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Subject: Baroreflex Stimulation Devices

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Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

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, 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.

Baroreflex stimulation devices (e.g., Barostim™ System) 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 Barostim neo® Legacy System was approved through a humanitarian device exemption (HDE) in 2014 for use in individuals with resistant hypertension who have had bilateral implantation of the Rheos® Carotid Sinus Leads.

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 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 and Analysis of Evidence: Coats et al (2022) conducted a patient-level meta-analysis (N=554) comparing patients who received baroreceptor activation therapy in addition to guideline-directed medical therapy or guideline-directed medical therapy alone. Patients included in the analysis were enrolled in 1 of 2 RCTs (HOPE4HF and Barostim Neo Baroreflex Activation Therapy for Heart Failure [BeAT-HF]. The studies were conducted between 2012 and 2018 in North American and European countries and enrolled patients with a left ventricular ejection fraction (LVEF) less than or equal to 35%. More than 80% of patients were male and all had NYHA Class III heart failure (or Class II with a recent history of Class III). Similar to the results of the individual trials, at 6 months, patients treated with baroreceptor activation therapy had improved 6-minute hall walk distance (48.5 meters; 95% confidence interval [CI], 32.7 to 64.2). More patients had improvements in NYHA in the baroreceptor activation therapy group with a 3.4 higher odds of improving at least 1 NYHA class compared to medical therapy alone. Quality of life as measured by the Minnesota Living with Heart Failure Questionnaire (MLHFQ) was also improved with the addition of baroreceptor activation therapy (-13.4 points; 95% CI, -17.1 to -9.6). This analysis is limited by the small number of RCTs and the open-label design of these trials.

Cai et al (2020) published a meta-analysis evaluating the efficacy of baroreflex activation therapy for heart failure. The meta-analysis included 4 RCTs and concluded that baroreflex activation therapy significantly improves quality of life score, 6-minute hall walk distance, New York Heart Association (NYHA) class, N terminal pro-B-type natriuretic peptide (NT-proBNP), and duration of hospitalization compared to control. However, the 4 RCTs included in the analysis all represented the same patient population from the Hope for Heart Failure (HOPE4HF) study, and did not account for the overlapping population between studies. Therefore, this meta-analysis likely overestimated the true effect of baroreflex activation therapy.

Halbach et al (2018) published a post hoc subgroup analysis from HOPE4HF evaluating baroreflex activation treatment for heart failure in patients with and without coronary artery disease (CAD). Patients (N=146) from 45 centers with LVEF less than 35% and NYHA Class III were randomized to the baroreflex activation treatment group (n=76) or control group (n=70). The rate of system- or procedure-related major adverse neurological or cardiovascular events was 3.8% for the CAD group and 0% for the no-CAD group (p>.99), while the system- or procedure-related complication rate was 11.5% for patients with CAD and 21.1% for those without CAD (p=.44). In the baroreflex activation group, from baseline to 6 months, quality of life scores decreased by 16.8 ± 3.4 points for CAD patients and by 18.9 ± 5.3 for no-CAD patients; NYHA classification decreased by 0.6 ± 0.1 for CAD patients and by 0.4 ± 0.2 for no-CAD patients. Left ventricular ejection fraction increased by 1.2 ± 1.4 for the CAD group and 5.2 ± 1.9 for the no-CAD group. No interaction was found between the presence of CAD and effect of baroreflex activation therapy (p>.05). The study was limited by its small sample size and by the subgroup analysis not being prespecified.

Guckel et al (2023) conducted a single-center prospective study evaluating BAT in 40 consecutive heart failure with reduced ejection fraction patients (mean age, 71 years; 20% female) with an indication for BAT. The study aimed to analyze patients' acceptance of BAT and outcomes compared to patients treated with guideline-directed medical therapy (GDMT), as well as the effects of angiotensin-receptor neprilysin inhibitors (ARNIs) on BAT response. Ten patients (25%) opted for BAT implantation, and the remaining 30 patients served as the control group. At 12 months follow-up BAT patients showed significant improvements in LVEF (+10% vs. +3%; p=.005), NYHA class ≥ 3 (88% improvement vs. -9%; p=.014), QoL on the EQ-5D-5L (+21% vs 0%; p=.020), NT-proBNP levels (-24% vs 35%; p=.044) and lower heart failure hospitalization rates compared to the control group (50% vs. 83%, p=.020). A subgroup analysis of these outcomes showed that patients who were treated with ARNIs in addition to BAT had greater effects than ARNIs alone. Major limitations of the trial include an absence of power calculations, a small sample size, and imbalances in patient characteristics.

Zile et al (2024) published the long-term results for the BeAT-HF trial. Involving the 264 participants from the pre-market phase and an additional randomized 59 participants, follow-up was a median of 3.6 years. Primary endpoint was a composite of the rate of cardiovascular mortality and heart failure morbidity. Additional endpoints included safety assessed by major adverse neurological and cardiovascular events (MANCE), improved symptom status assessed by MLWHFQ, New York Heart Association (NYHA) class, and 6-min hall walk distance. For the primary endpoint, there were no significant differences between BAT and control groups. In terms of safety, MANCE occurred in five participants within 30 days of implantation of baroreflex activation therapy. In terms of QOL, the estimated between group differences were −13.5 at 12 months, and −10.0 at 24 months. The change in exercise capacity between-group differences was 55.5 at 6 months and 43.5 at 12 months. The extent to which baroreflex activation therapy improved the 6-min hall walk distance, the QOL scores, and the NYHA class compared to control was similar at each time point. While long-term safety measures and symptomatic improvement favored the BAT group, there was no significant differences in cardiovascular mortality and heart failure morbidity.

A guideline for the management of heart failure by the American College of Cardiology and American Heart Association Joint Committee on Clinical Practice (Heidenreich et al, 2022) states, “(a)utonomic nervous system modulation is intriguing as a treatment for HFrEF because of the heightened sympathetic response and decreased parasympathetic response in HF. Trials of device stimulation of the vagus nerve, spinal cord, and baroreceptors have had mixed responses. In a prospective, multicenter, RCT with a total of 408 patients with current or recent NYHA class III HF, LVEF ≤35%, baroreceptor stimulation was associated with improvements in QOL, exercise capacity, and NT-proBNP levels. To date, there are no mortality or hospitalization rates results available with this device.”

UpToDate review “Investigational therapies for management of heart failure” (Colucci, 2025) states, “(i)n patients with <heart failure> (HF), the decrease in parasympathetic nervous system (PNS) activity may contribute to the pathophysiology of HF. One mechanism for increasing PNS activity is by vagus nerve stimulation, which activates the baroreflex, and is referred to as "baroreflex activation therapy" (BAT). Implantation of a baroreflex activation device is approved by the FDA, but there are no data to suggest that mortality or rehospitalization rates improve with such therapy. Clinical trials of BAT have shown improvements in exercise (six-minute walk distance) and quality of life (Minnesota Living with Heart Failure Questionnaire) but not mortality or hospitalization. BeAT-HF (Baroreflex Activation Therapy for Heart Failure) randomized 408 patients with current or recent NYHA class III, ejection fraction ≤35 percent, and N-terminal pro-B-type natriuretic peptide (NT-proBNP) <1600 pg/mL. BAT had a low rate of complications and significant improvements in exercise (six-minute walk distance), quality of life, and NT-proBNP levels. This trial led to FDA approval for patients with HF who met the entry criteria for BeAT-HF. An extension of this trial showed no significant effect on cardiovascular mortality or HF morbidity, and a meta-analysis reported similar findings. Another trial, ANTHEM-HFrEF, was prematurely discontinued after enrollment of 532 patients with HFrEF.”

POSITION STATEMENT:

Baroreflex stimulation therapy (baroreflex activation therapy (e.g., Barostim™ System) is considered **experimental or investigational** for all indications, including, but not limited to individuals with heart failure despite the use of maximally tolerated guideline-directed medical and device therapy. Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

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 **(Investigational)**
64655	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; lead only **(Investigational)**
64656	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; pulse generator only **(Investigational)**
64657	Removal of baroreflex activation therapy (BAT) modulation system; total system, including lead and pulse generator **(Investigational)**
64658	Removal of baroreflex activation therapy (BAT) modulation system; lead only **(Investigational)**
64659	Removal of baroreflex activation therapy (BAT) modulation system; pulse generator only **(Investigational)**
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 **(Investigational)**

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 **(Investigational)**

HCPCS Coding:

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

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

None applicable.

OTHER:

None applicable.

REFERENCES:

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 12/04/25.

GUIDELINE UPDATE INFORMATION:

01/01/26	New Medical Coverage Guideline.