Clinical Policy: Implantable Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea

Reference Number: LA.CP.MP.180 Coding Implications
Last Review Date: 11/2020 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 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 Louisiana Healthcare Connections 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 > 22 years;
C. BMI < 32 kg/m^2
D. Polysomnography performed within 24 months of first consultation for implant;
E. Apnea-hypopnea Index (AHI) of > 20 and < 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 20 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;
   3. Unable or do 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. Requirement of MRI for members/enrollees requesting Inspire Model 3024;
   6. For members/enrollees requesting Inspire Model 3028, requirement for an MRI other than as described in the Inspire MR Conditional labeling.

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 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/m^2, and no unfavorable collapse on drug-induced sleep endoscopy. 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 is able to configure the stimulation settings using the external physician programmer. The patient sleep remote allows the patient to turn therapy on before they go to sleep and to turn therapy off when they wake 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 percent reductions in AHI, 48 to 52 percent reductions in oxygen desaturation index, and significant improvements in sleepiness and quality of life at 3 to 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 created to collect demographic, surgical outcome, complications, quality of life and patient-reported outcomes undergoing treatment with 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.

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. Not all adult patients are candidates for UAS therapy and appropriate polysomnographic, age, BMI and objective upper airway evaluation measures are required for proper patient selection.[6]

American Academy of Sleep Medicine
The American Academy of Sleep Medicine do not currently address hypoglossal nerve stimulation in their guidelines. Their guideline on surgical treatment of OSA in adults is in the process of being updated.

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.

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 2019, 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
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
64568	Incision for 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

CPT® Codes	Description
64570	Removal 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 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

ICD-10-CM Diagnosis Codes that Support Coverage Criteria
+ Indicates a code requiring an additional character

ICD-10-CM Code	Description
G47.33	Obstructive sleep apnea (adult) (pediatric)

Reviews, Revisions, and Approvals	Date	Approval Date
Converted corporate to local policy.	11/2020	

References

1. Strollo PJ Jr, Soose RJ, Maurer JT, et al. Upper-airway stimulation for obstructive sleep apnea. N Engl J Med. 2014 Jan 9; 370 (2):139-49.
2. Kryger KH, Malhotra A. Management of obstructive sleep apnea in adults. In: UpToDate, Collop N (Ed), UpToDate, Waltham, MA. Accessed 11/3/20.
3. Weaver EM, Kapur VK. Surgical treatment of obstructive sleep apnea in adults. In: UpToDate, Collop N (Ed), UpToDate, Waltham, MA. Accessed 11/3/20.
4. United States Food and Drug Administration. Approval Letter for Inspire Upper Airway Stimulation (P130008) 4/30/2014. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130008 Accessed October 18, 2019.
5. Hayes Health Technology Assessment. Hypoglossal Nerve Stimulation (HGNS) for the Treatment of Obstructive Sleep Apnea. October 30, 2018.

6. American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea (OSA). Adopted 3/20/16. Available at: https://www.entnet.org/content/position-statement-hypoglossal-nerve-stimulation-treatment-obstructive-sleep-apnea-osa. Accessed October 18, 2019.
7. Kline LR. Clinical presentation and diagnosis of obstructive sleep apnea in adults. In: UpToDate, Collop N (Ed), UpToDate, Waltham, MA. Accessed 11/3/20.
8. Inspire Medical Systems. Inspire Therapy. Accessed October 18, 2019 at: https://professionals.inspiresleep.com/
9. Certal VF, Zaghi S, Riaz M, et al. Hypoglossal nerve stimulation in the treatment of obstructive sleep apnea: A systematic review and meta-analysis. Laryngoscope. 2015 May;125(5):1254-64. Epub 2014 Nov 12.
10. Woodson BT, Strohl KP, Soose RJ, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes. Otolaryngol Head Neck Surg. 2018;159(1):194. Epub 2018 Mar 27.
11. Heiser C, Steffen A, Boon M, et al. Post-approval upper airway stimulation predictors of treatment effectiveness in the ADHERE registry. Eur Respir J. 2019 Jan 3;53(1). pii: 1801405. doi: 10.1183/13993003.01405-2018. Print 2019 Jan.
12. Kent DT, Carden KA, Wang L, et al. Evaluation of Hypoglossal Nerve Stimulation Treatment in Obstructive Sleep Apnea. JAMA Otolaryngol Head Neck Surg. 2019 Sep 26. doi: 10.1001/jamaoto.2019.2723.
13. Aurora RN, Casey KR, Kristo D, et al. Practice Parameters for the Surgical Modifications of the Upper Airway for Obstructive Sleep Apnea in Adults SLEEP, Vol. 33, No. 10, 2010 1408.
14. National Institute of Health and Care Excellence (NICE). Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea. Interventional procedures guidance [IPG598] Published date: November 2017. Available at: https://www.nice.org.uk/guidance/ipg598 Accessed October 23, 2019.

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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. This clinical policy is not intended to recommend treatment for members. Members 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 LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members 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 and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.