

## Hypoglossal Nerve Stimulation

Published: 08/01/2019

Next Review: 06/2020

Last Review: 06/2019

Medicare Link(s) Revised: 08/01/2019

### 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

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\*** For **CPT code 64568 when used for hypoglossal nerve stimulation:**  
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 to this Medicare reference, services "related to" non-covered services are also not covered services.)

---

**National Coverage Determinations (NCDs)\*** None

---

**Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)\*** For **chest wall respiratory sensor insertion, revision, or removal (aka, hypoglossal nerve stimulation [HNS], Category III codes 0466T-0468T):**  
✓ Non-Covered Services ([L35008](#))

---

\*\*Scroll to the "Public Version(s)" section at the bottom of the LCD for links to prior versions if necessary.

---

## POLICY GUIDELINES

### 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 Investigational Device Exemption (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.*” 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*.

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.” (*Noridian LCD L35008*) 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	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
	0466T	Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)
	0467T	Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator
	0468T	Removal of chest wall respiratory sensor electrode or electrode array
HCPCS	None	

**\*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.