

Policy: MP368

Section: Medical Policy

Subject: Carotid Sinus Baroreflex Device

Applicable Lines of Business

Commercial	x	CHIP	x
Medicare	x	ACA	x
Medicaid	x		

I. Policy: Carotid Sinus Baroreflex Device

II. Purpose/Objective:

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking

into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

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.

The use of baroreflex stimulation devices (also known as baroreflex activation therapy [BAT]) is a potential alternative treatment for resistant hypertension and heart failure.

EXCLUSIONS:

The Plan does **NOT** provide coverage for Carotid Sinus Baroreflex Device because they are considered **unproven** and therefore **not medically necessary**. Although the devices are FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these treatments on health outcomes when compared to established treatments or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH:

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 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)
- 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 Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)
- 0271T Revision or removal 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

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Geisinger Health Plan Technology Assessment Committee. Dec 2023 Carotid Sinus Baroreflex Device

Zile MR, Abraham WT, Lindenfeld J, et al. First granted example of novel FDA trial design under Expedited Access Pathway for premarket approval: BeAT-HF. *Am Heart J.* Oct 2018; 204: 139-150.

Bisognano JD, Bakris G, Nadim MK, et al. Baroreflex activation therapy lowers blood pressure in patients with resistant hypertension: results from the double-blind, randomized, placebo controlled rheos pivotal trial. *J Am Coll Cardiol.* Aug 09, 2011; 58(7): 765-73.

Bakris GL, Nadim MK, Haller H, et al. Baroreflex activation therapy provides durable benefit in patients with resistant hypertension: results of long-term follow-up in the Rheos Pivotal Trial. *J Am Soc Hypertens.* Mar-Apr 2012; 6(2): 152-8.

Hoppe UC, Brandt MC, Wachter R, et al. Minimally invasive system for baroreflex activation therapy chronically lowers blood pressure with pacemaker-like safety profile: results from the Barostim neo trial. *J Am Soc Hypertens.* Jul-Aug 2012; 6(4): 270-6.

Scheffers IJ, Kroon AA, Schmidli J, et al. Novel baroreflex activation therapy in resistant hypertension: results of a European multi-center feasibility study. *J Am Coll Cardiol.* Oct 05, 2010; 56(15): 1254-8.

Wallbach M, Lehnig LY, Schroer C, et al. Effects of Baroreflex Activation Therapy on Ambulatory Blood Pressure in Patients with Resistant Hypertension. *Hypertension.* Apr 2016; 67(4): 701-9.

Cai G, Guo K, Zhang D, et al. The efficacy of baroreflex activation therapy for heart failure: A meta-analysis of randomized controlled trials. *Medicine (Baltimore).* Nov 06, 2020; 99(45): e22951.

Zile MR, Lindenfeld J, Weaver FA, et al. Baroreflex Activation Therapy in Patients with Heart Failure With Reduced Ejection Fraction. *J Am Coll Cardiol.* Jul 07, 2020; 76(1): 1-13.

Abraham WT, Zile MR, Weaver FA, et al. Baroreflex Activation Therapy for the Treatment of Heart Failure with a Reduced Ejection Fraction. *JACC Heart Fail.* Jun 2015; 3(6): 487-496.

Weaver FA, Abraham WT, Little WC, et al. Surgical Experience and Long-term Results of Baroreflex Activation Therapy for Heart Failure with Reduced Ejection Fraction. *Semin Thorac Cardiovasc Surg.* Summer 2016; 28(2): 320-328. PMID 28043438

Halbach M, Abraham WT, Butter C, et al. Baroreflex activation therapy for the treatment of heart failure with reduced ejection fraction in patients with and without coronary artery disease. *Int J Cardiol.* Sep 01, 2018; 266: 187-192.

Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Hypertension.* Jun 2018; 71(6): e13-e115.

2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *JACC.* Published online April 1, 2022. <https://doi.org/10.1016/j.jacc.2021.12.012>

National Institute for Clinical and Care Excellence (NICE). Implanting a baroreceptor stimulation device for resistant hypertension [IPG533]. 2015; <https://www.nice.org.uk/guidance/ipg533>

Coats AJS, Abraham WT, Zile MR, et al. Baroreflex activation therapy with the Barostim™ device in patients with heart failure with reduced ejection fraction: a patient level meta-analysis of randomized controlled trials. *Eur J Heart Fail.* Sep 2022; 24(9): 1665-1673.

Chunbin W, Fu S, Jing H. Efficacy and safety of baroreflex activation therapy for treatment of resistant hypertension: a systematic review and meta-analysis. *Clin Exp Hypertens.* 2018; 40(6):501-508

Wallbach M, Koziolok MJ. Baroreceptors in the carotid and hypertension-systematic review and meta-analysis of the effects of baroreflex activation therapy on blood pressure. *Nephrol Dial Transplant*. 2018; 33(9):1485-1493

Wallbach M, Born E, Kämpfer D, et al. Long-term effects of baroreflex activation therapy: 2-year follow-up data of the BAT Neo system. *Clin Res Cardiol*. 2020; 109(4):513-522.

de Leeuw PW, Bisognano JD, Bakris GL, et al. Sustained reduction of blood pressure with baroreceptor activation therapy: results of the 6-year open follow-up. *Hypertension*. 2017; 69(5):836-843.

McDonagh TA, Metra M, Adamo M, et al. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart J*. 2021; 42(36):3599-3726.

Wallbach M, Born E, Schafer A-K, Koziolok MJ. Effect of baroreflex activation therapy on dipping pattern in patients with resistant hypertension. *J Clin Hypertens (Greenwich)*. 2023;25(1):22-29.

Schmidt R, Rodrigues CG, Schmidt KH, Irigoyen MCC. Safety and efficacy of baroreflex activation therapy for heart failure with reduced ejection fraction: A rapid systematic review. *ESC Heart Fail*. 2020;7(1):3-14.

Ahmed M, Nudy M, Bussa R, et al. Non-pharmacologic autonomic neuromodulation for treatment of heart failure: A systematic review and meta-analysis of randomized controlled trials. *Trends Cardiovasc Med*. 2022 Oct 4

This policy will be revised as necessary and reviewed no less than annually.

Devised: 01/24

Revised:

Reviewed:

CMS UM Oversight Committee Approval:

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.