Medical Coverage Policy | Baroreflex Stimulation Devices

EFFECTIVE DATE: 08|01|2025
POLICY LAST REVIEWED: 04|02|2025

OVERVIEW
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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Use of baroreflex stimulation implanted devices is considered not covered in all situations, including but not limited to treatment of hypertension and heart failure as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Commercial Products
Use of baroreflex stimulation implanted devices is considered not medically necessary in all situations, including but not limited to treatment of hypertension and heart failure as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered surgical benefits/coverage.

BACKGROUND
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.

Regulatory Status
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 pro-B-type natriuretic peptide (NT-proBNP) less than 1600pg/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.

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 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.

CODING

The following CPT and HCPCS codes are considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

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)

0272T Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, 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 device diagnostics and programmed therapy values, with interpretation and report (eg,battery status, lead impedance, pulse

amplitude, pulse width, therapy frequency,pathway mode, burst mode, therapy start/stop times each day); with programming

C1825 Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)

RELATED POLICIES

Removal of Implantable Devices

PUBLISHED

Provider Update, June 2025

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2. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED). 16 Aug 2019; https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180050b.pdf. Accessed March 23, 2023.
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