Medical Policy
Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea

Policy Number: 028

<table>
<thead>
<tr>
<th>Authorization required</th>
<th>Commercial and Qualified Health Plans</th>
<th>MassHealth</th>
<th>Medicare Advantage</th>
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<tr>
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Overview
The purpose of this document is to describe the guidelines Mass General Brigham Health Plan utilizes to determine medical necessity for implantation of an FDA approved hypoglossal nerve stimulation (HGNS) device, for obstructive sleep apnea (OSA).

Coverage Guidelines
Mass General Brigham Health Plan covers implantation of an FDA approved hypoglossal nerve stimulator device for OSA in members when ALL the following are met:

- The member is 18 years of age or older with a diagnosis of OSA; and
- The member’s apnea hypopnea index (AHI) is 15-100 with predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); and
- There is absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy procedure; and
- The member’s body mass index (BMI) is less than 32 kg/m²; and
- There is documentation by a Board-Certified Sleep Medicine Specialist of continuous positive airway pressure (CPAP) trial and failure or intolerance (defined as use less than 4 hours per night, five nights per week).

Additionally, Mass General Brigham Health Plan covers implantation of an FDA approved hypoglossal nerve stimulator device for OSA in members when ALL the following are met:

- The member is 13-18 years of age with Down Syndrome; and
- The member has persistent severe OSA with AHI 10-50 with predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); and
- The member has previously had adenotonsillectomy or lacks clinical indication for adenotonsillectomy; and
- The member has BMI less than or equal to 95% percentile for age; and
- There is absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy procedure; and
- There is either nighttime tracheostomy dependence or documentation by a Board-Certified Sleep Medicine Specialist of (CPAP) trial with failure or intolerance (defined as use less than 4 hours per night, five nights per week).

Exclusions
- When the member does not meet the coverage criteria;
- The device is not an FDA-approved hypoglossal nerve stimulation system.
Medicare Variation
Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations. At the time of Mass General Brigham Health Plan’s most recent policy review, Medicare has an LCD: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387).

Definitions
Hypoglossal nerve stimulation (HGNS): HGNS, also known as upper airway stimulation, is a treatment that works by stimulating the hypoglossal nerve to restore tone to (or stiffen) the key tongue muscles that when relaxed, can block the airway causing obstruction that reduces or stops breathing during the night. The implantable pulse generator (and battery) is implanted into the chest, the respiratory sensor is implanted in the ribcage, and the stimulation cuff is implanted in the neck around the hypoglossal nerve. The sensing lead and stimulation lead wires are then tunneled to the chest incision and connected to the implantable pulse generator. The fully implanted system is then controlled with the use of a remote.

Obstructive Sleep Apnea: OSA is characterized by recurrent, functional collapse of the upper airway during sleep, causing substantially reduced or complete cessation of airflow despite ongoing respiratory effort. This leads to episodic hypoxemia and fragmented sleep due to arousals. When untreated, these result in short term quality of life impairment, such as excessive daytime sleepiness, and increased long term cardiovascular and neurocognitive morbidity and mortality.

Codes
The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

This list of codes applies to commercial and MassHealth plans only.

<table>
<thead>
<tr>
<th>Authorized Codes</th>
<th>Code Description</th>
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<tr>
<td>64582</td>
<td>Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array</td>
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<tr>
<td>64583</td>
<td>Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator</td>
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<tr>
<td>64584</td>
<td>Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array</td>
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Effective
July 2022: Annual update. References updated.
January 2022: Code update.
July 2021: Annual update. Under coverage guidelines, changed member age requirement from 22 to 18 years of age.
July 2020: Annual update. References updated.
January 2020: Effective Date
References


