Wyoming Medicaid Policy for Hypoglossal Nerve Stimulation for treatment of OSA

Wyoming Medicaid has instituted the following policy for hypoglossal nerve stimulation. This policy has been adopted in part from Centers for Medicare & Medicaid Services

Definition

Hypoglossal nerve stimulation is a treatment option for some people with obstructive sleep apnea. Also called upper airway stimulation, this treatment involves having surgery to place a small medical device under the skin. The device generates light electrical pulses that activate muscles in ways that help keep the airway open during sleep.

CPT Code

64582

Coverage Indications, Limitations, and/or Medical Necessity

Hypoglossal nerve stimulation (HNS) is reasonable and necessary for the treatment of moderate to severe obstructive sleep apnea (OSA) when **all** of the following criteria are met:

1) Beneficiary is 22 years of age or older; **and**
2) Body mass index (BMI) is less than 35 kg/m^2; **and**
3) A polysomnography (PSG) demonstrating an apnea-hypopnea index (AHI) of 15 to 65 events per hour within 24 months of initial consultation for HNS implant; **and**
4) Beneficiary has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); **and**
5) Shared Decision-Making (SDM) between the Beneficiary, Sleep physician, AND qualified otolaryngologist (if they are not the same) who determines that the Beneficiary demonstrates continuous positive airway pressure (CPAP) failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as CPAP machine-derived compliance reporting with usage less than 4 hours a night for at least 70% of the nights in 1 month, or the CPAP has been returned) despite CPAP interface and/or setting optimizations.
6) Confirmed absence of complete concentric collapse at the soft palate level by a drug-induced sleep endoscopy (DISE) procedure; **and**
7) Absence of anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale).
8) Use of HNS devices with United States (U.S.) Food and Drug Administration (FDA)-approval for implantation to treat OSA (e.g., Inspire® II Upper Airway Stimulator).

HNS is not reasonable or necessary when any 1 of the following contraindications are present:

1) Beneficiaries with central and mixed apneas that make up more than one-quarter of the total AHI
2) BMI 35 kg/m^2 or greater
3) Neuromuscular disease
4) Hypoglossal-nerve palsy
5) Severe restrictive or obstructive pulmonary disease
6) Moderate-to-severe pulmonary arterial hypertension
7) Severe valvular heart disease
8) New York Heart Association class III or IV heart failure
9) Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months)
10) Persistent uncontrolled hypertension despite medication use
11) Acute psychiatric disease
12) Coexisting non-respiratory sleep disorders that would confound functional sleep assessment
13) Beneficiaries who are, or who plan to become pregnant
14) Beneficiaries who are unable or do not have the necessary assistance to operate the device's external programmer
15) Beneficiaries with any condition or procedure that has compromised neurological control of the upper airway
16) HNS implants that are not compatible with magnetic resonance imaging (MRI) in Beneficiaries who require MRI

NOTE: Beneficiaries with certain HNS devices can undergo MRI of the head and extremities if certain conditions and precautions are met. Please refer to the Manufacturer Guidelines for the relevant model for more information.

Credentialing and Accreditation Standards

Provider Qualifications for HNS Implantation and Device Management:

1) All HNS implantation procedures must be performed by a licensed qualified physician
2) A licensed qualified physician (MD or DO) for HNS services is defined as:
   a) Having trained and acquired expertise within the framework of an accredited residency **or** fellowship program in the applicable specialty/subspecialty (e.g., Board-eligible (BE) or Board-certified (BC) otolaryngologist) **or** must reflect equivalent education, training and expertise endorsed by a relevant specialty/subspecialty society, **and**
   b) Prior to implanting the system, surgeons will have received education and proctoring by an FDA-approved device manufacturer or equivalent proctoring body on device implant techniques, including cadaver training. Documentation must be available for contractor review to provide confirmation of proficiency in the performance and management of HNS implantation and the corresponding relevant devices.
3) The provider performing DISE 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. Documentation of this proficiency must be available to submit for contractor review.