

# Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea

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[Terms and Conditions](#)

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**Related Medicare Advantage Policy Guidelines**

- [Category III CPT Codes](#)
- [Continuous Positive Airway Pressure \(CPAP\) Therapy for Obstructive Sleep Apnea \(OSA\) \(NCD 240.4\)](#)
- [Vagus Nerve Stimulation \(VNS\) \(NCD 160.18\)](#)

**Related Medicare Advantage Coverage Summary**

- [Sleep Apnea Diagnosis and Treatment](#)

## Policy Summary

[See Purpose](#)

### Overview

Obstructive sleep apnea (OSA) is a disease characterized by recurrent episodes of upper airway obstruction during sleep. The disruption in airflow caused by OSA has been associated with multiple comorbidities, including hypertension, cardiovascular disease, cardiac arrhythmia, cerebrovascular disease, excessive daytime sleepiness, and mood disorders. Continuous positive airway pressure (CPAP) has long been the primary treatment modality of choice for OSA, showing improvements in many comorbidities. Unfortunately, despite attempts to improve compliance, many people are unable to tolerate treatment with CPAP. Because of the large percentage of patients not tolerating CPAP, alternative treatment strategies are necessary.

The hypoglossal nerve is the twelfth cranial nerve and innervates all the extrinsic and intrinsic muscles of the tongue, except for the palatoglossus, which is innervated by the vagus nerve. It is a nerve with a solely motor function. The nerve arises from the hypoglossal nucleus in the brain stem as a number of small rootlets, passes through the hypoglossal canal and down through the neck, and eventually branches within the tongue and innervates the tongue. There are two hypoglossal nerves in the body: one on the left, and one on the right.

The only Food and Drug Administration (FDA)-approved Hypoglossal Nerve Stimulation (HGNS) system has three implantable components: a stimulation lead that delivers mild stimulation to maintain multilevel airway patency during sleep, a breathing sensor lead that senses breathing patterns, and a generator that monitors breathing patterns. The two external components are a patient sleep remote that provides a noninvasive means for a patient to activate the generator and a physician programmer that allows the physician to noninvasively interrogate and configure the generator settings. The system battery life for the implantable components is 7 to 10 years.

A surgeon implants the system containing a neurostimulator subcutaneously in the patient’s chest, with one lead attached to the patient’s hypoglossal nerve (cranial nerve XII) at the base of the tongue and one lead implanted in the patient’s chest. The lead in the chest consists of a pressure sensor that detects breathing. Information about respiration rate is relayed to the device, which stimulates the hypoglossal nerve in the tongue. When stimulated, the tongue moves forward, opening the airway. The patient can operate the device by remote control, which the patient activates before going to sleep. The device turns on

after 20 minutes to minimize disrupting the patient's sleep onset; the device must be manually turned off via remote when the patient wakes.

## Guidelines

FDA-approved hypoglossal nerve neurostimulation is considered medically reasonable and necessary for the treatment of moderate to severe obstructive sleep apnea when all of the following criteria are met:

- Beneficiary is 22 years of age or older; and
- Body mass index (BMI) is less than 35 kg/m<sup>2</sup>; and
- A polysomnography (PSG) is performed within 24 months of first consultation for HGNS implant; and
- Beneficiary has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); and
- AHI is 15 to 65 events per hour; and
- Beneficiary has documentation that demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than 4 hours per night, 5 nights per week or the CPAP has been returned) including shared decision making that the patient was intolerant of CPAP despite consultation with a sleep expert; and
- Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; and
- No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale).

The following are not considered reasonable and necessary and therefore will be denied:

- Hypoglossal nerve neurostimulation is considered not medically reasonable and necessary for all other indications.
- Non-FDA-approved hypoglossal nerve neurostimulation is considered not medically reasonable and necessary for the treatment of adult obstructive sleep apnea due to insufficient evidence of being safe and effective.
- Hypoglossal nerve neurostimulation is considered not medically reasonable and necessary when any of the following contraindications are present:
  - Beneficiaries with central and mixed apneas that make up more than one-quarter of the total AHI.
  - Beneficiaries with an implantable device could experience unintended interaction with the HGNS implant system.
  - BMI equal to or greater than 35.
  - Neuromuscular disease affecting the respiratory system.
  - Hypoglossal-nerve palsy.
  - Severe restrictive or obstructive pulmonary disease.
  - Moderate-to-severe pulmonary arterial hypertension.
  - Severe valvular heart disease.
  - New York Heart Association class III or IV heart failure.
  - Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months).
  - Persistent uncontrolled hypertension despite medication use.
  - An active, serious mental illness that reduces the ability to carry out Activities of Daily Living (ADLs) and would interfere with the patient's ability to operate the HNS and report problems to the attending provider.
  - Coexisting nonrespiratory sleep disorders that would confound functional sleep assessment
  - Beneficiaries who are, or who plan to, become pregnant.
  - Beneficiaries who require magnetic resonance imaging (MRI) with model 3024.
  - Beneficiaries, who require MRI with model 3028, can undergo MRI on the head and extremities if certain conditions and precautions are met. Please refer to the Manufacturer Guidelines for this model and future models for more information.
  - Beneficiaries who are unable or do not have the necessary assistance to operate the sleep remote.
  - Beneficiaries with any condition or procedure that has compromised neurological control of the upper airway.
- Drug Induced Sleep Endoscopy (DISE): Due to documented inconsistency in determining if complete concentric collapse (CCC) is present, the inserting provider shall be certified by the FDA approved manufacturer's second opinion service of validation via video clip submissions of at least 80% agreement in at least 15 consecutive studies.
- Shared Decision Making (SDM), by definition, is any documented conversation between an attending provider and the patient, and not between multiple providers.

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
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) (Deleted 12/31/2021—see 64582)
0467T	Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator (Deleted 12/31/2021—see 64583)
0468T	Removal of chest wall respiratory sensor electrode or electrode array (Deleted 12/31/2021—see 64584)
64568	Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator [See the Medicare Advantage Policy Guideline titled <a href="#">Vagus Nerve Stimulation (VNS) (NCD 160.18)</a> ] (Effective on or before 12/31/2021)
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array (Effective 01/01/2022)
64583	Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator (Effective 01/01/2022)
64584	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array (Effective 01/01/2022)

*CPT® is a registered trademark of the American Medical Association*

Coding Clarification: Refer to the appropriate LCDs/articles for specific billing and coding criteria, as applicable.

## References

### CMS National Coverage Determinations (NCDs)

Reference NCD: [NCD 160.18 Vagus Nerve Stimulation](#)

### CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
<a href="#">L38276 Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea</a>	<a href="#">A58075 Billing and Coding: Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea</a>	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
<a href="#">L38307 Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a>	<a href="#">A57149 Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea</a>	CGS	KY, OH	KY, OH
<a href="#">L38310 Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a>	<a href="#">A57948 Billing and Coding: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a>	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
<a href="#">L38312 Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a>	<a href="#">A57949 Billing and Coding: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a>	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY

LCD	Article	Contractor	Medicare Part A	Medicare Part B
<a href="#">L38385 Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a>	<a href="#">A56938 Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea</a>	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
<a href="#">L38387 Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a>	<a href="#">A57092 Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea</a>	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
<a href="#">L38398 Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a>	<a href="#">A56953 Billing and Coding: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a>	First Coast	FL, PR, VI	FL, PR, VI
<a href="#">L38528 Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea</a>	<a href="#">A57944 Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea</a>	WPS	AL, AK, AR, AZ, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MS, MO, MT, NC, ND, NE, NV, NH, NJ, NM, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY	IA, IN, KS, MI, MO, NE

## CMS Transmittals

[Transmittal 2243, Change Request 11134, Dated February 1, 2019 \(International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\)\)](#)

[Transmittal 11025, Change Request 12399, Dated September 28, 2021 \(International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\)–January 2022\)](#)

## UnitedHealthcare Commercial Policy

[Obstructive and Central Sleep Apnea Treatment](#)

## Others

[CMS CY 2022 Final Rule \(CMS-1751-F\): Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies](#)

[Federal Register, Vol. 816, No. 221/ Friday, November 19, 2021/ Rules and Regulations for CMS \(1751-F\)](#)

## Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/13/2022	<ul style="list-style-type: none"> <li>Routine review; no change to guidelines</li> <li>Archived previous policy version MPG386.03</li> </ul>

## Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

## Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document\* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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\*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).