



MASSACHUSETTS

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## Medical Policy

### Baroreflex Stimulation Devices

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#### Policy Number: 595

BCBSA Reference Number: 8.01.57

NCD/LCD: Local Coverage Determination (LCD): Category III CPT® Codes (L33392) (A56195)

#### Related Policies

- Radiofrequency Ablation of the Renal Sympathetic Nerves as a Treatment for Resistant Hypertension, [#919](#)

#### Policy

##### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Use of baroreflex stimulation implanted devices is **INVESTIGATIONAL** in all situations including but not limited to treatment of hypertension and heart failure.

##### Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

This is not a covered service.

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link below.

[Local Coverage Determinations \(LCDs\) for National Government Services, Inc.](#)

Local Coverage Determination (LCD): Category III CPT® Codes (L33392) (A56195)

**Note:** To review the specific LCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

For medical necessity criteria and coding guidance for **Medicare Advantage members living outside of Massachusetts**, please see the Centers for Medicare and Medicaid Services website at <https://www.cms.gov> for information regarding your specific jurisdiction.

#### Prior Authorization Information

##### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

**Outpatient**

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

|  | <b>Outpatient</b>                     |
|--|---------------------------------------|
| <b>Commercial Managed Care (HMO and POS)</b> | This is <b>not</b> a covered service. |
| <b>Commercial PPO and Indemnity</b>          | This is <b>not</b> a covered service. |
| <b>Medicare HMO Blue<sup>SM</sup></b>        | This is <b>not</b> a covered service. |
| <b>Medicare PPO Blue<sup>SM</sup></b>        | This is <b>not</b> a covered service. |

**CPT Codes / HCPCS Codes / ICD Codes**

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

**The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

**CPT Codes**

| <b>CPT codes:</b> | <b>Code Description</b>  |
|-------------------|--|
| 0266T             | Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)  |
| 0267T             | Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning when performed)   |
| 0268T             | Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning when performed)  |
| 0269T             | Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)  |
| 0270T             | Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning when performed)   |
| 0271T             | Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning when performed)  |
| 0272T             | Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor system diagnostics and programmed therapy values, with interpretation and report (e.g., battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day) |
| 0273T             | Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor system diagnostics and programmed therapy values, with interpretation and report (e.g., battery status, lead impedance, pulse amplitude, pulse width, therapy   |

|  |   |
|--|---|
|  | frequency, pathway mode, burst mode, therapy start/stop times each day); with programming |
|--|---|

## Description

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.

## Summary

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 (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.

## Policy History

| Date   | Action  |
|--------|---|
| 7/2020 | BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged. |
| 6/2019 | BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged. |

|                |   |
|----------------|---|
| 6/2018         | New references added from BCBSA National medical policy. Summary clarified.   |
| 6/2017         | New references added from BCBSA National medical policy.  |
| 2/2016         | BCBSA National medical policy review. Hypertension and heart failure added as examples in investigational policy statement. Effective 2/1/2016. |
| 12/2013        | New references from BCBSA National medical policy.  |
| 11/2011-4/2012 | Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.                                     |
| 1/1/2012       | New policy, effective 1/1/2012, describing ongoing non-coverage.  |

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

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 2, 2020.
2. 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>. Accessed April 13, 2020.
3. Zile MR, Abraham WT, Lindenfeld J, et al. First granted example of novel FDA trial design under Expedited Access Pathway for premarket approval: BeAT-HF. *Am Heart J.* Oct 2018; 204: 139-150. PMID 30118942
4. 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 09 2011; 58(7): 765-73. PMID 21816315
5. 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): 152-8. PMID 22341199
6. 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): 619-26. PMID 20101001
7. 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.* Jul-Aug 2012; 6(4): 270-6. PMID 22694986
8. 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 05 2010; 56(15): 1254-8. PMID 20883933
9. 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): 701-9. PMID 26902491
10. Halbach M, Abraham WT, Butter C, et al. Baroreflex activation therapy for the treatment of heart failure with reduced ejection fraction in patients with and without coronary artery disease. *Int J Cardiol.* Sep 01 2018; 266: 187-192. PMID 29705650
11. 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
12. 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

13. 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 2, 2020.