CLINICAL MEDICAL POLICY	
Policy Name:	Hypoglossal Nerve Stimulation in the Treatment of Obstructive Sleep Apnea
Policy Number:	MP-079-MD-DE
Responsible Department(s):	Medical Management
Provider Notice Date:	04/01/2019
Issue Date:	05/06/2019
Effective Date:	05/06/2019
Annual Approval Date:	03/12/2020
Revision Date:	N/A
Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 7

DISCLAIMER

Highmark Health Options 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 Health Options does not provide coverage under the medical-surgical benefits of the Company's Medicaid products for hypoglossal nerve stimulation 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.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

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.

PROCEDURES

1. The implantation of a hypoglossal nerve stimulation device is not covered in the treatment of obstructive sleep apnea and any other medical condition. In addition, all non-FDA hypoglossal nerve stimulation systems (the Apnex Hypoglossal Nerve Stimulation, the aura6000 Neurostimulation system, IMThera Targeted Hypoglossal Neurostimulation Therapy, and WellStar Upper Airway Neurostimulation Implant) are not covered.

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

3. Place of Service
   The place of service for hypoglossal nerve stimulation implantation is outpatient.

GOVERNING BODIES APPROVAL

In the United States, the FDA approved the implantable upper airway stimulation for obstructive sleep apnea (Inspire II 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.

A condition of the PMA from the FA requires that the manufacturer conduct tow 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 trial is the Inspire Post-Approval Study Protocol Number 201-001. New enrollment multi-center, prospective, single arm cohort study to evaluate the long-term device safety and effectiveness. September 2021 is the expected completion date.

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.

On March 29, 2017 the FDA approved the Inspire II Upper Airway Stimulator.

CMS
Novitas
LCD L35064 list the procedure codes for hypoglossal nerve stimulation as services that are not reasonable and necessary.

Palmetto GBA
LCD L34555 list the associated procedure codes as noncovered Category III CPT codes.

Noridian
LCD L36219 lists the identified procedure codes as noncovered.

CODING REQUIREMENTS

*Non-covered Procedure Codes

CPT Codes	Description
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

*These procedure codes will not be reimbursed without Medical Director approval.

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

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 (American Sleep Association). Individuals at higher risk of developing sleep apnea include individuals diagnosed with hypertension, males, obese (BMI >30), use of alcohol or sedatives excessively, smoking, family history of OSA, have a large neck circumference (>17" in men and >16"in women), suffer from endocrine and metabolic disorders, or have upper airway or facial abnormalities (Sesso, 2016). 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.

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).

Management of OSA is based on symptomatology, the severity of the disease, and patient education regarding the risk factors and associated outcomes of OSA. Management begins with appropriate diagnostic testing to confirm OSA diagnosis. Several behavior modifications are recommended for patients with OSA and a modifiable risk factor. These include education, weight loss and exercise, sleep positioning, alcohol avoidance, and concomitant medications. The gold standard treatment for OSA patients is use of continuous positive airway pressure (CPAP) machine.

A relatively new proposed treatment for OSA is the neuromodulation or hypoglossal nerve stimulator. 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 sleep apnea
- Be at least 22 years old
- Have tried and failed at CPAP
- Recommended patients have a Body Mass Index (BMI) less than 32

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.

Strollo (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.

The International Surgical Sleep Society supports Cranial nerve (hypoglossal nerve) stimulation as effective in the treatment of sleep disordered breathing/obstructive sleep apnea syndrome in adults (and/or

children) when applied to selected patients based on their anatomy, physiology, body mass index and neck size, prior therapy and co-morbidities. 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.

In the 2013 guidelines for the management of OSA in adults, the American College of Physicians (ACP) recommended that overweight and obese OSA patients to lose weight; CPAP treatment should be used as the initial therapy, and mandibular advancement devices can be used as an alternative to CPAP. The guidelines do not include any recommendations on the use of the hypoglossal nerve stimulator as a treatment of OSA.

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.

A systematic review of 15 publications on hypoglossal upper airway stimulation in the treatment of OSA was performed by Hayes in 2016. These 15 publications involved 6 pretest/posttest studies which had 9 associated subsequent reports with follow up data, additional outcomes, overlapping samples, and/or subgroup analysis. The findings stated that the investigators consistently reported improved AHI, ODI, and airflow mechanics with the device, but inconsistent evidence supported no change in various sleep parameters. Hayes assigned a D2 rating in the use of hypoglossal nerve stimulation for the treatment of moderate-to-severe OSA in adult patients for whom CPAP failed to provide relief. This rating is based on the paucity of good-quality comparative studies with sufficient sample sizes assessing the device for OSA.

In 2015, an UpToDate review stated that the hypoglossal nerve stimulation is a novel treatment strategy that may have a unique place for selected patients with moderate-to-severe OSA that declined or fail to adhere to positive airway pressure therapy. However, the review stated that further data are necessary.

Rationale
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.

POLICY SOURCE(S)

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Policy History

Date	Activity
10/16/2018	Initial policy developed
03/12/2019	QI/UM Committee approval
05/06/2019	Provider effective date