Cohere Medical Policy - Carotid Sinus Stimulators

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: December 19, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Carotid Sinus Stimulators

Date of last literature review: 12/18/2024
Document last updated: 12/18/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

Table of Contents

Medical Necessity Criteria

Service: Carotid Sinus Stimulators

Recommended Clinical Approach

This service is clinically unproven and not medically necessary. This policy addresses carotid sinus nerve stimulators for hypertension and heart failure only; however, there may be indications in other specialties where this treatment is considered medically necessary and supported by the medical literature.

Medical Necessity Criteria

Indications

- **Carotid sinus stimulators** are considered appropriate if **ANY** of the following is **TRUE**:
  - This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

- **Carotid sinus stimulators** are not considered appropriate if **ANY/ALL** of the following is **TRUE**:
  - This is not applicable, as there are no indications.

Level of Care Criteria

None

Procedure Codes (HCPCS/CPT)

HCPCS/CPT Code	Code Description
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 (e.g., 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 (e.g., battery status, lead impedance,

	pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming
C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)

Medical Evidence

Autonomic nervous system modulation has been developed to diminish excessive sympathetic response that characterizes disease conditions such as uncontrolled hypertension and heart failure. Trials with direct vagal nerve and spinal cord stimulation have shown poor performance. Increased vagal tone through carotid sinus baroreflex activation systems was developed as an improved approach. The BAROSTIM NEO system CVRx was developed and subsequently approved by the US Food and Drug Administration (FDA) for first in man trial BeAT–HF trial (NCT 02627196).[1]

In the INOVATE-HF trial (Gold et al, 2016) baroreceptor activation therapy (BAT) did not improve rates of death or heart failure (HF) events. The BeAT-HF trial in 2020 was a randomized, non-blinded study of 408 patients (Zile et al., 2020) that showed improvement in symptoms and quality of life; however, it was not designed to measure changes in mortality or CHF hospitalization.[2]

Societies such as the American College of Cardiology have published recommendations regarding BAT. The 2022 guideline for the American College of Cardiology/American Heart Association/Heart Failure Society of America (ACC/AHA/HFSA) by Heidenreich et al. concluded that while early results to date were promising, the largest trial published in 2020 did not show a reduction in mortality or heart failure hospitalizations.[3]

Additionally, the 2021 guidelines for the European Society of Cardiology for diagnosing and treating acute and chronic HF (McDonagh et al.) state that baroreflex therapy shows potential for improved quality of life, reduced mortality, and reduced rates of hospitalization. However, it was concluded that current evidence was insufficient to support guideline recommendations given the lack of evidence showing a reduction in CHF hospitalization or mortality.[4]

On behalf of the American Heart Association (AHA), Carey et al. published a 2018 scientific statement on detecting, evaluating, and managing resistant hypertension. A randomized trial of 322 patients with resistant hypertension

failed to meet the primary trial end point; however, the device was found to be safe and efficacious in the long term for resistant hypertension.[5]

The National Institute for Health and Care Excellence (NICE) published guidance on *Implanting a Baroreceptor Stimulation Device for Resistant Hypertension*. Based on current evidence, the efficacy of the treatment is not yet proven. The reviewing committee considered separate evidence for unilateral and bilateral implantation, with much of the available evidence at the time based upon bilateral usage. The committee also noted that medication non-compliance is an important factor to consider in resistant hypertension trials.[6]

In total, there is insufficient evidence to date that baroreflex activation therapy (BAT) therapy with carotid sinus stimulators improves hard clinical outcomes in the setting of other proven therapies such as guideline-directed medical therapy (GDMT) and cardiac resynchronization therapy.

References

1. US Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). Premarket Approval (PMA) no. P180050: Barostim neo® System. Decision Date August 16, 2019. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180050.
2. Zile MR, Lindenfield J, Weaver FA, et al. Baroreflex activation therapy in patients with heart failure with reduced ejection fraction. *J Am Coll Cardiol.* 2020;76(1):1-13. http://www.jacc.org/doi/epdf/10.1016.
3. Heidenreich PA, Bozkurt B, Aguilar D, et al. 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. *Circulation*. 2022 May 3;145(18):e895-e1032. doi: 10.1161/CIR.0000000000001063. PMID: 35363499.
4. McDonagh TA, Metra M, et al. 2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart J*. 2021 Sep 21;42(36):3599-3726. doi: 10.1093/eurheartj/ehab368. PMID: 34447992.
5. Carey RM, Calhoun DA, Bakris GL, et al. Resistant hypertension: Detection, evaluation, and management - a scientific statement from the American Heart Association. *Hypertension*. 2018 Nov;72(5):e53-e90. doi: 10.1161/HYP.0000000000000084. PMID: 30354828; PMCID: PMC6530990.
6. National Institute for Health and Care Excellence (NICE). Implanting a baroreceptor stimulation device for resistant hypertension [IPG533]. Published October 28, 2015. https://www.nice.org.uk/guidance/ipg533.

Clinical Guideline Revision History/Information

Original Date: August 30, 2023		
Review History		
Version 2	12/19/2024	Annual review. No changes to medical necessity criteria or procedure codes.