Subject: Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea

Background: Hypoglossal nerve stimulation (HGNS) is used for the treatment of moderate-to-severe obstructive sleep apnea (OSA) in adult patients for whom continuous positive airway pressure (CPAP) therapy has failed. The stimulator is an implanted medical device which is intended to reduce the occurrence of OSA by electrically stimulating the hypoglossal nerve, resulting in tongue movement. The device stimulates the nerve in time with breathing to relieve any upper airway obstruction. Current FDA approved hypoglossal nerve stimulators are the Inspire II System, Inspire 3028 system for Upper Airway Stimulation (UAS) Therapy.

Authorization: Prior authorization is required for hypoglossal nerve stimulators requested for members enrolled in commercial (HMO, POS, and PPO) products.

Policy and Coverage Criteria: Harvard Pilgrim Health Care (HPHC) considers FDA-approved hypoglossal nerve stimulation as reasonable and medically necessary in adults with moderate-to-severe Obstructive Sleep Apnea (OSA) when documentation confirms ALL of the following:

- Member is 22 years of age or older; AND
- Body Mass Index (BMI) is ≤ 32 kg/m²; AND
- A polysomnography (PSG) is performed within 24 months of the first consultation for HGNS implant; AND
- Apnea hypopnea index (AHI) is 20 to 65 events per hour; AND
- Member has demonstrated CPAP failure for minimum of one month (residual AHI ≥ 20 or failure to use CPAP ≥ 4 hours per night for ≥ 5 nights per week) or documentation confirming inability to tolerate CPAP
- Absence of complete concentric collapse at the soft palate level as seen on a drug induced sleep endoscopy (DISE)
- No anatomical findings that would compromise performance of the device

Exclusions: Harvard Pilgrim Health Care (HPHC) considers hypoglossal nerve stimulation as experimental and investigational for all other indications. In addition, HPHC does not cover HGNS for members with the following:

- BMI >32 kg/m²
- Neuromuscular disease affecting the respiratory system
- Hypoglossal-nerve palsy
- Severe restrictive or obstructive pulmonary disease
- Moderate-to-severe pulmonary arterial hypertension
- Severe valvular heart disease
- NYHA class III or IV heart failure
- Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months)
- Persistent uncontrolled hypertension despite medication use
- Active, serious mental illness that would interfere with the patient’s ability to operate the HSN
- Coexisting nonrespiratory sleep disorders that would confound functional sleep assessment
- Members with a condition or procedure that has compromised neurological control of the upper airway
In addition, HPHC considers non-FDA approved hypoglossal nerve stimulators (e.g., the Apnex Hypoglossal Nerve Stimulation (HGNS™) System, the aura6000™ Neurostimulation System, ImThera’s Targeted Hypoglossal Neurostimulation Therapy, and WellStar upper airway neurostimulation implant) as experimental and investigational for the treatment of obstructive sleep apnea due to insufficient evidence.

**Coding:**
Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>64568</td>
<td>Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator</td>
</tr>
<tr>
<td>0466T</td>
<td>Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (list separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>0467T</td>
<td>Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator</td>
</tr>
<tr>
<td>0468T</td>
<td>Removal of chest wall respiratory sensor electrode or electrode array</td>
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</tbody>
</table>

**Billing Guidelines:**
Member’s medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

**References:***

**Summary of Changes:**
<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
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<tbody>
<tr>
<td>5/20</td>
<td>New Policy</td>
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</table>

Approved by Medical Policy Committee: 06/09/20
Approved by Clinical Policy Operational Committee: 8/20
Policy Effective Date: 11/01/20
Initiated: 5/2020

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HPHC Medical Policy
Hypoglossal Nerve Stimulation

HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members’ unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.

Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g. Benefit Handbook, Certificate of Coverage) for member-specific benefit information.

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