

Clinical Policy: Implantable Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea

Reference Number: CP.MP.180

Date of Last Review: 11/22

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Description

Hypoglossal nerve stimulation, also referred to as an upper airway stimulation (UAS) system, is proposed as a treatment strategy for select patients with moderate to severe obstructive sleep apnea (OSA), who have failed continuous positive airway pressure. Appropriate polysomnographic, age, body mass index (BMI) and objective upper airway evaluation measures are required for proper patient selection. This policy addresses the medical necessity criteria for hypoglossal nerve stimulation.

Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation® that *implantable hypoglossal nerve neurostimulation* is **medically necessary** for the treatment of moderate to severe OSA when all of the following criteria are met:
 - A. Device is FDA-approved for implantation to treat OSA (e.g., Inspire Upper Airway Stimulation);
 - B. Age \geq 22 years;
 - C. BMI \leq 35 kg/m²;
 - D. Polysomnography performed within 24 months of first consultation for implant;
 - E. Apnea-hypopnea Index (AHI) of \geq 15 and \leq 65 with less than 25% central and mixed apneas;
 - F. Failure or intolerance of Positive Airway Pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines):
 1. PAP failure, defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage); or
 2. PAP intolerance, defined as less than 4 hours of PAP use per night, 5 nights per week;
 - G. Absence of a complete concentric collapse at the soft palate level as determined by endoscopy performed during drug-induced sleep;
 - H. Absence of other anatomical finding that would compromise the performance of upper airway stimulation (e.g., tonsil size of 3 or 4; tonsils visible beyond the pillars or extending to midline);
 - I. None of the following contraindications:
 1. Any condition or procedure that has compromised neurological control of the upper airway;
 2. Currently pregnant or planning to become pregnant;
 3. Unable or does not have the necessary assistance to operate the sleep remote;
 4. Any implantable device that may be susceptible to unintended interaction with the hypoglossal nerve stimulation device (consult the device manufacturer to assess the possibility of interaction);
 5. Central plus mixed apneas $>$ 25% of the total AHI;
 6. Requirement of MRI for members/enrollees requesting Inspire Model 3024;

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7. For members/enrollees requesting Inspire Model 3028, requirement for an MRI other than as described in the Inspire MR Conditional labeling;
8. Severe restrictive or obstructive pulmonary disease;
9. Moderate to severe pulmonary arterial hypertension;
10. Severe valvular heart disease;
11. New York Heart Association class III or IV heart failure;
12. Recent myocardial infarction or severe cardiac arrhythmias (within the past six months);
13. Persistent, uncontrolled hypertension despite medication use;
14. Presence of active, serious mental illness that limits the ability to operate the device and report problems to the attending provider.

Background

Obstructive sleep apnea (OSA) is a disorder characterized by obstructive apneas and hypopneas due to repetitive collapse of the upper airway during sleep. Untreated OSA has many potential consequences and adverse clinical associations, including excessive daytime sleepiness, impaired daytime function, metabolic dysfunction, and an increased risk of cardiovascular disease and mortality.² Positive airway pressure (PAP) therapy is the mainstay of therapy for adults with OSA, however, the general effectiveness of continuous PAP therapy is dependent on patient acceptance of and adherence to the treatment. Alternative treatments to PAP therapy include custom-made oral appliance therapy and various upper airway surgeries.

Hypoglossal nerve stimulation is proposed as a treatment strategy for select patients with moderate to severe OSA, who have failed CPAP, a BMI ≤ 32 kg/m², and no unfavorable collapse on drug-induced sleep endoscopy. Not all adult patients are candidates for UAS (upper airway stimulation) therapy and appropriate polysomnographic, age, BMI and objective upper airway evaluation measures are required for proper patient selection.^{16,17} At this time, the only FDA approved device (Inspire[®] Upper Airway Stimulation device) consists of implantable pulse generator (IPG), stimulation lead and sensing lead, and external components (i.e., physician and patient programmer). The IPG detects respiratory effort and maintains airway patency with mild stimulation of the hypoglossal nerve during inspiration. The physician can configure the stimulation settings using the external physician programmer. The patient-operated sleep remote allows the patient to turn therapy on prior to going to sleep and turn therapy off upon waking up. It also provides the ability to pause therapy and adjust stimulation amplitude within physician defined limits that are within the therapeutic range of treatment.⁴

A meta-analysis of uncontrolled studies of upper airway stimulation therapy showed 50 to 57% reductions in AHI, 48 to 52% reductions in oxygen desaturation index, and significant improvements in sleepiness and quality of life at 3 and 12 months.⁹ The largest individual study of 126 highly selected patients showed major improvements in polysomnography parameters in about two-thirds of patients, improvement in subjective measures of sleepiness, and high adherence (84 percent).¹ These benefits were maintained at five years postoperatively.¹⁰ A pooled analysis of all available patient-level data from the 4 published studies using a single type of hypoglossal nerve stimulator (Inspire II) for OSA reported that hypoglossal nerve stimulation appeared to demonstrate clinically significant improvements in objective measures of OSA severity and subjective measures of daytime sleepiness and sleep-related quality of life in CPAP-

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intolerant patients with moderate to severe OSA. They noted further that younger and heavier adults tended to have less improvement in disease.¹²

The ADHERE (Adherence and Outcome of Upper Airway Stimulation for OSA International Registry) registry was created to collect demographic, surgical outcome, complications, quality of life and patient-reported outcomes undergoing treatment with upper airway stimulation (UAS) in the U.S. and Europe. The post-approval registry reported median AHI was reduced from 34 to 7 events, median Epworth sleepiness scale reduced from 12 to 7 from baseline to final visit at 12-month post-implant. In post hoc analyses, for each 1-year increase in age, there was a 4% increase in odds of treatment success. For each 1-unit increase in body mass index (BMI), there was 9% reduced odds of treatment success. In the multivariable model, age persisted in serving as statistically significant predictor of treatment success. The authors concluded, UAS is an effective treatment option with high patient satisfaction and low adverse events. Increasing age and reduced BMI are predictors of treatment response.¹¹

Studies comparing hypoglossal nerve stimulation to other treatments of OSA as well as large long term randomized controlled trials are lacking. This treatment is continuing to evolve with ongoing enhancements in the device hardware, software, implantation procedure, and treatment protocols. Additional research is needed to determine criteria for outcomes assessment, patient selection, predictors of treatment success, and the possibility of combination therapy to eradicate OSA and address additional accompanying comorbidities.¹⁹

American Academy of Otolaryngology-Head and Neck Surgery

The American Academy of Otolaryngology-Head and Neck Surgery considers UAS via the hypoglossal nerve for the treatment of adult OSA syndrome to be an effective second-line treatment of moderate to severe OSA in patients who are intolerant or unable to achieve benefit with PAP.⁶

American Academy of Sleep Medicine

The American Academy of Sleep Medicine suggests referral to a sleep surgeon for adults meeting certain clinical parameters and persistent inadequate PAP adherence due to pressure-related side effects as part of a patient-oriented discussion of adjunctive or alternative treatment options. Available data indicate upper airway surgery elicits a moderate effect in decreasing minimum therapeutic PAP level and improving compliance with PAP use.²⁰

International Society for Sleep Surgery

The International Society for Sleep Surgery indicates that hypoglossal nerve stimulation has been shown to be effective in the treatment of sleep disordered breathing/obstructive sleep apnea syndrome in adults when applied to select patients based on their anatomy, physiology, body mass index and neck size, prior therapy and co-morbidities. Treatment should be preceded by an appropriate evaluation, which may include polysomnography, home sleep testing, awake or drug induces sleep endoscopy and possible cephalometric or other radiographic evaluations.¹⁷

National Institute of Health and Care Excellence (NICE)

Current evidence on the safety and efficacy of hypoglossal nerve stimulation for moderate to severe obstructive sleep apnea is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.¹⁴

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Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2021, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
64583	Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator
64584	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array

HCPCS Codes	Description
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Original approval date. Specialist review.	11/19	11/19
Added codes 61886 and 61888. Replaced “member” with “member/enrollee” in all instances. References reviewed and updated.	11/20	11/20
Annual review. References reviewed and updated. Changed "Last Review Date" in the header to "Date of Last Review" and "Date" in revision log to "Revision Date." Added CPT code 64585. Reviewed by specialist.	11/21	11/21
Annual review completed. I.C. Changed BMI to 35 kg/m ² ; I.E. Adjusted AHI to ≥15 to ≤ 65 events per hour; I.F.1. Adjusted 20 to 15. Added criteria I.I.5. and I.I.8. through 14. Background updated and minor rewording with no clinical significance. Added CPT codes 64582, 64583, and 64584. Removed CPT codes 0466T, 0467T, 0468T, 61886, 61888, 64568, 64569, 64570, and 64585.	11/22	11/22

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Removed ICD-10 diagnosis table. References reviewed, reformatted and updated. Reviewed by internal specialist.		

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

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discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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