Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 3/1/25**
(See policy history boxes for previous effective dates)

Title: Baroreflex Stimulation Devices

Description/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 (BP). When these receptors are stretched, which 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, expensive and can lead adverse effects. 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 (FDA) 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.(1)

In 2019, Barostim Neo™ was granted premarket approval (PMA P180050) and is indicated for the improvement of symptoms of heart failure (i.e., quality of life, six-minute hall walk, and

functional status) for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are NYHA Class III or Class II (with a recent history of Class III), and have a left ventricular ejection fraction ≤ 35% and a N-terminal pro-B-type natriuretic peptide (NT-proBNP) < 1600 pg/ml, excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines.

It was the first device to be granted approval via the Expedited Access Pathway (EAP).(2,3) The EAP was a mechanism used to hasten the approval of novel therapies that target life-threatening conditions. The Expedited Access Pathway was subsequently replaced by the Breakthrough Devices Program.

Medical Policy Statement

Use of baroreflex stimulation implanted devices are experimental/investigational in all situations, including but not limited to the treatment of hypertension and heart failure. Further studies are needed to evaluate the long-term effects of these devices.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0266T	0267T	0268T	0269T	0270T	0271T
0272T	0273T	C1825			

Rationale

TREATMENT RESISTANT HYPERTENSION

Randomized Controlled Trials

RCTs are important in determining the efficacy of baroreflex stimulation devices due to the natural variability in blood pressure (BP), the heterogeneity of the patient populations with high BP, and the presence of many potential outcome confounders. Case series have limited utility for determining efficacy. They can be useful for demonstrating the potential of the technique, to determine the rate of short and long-term adverse events of treatment, and to evaluate the durability of treatment response.

The Rheos® pivotal RCT evaluated the efficacy of baroreflex stimulation for lowering blood pressure.(4) Bisognano et al (2011), reported on this double-bind trial, which included patients with treatment-resistant hypertension defined as at least one systolic blood pressure (SBP) measurement of 160 mm Hg or more with diastolic BP (DBP) measurement of 80 mm Hg or more after at least one month of maximally tolerated medical therapy. A total of 322 patients had the Rheos® system implanted, and 265 patients underwent randomization. Participants were randomized in a 2:1 fashion to the device turned on or off for a 6-month period. After 6 months, all patients had the device turned on. The primary efficacy end points were the percent of patients achieving at least 10 mm Hg decrease in SBP at the 6 months (acute efficacy) and the percent of patients who maintained their BP response over the 6 to 12-month study period (sustained efficacy). Primary safety outcomes were defined thresholds for procedural safety (at least 82% of patients free from procedural adverse events at 30 days), therapy safety (not more than 15% excess treatment-related adverse events in experimental group), and device safety (at least 72% of patients free from procedural or therapy-related adverse events at 12 months). At baseline, mean age was about 53 years, 70% to 81% of patients were White, and 17% to 21% of patients were Black.

At 6 months, 54% of patients in the stimulation group had an SBP decrease of 10 mm Hg or more, compared with 46% of patients in the control group (p=0.97), indicating that the primary acute efficacy outcome was not met. The primary sustained efficacy outcome was met, with 88% of patients who responded at six months maintaining a response at 12 months. A secondary efficacy outcome (the percent of patients reaching target SBP) showed a significant between-group difference. A total of 42% of the patients in the active treatment group reached a target SBP of 140 mm Hg, compared with 24% in the control group (p=0.005). For the primary procedural safety end point, the predefined threshold of 82% was not met. At 30 days, the percent of patients free of procedural adverse events was 74.8%. The primary safety end point of therapy safety was met, with a similar percent of patients free of treatment-related adverse effects at 6 months (91.7% vs 89.3%, p<0.001 for non-inferiority). The primary safety end point of device safety was also met, with 87.2% of patients free of device-related adverse events at 12 months, exceeding the predefined threshold of 72%.

Bakris et al (2012) reported on additional data in an extension of the Rheos trial.(5) A total of 276 (86%) of the 322 implanted patients consented to long-term open-label follow-up. After a mean follow-up of 28 months, 244 (88%) of 276 were considered to be clinically significant responders. Response was defined as sustained achievement of the target SBP (≤140 mm Hg, or ≤130 mm Hg for patients with diabetes or renal disease), or a reduction in SBP of 20 mm Hg or more from device activation. Alternatively, patients could qualify as a responder if their implanted device was deactivated and if they had an increase in SBP of at least 20 mm Hg in the 30 days after device deactivation. The extension study lacked a comparison group.

Observational Studies

Several uncontrolled observational studies have also been published.(6-9) Scheffers et al (2010) reported on the largest of these, the Device Based Therapy in Hypertension Extension Trial (DEBut-HT), which was a multicenter, single-arm feasibility study of the Rheos® baroreflex activation therapy system.(8) This trial enrolled 45 patients with treatment-resistant hypertension defined as a BP of greater than 160/90 mm Hg, despite treatment with at least three antihypertensive drugs, including a diuretic. The planned follow-up was 3 months, with a smaller number of patients followed up to 2 years. In 37 patients completing the 3-month

protocol, office SBP was reduced by 21 mm Hg (p<0.001) and DBP was reduced by 12 mm Hg (p<0.001). There was a smaller reduction in 24-hour ambulatory BP (n=26), with a decrease of 6 mm Hg in SBP (p=0.10) and a decrease of 4 mm Hg in DBP (p=0.04). In 26 patients followed for 1 year, the declines in office BP were 30 mm Hg systolic (p<0.001) and 20 mm Hg diastolic (p<0.001). For ambulatory BP (n=15), the 1-year declines were 13 mm Hg systolic (p<0.001) and 8 mm Hg diastolic (p=0.001). A total of 7 (16.7%) of 42 patients experienced adverse events. Three patients required device removal due to infection, 1 experienced perioperative stroke, 1 experienced tongue paresis due to hypoglossal nerve injury, 1 had postoperative pulmonary edema; and 1 required reintervention for device explantation.

Wallbach et al (2016) published a single arm study using the second-generation Neo device to treat uncontrolled hypertension.(9) The study reported on 44 patients with resistant, hypertension, defined as an office BP ≥ 140 mm Hg or ≥ 130 mm Hg in patients with chronic kidney disease and proteinuria, despite treatment with at least 3 antihypertensive medications including a diuretic. Mean baseline office BP was 171/91 mm Hg. After 6 months of baroreflex activation therapy, mean office BP decreased to 151 mm Hg over 82 mm Hg (pre to post, p<0.001). At 6 months, the mean number of BP medications used per patient decreased from 6.5 at baseline to 6.0 (p<0.03). One procedure-related major adverse event occurred, a contralateral stroke. Ten (23%) of the 44 patients experienced a minor procedure-related complication. The most common minor adverse events were disturbance of wound healing (n=5 [11%]) and postoperative hematoma (n=4 [9%]). One patient had revision surgery but explantation was not needed.

Section Summary: Treatment Resistant Hypertension
One RCT has evaluated baroreflex stimulation devices. This trial, which compared the first-generation Rheos device plus medical management to medical management alone, met some but not all of its efficacy end points. Baroreflex stimulation-treated patients were no more likely to achieve at least a 10 mm Hg decrease in SBP at 6 months but were more likely to reach the target SBP of 140 mm Hg or less at six months. The trial met two of its three predefined safety end points (therapy safety and device safety but not procedural safety). In addition, several uncontrolled studies have reported short-term reductions in blood pressure, and in adverse events such as infection, hypoglossal nerve injury, and wound complications. Additional RCTs - particularly those using the second-generation device, are needed to draw conclusions about safety and efficacy.

TREATMENT-RESISTANT HEART FAILURE

Systemic Reviews
In 2020, Cai et al published a meta-analysis evaluating the efficacy of baroreflex activation therapy for heart failure.(10) 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 (NCT01471860 and NCT01720160) and did not account for the overlapping population between studies. Therefore, this meta-analysis likely overestimated the true effect of baroreflex activation therapy. The HOPE4HF RCT and post hoc/subgroup analyses are summarized below.

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.(11) Patients included in the analysis were enrolled in 1 of 2 RCTs (HOPE4HF and Barostim Neo-Baroreflex Activation Therapy for Heart Failure [BeAT-HF; both described below]). 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.

Randomized Controlled Trials

In 2019, the Barostim Neo System was the first device to receive premarket approval through the U.S. Food and Drug Administration's (FDA's) Expedited Access Pathway (see Regulatory section).(2) The safety and effectiveness data reviewed by the FDA was reported in the Barostim Neo-Baroreflex Activation Therapy for Heart Failure (BeAT-HF) trial.(3,12)

BeAT-HF examined the safety and effectiveness of baroreflex activation therapy (BAT) in patients with heart failure with reduced ejection fraction using an Expedited and Extended Phase design. In the Expedited Phase, BAT plus guideline-directed medical therapy (GDMT) was compared at 6 months post-implant to GDMT alone using 3 intermediate endpoints: 6-minute hall walk distance, Minnesota Living with Heart Failure Questionnaire, and N-terminal pro-B-type natriuretic peptide.(12) The rate of heart failure morbidity and cardiovascular mortality was compared between the arms to evaluate early trending using predictive probability modeling.

In the Expedited Phase, investigators randomized 264 intended use patients (White, 73%; Black, 17%; Asian, 1.9%).(12) The primary safety endpoint was major adverse neurological and cardiovascular event free rate, which was only measured in the baroreflex group; the lower bound of the one-sided 95% confidence interval (CI) of the event-free rate had to be > 85%. Results analysts were blinded to arm assignment. At 6 months, the event-free rate was 96.8% (121 of 125 patients), and the one-sided 95% CI lower bound was 92.8% ($p<0.001$).Effective endpoint results are summarized in Table 1. The FDA concluded from these results that the system was safe for the intended use population, and all effectiveness endpoints showed a statistically significant for baroreflex activation therapy plus guideline-directed medical therapy compared to guideline-directed medical therapy alone.

Table 1. 6-Month Change from Baseline for Effectiveness Endpoints in the BeAT-HF Expedited Phase Trial

	6MHWD		QOL[a]		NT-proBNP	
	BAT + GDMT	***GDMT***	***BAT + GDMT***	***GDMT***	***BAT + GDMT***	***GDMT***
N	118	120	120	125	120	123
Mean (SD)	48.6 (66.3)	-7.9 (88.4)	-20.7 (25.4)	-6.2 (20.1)	-21.1% (0.4)	3.3% (0.3)

95% CI	36.5 to 60.7	-23.9 to 8.1	-25.3 to -16.1	-9.8 to -2.7	-32.3% to -8.2%	-8.9% to 17.2%
Difference	60.1		-14.1		-24.6%	
95% CI	40.3 to 79.9		-19.2 to -8.9		-37.6% to -8.7%	
P-value	<.001		<.001		.004	

6MHWD: 6-minute hall walk distance; BAT: Barostim therapy; BeAT-HF: Barostim Neo-Baroreflex Activation Therapy for Heart Failure; CI: confidence interval; GDMT: guideline directed medical therapy; NT-proBNP: N-terminal pro-B-type natriuretic peptide; QOL: quality of life; SD: standard deviation.

[a] Measured by the Minnesota Living With Heart Failure Quality of Life questionnaire.

BeAT-HF includes an Extended Phase in which the heart failure morbidity and cardiovascular mortality end point is based on an expected event rate of 0.4 events/patient/year in the guideline-directed medical therapy arm. This trial has preliminary results but is not yet fully published.(13)

Abraham et al (2015) reported on the HOPE4HF RCT, that evaluated baroreflex stimulation for treatment of heart failure. This trial was non-blinded and included 146 patients (White, 81.7% and 89.9% in treatment and control groups, respectively) with NYHA class III heart failure and an ejection fraction of ≤ 35% despite guideline-directed medical therapy.(14) Patients were randomized to receive baroreflex stimulation (Barostim Neo system) plus medical therapy (n=76) or to continued medical therapy alone (n=70) for 6 months. The primary safety outcome was the proportion of patients free from major adverse neurological and cardiovascular events. The trialists specified 3 primary efficacy end points: changes in NYHA functional class, quality of life-score, and 6-minute walk distance.

The overall major adverse neurologic and cardiovascular events - free rate was 97.2%; rates were not reported separately for the baroreflex stimulation and control groups.(14) In terms of the efficacy outcomes, there was significant improvement in the baroreflex stimulation group versus the control group on each of the three outcomes. Significantly more patients in the treatment group (55%) had improvement of at least one level in NYHA functional class than in the control group (24%; p<0.002). Mean quality of life scores, as assessed by the Minnesota Living with Heart Failure Questionnaire, improved significantly more in the treatment group (-17.4 points) than in the control group (2.1 points; p<0.001). Similarly, 6MWD improved significantly more in the treatment group (59.6 meters) than in the control group (1.5 meters, p=0.004).

Weaver et al (2016) reported 12-month results for 101 (69%) of 146 patients from this RCT.(15) No additional system- or procedure-related major adverse neurologic and cardiovascular events occurred between 6 and 12 months. Moreover, outcomes for NYHA functional class improvement, QOL score, and 6-minute walk distance were all significantly better in the treatment group than in the control group at 12 months. This analysis had a substantial amount of missing data.

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).(16) Patients (N = 146) from 45 centers with left ventricular ejection fraction < 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 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 Class 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.

Overall, the limitations of this RCT included a relatively small sample size for a common condition, relatively short intervention period, and lack of blinding; some of the positive findings on the subjective patient-reported outcomes may be due, at least in part, to a placebo effect. Additional RCTs with larger sample sizes and longer follow-up are needed to confirm these positive findings.

Section Summary: Treatment Resistant Heart Failure
The available evidence for baroreflex activation therapy for heart failure includes 2 RCTs, a post hoc subgroup analysis of an RCT and meta-analyses of these RCTs. Both RCTs compared baroreflex stimulation plus medical therapy with medical therapy alone in patients with heart failure. The expedited trial that was used by the FDA to approve the Barostim Neo System, demonstrated that the system is safe and effective for its intended use population; however, longer-term outcomes have not yet been determined. A 2018 RCT found a low rate of major adverse events and met all three efficacy end points (improvements in NYHA functional class, QOL, and 6-minute walk distance). However, the study had methodologic limitations, including lack of blinding, a relatively small sample size for a common condition, and relatively short intervention period.

SUMMARY OF EVIDENCE
For individuals who have treatment-resistant hypertension who receive baroreflex stimulation therapy, the evidence includes a 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 two of its three predefined safety end points. 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-analysis of these trials. Relevant outcomes are overall survival, 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 results of the extended trial are not published, and longer-term outcomes have not been determined. A 2018 RCT met all three 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.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Ongoing and Unpublished Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01679132[a]	CVRx Barostim Hypertension Pivotal Trial	10	Mar 2026 (suspended - Company resources only allows adequate oversight for one pivotal trial at a time) last update posted Dec 2021
NCT04502316[a]	BAROSTIM THERAPY™ in Heart Failure With Reduced Ejection Fraction: A Post-Market Registry With the Barostim™ System	5000	Jun 2028
NCT02876042[a]	BAROSTIM THERAPY ™ in Heart Failure With Preserved Ejection Fraction: A Post-Market Registry With the CE-Marked BAROSTIM NEO™ System	70	Jul 2024
NCT02880618[a]	BAROSTIM THERAPY™ in Heart Failure With Reduced Ejection Fraction: A Post-Market Registry With the CE-Marked BAROSTIM NEO™ System	500	Jul 2024
NCT02880631[a]	BAROSTIM THERAPY™ In Resistant Hypertension: A Post-Market Registry With the CE-Marked BAROSTIM NEO™ System	500	Jul 2024
NCT01471834[a]	Neo Non-Randomized Hypertension Study	40	Aug 2026

NCT: national clinical trial.
[a]Denotes industry-sponsored or cosponsored trial

Supplemental Information

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Heart Association

In 2017, the American Heart Association issued a joint guideline for the management of high blood pressure in adults with the American College of Cardiology and multiple other organizations.(17) This guideline notes that studies have not provided sufficient evidence to support the use of baroreceptor pacing for managing resistant hypertension.

In 2022, the American Heart Association, American College of Cardiology, and multiple other organizations published a guideline on management of heart failure.(18) The guideline states that baroreceptor stimulation has produced mixed results and data regarding mortality and hospitalization are lacking.

National Institute for Health and Care Excellence
National Institute for Health and Care Excellence (2015) issued guidance that stated: “Current evidence on the safety and efficacy of implanting a baroreceptor stimulation device for resistant hypertension is inadequate. Therefore, this procedure should only be used in the context of research.”(19)

European Society of Cardiology Guidelines
The European Society of Cardiology (2016) Guidelines on the Diagnosis and Treatment of Acute and Chronic Heart Failure notes that the evidence is insufficient to support specific guideline recommendations for baroreflex activation therapy as a device treatment for HF with reduced ejection fraction.(20)

The 2023 Focused Update of the ESC guidelines for the diagnosis and treatment of acute and chronic heart failure does not include recommendations on the use of the Barostim neo System for the treatment of HF.(21)

The American College of Cardiology/American Heart Association/Heart Failure Society of America
The American College of Cardiology/American Heart Association/Heart Failure Society of America (2022) Guideline for the Management of Heart Failure does not include recommendations on the use of the Barostim neo System for the treatment of HF.(22)

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS
Not applicable.

Government Regulations
National/ Local:
There is no national or local coverage determination for this technology.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 9/26/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/11	4/19/11	5/3/11	Joint policy established
9/1/12	6/12/12	6/19/12	Routine review; title changed from "Implantable Carotid Sinus Baroreflex Devices" to "Baroreflex Stimulation Devices".
1/1/14	10/17/13	10/25/13	Routine maintenance
3/1/15	12/12/14	12/29/14	Routine maintenance
3/1/16	12/10/15	12/10/15	Routine maintenance
3/1/17	12/13/16	12/13/16	Routine maintenance
3/1/18	12/12/17	12/12/17	Routine maintenance
3/1/19	12/11/18		Routine maintenance
3/1/20	12/17/19		Routine maintenance
3/1/21	12/15/20		Routine maintenance
3/1/22	12/14/21		Routine maintenance C1825 added as EI
3/1/23	12/20/22		Routine maintenance (slp)
3/1/24	12/19/23		Routine maintenance (slp) Vendor managed: N/A
3/1/25	12/17/24		Routine maintenance (slp) Vendor managed: N/A

Next Review Date: 4th Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: BAROREFLEX STIMULATION DEVICES

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.