Medical Coverage Policy | Baroreflex Stimulation Devices

EFFECTIVE DATE: 01|01|2026
POLICY LAST REVIEWED: 09|02|2026

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. The purpose of baroreflex stimulation devices is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as medical therapy in individuals with treatment-resistant heart failure.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Use of baroreflex stimulation therapy with a device approved by the U.S. FDA is considered not covered in all situations, including but not limited to treatment of heart failure despite the use of maximally tolerated guideline-directed medical and device therapy 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 therapy with a device approved by the U.S. FDA is considered not medically necessary in all situations, including but not limited to treatment of heart failure despite the use of maximally tolerated guideline-directed medical and device therapy 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 heart failure. Heart failure is a relatively common condition, and is 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. The Rheos device did not receive FDA approval, and no additional patients will be accrued under the humanitarian device exemption. Barostim is no longer marketed for individuals with treatment-resistant hypertension, and this indication is not presented in this policy.

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 was subsequently replaced by the Breakthrough Devices Program.

In 2023, following the extended phase of the BEAT-HF study, Barostim Neo's indication was updated to patients who are NYHA Class III or Class II (who had a recent history of Class III) despite treatment with guideline-directed medical therapies (medications and devices), have a left ventricular ejection fraction of ≤ 35%, and a NT-proBNP <1600 pg/mL. The product labeling now states that Barostim improves heart failure functional status, six-minute hall walk, and quality of life.

For individuals who have treatment-resistant heart failure who receive baroreflex stimulation therapy, the evidence includes 2 randomized controlled trials (RCTs), a post hoc subgroup analysis of an RCT, a non-randomized controlled trial, and meta-analyses of these trials. Relevant outcomes are overall survival (OS), functional outcomes, quality of life (QoL), 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 met its primary efficacy endpoints of improving QOL, 6 minute hall walking distance (6MHWD), and N-terminal pro-B-type natriuretic peptide (NT-proBNP) levels in the short term. In the extended phase of the trial, no statistically significant benefit for the primary efficacy composite outcome of cardiovascular mortality and heart failure morbidity was observed. The pre-specified safety outcome and secondary outcomes in the extended phase were met. QoL,, New York Heart Association (NYHA) class, and 6MHWD showed a statistically and clinically significant advantage for the baroreflex stimulation plus medical therapy group through up to 2 years post-treatment. 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. The non-randomized study found that baroreflex stimulation was associated with improvements in left ventricular ejection fraction (LVEF), NYHA class, QoL, and NT-proBNP levels relative to guideline-directed medical therapy (GDMT) at 12 months post-intervention. Overall, baroreflex stimulation demonstrates a favorable safety profile and produces modest improvements in functional capacity and Qol; however, it has not shown significant reductions in either heart failure morbidity or mortality compared to guideline-directed medical therapy. Existing trials suffer from methodological limitations, highlighting the need for a rigorously designed sham-controlled study. 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:

64654 Initial open implantation of baroreflex activation therapy (bat) modulation system, including lead placement onto the carotid sinus, lead tunnelling, connection to a pulse generator placed in a distant subcutaneous pocket (ie, total system), and intraoperative interrogation and programming (New Code Effective 1/1/2026)

64655 Revision or replacement of baroreflex activation therapy (bat) modulation system, with intraoperative interrogation and programming; lead only (New Code Effective 1/1/2026)

64656 Revision or replacement of baroreflex activation therapy (bat) modulation system, with intraoperative interrogation and programming; pulse generator only (New Code Effective 1/1/2026)

93145 Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (bat) modulation 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); without programming (New Code Effective 1/1/2026)

93146 Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (bat) modulation 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, including optimization of tolerated therapeutic level setting (New Code Effective 1/1/2026)

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 (Code Deleted Effective 12/31/2025)

0267T Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed) (Code Deleted Effective 12/31/2025)

0268T Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed) (Code Deleted Effective 12/31/2025)

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) (Code Deleted Effective 12/31/2025)

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 (Code Deleted Effective 12/31/2025)

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

RELATED POLICIES

Removal of Implantable Devices

PUBLISHED

Provider Update, November 2026
Provider Update, June/November 2025

REFERENCES

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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 July 7, 2026.
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