BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Baroreflex Stimulation Devices

Policy #: 480
Category: Surgical

Latest Review Date: May 2021
Policy Grade: B

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after March 24, 2020:
Blue Advantage will treat **the use of baroreflex stimulation implanted devices** as a **non-covered benefit** and as **investigational** in all situations.

Effective for dates of service February 26, 2018, through March 23, 2020, refer to LCD L34555

Effective for dates of service prior to February 26, 2018:
Blue Advantage will treat the **use of baroreflex stimulation implanted devices** as a **non-covered benefit** and as **investigational**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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.

KEY POINTS:

This policy is updated regularly with searches of the MEDLINE database. The most recent update reviews the literature through March 30, 2021.

Summary of Evidence:

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 the efficacy and safety. In addition Baroreflex stimulation for treatment-resistant hypertension is accessible only through a Humanitarian Device Exemption (HDE) 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 and a post hoc subgroup analysis of an RCT. Relevant outcomes are overall survival, (OS) functional outcomes, quality of life, hospitalizations, medication use, and treatment-resistant morbidity. The expedited phase of the 2019 RCT was used by the FDA 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 the extended trial is still underway, 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. A second, larger, RCT designed to assess the effects of the intervention on mortality, safety, functional, 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.

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. This guideline notes that studies have not provided sufficient evidence to support the use of baroreceptor pacing for managing resistant hypertension.

National Institute for Health and Care Excellence

In 2015, the National Institute for Health and Care Excellence (NICE) 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.”

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Baroreflex activation therapy®, BAT®, Rheos® Hypertension system, baroreflex stimulation, carotid baroreflex stimulation, Rheos® BAT system, Barostim Therapy®, Barostim neo® Legacy System

APPROVED BY GOVERNING BODIES:
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.

In 2019, Barostim Neo™ was granted premarket approval (PMA P180050) and is indicated for the improvement of symptoms of heart failure – 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), have a left ventricular ejection fraction ≤ 35%, a NT-proBNP < 1600 pg/ml excluding patients indicated for Cardiac Resynchronization Therapy (CRT) 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. Expedited Access Pathway will hasten the approval of novel therapies that target life-threatening conditions.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT Codes:

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	; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning when performed)

0268T	; 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	; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning when performed)
0271T	; 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 diagnostic 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	; with programming

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POLICY HISTORY:

Adopted for Blue Advantage, August 2011
Available for comment September 22 through November 7, 2011
Medical Policy Group, August 2012
Medical Policy Group, August 2013
Medical Policy Group, August 2014
Medical Policy Group, March 2015
Medical Policy Group, September 2015
Medical Policy Group, June 2017
Medical Policy Group, February 2018
Medical Policy Group, April 2020: Reinstated policy effective March 24, 2020.
Medical Policy Group, May 2020
Medical Policy Group, May 2021
