

VHA Office of Integrated Veteran Care
Community Care Medical Policy
Obstructive Sleep Apnea Treatment

Policy Number: 00001

Effective Date: January 01, 2023

I. Important Information – Please read before using this policy

This policy is intended to be used as a reference for non-VA providers.

These guidelines do not guarantee benefits or constitute medical advice.

II. Community Care Medical Policy

a. Hypoglossal Nerve Stimulation

i. Indications for Hypoglossal Nerve Stimulation

Hypoglossal nerve stimulation (HGNS) with a Food and Drug Administration (FDA)-approved HGNS device is considered medically reasonable and necessary for the treatment of moderate to severe obstructive sleep apnea (OSA) when all the following criteria are met:

- Beneficiary is between 22 and 80 years of age; **and**
- Body mass index (BMI) is less than 35 kg/m². Exemption consideration for BMI up to 36 kg/ m² with supporting documentation of stable weight, **and**
- An overnight polysomnography (PSG) performed in a sleep laboratory within 24 months of first consultation for HGNS implant. Lab test is preferred, but Type III Home Sleep Apnea Tests (HSATs) are allowed with a recommendation for multi-night HSATs when competing sleep disorders are present (e.g., insomnia); **and**
- Beneficiary has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total apnea-hypopnea index (AHI)); **and**
- AHI is 15 to 80 events/hr. Exemption consideration for AHI up to 90 with supporting documentation for necessity; **and**
- Documentation that demonstrates CPAP failure or CPAP intolerance 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).

ii. Limitations

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

- Use for all other indications.
- Non-FDA-approved hypoglossal nerve stimulation.
- Presence of any of the following:
 - Beneficiaries with central and mixed apneas that make up more than 25% of the total AHI.
 - Beneficiaries with an implantable device could experience unintended interaction with the HGNS implant system.

Limitations are:

- BMI equal to or greater than 35 (see exemption in Section II.a.i Indications for Hypoglossal Nerve Stimulation)
- Neuromuscular disease affecting the respiratory system
- Hypoglossal-nerve palsy. Alternative consideration for implant with hypoglossal nerve on opposite side
- 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 HGNS and report problems to the attending provider
- Cognitive impairment that would interfere with the patient's ability to operate the HGNS and report problems to the attending provider
- Coexisting non-respiratory sleep disorders that would confound functional sleep assessment
- Beneficiaries who are, or who plan to become pregnant.

- Beneficiaries, who require magnetic resonance imaging (MRI) require evaluation for device specific contraindications, including but not limited to tissue damage. Please refer to the Manufacturer Guidelines for information.
- Beneficiaries will be required to turn the therapy on and off and adjust the strength of the stimulation with a remote, therefore those 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.

iii. Investigational or Experimental Treatment

Implantable hypoglossal nerve stimulators are considered experimental, investigational and/or unproven for all indications other than listed above in Section II.a.i Indications for Hypoglossal Nerve Stimulation.

Investigational or experimental treatments are not generally approved treatments or services according to VA standards. However, treatments may be evaluated on a case-by-case basis to determine medical necessity and coverage.

Requests for investigational or experimental treatments may be submitted through the Request for Services (RFS) process using VA Form 10-10172, Community Care Provider-Request for Service Form, signed by the ordering provider, and must include accompany supporting medical documentation.

iv. Research/Clinical Trials

The concept of stimulating the tongue musculature to increase upper airway size and limit the pathophysiologic obstruction leading to OSA was introduced in the late 1980s. A variety of strategies were utilized, including transcutaneous stimulation with placement of electrodes in the submental region, sublingual mucosa, and soft palate. However, these studies were limited by their lack of selective stimulation of the primary protrusion of the tongue, the genioglossus muscle.

- Strollo et al (2014) evaluated the clinical safety and effectiveness of upper-airway stimulation at 12 months for the treatment of moderate-to-severe obstructive sleep apnea. The study included 126 participants and was designed by the sponsor (INSPIRE Medical Systems), the investigators, and

the FDA as a multicenter, prospective, single-group trial with participants serving as their own controls.

The 12-month study outcomes on the apnea-hypopnea index (AHI) and oxygen desaturation index (ODI) scores were lower, indicating fewer episodes of sleep apnea, compared to baseline. The median AHI score decreased 68%, from the baseline value of 29.3/hr. to 9.0/hr. The median ODI score decreased 70%, from 25.4/hr. to 7.4/hr. At the 12-month visit, the criteria for AHI score outcome required a reduction of at least 50% from baseline and an AHI score of less than 20/hr. were met by 66% of the participants. The criterion for the ODI score outcome required a reduction of at least 25% from baseline was met by 75% of participants. Both exceeded the predefined study objectives. Supplementary data identified 29% participants with an AHI <5/hr., 53% with an AHI < 10, and 63% with an AHI <15.

In 2014, the Stimulation Therapy for Apnea Reduction (STAR) Trial was published as the initial clinical trial using an INSPIRE Medical Systems upper airway stimulation (UAS) device as an alternative therapy to CPAP for treatment of OSA which led to FDA approval.

- The STAR Trial group evaluated the stability of improvement of 123/126 (98%) subjects using polysomnographic measures of sleep disordered breathing, patient reported outcomes, and the durability of hypoglossal nerve and safety at 18 months [Dedhia et al (2015)]. The median AHI was reduced by 67.4% and the median ODI was reduced by 67.5% at 18 months. The Functional Outcomes of Sleep Questionnaire (FOSQ) and Epworth Sleepiness Scale (ESS) improved at 18 months compared to baseline while the functional threshold was unchanged from baseline at 18 months. The research concluded that upper airway stimulation via the hypoglossal nerve maintained a durable effect of improving airway stability during sleep and improved patient reported outcomes without an increase of the stimulation thresholds or tongue injury at 18 months.
- Soose et al (2016) evaluated 111/126 (88%) of the STAR Trial participants at the 24-month interval, measuring self- and bedpartner-report of snoring intensity, ESS, and FOSQ. The study identified sustained improvement in mean FOSQ score

from baseline (14.3) to 24 months (17.2). Similar sustained improvements were observed with all FOSQ subscales and FOSQ-10. Subjective daytime sleepiness, as measured by mean ESS, improved from baseline (11.6) to 24 months (7.1). Self-reported snoring severity showed an increased percentage of "no" or "soft" snoring from 22% at baseline to 91% at 24 months. Researchers concluded that hypoglossal nerve stimulation therapy can provide improvement in sleep related quality-of-life outcomes and can be maintained throughout a 24-month period.

- Woodson et al (2016) evaluated 116/126 (92%) of the STAR clinical trial participants at the 36-month interval. 98 participants additionally agreed to a voluntary 36-month polysomnography (PSG). Self-report daily device usage of 81%. In the PSG group, 74% reduced the AHI median value of 28.2/hr., at baseline to 8.7 and 6.2 at 36 months. Improved self-reported outcomes maintained at 36 months. Researchers concluded that treatment with hypoglossal nerve stimulation continued to show improvements in respiratory and quality-of-life outcomes throughout a 36-month period.
- Gillespie et al (2017) evaluated 91/126 (72%) of the STAR Trial participants at the 48-month interval. Subjective daytime sleepiness, as measured by ESS, and quality-of-life, as measured by FOSQ, maintained reduction compared to baseline. Soft to no snoring was reported by 85% of bed partners. Researchers concluded that UAS benefits had been maintained.
- Woodson et al (2018) published the STAR investigators' 5-year patient outcomes for 97/126 (77%) participants, and 71 (56 %) consented to voluntary PSG. Improvement in sleepiness and quality of life were observed, with normalization of scores increasing from 33% to 78% and 15% to 67%, respectively. AHI response rate (AHI less than 20/hr. and greater than 50% reduction) was 75% (n equal to 71). Researchers concluded that improvements were maintained in sleepiness, quality of life, and respiratory outcomes observed with 5 years of UAS.

v. Description of Treatment

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. The hypoglossal nerve stems from the hypoglossal nucleus in the brain stem as a number of small rootlets and passes through the hypoglossal canal and down through the neck, branching and innervating the tongue. There are two hypoglossal nerves, one on the left, and one on the right.

The only FDA - approved HGNS system, Inspire, has three implantable components: a stimulation lead that delivers mild stimulation to maintain multilevel airway patency during sleep, a breathing sensor lead identifying 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.

vi. Required Clinical Information

Supporting documentation from medical records including but not limited to visit notes, diagnostic imaging, diagnostic studies, shall be provided upon request.

vii. Credentialing and Accreditation Standards

Place of Service (POS)

Hypoglossal nerve stimulation for the treatment of OSA must be furnished in accordance with the accepted standards of medical practice in a setting appropriate to the patient's medical needs and condition.

Provider Qualifications

Hypoglossal nerve stimulation for the treatment of OSA must be ordered and furnished by qualified personnel. The hypoglossal nerve (HN) may be damaged during neck surgeries. A detailed understanding of the anatomy of the hypoglossal nerve in relation to various anatomical landmarks and surrounding structures is important to reduce procedural complications and the risk of nerve damage.

Provider Specialties

- Insertion of an FDA-approved hypoglossal nerve stimulation device must be performed by a qualified physician (MD or DO) who is a board certified, a board eligible otolaryngologist, or oral/maxillofacial surgeon (OMFS) having completed the appropriate American Medical Association (AMA) or American Osteopathic Association (AOA) certified residency and/or fellowship program and maintains ongoing certification in otolaryngology. In addition, prior to implanting the system, surgeons will need to receive instruction by an FDA approved device manufacturer or equivalent on device implant techniques as well as cadaver training. Documentation must be provided to support completion of training to an exemplary level by the manufacturer.
- Sleep physicians, sleep technicians and surgeons shall receive instruction from device manufacturer on how to titrate the device including hands on operation of the programmer. Evaluation, referral, and post implant evaluation of the hypoglossal nerve stimulator should be performed by the appropriate licensed independent practitioner with qualifications as outlined in Centers for Medicare and Medicaid Services (CMS) Article A53019, Polysomnography and Sleep Studies – Medical Policy Article. Sleep Technicians shall meet the same qualifications as outlined in the Article A53019. Non-VA Sleep studies will also be required to be performed in an accredited sleep facility as outlined in Article A53019.
- Drug Induced Sleep Endoscopy (DISE): Due to documented inconsistency determining if complete concentric collapse (CCC) is present, the DISE should be performed by qualified practitioners based on local regulation.

viii. Health Care Procedural Coding Information

- 64582 Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
 - Report 64582 for implantation of the neurostimulator array, pulse generator, and respiratory sensor electrode/array.
 - Report 64583 for revision or replacement of the neurostimulator array and respiratory sensor electrode/array with connection to the existing pulse generator.
 - Report 64584 for removal of the entire system.
- 64568 Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator is still valid however has a definition changed as of 01/02/2022 and Device-intensive procedure; paid at adjusted rate.

ix. FDA Approval

Product Name: Inspire® Upper Airway Stimulation (UAS)

PMA Applicant: Inspire Medical Systems, Inc.

Address: 5500 Wayzata Blvd. Suite 1600

Golden Valley, MN 55416 US

Approval Date: April 14, 2020

Approval Letter: [Approval Order](#)

x. Medicare Coverage

Available Medicare coverage determinations are listed below as a resource. This does not indicate VA exclusively follows CMS coverage determinations.

- National Medicare Coverage Position
 - NA
- Local Medicare Coverage Determination
 - Palmetto GBA
 - CGS Administrators, LLC
 - First Coast Service Options, Inc.
 - National Government Services, Inc.
 - Noridian healthcare Solutions, LLC (2)
 - Novitas Solutions, Inc.
 - Wisconsin Physicians Service Insurance Corporation

III. Background

Obstructive sleep apnea (OSA) is a sleep disorder that involves cessation or significant decrease in airflow in the presence of breathing effort. It is the most common type of sleep-disorder breathing and is characterized by recurring

episodes of upper airway collapse during sleep. These episodes are associated with oxyhemoglobin desaturations and arousals from sleep.

The cardinal symptoms of sleep apnea include the "3 S's": Snoring, Sleepiness, and Significant-other report of sleep apnea episodes. Often, individuals are unaware that they have OSA and associated daytime sleepiness risks as well as the association with other debilitating medical conditions, including hypertension, cardiovascular disease, and coronary artery disease.

IV. Definitions

Terms	Definitions
Apnea	The cessation of airflow for at least 10 seconds. [4] Apnea may last for 30 seconds or even longer.
Hypopnea	Peak signal excursions drop by at least 30% of pre-event baseline using nasal pressure (diagnostic study), positive airway pressure device flow (titration study), or an alternative hypopnea sensor (diagnostic study); duration of the at least 30% drop in signal excursion is 10 or more seconds; and there is 3% or greater oxygen desaturation from pre-event baseline and/or the event is associated with an arousal.
Respiratory Event Related Arousal (RERA)	An event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increasing respiratory effort, terminating in an arousal but not otherwise meeting criteria for apnea or hypopnea.
Apnea/Hypopnea Index (AHI)	The average number of apneas or hypopneas per hour of sleep.
Respiratory Disturbance Index (RDI)	The number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.

Terms	Definitions
Respiratory event index (REI)	The number of events per hour of monitoring time. Used as an alternative to AHI or RDI in home sleep studies when actual sleep time from EEG is not available.
Obstructive sleep apnea (OSA)	Repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep.
Mild OSA	In adults: AHI of 5 to <15.
Moderate OSA	AHI of 15 to < 30.
Severe OSA	Adults: AHI \geq 30.
Positive airway pressure (PAP)	Positive airway pressure may be continuous (CPAP) or auto-adjusting (APAP) or Bi-level (Bi-PAP).
PAP Intolerance	PAP use for less than 4 hours per night for 5 nights or more per week, or refusal to use CPAP. CPAP intolerance may be observed in patients with mild, moderate, or severe OSA.

V. References

Strollo PJ Jr, Soose RJ, Maurer JT, de Vries N, Cornelius J, Froymovich O, Hanson RD, Padhya TA, Upper-Airway Stimulation for Obstructive Sleep Apnea. *N Engl J Med*. 2014 Jan 9; 370 (2):139-49.

U.S. Food and Drug Administration (FDA) Premarket Approval (PMA) for Inspire Upper Airway Stimulation. PMA number P130008.

Dedhia RC, Strollo PJ, Soose RJ. Upper Airway Stimulation for Obstructive Sleep Apnea: Past, Present, and Future. *Sleep*. 2015 Jun 1; 38 (6): 899-906.

Soose RJ, Woodson BT, Gillespie MB, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: Self-Reported Outcomes at 24 Months. *J Clin Sleep Med*. 2016 Jan; 12 (1): 43-8.

Woodson BT, Soose RJ, Gillespie MB, et al. Three-Year Outcomes of Cranial Nerve Stimulation for Obstructive Sleep Apnea: The STAR Trial. *Otolaryngol Head Neck Surg*. 2016 Jan; 154 (1):181-8.

Gillespie MB, Soose RJ, Woodson BT, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: Patient-Reported Outcomes after 48 Months of Follow-up. *Otolaryngol Head Neck Surg*. 2017 Apr; 156 (4): 765-771.

Woodson BT, Strohl KP, Soose RJ, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes. *Otolaryngol Head Neck Surg*. 2018 Jul; 159 (1): 194-202.

Centers for Medicare and Medicaid Services (CMS). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea Local Coverage Determination (LCD), ID # L38387. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38387&ver=7&keyword=hypoglossal&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>

Centers for Medicare and Medicaid Services (CMS). Polysomnography and Sleep Studies – Medical Policy Article, ID # A53019. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=53019&DocID=A53019>

VI. Policy History/Revision Information

- a. Explanation of changes to Policy
- b. Link to previous versions
- c. Table of Applicable Dates

Revision Type	Date of Revision	Update(s) Made to Community Care Medical Policies
Original Effective Date	01/01/23	Development
Content Updates	03/21/23	Updated sections <ul style="list-style-type: none"> • II.a.iii - Investigational or Experimental Treatment • II.a.x - Medicare Coverage
Last Review Date	NA	NA



VII. **Instructions for Use**

This policy is to be used as a reference and not intended to replace clinical judgement when determining care pathways.