Phrenic Nerve Stimulation for Central Sleep Apnea

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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, including care that may be both medically reasonable and necessary.

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 Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. 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 a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). 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. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Central sleep apnea (CSA) is characterized by repeated cessation or decrease in airflow and ventilatory effort during sleep. Currently, the use of positive airway pressure devices is the most common treatment for CSA; however, an implantable phrenic nerve stimulator device is being considered as a potential alternative treatment, to normalize sleep-related breathing patterns.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: This policy only addresses **phrenic** nerve stimulation for *central* sleep apnea (CSA). It does not address **hypoglossal** nerve stimulation for *obstructive* sleep apnea (OSA). See Cross References for other Medicare Advantage medical policies.

CMS Coverage Manuals*	For ***HCPCS code C1823 when used for phrenic nerve stimulation for CSA, as well as removal of the device only (removal <u>without</u> replacement; Category III codes 0428T-0430T)***: Medicare Benefit Policy Manual, Chapter 16 *See Section 180 in the following link:* §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare *(According this this Medicare reference, services "related to" non-covered services are also not covered services; however, Medicare may allow certain procedures to be covered, such as the removal of a device, for separate medically indicated reasons [e.g., infection, etc.] The entire section should be considered, in its entirety for full Medicare coverage details. Removal with replacement for the continued use of a non-covered device would not be medically necessary under Medicare and the Social Security Act, §1862(a)(1)(A).)*
National Coverage Determinations (NCDs)*	None While the NCD for *Phrenic Nerve Stimulator* (160.19) addresses the use of phrenic nerve stimulation as an alternative for patients with respiratory insufficiency who are dependent upon the use of a mechanical ventilator as well as maintenance of a permanent tracheotomy stoma, it does not address the use of a phrenic nerve stimulator as a treatment of CSA. Therefore, see below for further guidance.
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	*Medicare coverage guidance is not available for phrenic nerve stimulation when used for CSA. Therefore, the health plan's medical policy is applicable.* For ***insertion, replacement, repositioning, and device evaluations*** ✓ Phrenic Nerve Stimulation for Central Sleep Apnea, Surgery, Policy No. 212 *(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

REGULATORY STATUS

In October 2017, the FDA granted approval for the **rem**edē® System (Respicardia, Inc.) through the premarket approval application process. The approved indication is for treatment of moderate to severe central sleep apnea in adults.

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

Surgeries for Snoring, Obstructive Sleep Apnea Syndrome, and Upper Airway Resistance Syndrome, Surgery, Policy No. M-166

Hypoglossal Nerve Stimulation, Surgery, Policy No, M-215

REFERENCES

None

CODING

NOTE: According to CPT guidelines, "If a category III code is available, this code must be reported instead of a Category I unlisted code." If a different CPT code (including an unlisted code, such as 64999) is used instead of one of the applicable Category III codes, the service is still noncovered per the Medicare reference noted in the "Medicare Advantage Policy Criteria" section of the policy.

Codes	Number	Description
CPT	33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed

	33277	Insertion of phrenic nerve stimulator transvenous sensing lead (List separately in addition to code for primary procedure)
	33278	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)
	33279	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only
	33280	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only
	33281	Repositioning of phrenic nerve stimulator transvenous lead(s)
	33287	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator
	33288	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s)
	93150	Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and programming
	93151	Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system
	93152	Interrogation and programming of implanted phrenic nerve stimulator system during polysomnography
	93153	Interrogation without programming of implanted phrenic nerve stimulator system
HCPCS	C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads

***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.*