THE OHIO STATE UNIVERSITY
HEALTH PLAN

Subject: Hypoglossal Nerve Stimulation for OSA **Revision Date**: 12/25

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.

APPLICABILITY

This policy applies to all OSU Health Plan (OSUHP) benefit plans.

DEFINITIONS

Hypoglossal nerve stimulation is a treatment for sleep apnea that helps keep your airway open by gently moving your tongue forward with stimulation to the nerve while you sleep.

Positive Airway Pressure is a treatment that uses a gentle stream of air from a machine to help keep your airway open while you sleep.

Dilator muscles help move the tongue forward to keep your airway open, especially during sleep.

Neurostimulator is a small device that sends gentle electrical signals to nerves to help relieve pain or improve body functions.

Lead is a thin wire that carries electrical signals between the device and your body.

Polysomnography**,** also called a sleep study, is a test that checks how your body functions while you sleep to find out if you have a sleep disorder.

Apnea-Hypopnea Index (AHI) measures how often your breathing slows down or stops during sleep.

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 100, documented by polysomnography within the past 24 months.
2. Failure of Lifestyle changes and Positive Airway Pressure (PAP) therapy, as indicated by ALL of the following:
    a) Weight is not a concern, or weight loss tried and failed in obese patients.
    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; or
        2. Claustrophobia; or

3. Difficulty tolerating pressure; or
4. Intolerance to device

3. BMI ≤ 40 kg/m^2
4. Drug-induced sleep endoscopy (DISE) 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)

PROCEDURE

OSU Health Plan will approve Hypoglossal Nerve Stimulation for OSA when the above criteria has been met.

PRIOR AUTHORIZATION

Prior authorization is required.

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.

CODES

CPT codes covered if selection criteria are met:

CPT Code	Description
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
64583	Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator
64584	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array

HCPC codes covered if selection criteria are met:

HCPC Code	Description
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

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