

# Baroreflex Stimulation Devices

**Medicare Advantage Medical Policy # 006**

Original Effective Date: 02/20/2024

Current Effective Date: 02/01/2025

*Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

## 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 Health Plan 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.

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

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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 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

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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.<sup>17</sup> 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.<sup>18</sup> 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 <sup>a</sup> | Barostim Neo®‡ -Baroreflex Activation Therapy®‡ for Heart Failure (BeAT-HF)   | 1200               | Dec 2023  |
| NCT01679132 <sup>a</sup> | 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 <sup>a</sup> | Real-World Experience -- Barostim™‡ Advancing the Level of Clinical Evidence (REBALANCE Registry) A Post-Market Registry With the Barostim™‡ System | 5000               | June 2028   |
| NCT02876042 <sup>a</sup> | BAROSTIM THERAPY™‡ in Heart Failure With Preserved Ejection Fraction: A PostMarket Registry With the CE-Marked BAROSTIM NEO™‡ System                | 70                 | Jul 2024  |
| NCT02880618 <sup>a</sup> | BAROSTIM THERAPY™‡ in Heart Failure With Reduced Ejection Fraction: A Post-Market Registry With the CE-Marked BAROSTIM NEO™ System                  | 500                | Jul 2024  |
| NCT02880631 <sup>a</sup> | BAROSTIM THERAPY™‡ In Resistant Hypertension: A Post-Market Registry With the CE-Marked BAROSTIM NEO™‡ System                                       | 500                | Jul 2024  |
| NCT01471834 <sup>a</sup> | Neo Non-Randomized Hypertension Study   | 40                 | Aug 2026  |

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## References

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## Policy History

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02/20/2024 Utilization Management Committee review and approval. New policy.

01/21/2025 Utilization Management Committee review and approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 01/2026

## Coding

*The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 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 the Health Plan Medical Policy Coverage Guidelines is with the Health Plan 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 the Health Plan 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 the Health Plan Medical Policy Coverage Guidelines should refer to the most current Procedural Terminology which*

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*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.

**NOTICE:** If the Patient’s health insurance contract contains language that differs from the Health Plan’s 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 Health Plan 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.

### Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: <https://www.cms.gov/medicare-coverage-database/search.aspx>. You may wish to review the Guide to the MCD Search here: <https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx>.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

### InterQual®

InterQual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.