Carotid Sinus Stimulators

Clinical Guidelines for Medical Necessity Review

Version: 1.0
Effective Date: August 30, 2023

Important Notices

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Guideline Information:

Specialty Area: Cardiology
Guideline Name: Carotid Sinus Stimulators - Single Service

Literature review current through: August 30, 2023
Document last updated: August 30, 2023
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Carotid Sinus Stimulators

General Guidelines

- **Units, Frequency, & Duration:** This service is experimental/investigational.
- **Criteria for Subsequent Requests:** This service is experimental/ investigational.
- **Recommended Clinical Approach:** This service is experimental/ investigational. [1]
- **Exclusions:** 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 **ALL** of the following are **TRUE**:

- ◆ Currently, there are no evidence-based indications for this service in the peer-reviewed, published literature.

Non-Indications

➔ **Carotid Sinus Stimulators** are not considered appropriate if **ALL** of the following are **TRUE**:

- ◆ These are considered experimental/investigational for treating hypertension, heart failure, or any other indication, including but not limited to **ANY** of the following[2-3]:
  - Barostim neo™ System; **OR**
  - Rheos Baroreflex Hypertension Therapy System.

Site of Service Criteria

Inpatient or outpatient.

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

The **American College of Cardiology/American Heart Association/Heart Failure Society of America (ACC/AHA/HFSA)** published a guideline for the management of heart failure (HF). Research trials of stimulator devices do not support a recommendation by the ACC/AHA/HFSA.[2]

The **American Heart Association (AHA)** published a scientific statement on detecting, evaluating, and managing resistant hypertension. A recommendation is not available for the use of the Rheos system (or other devices).[4]

The **European Society of Cardiology (ESC)** published the 2021 guidelines for diagnosing and treating HF. Baroreflex therapy shows potential for improved quality of life, reduced mortality, and rates of hospitalization; however, research is ongoing to support the efficacy of implantable electrical therapeutic technologies.[3]

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 and safety of the treatment is not yet proven.[5]

The **United States Food and Drug Administration (FDA)** granted a humanitarian device exemption in 2016 for the Barostim Neo™ System for the treatment of resistant hypertension in patients who have had bilateral implantation of the Rheos® Carotid Sinus Lead and were responders in the Rheos® clinical trial.[6]

The FDA granted premarket approval for the Barostim Neo™ System in 2019 for the treatment of heart failure. Citing AHA/ACC/ESC guidelines, the Barostim Neo™ System is indicated for patients with symptoms "despite treatment with guideline-directed medical therapy, are NYHA Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction ≤ 35%, an NT-proBNP < 1600 pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines."[7]

References

1. Center for Medicare and Medicaid Services (CMS). National coverage determination (NCD): Carotid Sinus Nerve Stimulator (160.6). No effective date; longstanding NCD. Accessed August 8, 2023. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=236&ncdver=1&bc=0.
2. 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.
3. McDonagh TA, Metra M, ESC Scientific Document Group, 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.
4. 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.
5. National Institute for Health and Care Excellence (NICE). Implanting a baroreceptor stimulation device for resistant hypertension [IPG533]. Published October 28, 2015. Accessed August 9, 2023. https://www.nice.org.uk/guidance/ipg533.
6. United States Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). Humanitarian Device Exemption (HDE) no. H130007: Barostim neo® Legacy System. Decision Date July 8, 2016. Accessed August 8, 2023. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=388273.
7. United States 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. Accessed August 8, 2023. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180050.

Clinical Guideline Revision History/Information

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Review History	