MEDICAL POLICY

POLICY TITLE	BAROREFLEX STIMULATION DEVICE
POLICY NUMBER	MP 1.142

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**2/1/2025**

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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 general conclusion concerning the health outcomes or benefits associated with this procedure.

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI below. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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Baroreflex stimulation devices provide electrical stimulation of the baroreceptors in the carotid arteries using an implanted device. Activation of the baroreflex inhibits the sympathetic nervous system, resulting in various physiologic changes, including slowed heart rate and lower blood pressure.

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 approval (PMA P180050) and is indicated for the improvement of symptoms of heart failure (i.e., quality of life, six-minute hall walk and functional status, for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are New York Heart Association (NYHA) Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction ≤ 35%, an N-terminal pro-B-type natriuretic peptide (NT-proBNP) < 1600 pg/ml, excluding patients indicated for Cardiac Resynchronization Therapy according to American Heart Association/American College of Cardiology/European Society of Cardiology guidelines.

It was the first device to be granted approval via the Expedited Access Pathway. The Expedited Access Pathway will hasten the approval of novel therapies that target life-threatening conditions.

IV. RATIONALE

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Summary of Evidence

For individuals who have treatment-resistant hypertension who receive baroreflex stimulation therapy, the evidence includes a randomized controlled trial (RCT) and several small uncontrolled studies. Relevant outcomes are overall survival (OS), 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 endpoints but not others, as well as 2 of its 3 predefined safety endpoints. Additional RCTs are needed to permit conclusions on the efficacy and safety. Baroreflex stimulation for treatment-resistant hypertension is accessible only through a Humanitarian Device Exemption (HDE) for patients who previously participated in a pivotal trial.

The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have treatment-resistant heart failure who receive baroreflex stimulation therapy, the evidence includes 2 RCTs, a post hoc subgroup analysis of an RCT, and meta-analyses of these trials. Relevant outcomes are OS, functional outcomes, quality of life, hospitalizations, medication use, and treatment-resistant morbidity. The expedited phase of a 2019 RCT was used by the U.S. Food and Drug Administration to approve the Barostim Neo System. The trial demonstrated that the system is safe and effective for its intended use population in the short term; however, results of the extended trial are not published, 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. Another larger RCT designed to assess the effects of the intervention on mortality, safety, function, and quality of life outcomes is underway. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' 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. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross 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:

Procedure Codes							
0266T	0267T	0268T	0269T	0270T	0271T	0272T	0273T
C1825							

IX. REFERENCES

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12. *Zile MR, Lindenfeld J, Weaver FA, et al. Baroreflex Activation Therapy in Patients With Heart Failure With Reduced Ejection Fraction. J Am Coll Cardiol. Jul 07, 2020; 76(1): 1-13. PMID 32616150*
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15. *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*
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X. POLICY HISTORY

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	04/15/2020 Consensus Review. Policy statement unchanged. References updated. Coding reviewed.
	12/09/2020 Administrative Update. New HCPC code C1825 added. Effective 1/1/2021
	04/15/2021 Consensus Review. Updated Description/Background, Rationale, and References. No changes to coding.
	06/30/2022 Consensus Review. No change to policy statement. FEP language updated. Background and Rationale revised. References added
	06/06/2023 Consensus Review. No change to policy statement. Background and Rationale updated. Reference added.

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	08/07/2024 Consensus Review. No change to policy statement.

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