CLINICAL MEDICAL POLICY	
Policy Name:	Hypoglossal Nerve Stimulation Implantation in the Treatment of Obstructive Sleep Apnea
Policy Number:	MP-079-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	02/01/2025; 02/01/2024; 02/01/2023; 01/21/2022; 02/13/2021; 02/17/2020; 03/19/2019
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Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 11

Policy History

Date	Activity
03/01/2025	Provider Effective date
01/16/2025	PARP Approval
11/20/2024	QI/UM Committee review
11/20/2024	Annual Review: Updated HGNS clinical criteria under 'Procedures' section. Updated 'Summary of Literature' and 'Reference Sources' sections.
03/01/2024	Provider Effective date
01/10/2024	PARP Approval
11/15/2023	QI/UM Committee review
11/15/2023	Annual Review: Added clinical criteria under 'Procedure' section for hypoglossal nerve stimulator guidance for individuals with Down syndrome. Updated 'Summary of Literature' and 'Reference Sources' sections.
03/01/2023	Provider Effective date
01/10/2023	PARP Approval
11/16/2022	QI/UM Committee review
11/16/2022	Annual Review: Changed BMI requirement from '*less than 32*' to '*less than 35'* per CMS guidance. Added the following CPT codes: 64582, 64583, & 64584. Removed deleted CPT codes: 64568, 0466T, 0467T, & 0468T. Added the following ICD-10 codes: Z68.33 & Z68.34. Updated 'Summary of Literature' and 'Reference Sources' sections.
02/21/2022	Provider Effective Date

01/10/2022	PARP Approval
11/17/2021	QI/UM Committee Review
11/17/2021	Annual Review: No changes to clinical criteria. Updated Summary of Literature, and References.
03/15/2021	Provider Effective Date
10/16/2018	Initial policy developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ may provide coverage under the medical-surgical benefits of the Company's Medicaid products for FDA-approved hypoglossal nerve stimulation implantation in the treatment of obstructive sleep apnea.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) - A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Apnea - Cessation of airflow for at least 10 seconds.

Hypopnea - An abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoraco-abdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.

Apnea-Hypopnea Index (AHI) - The average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device.

Continuous Positive Airway Pressure (CPAP) - breathing therapy device that delivers air to a mask worn over the nose and/or mouth to help consistent breathing; it is used primarily for sleep apnea, but also in the treatment of other breathing conditions

Bi-level Positive Airway Pressure (BiPAP) - breathing therapy that pressurizes the air to a higher level than the air in the room, and so it helps a person to take in oxygen and exhale carbon dioxide; this helps the patient to breathe more easily, either while sleeping or when experiencing a flare-up of symptoms.

Drug-Induced Sleep Endoscopy - diagnostic tool to assess the upper airway of snorers and obstructive sleep apnea patients in conditions that mimic natural sleep.

Procedures

1. The implantation of an FDA-approved hypoglossal nerve stimulation (HGNS) device is considered medically necessary for the treatment of obstructive sleep apnea (OSA). HGNS systems may be considered medically necessary when ALL of following conditions exist:
    A. The individual is 18 years of age or older; AND
    B. Documented AHI greater than or equal to 20 with less than 25% central apneas; AND
    C. CPAP failure (residual AHI greater than 20 or failure to use CPAP greater than or equal to four (4) hours per night for five (5) or more nights per week) or an inability to tolerate CPAP; AND
    D. Body mass index less than or equal to 32; AND
    E. Non-concentric retropalatal obstruction on drug-induced sleep endoscopy (DISE).

2. HGNS may be considered medically necessary in young adults with Down syndrome & OSA when ALL of the following conditions exist:
    A. The individual is between the ages of 10 years of age or older; AND
    B. The individual has an AHI greater than 10 and less than 50 with less than 25% central apnea after prior adenotonsillectomy; AND
    C. The individual has EITHER of the following:
        1) A tracheotomy; OR

2) Previous CPAP treatment has been ineffective due to noncompliance, discomfort, undesirable side effects, persistent symptoms despite compliance use, or refusal to use the CPAP device; AND

D. A BMI less than or equal to the 95th percentile for age; AND

E. Non-concentric retropalatal obstruction on DISE.

3. All non-FDA-approved HGNS systems (e.g., the Apnex Hypoglossal Nerve Stimulation System, the aura6000 System, IMThera Targeted Hypoglossal Neurostimulation Therapy, WellStar Upper Airway Neurostimulation Implant, etc.) are considered experimental/investigational, and therefore not medically necessary.

4. Contraindications
   - Central and mixed apneas > 25% of the total apnea-hypopnea index (AHI)
   - Any anatomical finding that would compromise the performance of the upper airway stimulation, such as the presence of complete concentric collapse of the soft palate
   - Any condition or procedure that has compromised neurological control of the upper airway
   - Patients with hypoglossal nerve palsy
   - Active psychiatric disease
   - Patients who are unable to or do not have the necessary assistance to operate the sleep remote
   - BMI greater than 35
   - Severe restrictive or obstructive pulmonary disease
   - Severe valvular heart disease

5. Precautions
   - Should not be used for individualss who are or plan to become pregnant.
   - Patients that require MRI must be alert to their specific stimulator model which may preclude this service.

6. Place of Service
   HGNS for the treatment of OSA must be furnished in accordance with the accepted standards of medical practice in a setting most appropriate to the patient's medical needs and condition. Therefore, the service may be provided in either the inpatient or outpatient setting. Hospitalization is generally not required for device implantation.

7. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

8. Related Policy
   - MP-069-MD-PA Home Oxygen Therapy (HOT)

Governing Bodies Approval

In the United States, the FDA approved the implantable upper airway stimulation for obstructive sleep apnea (Inspire Upper Airway Management Stimulation) on April 30, 2014. It is classified as a Class III device, PMA P130008, product code MNQ. This first-in-class device is intended to treat a subset of adult patients who are at least 22 years of age with moderate-to-severe OSA, who have failed or cannot tolerate PAP treatments. In addition, the patients cannot have a complete concentric collapse at the soft palate level. The device was not tested in individuals with a BMI greater than 32.

A condition of the PMA from the FDA requires that the manufacturer conduct two post-approval studies. The first study is the extended follow-up of the Premarket Cohort (Stimulation Therapy for Apnea Reduction, ClinicalTrials.gov identifier: NCT01161420). The second study is the Inspire Post-Approval Study Protocol Number 201-001. This trial will involve enrollment of multi-centers in a prospective, single arm cohort study to evaluate the long-term device safety and effectiveness. September 2021 is the expected completion date.

On June 5, 2017, the FDA approved the next-generation Inspire 3028 Upper Airway Stimulator. This model includes magnetic resonance conditional labeling, allowing patients to undergo MRI safely.

In November 2014, ImThera Medical Inc. announced that the FDA approved an Investigational Device Exemption (IDE) for a clinical study to evaluate the aura6000 in patients with moderate-to-severe OSA unable or unwilling to try positive airway pressure therapy or other OSA treatments.

The Centers for Medicare and Medicaid Services (CMS) has published the following guidance:

- Local Coverage Determination (LCD) Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38385)
- Local Coverage Article (LCA) Billing and Coding: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (A56938)

Summary of Literature

Obstructive sleep apnea (OSA) is a common condition in which the airway becomes obstructed during sleep which causes periods of apnea and hypopnea due to repetitive collapse of the upper airway during sleep. Recent studies have indicated that 1 in 4 adults in the United States (31% of all men and 21% of all women over age 18) are at high risk for developing OSA, and it is estimated that 25 million U.S. adults have OSA (AASM, 2014). Individuals at higher risk of developing sleep apnea include individuals diagnosed with hypertension, males, obesity (BMI > 30), use of alcohol or sedatives excessively, smoking, family history of OSA, having a large neck circumference (> 17” in men and > 16” in women), suffering from endocrine and metabolic disorders, or having upper airway or facial abnormalities. Complications from OSA include excessive daytime sleepiness, mental impairment, metabolic dysfunction, cardiovascular problems, heart attack, stroke, diabetes, impotence, acid reflux, and even death if untreated (Sesso, 2016).

OSA occurs at one or more levels of the nasopharyngo-tracheal airway. Type I disease involves narrowing or collapse of the retropalatal region. Type II disease involves collapse in the retrolingual area (tongue base). Type III disease involves narrowing or collapse of both the retropalatal and retrolingual areas. Major OSA is usually a multi-level disorder, with tissues of the soft palate, lateral pharyngeal walls, and tongue

base all contributing to airway impingement. Intra-nasal tissue, adenoids, and tonsils may also play a role (AASM, 2008).

The goals of OSA therapy are to resolve signs and symptoms of OSA, improve sleep quality, and normalize the apnea-hypopnea index and oxyhemoglobin saturation levels. OSA should be approached as a chronic disease that requires long-term, multidisciplinary management. The potential benefits of successfully treating OSA include clinical improvement (eg, less daytime sleepiness), reduced health care utilization and costs, and, possibly, decreased cardiovascular morbidity and mortality. Patient education and behavior modifications should be introduced, including weight loss, exercise, changes to sleep positions, alcohol avoidance, and concomitant medications (UpToDate, 2022).

A possible treatment for OSA is neuromodulation or a hypoglossal nerve stimulator (HGNS). The hypoglossal nerve stimulator is an implanted device similar to a cardiac pacemaker that is surgically implanted. A neurostimulator is implanted subcutaneously beneath the clavicle, and one lead is attached to the hypoglossal nerve at the base of the tongue, and a second pressure sensor lead is implanted in the chest to detect breathing. The device is turned on one month post-implantation. The implant activates the hypoglossal nerve in order to tighten the muscles of the tongue and upper airway during sleep which promotes airflow and reduces sleep apnea. In addition to the implant, the device requires the use of a remote control. After the device is implanted, the user has to push a button on the remote control to activate and deactivate the neurostimulator. According to the manufacturer Inspire Medical Systems, the patient must meet the following criteria:

- Have moderate-to-severe obstructive sleep apnea
- Be at least 22 years old
- Have tried and failed at CPAP or bi-level positive airway pressure (BiPAP) machines
- Individuals who do not have a complete concentric collapse at the soft palate level (Inspire Medical Systems, 2017).

Identified contraindications of the device include allergies that result in obstruction of the nose, deviated nasal septum, various skeletal anatomy conditions such as small or recessed lower jaw, enlarged tonsils, and certain neuromuscular conditions that affect the ability to swallow or contribute to slurred speech, and the need for frequent MRIs for other medical conditions (Inspire Medical Systems, 2017).

Strollo et al. (2014) performed a case series study on the Stimulation Treatment for Apnea Reduction (STAR). In this study, a multicenter, prospective single group of 126 participants had upper airway stimulation devices implanted. All participants had been diagnosed with moderate-to-severe obstructive sleep apnea (OSA), had a BMI between 18.4 and 32.5, and had experienced difficulty either accepting or complying with CPAP therapy. The study evaluated the clinical safety and effectiveness of the implanted device at 12 months. A total of 124 participants completed the follow-up at 12 months and had a mean BMI of 28.5. Scores on the apnea-hypopnea index (AHI) and oxygen desaturation index (ODI) were lower at 12 months than at baseline. The median AHI score decreased 68%, and the ODI score decreased 70%.

Participants (23) who had not had a response were not included in part of the study. There was no control group in the study. The study was designed by the sponsor (Inspire Medical Systems), the investigators, and the FDA.

The American Academy of Otolaryngology-Head and Neck Surgery considers upper airway stimulation (UAS) via the hypoglossal nerve for the treatment of adult obstructive sleep apnea syndrome to be an effective second-line treatment of moderate-to-severe obstructive sleep apnea in patients who are

intolerant or unable to achieve benefit with positive pressure therapy (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 (AAO-HNS, 2019).

The International Sleep Surgery Society supports HGNS as effective in the treatment to increase the patency of the upper airway during sleep for patients with moderate-to-severe OSA who are intolerant to positive airway pressure (PAP) therapy. The patient should have undergone an appropriate evaluation(s) prior to treatment which may include polysomnography, home sleep testing, awake or drug-induced sleep endoscopy, and possible cephalometric or other radiographic evaluations (Suurna, Jacobowitz, Chang, et al., 2021).

An UpToDate review stated that HGNS is a novel treatment strategy that may have a unique place for selected patients with a body mass index <32, and moderate-to-severe OSA that declined or failed to adhere to positive airway pressure therapy. However, the review stated that further data are necessary (Kryger, Malhotra 2018).

In the Stimulation Therapy for Apnea Reduction (STAR) trial, HGNS use resulted in substantial reductions in the apnea-hypopnea index (AHI) and in the number of oxygen desaturations, as well as improvements in sleep quality. These results have proven to be reproducible across centers and stable over time. The trial provided that HGNS is an effective and evolving second-line therapy for OSA. Multiple factors can influence therapy outcomes, compliance, and long-term success. Further research is needed to establish criteria for outcomes assessment, patient candidacy, predictors of treatment success, and evaluation for combination therapy to eliminate OSA and address other associated comorbidities (Suura, Jacobowitz, Chang, et al., 2021).

The current position statement from the National Institute for Health and Clinical Excellence (NICE) is that the current evidence on the safety and efficacy of HGNS for moderate-to-severe obstructive sleep apnea is limited in quantity and quality. Therefore, the procedure should only be used with special arrangements for clinical governance, consent, and audit for research. There has been no update in the 2017 position statement (NICE, 2017).

A study reported that upper airway stimulation for the treatment of OSA is indicated in patients with positive airway pressure failure, who are 22 years of age or older, with AHI of 15 to 65, with body mass index less than or equal to 32, and with anatomy amenable to implantation and likelihood of high success (Gupta et al, 2019).

A 2020 meta-analysis stated that HGNS has obtained a high surgical success rate with reasonable long-term complication rate related to the device implanted. The procedure represents an effective and safe surgical treatment for moderate-severe OSA in selected adult patients who had difficulty accepting or adhering to CPAP treatment (Costantino, Rinaldi, Moffa, et al., 2020).

An evaluation of a 5-year outcome study of upper airway stimulations was reported by Woodson and colleagues (2018). This review involved a prospective cohort study of 126 patients with OSA that were treated with a unilateral hypoglossal nerve implant. The inclusion criteria were patients who had failed continuous positive airway pressure devices, had a BMI less than 32, and did not show collapse during a drug-induced sleep endoscopy. The review of literature indicates the hypoglossal nerve stimulation procedure is a promising new procedure which may be effective in the treatment of OSA. However, additional studies that include random controlled trials are needed. Trials are necessary to address the

effectiveness of this procedure compared to existing conventional treatments as well as to identify the most appropriate patients for the therapy. There is insufficient data to determine the effects of hypoglossal nerve stimulation on obstructive sleep apnea health outcomes or long-term risks.

Adolescents with Down syndrome may show several unique characteristics, such as generalized hypotonia, macroglossia, facial hypoplasia, small tracheal caliber, and lingual tonsillar hypertrophy. Up to 80% of children with Down syndrome have OSA, which is thought to be caused by these unique characteristics. Untreated OSA can affect a child's development, including reduced learning abilities, speech and language delays, and impaired cognitive flexibility and memory. Upper airway surgery and CPAP are the commonly used treatments for OSA. Residual airway obstruction following upper airway surgery can cause children to require breathing support. Also, compliance with CPAP may cause discomfort, inconvenience, and cognitive delays. Studies have shown that HGNS may be more tolerable and less irritating than CPAP and upper airway surgery and is an effective treatment for moderate-to-severe OSA in adolescent patients. HGNS can significantly reduce the AHI and improve the quality of life of adolescents with Down syndrome and can be considered as a potential alternative treatment for OSA (Liu, Kong, Fang, et al., 2022).

Coding Requirements

Procedure Codes

CPT Code	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

Diagnosis Codes

Hypoglossal nerve stimulation procedures on patients who meet coverage criteria set forth in this policy must include both a primary ICD-10-CM diagnosis code indicating the reason for the procedure and a secondary ICD-10-CM diagnosis code indicating the Body Mass Index (BMI) is less than 35. A primary diagnosis code from Group1 Code and a secondary diagnosis code from Group 2 Codes below must be reported.

ICD-10 Code	Description
Group 1 Code	
G47.33	Obstructive sleep apnea (adult) (pediatric) (Primary Diagnosis)
Group 2 Codes	
Z68.1	Body mass index (BMI) 19.9 or less, adult
Z68.20	Body mass index (BMI) 20.0-20.9, adult
Z68.21	Body mass index (BMI) 21.0-21.9, adult

Z68.22	Body mass index (BMI) 22.0-22.9, adult
Z68.23	Body mass index (BMI) 23.0-23.9, adult
Z68.24	Body mass index (BMI) 24.0-24.9, adult
Z68.25	Body mass index (BMI) 25.0-25.9, adult
Z68.26	Body mass index (BMI) 26.0-26.9, adult
Z68.27	Body mass index (BMI) 27.0-27.9, adult
Z68.28	Body mass index (BMI) 28.0-28.9, adult
Z68.29	Body mass index (BMI) 29.0-29.9, adult
Z68.30	Body mass index (BMI) 30.0-30.9, adult
Z68.31	Body mass index (BMI) 31.0-31.9, adult
Z68.32	Body mass index (BMI) 32.0-32.9, adult
Z68.33	Body mass index (BMI) 33.0-33.9, adult
Z68.34	Body mass index (BMI) 34.0-34.9, adult

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

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