

Baroreflex Stimulation Devices

Policy # 00315

Original Effective Date: 09/14/2011

Current Effective Date: 01/13/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Radiofrequency Ablation of the Renal Sympathetic Nerves as a Treatment for Resistant Hypertension is addressed separately in medical policy 00465.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of baroreflex stimulation implanted devices in all situations including but not limited to treatment of hypertension and heart failure to be **investigational**.*

Background/Overview

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, which occurs with increases in blood pressure, the baroreflex is activated. Activation of the baroreflex signals 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 events. As a result, there is a large unmet need for additional treatments.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2014, the Barostim Neo^{™‡} Legacy System received a humanitarian device exemption from the U.S. Food and Drug Administration 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 2019, Barostim Neo was granted premarket approval (PMA P180050) and is indicated for the improvement of symptoms of heart failure (ie, 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 (with a recent history of Class III), and have a left ventricular ejection fraction less than or equal to 35% and a N-terminal pro-B-type natriuretic peptide (NT-proBNP) less than 1600 pg/ml, excluding patients indicated for Cardiac Resynchronization Therapy according to the 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 hastens the approval of novel therapies that target life-threatening conditions.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

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.

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 efficacy and safety. Baroreflex stimulation for treatment-resistant hypertension is accessible only through a Humanitarian Device Exemption 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



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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.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association

In 2017, the American Heart Association issued a joint guideline for the management of high blood pressure in adults with the American College of Cardiology and multiple other organizations. This guideline notes that studies have not provided sufficient evidence to support the use of baroreceptor pacing for managing resistant hypertension.

In 2022, the American Heart Association, American College of Cardiology, and multiple other organizations published a guideline on management of heart failure. The guideline states that baroreceptor stimulation has produced mixed results, and data regarding mortality and hospitalization are lacking.

National Institute for Health and Care Excellence

In 2015, the NICE issued guidance that stated: "Current evidence on the safety and efficacy of implanting a baroreceptor stimulation device for resistant hypertension is inadequate. Therefore, this procedure should only be used in the context of research."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.



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Table 1. Summary of Key Ongoing and Unpublished Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02627196 ^a	Barostim Neo ^{®‡} -Baroreflex Activation Therapy ^{®‡} for Heart Failure (BeAT-HF)	1200	Dec 2023
NCT01679132 ^a	CVRx Barostim NEO Hypertension Pivotal Trial	10	Mar 2026 (suspended; company resources only allows adequate oversight for 1 pivotal trial at a time); last update posted Dec 2021
NCT04502316 ^a	Real-World Experience -- Barostim ^{™‡} Advancing the Level of Clinical Evidence (REBALANCE Registry) A Post-Market Registry With the Barostim ^{™‡} System	5000	Jun 2028
NCT02876042 ^a	BAROSTIM THERAPY ^{™‡} in Heart Failure With Preserved Ejection Fraction: A Post-Market Registry With the CE-Marked BAROSTIM NEO ^{™‡} System	70	Jul 2024
NCT02880618 ^a	BAROSTIM THERAPY ^{™‡} in Heart Failure With Reduced Ejection Fraction: A Post-Market Registry With the CE-Marked BAROSTIM NEO ^{™‡} System	500	Jul 2024
NCT02880631 ^a	BAROSTIM THERAPY ^{™‡} In Resistant Hypertension: A Post-Market Registry With the CE-Marked BAROSTIM NEO ^{™‡} System	500	Jul 2024
NCT01471834 ^a	Neo Non-Randomized Hypertension Study	40	Aug 2026

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.



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References

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09/01/2011	Medical Policy Committee review
09/14/2011	Medical Policy Implementation Committee approval. New policy.
09/06/2012	Medical Policy Committee review
09/19/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/19/2013	Coding revised
09/05/2013	Medical Policy Committee review
09/18/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/06/2014	Medical Policy Committee review
11/21/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Added situations of hypertension and heart failure to existing INV policy statement.
12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.



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01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/03/2020	Medical Policy Committee review
12/09/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/29/2020	Coding update
12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2022	Medical Policy Committee review
12/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/07/2023	Medical Policy Committee review
12/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2024	Medical Policy Committee review
12/11/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 12/2025

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical



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Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0266T, 0267T, 0268T, 0269T, 0270T, 0271T, 0272T, 0273T
HCPCS	C1825
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.



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NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

