Hypoglossal Nerve Stimulation

Summary

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

"Apnea-hypopnea index (AHI)" is the number of apneas and hypopneas per hour of sleep recorded during a sleep study. The AHI commonly determines the severity of sleep apnea. An apnea is defined as the cessation of airflow at the nose and mouth for a minimum of 10 seconds. A hypopnea is an abnormal respiratory event lasting ≥10 seconds with ≥ 30% reduction in thoracoabdominal movement or airflow compared to baseline, and with at least a 4% oxygen desaturation from the pre-event baseline.

"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 a reduced or complete halt in airflow despite an ongoing effort to breathe.

"Positive airway pressure devices" are non-invasive equipment that assists 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 (BPAP) devices
2. Continuous positive airway pressure (CPAP) devices
3. Adaptive servo-ventilation (ASV) devices

"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)" or "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.

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

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

1. Pediatric members with Down syndrome who are 13 to 18 years, when ALL of the following are met:
    a. Apnea hypopnea index (AHI) greater than 10 and less than 50; *and*
    b. No complete concentric collapse at the soft palate level; *and*
    c. Contraindication for, or not effectively treated by, adenotonsillectomy; *and*
    d. Failure of, or inability to tolerate, PAP therapy despite attempts to improve compliance; *and*
    e. Standard of care followed in considering all other alternative/adjunct therapies; *or*
2. Members 18 years of age or older, when ALL of the following are met:
    a. The last polysomnography (PSG) was performed within 24 months of first consultation for implant; *and*

b. Body mass index (BMI) is less than or equal to 40 kg/m2; *and*
c. Apnea hypopnea index (AHI) is 15 to 100 events per hour; *and*
d. The member has predominantly obstructive events with central and mixed apneas less than 25% of the total AHI; *and*
e. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure, *and*
f. No contraindications or anatomical findings that would compromise performance of the device; *and*
g. Tried and failed, or intolerant to, positive airway pressure (PAP) therapy, defined by ONE of the following:
    i. AHI is still greater than 15 events per hour despite PAP usage; *or*
    ii. Inability to use PAP for more than 4 hours per night, 5 nights per week; *or*
    iii. Unwilling to use PAP machine after attempting to use it; *and*
h. The device is FDA-approved (e.g., Inspire II System Model 3024, Inspire IV Model 3028 system).

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 or 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, Investigational, or Unproven / Not Medically Necessary

The Plan considers implantable hypoglossal nerve stimulation experimental,investigational, or unproven for any other indication not listed in this guideline. The Plan considers any non-FDA approved device for implantable hypoglossal nerve stimulation experimental or investigational.

Applicable Billing Codes

Table 1	
Hypoglossal Nerve Stimulation	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
31575	Laryngoscopy, flexible; diagnostic
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
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
92511	Nasopharyngoscopy with endoscope (separate procedure)
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

Table 1	
Hypoglossal Nerve Stimulation	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
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
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
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system.
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller
C8007	Open implantation of hypoglossal nerve neurostimulator array and pulse generator, not requiring insertion of a separate distal respiratory sensor electrode or electrode array
C8008	Revision or replacement of hypoglossal nerve neurostimulator array including connection to existing pulse generator

Table 1	
Hypoglossal Nerve Stimulation	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
C8009	Removal of hypoglossal nerve neurostimulator array and pulse generator
C8011	Open implantation of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver, including external power source and all system components
C8012	Revision or replacement of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C8013	Removal of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

Table 2	
ICD-10 codes considered medically necessary with Table 1 codes if criteria are met:	
Code	*Description*
G47.33	Obstructive sleep apnea (adult) (pediatric)
Q90.0 - Q90.9	Down syndrome
Z68.1	Body mass index BMI 19.9 or less, adult
Z68.20 - Z68.29	Body mass index BMI 20-29, adult
Z68.30 - Z68.39	Body mass index BMI 30-39, adult

Table 2	
ICD-10 codes considered medically necessary with Table 1 codes if criteria are met:	
Code	*Description*
Z68.41	Body mass index [BMI] 40.0-44.9 adult ● Due to multiple BMI values represented by this code, clarification is provided below: ● When billed for hypoglossal nerve stimulation in members with a BMI of 40.0, it is considered medically necessary

Table 3	
CPT/HCPCS codes considered experimental, investigational, or unproven for indications in this guideline:	
E0492	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application
E0493	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply

Table 4	
ICD-10 codes considered experimental, investigational, or unproven for hypoglossal nerve stimulation:	
Code	*Description*
G47.30	Sleep apnea, unspecified
G47.31	Primary central sleep apnea
G47.32	High altitude periodic breathing
G47.34	Idiopathic sleep related nonobstructive alveolar hypoventilation
G47.35	Congenital central alveolar hypoventilation syndrome
G47.36	Sleep related hypoventilation in conditions classified elsewhere
G47.37	Central sleep apnea in conditions classified elsewhere
G47.39	Other sleep apnea

Table 4	
ICD-10 codes considered experimental, investigational, or unproven for hypoglossal nerve stimulation:	
Code	*Description*
Z68.41	Body mass index [BMI] 40.0-44.9, adult ● Due to multiple BMI values represented by this code, specific exclusions are indicated: ● When billed for hypoglossal nerve stimulation in members with a BMI of 41.0-44.9, it is considered experimental, investigational, or unproven
Z68.42	Body mass index [BMI] 45.0-49.9, adult
Z68.43	Body mass index [BMI] 50.0-59.9, adult
Z68.44	Body mass index [BMI] 60.0-69.9, adult
Z68.45	Body mass index [BMI] 70 or greater, adult

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