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Medicare Advantage Policy Manual **Policy ID:** M-SUR215

Hypoglossal Nerve Stimulation

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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

Hypoglossal nerve stimulation involves the surgical implantation of a subcutaneous generator in the upper chest and an electrode tunneled from the generator to the hypoglossal nerve. The patient uses a hand-held remote to activate the device just prior to sleep and to turn it off upon waking. Some have sensors detect inspiratory efforts and the hypoglossal nerve is stimulated in a synchronized fashion. This stimulation is intended to maintain muscle tone of the tongue base to prevent airway occlusion.

Stimulation systems include respiratory sensing leads that permit intermittent stimulation during inspiration. Stimulation parameters are titrated during an in-laboratory polysomnography and can be adjusted by the patient during home use. The device is turned on only during sleep periods.

MEDICARE ADVANTAGE POLICY CRITERIA

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

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (Articles)*	Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38312) *(Companion article is A57949, which can be accessed directly from the LCD)* **Note:** For initial placement and replacement (including removal followed by replacement), see the above LCD. Removal only (without replacement) and revision of an existing medically necessary stimulator (64583 and 64584) may be considered medically reasonable and necessary for Medicare Advantage. **Scroll to the "Public Version(s)" section at the bottom of the LCD for links to prior versions if necessary.

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

For initial placement:

- Description of the planned treatment, including the indication being treated, symptoms, documented obstructive events, prior attempted therapies, body mass index (BMI), and the type of electrical stimulation;
- Name of stimulation device;
- Documentation of polysomnography (including date performed); and
- Any other documentation requested to support medical necessity criteria are met.

For replacement:

- For replacement of irreparable devices or their components, documentation must support reason for replacement (e.g., device malfunction, etc.) and whether or not the stimulator is still under manufacturer warranty.

For revisions and removal only (without replacement):

- Revisions to previously placed medically necessary devices and removals do not require additional documentation.

REGULATORY STATUS

In 2011, Apnex Medical received FDA approval to conduct a randomized investigational device exemption (IDE) trial for the Hypoglossal Nerve Stimulation (HGNS®) System; however, the trial was terminated and Apnex Medical has since ceased operations.

The *Inspire® II Upper Airway Stimulation System* (Inspire Medical Systems) received FDA approval in 2014 (P130008) for a subset of patients with moderate to severe obstructive sleep apnea. The original approval was for patients with an Apnea Hypopnea Index (AHI) of greater or equal to 20 and less than or equal to 65. In 2017, approval was granted to expand the AHI range to 15 to 65 events per hour (S021).

In 2014, ImThera™ Medical received FDA approval for an IDE trial with the aura6000® hypoglossal nerve stimulator system.

In 2016, Medicare approved the Category B IDE study titled, "*A Pilot Study to Evaluate the Safety and Efficacy of the Hypoglossal Nerve Stimulator in Adolescents and Young Adults With Down Syndrome and Obstructive Sleep Apnea.*"[G140209] However, inclusion criteria limited participation to "children and young adults with Down Syndrome age 10-21 years," and thus, anticipated impact to the general Medicare population is expected to be minimal. The device used in this study was the *Inspire® Upper Airway Stimulation System.*

Nyxoah received IDE approval from the FDA in June 2020 for the Dual-sided Hypoglossal neRvE stimulAtion for the treatMent of Obstructive Sleep Apnea (DREAM) study to evaluate the safety and effectiveness of the Genio system in patients with OSA who failed first line continuous positive airway pressure (CPAP) therapy. Medicare approved this Category B IDE study [G190068] in 2020 as well. While the device used in this study was the *Genio® system by Nyxoah*, according to the Genio® website, this device is not for sale in the U.S. The Genio System 2.1 received premarket approval from the FDA in 2025 (P240024) and is indicated for adult patients 22 years of age and older who have been confirmed to fail, cannot tolerate or are ineligible to be treated with current standard of care treatments including lifestyle modifications, PAP) treatments, oral appliances (such as mandibular advancement devices), and pharmacotherapy (such as tirzepatide).

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

Orthognathic Surgery, Surgery, Policy No. M-137

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

Phrenic Nerve Stimulation for Central Sleep Apnea, Surgery, Policy No. M-212

REFERENCES

None

CODING

Codes	Number	Description
CPT	64568	Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
	64582	Hypoglossal nerve neurostimulator implantation; open
	64583	Hypoglossal nerve neurostimulator revision or replacement
	64584	Hypoglossal nerve neurostimulator removal
HCPCS	C1767	Generator, neurostimulator (implantable), nonrechargeable

***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.*