



# Louisiana

## Baroreflex Stimulation Devices

**Policy #** 00315

**Original Effective Date:** 09/14/2011

**Current Effective Date:** 01/11/2021

*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, as 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.

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## **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 (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 – 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 had a recent history of Class III), have a left ventricular ejection fraction  $\leq 35\%$ , a NT-proBNP  $< 1600$  pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines.

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

## **Rationale/Source**

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.

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

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(HDE) for patients who previously participated in a pivotal trial). 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 2 RCTs and a post hoc subgroup analysis of an RCT. Relevant outcomes are overall survival, (OS) functional outcomes, quality of life, 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 the 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 effect of the technology on health outcomes.

## **Supplemental Information**

### **Practice Guidelines and Position Statements**

#### **National Institute for Health and Care Excellence**

In 2015, the National Institute for Health and Care Excellence (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 unpublished trials that might influence this review are listed in Table 1.

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**Table 1. Summary of Key Trials**

<b>NCT No.</b>	<b>Trial Name</b>	<b>NCT No.</b>	<b>Trial Name</b>
<i>Ongoing</i>		<i>Ongoing</i>	
NCT01720160 <sup>a</sup>	Barostim HOPE4HF Study	NCT01720160 <sup>a</sup>	Barostim HOPE4HF Study
NCT02627196 <sup>a</sup>	Barostim Neo <sup>®‡</sup> -Baroreflex Activation Therapy <sup>®‡</sup> for Heart Failure (BeAT-HF)	NCT02627196 <sup>a</sup>	Barostim Neo <sup>®‡</sup> -Baroreflex Activation Therapy <sup>®‡</sup> for Heart Failure (BeAT-HF)
NCT03730519	Investigation of the Efficacy and Safety of Baroreflex Activation Therapy in Patients With Refractory Hypertension and Those With Highly Variable Blood Pressure Due to Peripheral Baroreflex Failure	NCT03730519	Investigation of the Efficacy and Safety of Baroreflex Activation Therapy in Patients With Refractory Hypertension and Those With Highly Variable Blood Pressure Due to Peripheral

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NCT No.	Trial Name	NCT No.	Trial Name
			Baroreflex Failure
NCT01679132 <sup>a</sup>	CVRx Barostim NEO Hypertension Pivotal Trial	NCT01679132 <sup>a</sup>	CVRx Barostim NEO Hypertension Pivotal Trial

NCT: national clinical trial.

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

## References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Baroreflex Stimulation Devices”, 8.01.57, June 2020.
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3. Food and Drug Administration. Premarket Approval (PMA): Barostim Neo System. 16 Aug 2019; <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180050>.
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14. 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>.

## **Policy History**

Original Effective Date: 09/14/2011

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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

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- 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.
- 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.

Next Scheduled Review Date: 12/2021

### **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of*

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*descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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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	No codes
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

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- 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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

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**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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