



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 BlueSM and Medicare PPO BlueSM 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**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO BlueSM	This is not a covered service.
Medicare PPO BlueSM	This is not 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

CPT codes:	Code Description
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
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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 (BP). When these receptors are stretched, as occurs with increases in BP, 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 BP, 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 and can lead to high costs and adverse effects. As a result, there is a large unmet need for additional treatments.

Specific devices for baroreflex stimulation have been developed, but none has been approved by the U.S. Food and Drug Administration (FDA) for any indication. One device, called the Barostim neo™ (CVRx™, Minneapolis, MN, previously called the Rheos® Baroreflex Hypertension Therapy System) is approved for sale in Europe for hypertension and heart failure patients.. The system consists of a unilateral electrode and lead that is attached to the carotid sinus and a pulse generator that is implanted subcutaneously in the chest wall. Programming is performed via radiofrequency telemetry using an external laptop computer and software.

Summary

For individuals who have treatment-resistant hypertension who receive baroreflex stimulation therapy, the evidence includes an RCT and several small uncontrolled studies. Relevant outcomes are overall survival, 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 end points but not others as well as 2 of its 3 predefined safety end points. Additional RCTs are needed to permit conclusions on the efficacy and safety. In addition, baroreflex stimulation currently has a very narrow Food and Drug Administration approval (ie, for patients who previously participated in a pivotal trial) and broader approval or clearance is needed for wider application. 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 an RCT. Relevant outcomes are overall survival, functional outcomes, quality of life, hospitalizations, medication use, and treatment-resistant morbidity. The RCT met all 3 efficacy end points but had methodologic limitations, including lack of blinding, a relatively small sample size for a common condition and a relatively 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. In addition, the only baroreflex stimulation device with humanitarian device exemption approval currently has only a very narrow Food and Drug Administration approval (ie, for patients who previously participated in a pivotal trial) and broader approval or clearance is needed for wider application. The evidence is insufficient to determine the effect of the technology on health outcomes.

Policy History

Date	Action
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 11, 2018.
2. CVRx. CVRx® Announces Expedited Access Pathway Designation by FDA for Barostim Therapy® for the Treatment of Heart Failure in Order to Accelerate Access for US Patients. 2015; <http://www.cvr.com/newsroom/cvr-announces-expedited-access-pathway-designation-by-fda-for-barostim-therapy-for-the-treatment-of-heart-failure-in-order-to-accelerate-access-for-us-patients/>. Accessed April 11, 2018.
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