Clinical Policy: Implantable Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea

Reference Number: CP.MP.180
Date of Last Revision: 01/26

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 polysomnography (PSG), 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.

Note: For criteria regarding titration PSG following implantation of hypoglossal nerve stimulator, please see CP.MP.248 Facility-based Sleep Studies for Obstructive Sleep Apnea.

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 obstructive sleep apnea (OSA) when either of the following criteria are met:

A. Request is for Inspire® Upper Airway Stimulation System and all of the following:
   1. BMI ≤ 40 kg/m^2;
   2. Polysomnography (PSG) performed within 24 months of first consultation for the hypoglossal nerve stimulator implant;
   3. One of the following;
      a. Age is ≥ 22 years and all of the following;
         i. Diagnosis of moderate to severe OSA with an apnea-hypopnea index (AHI) of ≥ 15 and ≤ 100;
         ii. Failure or intolerance of positive airway pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines), one of the following:
            a.) Inability to eliminate OSA (AHI of greater than 15 despite PAP usage);
            b.) Inability to use PAP (greater than five nights per week of usage; usage defined as greater than four hours of use per night);
            c.) Unwillingness to use PAP (i.e., member/enrollee returns the PAP system after attempting to use it);
      b. Age is 18 to 21 years and all of the following;
         i. Diagnosis of moderate to severe obstructive sleep apnea with an AHI of ≥ 15 and ≤ 100;
         ii. Adenotonsillectomy is contraindicated or ineffective;
         iii. Failed, or intolerance to PAP therapy despite attempts to improve usage;
         iv. Considered all other standard of care alternative/adjunct therapies;
      c. Members/enrollees with Down syndrome age 13 to 18 years and all of the following:

i. Diagnosis of moderate to severe obstructive sleep apnea with an apnea-hypopnea index (AHI) > 10 and < 50;
ii. Adenotonsillectomy is contraindicated or ineffective;
iii. Failed, or intolerance to PAP therapy despite attempts to improve usage;
iv. Considered all other standard of care alternative/adjunct therapies;

4. None of the following contraindications:
   a. Central and mixed apneas > 25% of the total AHI;
   b. Any anatomical finding that would compromise the performance of upper airway stimulation, such as the presence of complete concentric collapse of the soft palate;
   c. Any condition or procedure that has compromised neurological control of the upper airway;
   d. Member/enrollee is unable or does not have the necessary assistance to operate the device remote;
   e. Members/enrollees who are pregnant or plan to become pregnant as upper airway stimulation therapy has not been evaluated for safety or efficacy during pregnancy;
   f. Members/enrollees with an implantable device that may be susceptible to unintended interaction with the Inspire system;
   g. Members/enrollees who require magnetic resonance imaging (MRI) other than what is specified in the MR Conditional labeling;
   h. Member/enrollee has rhabdomyolysis.

B. Request is for Genio® System, and all of the following:
   1. Age ≥ 22 years;
   2. BMI ≤ 32 kg/m^2;
   3. PSG performed within 24 months of first consultation for the hypoglossal nerve stimulator implant;
   4. Diagnosis of moderate to severe OSA with an AHI ≥ 15 and ≤ 65;
   5. Cricomental space positive (≥ 0 cm);
      Note: The cricomental space is the distance between the neck and the bisection of a line from the chin to the cricoid membrane when the head is in a neutral position.
   6. Non-supine AHI > 10 events on the screening PSG, or participant has either not tolerated, has failed or refused positional therapy;
   7. Failure, refusal, or intolerance of current standard of care treatments including lifestyle modifications, PAP treatments (e.g., CPAP or BiPAP machines), oral appliances (e.g., mandibular advancement devices), and pharmacotherapy (e.g., tirzepatide), one of the following:
      a. Inability to eliminate OSA (AHI > 15 despite PAP usage);
      b. Inability to use PAP (at least five nights per week of usage; usage defined as > four hours of use per night);
      c. Unwilling to use PAP (i.e., member/enrollee initiates PAP therapy and subsequently discontinues by choice);
   8. None of the following contraindications:
      a. Combined central and mixed apneas > 25% of total AHI;

b. Member/enrollee has any functional or structural problem, medical illness or condition, including additional sleep disorders, that would prevent or interfere with implantation, activation or continued use of the Genio therapy.
c. Member/enrollee has an active implantable medical device which may be susceptible to unintended interaction with the Genio® System;
d. Member/enrollee is planning to become pregnant, currently pregnant, or breastfeeding;
Any condition or procedure that has compromised neurological control of the upper airway;

II. It is the policy of health plans affiliated with Centene Corporation that drug induced sleep endoscopy (DISE) is medically necessary when completed to evaluate the appropriateness of a hypoglossal nerve stimulation device.

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 $\leq$ 40 kg/m^2, and no unfavorable collapse on drug-induced sleep endoscopy (DISE). 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.[21]

A meta-analysis of uncontrolled studies of upper airway stimulation therapy showed 50 to 57% reductions in apnea-hypopnea index (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-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]

Another study was completed on patients who had undergone implantation of the Inspire system and had at least one follow-up visit recorded in the ADHERE database as of June 8, 2021. Patients were placed into 5 subgroups according to baseline AHI: subgroup 1 (AHI 0 to15), 2 (AHI 15 to 30), 3 (AHI ≥ 30 to 50), 4 (AHI > 50 to 65), and 5 (AHI > 65). After 12 months there was significant improvement in objective sleep parameters in subgroups with a baseline AHI of 15 or above. The results suggest that UAS is an effective treatment for patients with an AHI ≥ 15 events per hour, independent of preoperative OSA severity. These results clearly support that the indication of UAS could be broadened for patients with an AHI above 65 events per hour, which, to date, is not common practice.[23] Another study suggested that patients with a BMI up to 35 kg/m^2 had a positive treatment response with UAS therapy.[24] The findings, together with the results of the present analysis, suggest that the current indications for Inspire could be broadened. Patient satisfaction remained high in all subgroups. The results support the broader indication for UAS therapy in patients with an AHI above 50 events/h and even above 65 events per hour of sleep. This group of patients has the highest burden of disease, in whom no other effective treatment options are available in case of CPAP failure.

The Inspire V neurostimulator for OSA received FDA approval in 2024. The Inspire® V system incorporates respiratory sensing internal to the neurostimulator. This eliminates the need to implant the pressure-sending lead, thus providing one less component.

In August 2025, the United Stated FDA approved the Genio® System for the treatment of moderate to severe OSA. The Genio® System is a bilateral hypoglossal nerve stimulator, which consists of an implantable stimulator placed under the chin and a wearable device that serves as both the power source and the controller programmed with therapy settings.[28,29] The implantable stimulator stimulates both the left and the right hypoglossal nerve terminal branches and operates without a battery or software. Instead, the implantable stimulator receives energy pulses transmitted either from the external stimulator during implantation or from the activation chip during therapy, which is attached to an adhesive disposable patch placed under the patient's chin.[28] The battery-free stimulator promotes airway patency by delivering bilateral stimulation to

the hypoglossal nerve branches, causing contraction of specific tongue muscles.[28,30] The wearable component connects to a smartphone application, allowing patients to pause or resume treatment, adjust the intensity of the stimulation, and monitor their sleep progress.[30,31]

The FDA approval of Genio® was based on data from the DREAM trial, a multi-center, prospective, open-label, single arm clinical study. The DREAM trial was designed to assess the safety and efficacy of the Genio® bilateral hypoglossal nerve stimulation system in the treatment of moderate to severe OSA in patients age 22 years or older over a 12-month period after device implantation.[27,28] The DREAM trial achieved its primary and secondary endpoints with a 63.5% AHI responder rate and a 71.3% oxygen desaturation index (ODI) responder rate.[28,31] Participants demonstrated a median 70.8% reduction in AHI, and 82% achieved an AHI below 15. The findings also demonstrated that Genio was effective regardless of sleep position.[31]

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]

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 2024, 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
42975	Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic
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
64568	Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator

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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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/m2; 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. Removed ICD-10 diagnosis table. References reviewed, reformatted and updated. Reviewed by internal specialist.	11/22	11/22
Annual review. Edits were made to criteria to align with the FDA updates issued June 8, 2023, for the Inspire Upper Airway Stimulation System. Updated criteria B. from "Age > 22 years" to "BMI ≤ 40 kg/m2"; changed C. from "BMI < 35 kg/m2" to "One of the following:" adding C.1 to C.3, indicating the updated age ranges and associated criteria. Contraindications were updated to I.D.a to I.D.g. The original criteria points I.E to I.I were removed. Background updated with no clinical significance. References reviewed and updated. Reviewed by external specialist.	11/23	11/23
Added criteria II. regarding drug induced sleep endoscopy (DISE) being medically necessary when completed to evaluate the appropriateness of a hypoglossal nerve stimulation device. Background updated with no clinical significance. CPT code "42975" added.	08/24	08/24
Annual review. Updated description with no impact to criteria. Updated I.C.3.a. from apnea-hypopnea index (AHI) of >15 and < 100 to ≥ 15 and ≤ 100. Added contraindication I.D.8. Member/enrollee has rhabdomyolysis. References reviewed and updated.	11/24	11/24
Added new codes, 64568 and 64569, for Inspire V to coding table.	06/25	06/25
Annual review. Added note under Description regarding criteria for titration polysomnography (PSG) following implantation of hypoglossal nerve stimulator…Updated verbiage in Criteria I.A. to specify that criteria is for the Inspire® Upper Airway Stimulation system. Added Criteria I.A.2. regarding PSG performed within 24 months of first consultation…Removed Criteria I.A.3.b.ii. and I.A.3.c.ii. regarding absence of complete concentric collapse at the soft palate level since this is addressed in Criteria I.A.4.b. Changed Criteria I.A.3.c.i. from apnea-hypopnea index (AHI) ≥ 10 and ≤ 50 to AHI > 10 and < 50. Added Criteria I.B. for criteria for the Genio® System. Background updated to include information on Genio® system. Coding and descriptions reviewed. References reviewed and updated. Reviewed by external specialist.	11/25	11/25

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Updated verbiage in Criteria I. from "all of the following criteria" to "either of the following criteria."	01/26	01/26

References

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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 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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

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.