n05692

Hypoglossal Nerve Stimulation

Values

Accountability ● Integrity ● Service Excellence ● Innovation ● Collaboration

Abstract Purpose:

Network Health Plan/Network Health Insurance Corporation/Network Health Administrative Services, LLC's (NHP/NHIC/NHAS) utilization management (UM) team applies review guidelines for determinations involving medical necessity for Food and Drug Administration (FDA) approved hypoglossal nerve stimulation, implantable (e.g., Inspire II System, Inspire 3028 system for Upper Airway Stimulation (UAS) Therapy). This policy provides guidance for approving this procedure/device.

Policy Detail:

Refer to the appropriate Certificate of Coverage, Evidence of Coverage, Summary Plan Description or Individual and Family Plan to determine eligibility and coverage because Employer Group/Plan Sponsor and government contracts may vary. NHIC follows Medicare's National/Local (Wisconsin area) Coverage Determinations for its Medicare Advantage membership.

Procedure Detail:

I. Description:

A. Hypoglossal nerve stimulation (HGNS) is the use of an implanted medical device that works to reduce the occurrence of obstructive sleep apnea by electrically stimulating the hypoglossal nerve to the tongue. This stimulation activates the muscles of the tongue, increasing tone and moving it forward away from the back of the airway.

II. Medical Indications/Criteria:

A. Medical Conditions & Diagnosis (**All required**)

a. Member is 18 years of age or older, **AND**

b. Body mass index (BMI) is less than 35kg/m2, **AND**

c. A polysomnography (PSG) is performed within 24 months of first consultation for HGNS, **AND**

d. Member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI), **AND**

e. AHI is 15 to 65 events per hour, **AND**

f. Member has documentation that demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than four (4) hours per night, five (5) nights per week for a minimum of one month or the CPAP has been returned) including shared decision making that the patient was intolerant of CPAP despite consultation with a sleep expert, **AND**

g. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure, **AND**

h. No other anatomical findings that would compromise performance of device (e.g. tonsil size three (3) or four (4) per standardized tonsillar hypertrophy grading scale).

B. The replacement of an FDA-approved implantable upper airway hypoglossal nerve stimulation device, generator battery and/or leads is considered medically necessary when a previously implanted device, generator battery and/or leads is no longer functioning appropriately, and the device is no longer under warranty.

C. The replacement of a remote that is used with an FDA-approved implantable upper airway hypoglossal nerve stimulation device is considered medically necessary when there is documentation confirming that the remote is malfunctioning and is no longer under warranty.

B. Documentation Required (**All required**)

1. History of sleep apnea condition, **AND**

2. Sleep study confirming diagnosis of sleep apnea, **AND**

3. Excessive daytime sleepiness documented by:
   a. Epworth Sleepiness Scale or other validated scale
   b. Interference with daily activity or work (e.g., causes safety issues), **AND**
4. Failed response or intolerance to pap device.

C. Hypoglossal nerve stimulation implantation is not a covered benefit if the above indications are not met and would be considered experimental and investigational.

III. Coverage:

A. NHP/NHIC/NHAS may extend coverage for hypoglossal nerve stimulation implantation for medically necessary indications as noted in this policy.

B. NHIC follows CMS National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) for application to its Medicare Advantage membership.

IV. Limitations/Exclusions:

A. NHP considers hypoglossal nerve stimulation for any other indication not medically necessary.

B. Non-FDA approved Hypoglossal nerves neurostimulation (e.g., the Apnex Hypoglossal Nerve Stimulation (HGNS) Systems, the aura6000 Neurostimulation System, Im Thera's Targeted Hypoglossal Neurostimulation Therapy, and WellStar upper airway neurostimulation implant) would be considered experimental and investigational for the treatment of adult obstructive sleep apnea.

C. Presence of **ANY** of the following conditions would not allow for coverage of the hypoglossal nerve stimulation implantation:
   a. Members with central or mixed apneas that make up more than one-quarter of the total AHI.
   b. Members with an implantable device could experience unintended interaction with the HGNS implant system. Limitations are:
      i. BMI equal or greater than 35
      ii. Neuromuscular disease affecting the respiratory system
      iii. Hypoglossal nerve palsy

iv. Severe restrictive or obstructive pulmonary disease
v. Moderate-to-severe pulmonary arterial hypertension
vi. Severe valvular heart disease
vii. New York Heart Association class II or IV heart failure
viii. Recent myocardial infarction or severe cardiac arrhythmias (within the past six (6) months)
ix. Persistent uncontrolled hypertension despite medical use
x. An active, serious mental illness that reduces the ability to care 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
xi. Coexisting non-respiratory sleep disorders that would confound functional sleep assessment

c. Members who are, or who plan to become pregnant
d. Members who require magnetic resonance imaging (MRI) with model 3024. Members, who require magnetic resonance imaging (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 model for information.
e. Members who are unable or do not have the necessary assistance to operate the sleep remote.
f. Members with any condition or procedure that has comprised neurological control of the upper airway.

D. NOTE: Off-the-shelf batteries, used in the remote for the hypoglossal nerve stimulation device, are generally considered not medically necessary because they are not primarily medical in nature.

Definitions

1. Drug Induced Sleep Endoscopy (DISE):
   a. Due to documented inconsistency in determining if complete concentric collapse (CCC) is present, the inserting provider shall 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. Inserting providers shall have documentation to submit to this contractor if necessary.
   b. A Drug Induced Sleep Endoscopy (CPT Code 42975) is only medically necessary to evaluate appropriateness of FDA approved hypoglossal nerve stimulation if all other hypoglossal nerve stimulation criteria have been met.
2. Shared Decision Making (SDM):
   SDM, by definition, is any documented conversation between an attending provider and the patient, and not between multiple providers. Providers shall provide these documents if requested by the contractor.

V. Provider Qualifications

Hypoglossal nerve stimulation for the treatment of OSA must be ordered and furnished by qualified personnel. The hypoglossal nerve (HN) may be damaged during neck surgeries. A detailed understanding of the anatomy of the hypoglossal nerve in relation to various anatomical landmarks and surrounding structures is important to reduce procedural complications and the risk of nerve damage.

Provider Specialties

- Insertion of an FDA-approved hypoglossal nerve stimulation device must be performed by a qualified physician (MD or DO) who is a board certified or a board eligible otolaryngologist having completed the appropriate AMA or AOA certified residency and/or fellowship program and maintains ongoing certification in otolaryngology. In addition, prior to implanting the system, surgeons will need to receive classroom instruction by an FDA approved device manufacturer or equivalent on device implant techniques as well as cadaver training. Documentation must be provided to support completion of training to an exemplary level by the manufacturer.

Regulatory Citations:

UM 2

Related Policies:

None

Related Documents:

None

CPT Codes*:

61886	Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two 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
95970	Electronic analysis of a simple or complex brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programing
95976	simple cranial nerve neurostimulator pulse generator/transmitter programming

97977	Neurostimulators Analysis-Programming Procedures
0466T	Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (list separately in addition to code for primary procedure)
0467T	Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator
0468T	Removal of chest wall respiratory sensor electrode or electrode array
*CPT codes are subject to change as codes are retired or new ones developed	

References:

1. Medicare (CMS) Local Coverage Determination, Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea L38387, 04/01/2020

2. MCG Ambulatory Care 28th Edition Guidelines, Hypoglossal Nerve Stimulation, Implantable AGC: A-0973(AC)

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Disclaimer:

Contract language as well as state and federal laws take precedence over any medical policy. Network Health coverage documents (i.e. Certificate of Coverage, Evidence of Coverage, Summary Plan Descriptions) outline contractual terms of the applicable benefit plan for each line of business and will be considered first in determining eligibility. Not all Network Health coverage documents are the same. Coverage may differ. Our Medicare membership follows applicable Centers for Medicare and Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). Please refer to the CMS website at www.cms.gov.

Network Health reserves the right to review and update our medical policies on occasion as medical technologies are constantly evolving. The documentation of any brand name of a test, product and/or procedure in a medical policy is in no way an endorsement of that product; it is for reference only. Network Health's medical policies are for guidance and not intended to prevent the judgement of the reviewing medical director(s) no dictate to health care providers how to practice medicine.