



Subject: Hypoglossal Nerve Stimulation for OSA Policy

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DESCRIPTION

Obstructive Sleep Apnea (OSA) is defined as the obstruction of the upper airway during sleep that occurs because of inadequate motor tone of the tongue and/or airway dilator muscles resulting in temporary cessation of breathing. The optimal approach for treatment is lifestyle changes (weight loss) and education, and then Positive Airway Pressure (PAP). After the failure of PAP or refusal to use PAP machine, the clinical guidelines indicate the order as behavioral/positional therapy, oral appliances, and then surgical therapy. Another viable option after failure of PAP is Hypoglossal nerve stimulation. The goal of Hypoglossal nerve stimulation (HGNS) is to restore the tone of upper airway dilator muscles, including the genioglossus, thus preventing obstruction of the airway. The HGNS system consists of an implantable device, similar to a pacemaker, which contains a neurostimulator, a lead in the patient's chest, and a lead that is attached to the hypoglossal nerve at the base of the tongue. The lead in the chest detects breathing by a pressure sensor and relays respiration rate information to the device, which stimulates the hypoglossal nerve in the tongue. When stimulated, the tongue moves forward, thus opening the airway. The device, which can be operated by a remote control, turns on after 20 minutes to minimize disrupting the patient's sleep onset; the device turns off via remote when the patient wakes up. The decision to perform Hypoglossal nerve stimulation to treat Obstructive Sleep Apnea should be made on a case-by-case basis.

POLICY

The OSU Health Plan considers Hypoglossal nerve stimulation procedures medically necessary for the treatment of Obstructive Sleep Apnea when the ALL of the following criteria are met:

1. Apnea-Hypopnea Index (AHI) between 15 and 65, documented by polysomnography.
2. Failure of Lifestyle changes and Positive Airway Pressure (PAP) therapy, as indicated by ALL of the following:
 - a) Weight not a concern, or weight loss tried and failed in obese patient.
 - b) PAP trial (usage greater than 5 nights per week and greater than 4 hours per night for a minimum of 1 month) with well-supported follow-up and involvement by qualified sleep specialist has clearly failed due to 1 or more of the following:
 1. Failure to improve symptoms as evidenced by AHI of greater than 15 despite PAP usage
 2. Claustrophobia
 3. Difficulty tolerating pressure
 4. Intolerance to device
3. BMI \leq 35
4. Endoscopy shows incomplete concentric collapse at the level of soft palate.
5. No contraindications are present:

- a) Central and mixed apneas greater than 25% of the total AHI
- b) Any anatomical finding that would affect the performance of upper airway stimulation, such as the presence of complete concentric collapse of the soft palate
- c) Any condition or procedure that would affect neurological control of the upper airway.
- d) Patients who are unable or do not have the necessary assistance to operate the sleep remote.
- e) Patients who are pregnant or plan to become pregnant.
- f) Patients who will require magnetic resonance imaging (MRI).
- g) Patients with an implantable device that may have unintended interactions with the HGNS system such as Inspire system.

6. One of the following FDA approved devices will be utilized:

- a) Inspire® Upper Airway Stimulation device (Inspire Medical)

EXCLUSIONS

The OSU Health Plan considers Hypoglossal nerve stimulation experimental and investigational for all other indications. Prospective studies should seek to identify specific clinical settings where patients would be most likely to benefit from this procedure.

PRIOR AUTHORIZATION

Prior authorization is required.

RELATED CPT/HCPC CODES

CPT codes covered if selection criteria are met:	
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
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

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