

Hypoglossal Nerve Stimulation

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

The Plan members with moderate to severe obstructive sleep apnea (OSA) who are unable to tolerate positive airway pressure therapy, hypoglossal nerve stimulation can be an OSA treatment option. The hypoglossal nerve stimulator is an implanted medical device that reduces the occurrence of OSA by electrically stimulating the hypoglossal nerve, which causes tongue movement. This stimulation is timed with breathing to relieve upper airway obstruction. The hypoglossal nerve stimulation system is fully implanted beneath the skin and controlled with a remote, allowing patients to sleep free from devices on the face or in the mouth. The current FDA-approved device is made by Inspire Medical Systems© and has been available since 2014.

Definitions

“Obstructive Sleep Apnea (OSA)” is a sleep-related breathing disorder that occurs when the muscles relax during sleep, causing soft tissue in the back of the throat to collapse and block the upper airway. This causes reduced or complete halt in airflow despite an ongoing effort to breathe.

“Sleep-Study Testing” is a diagnostic test that is used to diagnose sleep-related disorders by recording a person's brain waves, blood oxygen levels, heart rate and breathing during sleep. Two types of sleep-study tests are recognized in the diagnosis of sleep disordered breathing:

1. “Unattended (Home) Polysomnography (PSG)”/Home Sleep Apnea Test (HSAT) is a portable sleep study that can be done at home without the need for a technician on-site to monitor data.

2. "Attended (Facility or Laboratory) Nocturnal Polysomnography" is a test performed overnight in a sleep lab or facility that is administered and overseen by a technician.

"Positive Airway Pressure Devices" are non-invasive equipment that assist in ventilation by delivering variable pressures of airflow during inspiration and expiration via an oral, nasal, or oronasal mask. They include:

1. Bi-level Positive Airway Pressure Devices (BPAP)
2. Continuous Positive Airway Pressure (CPAP)
3. Adaptive Servo-Ventilation devices (ASV)

Clinical Indications

The Plan considers implantable hypoglossal nerve stimulation medically necessary for initial requests to treat moderate to severe obstructive sleep apnea when ALL of the following criteria are met:

1. The member is 22 years of age or older; *and*
2. The last polysomnography (PSG) was performed within 24 months of first consultation for implant; *and*
3. Body Mass Index (BMI) is less than or equal to 32 kg/m²; *and*
4. Apnea hypopnea index (AHI) is 15 to 65 events per hour; *and*
5. The member has predominantly obstructive events with central and mixed apneas less than 25% of the total AHI; *and*
6. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; *and*
7. No contraindications or anatomical findings that would compromise performance of the device (e.g., tonsil size 3 or 4 per tonsillar hypertrophy grading scale); *and*
8. Tried and failed, or intolerant to, positive airway pressure (PAP) therapy, defined by ONE of the following:
 - a. AHI is still greater than 15 events per hour despite PAP usage; *or*
 - b. Inability to use PAP for more than 4 hours per night, 5 nights per week; *or*
 - c. Unwilling to use PAP machine after attempting to use it; *and*
9. The device is FDA-approved (e.g., Inspire II System Model 3024, Inspire IV Model 3028 system).

Medical Necessity Criteria for Surgical Revision, Explant, or Replacement

The Plan considers the revision, explant, or replacement of implantable hypoglossal nerve stimulation medically necessary when ONE of the following criteria are met:

1. FDA-approved implantable upper airway hypoglossal nerve stimulation device needs repositioning; *or*
2. FDA-approved implantable upper airway hypoglossal nerve stimulation device, generator battery and/or leads need replacement because they no longer function and the device is no longer under warranty; *or*
3. The remote for the FDA-approved implantable upper airway hypoglossal nerve stimulation device needs replacement because it no longer functions and is no longer under warranty.

Experimental or Investigational / Not Medically Necessary

The Plan considers implantable hypoglossal nerve stimulation experimental or investigational for any other indication not listed above. The Plan considers any non-FDA approved device for implantable hypoglossal nerve stimulation experimental or investigational.

Applicable Billing Codes (HCPCS/CPT Codes)

<i>Hypoglossal Nerve Stimulation</i>	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
31575	Laryngoscopy, flexible; diagnostic [Upper Airway Examination Coding for preoperative anatomical assessment]
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
64570	Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
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
64585	Revision or removal of peripheral neurostimulator electrode array
92502	Otolaryngologic examination under general anesthesia [Upper Airway Examination Coding for preoperative anatomical assessment]
92511	Nasopharyngoscopy with endoscope (separate procedure) [Upper Airway Examination Coding for preoperative anatomical assessment]
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters,

	responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming [Device analysis only, without programming, subsequent visits only (not at the time of generator implantation)]
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional [Device analysis only, without programming, subsequent visits only (not at the time of generator implantation)]
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional [Device analysis only, without programming, subsequent visits only (not at the time of generator implantation)]
ICD-10 codes considered medical necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
G47.33	Obstructive sleep apnea (adult) (pediatric)
Z68.1- Z68.32	Body mass index (BMI) 19.9 or less, to BMI 32.0 cutoff (Z68.32 includes 32.0-32.9), adult
ICD-10 codes <i>not</i> considered medically necessary or considered experimental or investigational:	
<i>Code</i>	<i>Description</i>
G47.30 - G47.32	All other sleep apnea not considered obstructive sleep apnea
G47.34 - G47.39	All other sleep apnea not considered obstructive sleep apnea
Z68.33 - Z68.45	Body Mass Index [BMI] 33.0 or greater, adult
Z68.51 - Z68.54	Body mass index [BMI] pediatric

References

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