Medical Necessity Guidelines: Hypoglossal Nerve Stimulation for Treatment of Moderate to Severe Obstructive Sleep Apnea

Effective: September 10, 2020

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	**Yes ☒ No ☐**

Applies to:

COMMERCIAL Products

☒ Tufts Health Plan Commercial products; Fax: 617.972.9409

☒ Tufts Health Freedom Plan products; Fax: 617.972.9409

○ CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

TUFTS HEALTH PUBLIC PLANS Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax:888.415.9055

☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404

☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304

*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

SENIOR Products

- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List
- Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

OVERVIEW

Obstructive sleep apnea (OSA) is characterized by recurrent episodes of partial or complete collapse of the upper airway during sleep, resulting in reduced (hypopnea) or absent (apnea) airflow. Individuals with OSA can experience recurrent arousals from sleep in addition to nocturnal hypoxemia, hypoxia (decreased O2 levels), hypercapnia (increased CO2 levels) and loud snoring. Obstructive sleep apnea is a major cause of excessive sleepiness in adults and can contribute to reduced quality of life and impaired work performance. OSA has been associated with considerable health risks, including hypertension, type 2 diabetes mellitus, cerebrovascular disease and coronary heart disease.

Obstructive sleep apnea is diagnosed and classified by home or laboratory based sleep testing. Severity is classified based on apnea hypopnea index (AHI). Although multiple non-invasive and surgical treatments exist for the treatment of OSA, positive airway pressure (PAP) remains the standard of care for individuals with mild to severe symptomatic OSA.

Upper airway stimulation is an alternative treatment of moderate to severe OSA when an individual has failed or is intolerant to PAP therapy. Contraction of upper airway dilator muscles is necessary to maintain airway patency during inspiration. The most important upper airway dilator muscle is the genioglossus muscle, which is innervated by the medial branch of the hypoglossal nerve and contracts with each inspiration, preventing posterior collapse of the tongue. Inspire upper airway stimulation (Inspire Medical Systems) is a system of unilateral hypoglossal nerve stimulation consisting of a small pulse generator surgically implanted in the chest wall, a stimulation electrode (lead) placed on the medial branch of the hypoglossal nerve and a respiratory pressure sensing electrode (lead) placed between internal and external intercostal muscles. The sensing electrode detects inspiratory effort which triggers hypoglossal nerve electrode stimulation, producing stimulation of the genioglossus muscle fibers that draw the tongue forward.

For Tufts Health Unify, refer to **Local Coverage Determination (LCD): HYPOGLOSSAL Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387)** at cms.gov/medicare-coverage-database/details/lcd-details

For all other Commercial and Tufts Health Public Plans Products, please use the following clinical coverage criteria.

CLINICAL COVERAGE CRITERIA

Tufts Health Plan may cover hypoglossal nerve stimulation (HGNS) implantation procedure when **ALL** the following criteria are met:

1. Member is 22 years of age or older[2]
2. Member's body mass index (BMI) is less than 35 kg/m
3. A polysomnography (PSG), performed no more than 24 months prior to initial consultation for HGNS implantation, confirms:

   a. Moderate to severe obstructive sleep apnea (OSA), with apnea hypopnea index (AHI) of 15 to 65 events per hour

   AND

   b. Predominantly obstructive events, defined as central and mixed apneas less than 25 percent of the total AHI

4. Member has trialed continuous PAP(CPAP) and/or bi-level PAP within previous 24 months **and** for a minimum of three months, AND documented failure and/or intolerance to CPAP and/or bi-level PAP is confirmed by the following:
   a. Continued AHI greater than 15 despite compliant use of CPAP and/or bi-level PAP 4 or more hours per night, 5 or more nights per week

   AND/OR

   b. Inability to tolerate CPAP and/or bi-level PAP a minimum of four or more hours per night, five or more nights per week.

   AND

   c. Failure of and/or intolerance to CPAP/bi-level PAP despite consultation with a sleep expert:
      i. Attempts to resolve reason(s) for failure/intolerance, including but not limited to poor mask fit, excessive leak, adjustments in humidification and improper treatment settings

      and

      ii. Alternative non-invasive treatments for treatment of OSA, after failure or intolerance of CPAP and/or bi-level PAP, were considered and these non-invasive treatments failed or were deemed inappropriate. Alternative non-invasive treatments include but are not limited to oral appliance therapy, positional therapy and/or weight loss.

   NOTE: Facility PAP titration study and unattended auto-titration of PAP (APAP) do not qualify as required 3 month trial of CPAP/bi-level PAP device

5. Surgical consultation indicating absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure
6. DISE procedure identifies no anatomical findings that would compromise performance of device (e.g., tonsil size three or four per standardized tonsillar hypertrophy grading scale)

LIMITATIONS

Tufts Health Plan will not cover the following:

1. Implantation of non-FDA-approved hypoglossal nerve neurostimulation device
2. Implantation of HGNS device for indications other than above

Tufts Health Plan will not cover HGNS implantation when:

3. Member is with presence of any of the following:
   a. Central and mixed apneas that make up greater than 25 percent of the total AHI
   b. BMI 35 or greater
   c. Neuromuscular disease affecting the respiratory system

d. Hypoglossal-nerve palsy
e. Severe restrictive or obstructive pulmonary disease
f. Moderate-to-severe pulmonary arterial hypertension
g. Severe valvular heart disease
h. New York Heart Association class III or IV heart failure
i. Recent myocardial infarction or severe cardiac arrhythmias (within the past six months)
j. Persistent uncontrolled hypertension despite medication use
k. An active, serious mental illness that reduces the ability to carry out Activities of Daily Living (ADLs) and would interfere with the patient's ability to operate the HNS and report problems to the attending provider
l. Coexisting nonrespiratory sleep disorders that would confound functional sleep assessment
m. Member is with any condition or procedure that has comprised neurological control of the upper airway

4. Member is unable or does not have the necessary assistance to operate the sleep remote
5. Member is, or is planning to become pregnant

NOTE: Individuals with certain Inspire stimulator models may not be eligible for MRI scans. Refer to MRI guidelines for Inspire Therapy manual: manuals.inspiresleep.com/

CODES

The following CPT code(s) require prior authorization:

Table 1: CPT Codes

CPT Code	Description
64568	Incision for implantation 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)

REFERENCES

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2. U.S. Food and Drug Administration (FDA) Premarket Approval (PMA) for the Inspire II Upper Airway Stimulator. Supplemental order SO21.
3. Hayes A TractManager Company. Hypoglossal Nerve Stimulation for the Treatment of Obstructive Nerve Stimulation. Health Technology Assessment. October 30, 2018. Annual Review October 25, 2019. Last accessed August 17, 2020 at https://evidence.hayesinc.com/report/dir.hypoglossal2981.
4. Patil SP, Ayappa IA, et. Al. Treatment of Adult Obstructive Sleep Apnea with Positive Airway Pressure: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2019;15(2):335–343.
5. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017; 13 (3):479–504.
6. Woodson BT, Strohl KP, Soose RJ, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes. Otolaryngol Head Neck Surg. 2018 Jul; 159 (1):194-202.
7. 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; 53: 1801405.
8. Withrow K, Evans S, et.al. Upper Airway Stimulation Response in Older Adults with Moderate to Severe Obstructive Sleep Apnea. Otolaryngol Head Neck Surg 2019; 1-6.
9. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) for Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387). Last accessed on August 17, 2020 at cms.gov/medicare-coverage

APPROVAL HISTORY

August 19, 2020: Reviewed by the Integrated Medical Policy Advisory Committee (IMPAC) for effective date September 10, 2020

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.

Provider Services