, the evidence includes an RCT. Relevant outcomes are overall survival, functional outcomes, quality of life, hospitalizations, medication use, and treatment-resistant morbidity. The RCT met all 3 efficacy end points but had methodologic limitations, including lack of blinding, a relatively small sample size for a common condition and a relatively 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. In addition, the only baroreflex stimulation device with humanitarian device exemption approval currently has only a very narrow Food and Drug Administration 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 effect of the technology on health outcomes.

V. DEFINITIONS

TOP

N/A

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

TOP

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

CPT Codes®							
0266T	0267T	0268T	0269T	0270T	0271T	0272T	0273T

IX. REFERENCES

TOP

1. *Food and Drug Administration. Humanitarian Device Exemption (HDE): Barostim Neo Legacy System. 2014; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=h130007. Accessed April 11, 2018.*
2. *CVRx. CVRx® Announces Expedited Access Pathway Designation by FDA for Barostim Therapy® for the Treatment of Heart Failure in Order to Accelerate Access for US Patients. 2015; http://www.cvrx.com/newsroom/cvrx-announces-expedited-access-pathway-designation-by-fda-for-barostim-therapy-for-the-treatment-of-heart-failure-in-order-to-accelerate-access-for-us-patients/. Accessed April 11, 2018.*
3. *Bisognano JD, Bakris G, Nadim MK, et al. Baroreflex activation therapy lowers blood pressure in patients with resistant hypertension results from the double-blind, randomized, placebo-controlled rheos pivotal trial. J Am Coll Cardiol. Aug 9 2011;58(7):765-773. PMID 21816315*
4. *Bakris GL, Nadim MK, Haller H, et al. Baroreflex activation therapy provides durable benefit in patients with resistant hypertension: results of long-term follow-up in the Rheos Pivotal Trial. J Am Soc Hypertens. Mar-Apr 2012;6(2):152-158. PMID 22341199*
5. *Heusser K, Tank J, Engeli S, et al. Carotid baroreceptor stimulation, sympathetic activity, baroreflex function, and blood pressure in hypertensive patients. Hypertension. Mar 2010;55(3):619-626. PMID 20101001*
6. *Hoppe UC, Brandt MC, Wachter R, et al. Minimally invasive system for baroreflex activation therapy chronically lowers blood pressure with pacemaker-like safety profile: results from the Barostim neo trial. J Am Soc Hypertens. Jun 11 2012;6(4):270-276. PMID 22694986*
7. *Scheffers IJ, Kroon AA, Schmidli J, et al. Novel baroreflex activation therapy in resistant hypertension: results of a European multi-center feasibility study. J Am Coll Cardiol. Oct 5 2010;56(15):1254-1258. PMID 20883933*
8. *Wallbach M, Lehnig LY, Schroer C, et al. Effects of baroreflex activation therapy on ambulatory blood pressure in patients with resistant hypertension. Hypertension. Apr 2016;67(4):701-709. PMID 26902491*
9. *Abraham WT, Zile MR, Weaver FA, et al. Baroreflex activation therapy for the treatment of heart failure with a reduced ejection fraction. JACC Heart Fail. Jun 2015;3(6):487-496. PMID 25982108*

10. *Weaver FA, Abraham WT, Little WC, et al. Surgical experience and long-term results of baroreflex activation therapy for heart failure with reduced ejection fraction. Semin Thorac Cardiovasc Surg. Summer 2016;28(2):320-328. PMID 28043438*
11. *National Institute for Clinical and Care Excellence (NICE). Implanting a baroreceptor stimulation device for resistant hypertension [IPG533]. 2015; https://www.nice.org.uk/guidance/ipg533. Accessed April 11, 2018.*
12. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 8.01.57, Baroflex Stimulation Device. May 2018.*

X. POLICY HISTORY

TOP

MP 1.142	**CAC 11/26/13** New policy. BCBSA adopted. Baroreflex stimulation implanted devices are considered investigational.
	CAC 11/25/14 Consensus review. References and rationale updated. No changes to the policy statement. LCD number changed from L31686 to L35094. Coding reviewed, no changes.
	CAC 11/24/15 Consensus review. References and rationale updated**.** Hypertension and heart failure added as examples in investigational policy statement. Remains investigational for all indications. Coding reviewed.
	CAC 11/29/16 Consensus review. No change to the policy statement. Variation reformatting completed. Reference and Rationale sections updated. Coding Reviewed
	CAC 11/28/17 Consensus review. Policy statement unchanged. Description/Background, Rationale, and Reference sections updated. Coding reviewed.
	7/16/18 Consensus review. No change to the policy statement. References updated. Rationale revised.

Top