



UM-CDG-053 Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea

**Approved By:
Director, Health Services**

**Effective Date:
10/20/2025**

This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address hypoglossal nerve stimulation for the treatment of obstructive sleep apnea (OSA). OSA is a disease characterized by recurrent episodes of upper airway obstruction during sleep. The hypoglossal nerve is the twelfth cranial nerve and innervates all the extrinsic and intrinsic muscles of the tongue, except for the palatoglossus, which is innervated by the vagus nerve. It is a nerve with a solely motor function. The nerve arises from the hypoglossal nucleus in the brain stem as several small rootlets, passes through the hypoglossal canal and down through the neck, and eventually branches within the tongue and innervates the tongue. There are two hypoglossal nerves in the body, one on the left, and one on the right.

The concept of stimulating the tongue musculature to increase upper airway size and limit the pathophysiologic obstruction leading to OSA was introduced in the late 1980s. A variety of strategies were utilized, including transcutaneous stimulation with placement of electrodes in the submental region, sublingual mucosa, and soft palate. However, these studies were limited by their lack of selective stimulation of the primary protruder of the tongue, the genioglossus muscle.

In 2001, a trial was conducted where they selectively stimulated the branches of the hypoglossal nerve, innervating the genioglossus. They noted a significant improvement in the apnea-hypopnea index (AHI) and O2 desaturation nadir. This technology was subsequently refined, and in 2014 the Stimulation Therapy for Apnea Reduction (STAR) trial was published as the initial clinical trial using upper airway stimulation (UAS) as an alternative therapy to CPAP for treatment of OSA.

The only US Food and Drug Administration (FDA) approved hypoglossal nerve stimulation (HGNS) system has 3 implantable components: a stimulation lead that delivers mild stimulation to maintain multilevel airway patency during sleep, a breathing sensor lead that senses breathing patterns, and a generator that monitors breathing patterns. The 2 external components are a patient sleep remote that provides a noninvasive means for a patient to activate the generator and a physician programmer that allows the physician to noninvasively interrogate and configure the generator settings. The system battery life for the implantable components is 7 to 10 years.

A surgeon implants the system containing a neurostimulator subcutaneously in the patient’s chest, with 1 lead attached to the patient’s hypoglossal nerve (cranial nerve XII) at the base of the tongue and 1 lead implanted in the patient’s chest. The lead in the chest consists of a pressure sensor that detects breathing. Information about respiration rate is relayed to the device, which stimulates the hypoglossal nerve in the tongue. When stimulated,

the tongue moves forward, opening the airway. The patient can operate the device by remote control, which the patient activates before going to sleep. The device turns on after 20 minutes to minimize disrupting the patient's sleep onset; the device must be manually turned off via remote when the patient wakes.

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

None

POLICY

SECUR Health Plan considers FDA-approved hypoglossal nerve neurostimulation as medically necessary for the treatment of OSA when the following is met:

1. Member is at least 22 years of age, and
2. Body mass index (BMI) is less than 35 kg/m², and
3. Polysomnography (PSG) is performed within 24 months of the first consultation for HGNS implant, and
4. Member has predominantly obstructive events, defined as central and mixed apneas less than 25% of the total AHI, and
5. AHI is 15 to 65 events per hour, and
6. Member has documentation that demonstrates continuous positive airway pressure (CPAP) failure or CPAP intolerance including shared decision making that the member was intolerant of CPAP despite consultation with a sleep expert, and
7. Absence of complete concentric collapse at the soft palate level as seen on a drug induced sleep endoscopy (DISE) procedure, and
8. No other anatomical findings that would compromise performance of device.

The following are considered not medically necessary:

1. Hypoglossal nerve neurostimulation is considered not medically reasonable and necessary for all other indications.
2. Non-FDA-approved hypoglossal nerve neurostimulation is considered not medically reasonable and necessary for the treatment of adult obstructive sleep apnea due to insufficient evidence of being safe and effective.
3. Hypoglossal nerve neurostimulation is considered not medically reasonable and necessary when any of the following contraindications are present:
 - Member with central and mixed apneas that make up more than one-quarter of the total AHI.
 - Member with an implantable device could experience unintended interaction with the HGNS implant system.
 - BMI equal to or greater than 35
 - Neuromuscular disease
 - Hypoglossal-nerve palsy
 - Severe restrictive or obstructive pulmonary disease
 - Moderate-to-severe pulmonary arterial hypertension
 - Severe valvular heart disease

- New York Heart Association class III or IV heart failure
 - Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months)
 - Persistent uncontrolled hypertension despite medication use
 - 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.
 - Coexisting nonrespiratory sleep disorders that would confound functional sleep assessment
 - Members who are, or who plan to become pregnant.
 - Members who require Magnetic Resonance Imaging (MRI) with model 3024.
 - Members, who require MRI with model 3028, can undergo MRI on the head and extremities if certain conditions and precautions are met. Please refer to the Manufacturer Guidelines for this model and future models for more information.
 - Members who are unable or do not have the necessary assistance to operate the sleep remote.
 - Members with any condition or procedure that has compromised neurological control of the upper airway.
4. Drug Induced Sleep Endoscopy (DISE):
- Due to documented inconsistencies in determining if complete concentric collapse (CCC) is present, the inserting provider must be certified by the FDA approved manufacturer's second opinion service of validation via video clip submissions of at least 80% agreement in at least 15 consecutive studies and should provide this information with the supporting documentation.
5. Shared Decision Making (SDM):
- SDM must be documented in the member's supporting documentation by the referring physician and implanting physician.

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