Hypoglossal Nerve Stimulation

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 a 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 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 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. For pediatric members ages 13 to 18 years with Down syndrome and apnea hypopnea index (AHI) greater than 10 and less than 50 who:
    a. Do not have complete concentric collapse at the soft palate level; *and*
    b. Have contraindication for, or not effectively treated by, adenotonsillectomy; *and*
    c. Have been confirmed to fail, or cannot tolerate, PAP therapy despite attempts to improve compliance; *and*
    d. Have followed the standard of care in considering all other alternative/adjunct therapies; *or*
2. The member is 18 years of age or older; *and*
    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 (e.g., tonsil size 3 or 4 per tonsillar hypertrophy grading scale); *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).

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)

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
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
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
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
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension

L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
ICD-10 codes considered medical necessary if criteria are met:	
Code	*Description*
G47.33	Obstructive sleep apnea (adult) (pediatric)
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
CPT/HCPCS codes considered experimental, investigational	
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
ICD-10 codes considered experimental or investigational:	
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
Z68.41	Body mass index [BMI] 40.0-44.9, adult
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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