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Medicare Advantage Policy Manual **Policy ID:** M-SUR183

Baroreflex Stimulation Devices

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Baroreflex stimulation devices are implantable devices used to provide electrical stimulation of the baroreceptors in the carotid arteries, aiming to control blood pressure.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	For ***removal of the baroreflex device only*** (Category III codes 0269T-0271T): Medicare Benefit Policy Manual Chapter 16 - General Exclusions From Coverage *See Section 180 in the following link:* §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare

	Note: Please read the applicable section, in its entirety, for complete criteria details. In select circumstances, coverage may be available for the ***removal*** of a non-covered device when the removal is required in order to treat a medical condition or complication, even if the complication or subsequent medical condition is the result of a prior non-covered service. However, a procedure or device that lacks scientific evidence regarding safety and efficacy is non-covered and any ***revision or replacement*** to allow for the *continued* use of the non-covered device would not meet Medicare's general requirements for coverage.
National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	*Medicare coverage guidance is not available for the use of baroreflex stimulation devices. Therefore, the health plan's medical policy is applicable.* For ***implantation, revision, replacement, and device evaluation*** (Category III codes 0266T-0273T): ✓ Baroreflex Stimulation Devices, Surgery, Policy No. 183 *(see "NOTE" below)*
NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).	

POLICY GUIDELINES

In December 2014, the Barostim neo® Legacy System (CVRx, Inc.) received Humanitarian Device Exemption (HDE) approval from the U.S. Food and Drug Administration (FDA) for use in patients with resistant hypertension who have had bilateral implantation of the Rheos®

Carotid Sinus Leads Models 1010R, 1010L, 1014L, and 1014R (which have been discontinued and are obsolete) and were determined responders in the Rheos® pivotal clinical study.

In 2019, Barostim neo™ was granted premarket approval (PMA P180050) and is indicated for the improvement of symptoms of heart failure such as 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%, and a NT-proBNP < 1600 pg/ml, excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines.

No other devices or indications have received FDA approval.

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

REFERENCES

None

CODING

Codes	Number	Description
CPT	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, intraoperative 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 system 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 system 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
HCPCS	C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*