Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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Plan: Keystone First	**Submission Date**: 9/1/2024
Policy Number: ccp.1270	**Effective Date:** 1/2017 **Revision Date:** August 1, 2024
Policy Name: Hypoglossal nerve stimulation	

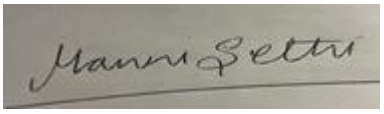
Type of Submission – Check all that apply:

New Policy
X Revised Policy*
Annual Review – No Revisions
Statewide PDL

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Hypoglossal nerve stimulation

Clinical Policy ID: CCP.1270

Recent review date: 8/2024

Next review date: 12/2025

Policy contains: Down syndrome; hypoglossal nerve stimulation; Inspire®; obstructive sleep apnea; upper airway stimulation.

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

Hypoglossal nerve stimulation is clinically proven and, therefore, may be medically necessary for treatment of persistent moderate-to-severe obstructive apnea in members with a body mass index ≤ 40 kg/m^2, absence of complete concentric collapse at the soft palate level, and all of the following criteria (American Academy of Otolaryngology-Head and Neck Surgery, 2019; Bosschieter, 2022; Suurna, 2021; Woodson, 2018):

Members aged 22 years or older and all of the following criteria:

- Apnea-hypopnea index 15 to 100 events per hour.
- Positive airway pressure failure or intolerance, defined as either:
- An apnea-hypopnea index > 15 despite positive airway pressure usage.
- Inability to use positive airway pressure (more than four hours of use per night for more than five nights per week)
- Unwilling to use positive airway pressure after attempting to use it.

Members aged 18 to 21 and all of the following criteria:

- Apnea-hypopnea index 15 to 100 events per hour.
- Contraindication to, or not effectively treated by, adenotonsillectomy.

- Confirmed failure or intolerance to positive airway pressure therapy despite attempts to improve compliance.
- Standard of care followed in considering all other alternative/adjunct therapies.

Members with Down syndrome ages 10 to 21 years and all of the following criteria:

- Apnea-hypopnea index 10 to 50 events per hour.
- Contraindication to, or not effectively treated by, adenotonsillectomy.
- Confirmed failure or intolerance to positive airway pressure therapy despite attempts to improve compliance.
- Standard of care followed in considering all other alternative/adjunct therapies.

Limitations

Contraindications to hypoglossal nerve stimulation include (U.S. Food and Drug Administration, 2023c):

- Sleep study showing greater than 25% central or mixed apneas.
- Any anatomical finding that would compromise the performance of upper airway stimulation, such as the presence of complete concentric collapse of the soft palate.
- Any condition or procedure that has compromised neurological control of the upper airway.
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- Pregnancy (existing or planned).

Members who require magnetic resonance imaging if Inspire® Model 3024 (Inspire Medical Systems, Inc. Golden Valley, Minnesota) is to be implanted, because it may cause tissue damage and/or damage to the device. Members implanted with Inspire Model 3028 can undergo magnetic resonance imaging on the head and extremities if certain conditions and precautions are met.Other implanted devices that may be susceptible to unintended interaction with the Inspire system. Magnetic resonance imaging is incompatible with Inspire® Model 3024 (Inspire Medical Systems, Inc. Golden Valley, Minnesota), as it may cause tissue damage and/or damage to the device. Members implanted with Inspire Model 3028 may undergo magnetic resonance imaging on the head and extremities if certain conditions and precautions are met.

Alternative covered services

- Weight management programs.
- Mandibular advancement devices (oral appliances).
- Positive airway pressure therapy.
- Surgery (e.g., uvulopalatopharyngoplasty, maxillomandibular advancement, tracheostomy, palatal implants, correction of discrete anatomic abnormalities of the upper airway that significantly contribute to obstructive sleep apnea, such as enlarged tonsils or tongue).

Background

Obstructive sleep apnea is a sleep disorder characterized by repetitive pauses in breathing (apnea) or instances of shallow or infrequent breathing, caused by an obstruction or partial obstruction of the upper airway during sleep. Untreated obstructive sleep apnea is associated with a reduction in blood oxygen saturation and symptoms of sleep deprivation and excessive sleepiness, cognitive dysfunction, diminished quality of life and productivity, sexual dysfunction, mood changes, increased accident risk, hypertension, non-insulin-dependent

diabetes and other metabolic abnormalities, cardiac disease, and stroke. It affects persons of all age groups, especially middle-aged and elderly persons, and rates of obstructive sleep apnea are increasing, likely due to escalating obesity rates (Slowik, 2024).

The goals of obstructive sleep apnea treatment are to alleviate airway obstruction during sleep, normalize sleep quality, and improve the apnea-hypopnea index and oxyhemoglobin saturation levels. Treatment may improve comorbidities associated with untreated sleep apnea, primarily cardiovascular disease, non-insulin-dependent diabetes, and associated mortality. Treatment for obstructive sleep apnea includes behavioral therapy (e.g., weight loss), positive airway pressure, dental or mandibular advancement devices, palatal implants, and surgery (Slowik, 2024).

Hypoglossal nerve stimulation uses a surgically implantable device that resembles a cardiac pacemaker. The surgeon implants a neurostimulator subcutaneously beneath the clavicle in the upper chest with one lead attached to the patient's hypoglossal nerve at the base of the tongue and one pressure sensor lead implanted in the patient's chest to detect breathing. Stimulation of the hypoglossal nerve occurs during sleep in parallel with a patient's breathing. Hypoglossal nerve stimulation contracts the genioglossus muscle, shifting the tongue forward and opening the retroglossal region of the airway. The patient can turn the device on or off by remote control. There is delayed activation of the device to minimize disrupting the patient's sleep onset.

One hypoglossal nerve stimulation system is available for commercial use in the United States. In 2014, the U.S. Food and Drug Administration granted premarket approval to the Inspire II Upper Airway Stimulator as a class III device. The original approval was for treating a subset of adult patients at least 22 years of age with moderate to severe obstructive sleep apnea (apnea-hypopnea index 20 - 65) who failed or could not tolerate positive airway pressure treatments and who did not have a complete concentric collapse at the soft palate level. Positive airway pressure intolerance is defined as either the inability to use positive airway pressure (more than five nights per week of usage; usage defined as more than four hours of use per night), or the unwillingness to use positive airway pressure (for example, a patient returns the positive airway pressure system after attempting to use it) (U.S. Food and Drug Administration, 2023d).

Recent regulatory changes include increasing the upper limit of body mass index from ≤ 32 kg/m^2 to ≤ 40 kg/m^2 and raising the upper limit of the apnea-hypopnea index from 65 to 100 events per hour in persons ages 18 or older (U.S. Food and Drug Administration, 2023d). Analysis of the interim data from a pediatric feasibility study in patients with Down's syndrome patients and data from the pivotal trial in adults ages 22 and older have provided consistent results and provide reasonable support for extrapolation to a subset of older adolescents age 18 to 21 (U.S. Food and Drug Administration, 2023c).

For patients between the ages of 18 and 21 with moderate to severe obstructive sleep apnea (apnea-hypopnea index 15 to 65 events per hour) and for pediatric patients ages 13 to 18 years with Down Syndrome and severe sleep apnea (apnea-hypopnea index 10 to 50 events per hour), candidates for hypoglossal nerve stimulation must meet all of the following criteria (U.S. Food and Drug Administration, 2023d):

- No complete concentric collapse at the soft palate level.
- Contraindication to or ineffectively treated by, adenotonsillectomy.
- Confirmed failure of, or intolerance to, positive airway pressure therapy despite attempts to improve compliance.
- Standard of care followed in considering all other alternative/adjunct therapies.

Findings

Guidelines

A position statement from the American Academy of Otolaryngology-Head and Neck Surgery (2019) supports hypoglossal nerve stimulation as an effective second-line treatment for moderate-to-severe obstructive sleep apnea in carefully selected patients who are intolerant or unable to achieve benefit with positive pressure therapy.

A recent guideline from the European Respiratory Society on treatment of obstructive sleep apnea mentioned hypoglossal nerve stimulation, but offered few citations on efficacy of this option (Randerath, 2021).

Evidence review

There is sufficient evidence to support distal hypoglossal nerve stimulation as a second-line treatment for moderate to severe obstructive sleep apnea in selected adults and adolescents who have failed positive airway pressure therapy. The evidence suggests consistent improvements in symptoms of obstructive sleep apnea but inconsistent improvement in sleep quality or quality of life, in persons with moderate-to-severe obstructive sleep apnea in whom continuous positive airway pressure had failed. Adverse events included device malfunction, lead dislodgement, pain, numbness, swelling, and discomfort.

Several clinical trials have published results supporting the efficacy of hypoglossal nerve stimulation in different populations. Results from the Stimulation Therapy for Apnea Reduction trial (Gillespie, 2017; ClinicalTrials.gov identifier NCT01161420) and a multicenter, single-arm trial in Germany (Hofauer, 2017; Steffen, 2018; ClinicalTrials.gov identifier NCT02293746) provide low-quality evidence of sustained benefit on patient-reported outcomes (Epworth Sleepiness Scale, Functional Outcomes of Sleep Questionnaire, and snoring levels) up to 48 months after implantation, and short-term improvement in sleep architecture in a small subset of participants in the German study (Heiser, 2017). Reported adverse effects in the trials were rare and generally unrelated to the device or the procedure.

Long-term (five-year) results from the multicenter Stimulation Therapy for Apnea Reduction trial (Woodson, 2018; ClinicalTrials.gov identifier NCT01161420) and new systematic review findings (Constantino, 2020; Kompelli, 2019) confirm the effectiveness of hypoglossal nerve stimulation for providing significant and durable improvements in outcome measures, such as quality of life, the Epworth Sleepiness Scale, snoring, and polysomnography. Common adverse events were pain (6.2%, 95% confidence interval 0.7 to 16.6), tongue abrasion (11.0%, 1.2 to 28.7), and internal (3.0%: 0.3 to 8.4)/external (5.8%: 0.3 to 17.4) device malfunction (Kompelli, 2019).

Results from the ADHERE post-marketing registry study (ClinicalTrials.gov identifier NCT02907398) provided support for expanding regulatory approval to patients with severe obstructive sleep apnea (apnea-hypopnea index > 65 events per hour) and with higher body mass index (> 32 kg/m^2) (Bosschieter, 2022; Suurna, 2021). One study stratified 1,963 adult patients into five categories of obstructive sleep apnea severity at baseline. Twelve months after implantation, there was a significant ($P < .0001$) improvement in objective sleep parameters in all subgroups, with an apnea-hypopnea index above 15 events per hour. Rates of overall treatment success (66.6%) and improvement in self-reported outcomes were similar across categories. Subgroup 5 (n = 77) with the highest preoperative apnea-hypopnea index (> 65 events per hour) experienced the greatest reduction in apnea-hypopnea index at final visit, despite lower treatment adherence and higher body mass index (mean ± standard deviation 30.6 ± 3.6 kg/m^2; n = 76) (Bosschieter, 2022).

Suurna (2021) assessed the impact of body mass index on therapy discomfort in 843 participants who completed the final visit after one year post-implantation. The rates of serious adverse events and device revisions were

2.3% and 1.9%, respectively. Device discomfort was associated with significantly lower therapy use and higher final visit mean apnea-hypopnea index (both P = .01). Compared to the lower body mass index group (≤ 32 kg/m^2), the higher body mass index group (≤ 35 kg/m^2) group experienced significantly less daily device use (P = .028) and lower surgical success (P = .02), but comparable changes in the apnea-hypopnea index and sleepiness (Epworth Sleepiness Scale).

A retrospective cohort study compared post-operative readmission rates and complication rates of hypoglossal nerve stimulation to those of palatal or multilevel surgery in 2,776 adults with obstructive sleep apnea. Those treated with hypoglossal nerve stimulation had lower 90-day readmission rates (4% versus 12%, P < .0001) and complication rates (2% versus 21%, P < .0001). No efficacy data were reported (Nord, 2022).

Targeted hypoglossal nerve stimulation of the proximal hypoglossal nerve may address the limitations of distal hypoglossal nerve stimulation that leaves some inadequately treated. In a multisite, randomized controlled trial of 138 adults with obstructive sleep apnea and positive airway pressure intolerance, targeted hypoglossal nerve stimulation produced superior response rates compared to untreated controls after four months, in terms of a 50% or greater reduction in the apnea-hypopnea index to 20 or fewer events per hour (52.3% versus 19.6%) and a decrease of 25% or greater in oxygen desaturation index (62.5% versus 41.3%); differences were sustained after 15 months (Schwartz, 2023). Direct comparisons to distal hypoglossal nerve stimulation are needed.

Recent systematic review findings confirm the significant and sustained improvements of breath-synchronized or continuous hypoglossal nerve stimulation therapy in patient-reported outcomes of daytime sleepiness, daytime functioning, and sleep quality (Braun, 2023). Compared to surgical interventions, hypoglossal nerve stimulation resulted in significantly lower apnea-hypopnea index measures but similar improvements in sleep quality measured by the Epworth Sleepiness Scale (Kim, 2024).

Pediatric patients

In 2018, results of hypoglossal nerve stimulation in pediatric patients began to emerge. One systematic review/meta-analysis found most children undergoing tongue surgeries were syndromic with craniofacial disorders, comorbidities, or other serious medical issues, and patients with Down syndrome had a higher incidence of obstructive sleep apnea than the general pediatric population. Evidence for hypoglossal nerve stimulation was limited to a case report (Camacho, 2017). For adolescents and young adults with Down syndrome, obstructive sleep apnea often persists after adenotonsillectomy, and tongue-based obstruction is inadequately treated with positive airway pressure (Ishman, 2018).

A prospective multicenter cohort study of hypoglossal nerve stimulation was carried out in 42 adolescents 10 to 21 years of age with Down syndrome, persistent severe obstructive sleep apnea after adenotonsillectomy, and intolerance to positive airway pressure (Dierks, 2018; ClinicalTrials.gov identifier NCT02344108). Final trial results show hypoglossal nerve stimulation is safe and significantly improved polysomnographic and quality of life outcomes one year after implantation. Four participants had device- or surgery-related readmissions, and two had reoperations. The most common non-serious complication was temporary tongue or oral discomfort (11.9%). The mean apnea-hypopnea index decreased from 23.5 events per hour (standard deviation 9.7) at baseline to 11.0 events per hour (13.4) at 12 months postoperatively. The 12-month response rate was 65.9% (27 of 41 participants), although most participants still had an apnea-hypopnea index > 5 events per hour at the end of the study or residual moderate sleep apnea. There were significant improvements in parent-reported quality of life outcomes (Yu, 2022).

A systematic review/meta-analysis of nine studies (n = 106) assessed adolescents with Down syndrome and obstructive sleep apnea treated with hypoglossal nerve stimulation and followed up to 44-58 months. All studies

concluded apnea-hypopnea index (decreased at least 50%), and obstructive sleep apnea index improved significantly ($P < .001$) (Liu, 2022).

In 2019, we received a request for reconsideration of medical necessity criteria for the use of hypoglossal nerve stimulation in pediatric populations and added new findings of safety and efficacy in adult and pediatric populations. We changed the policy coverage for hypoglossal nerve stimulation from investigational to medically necessary for adults age 22 years or older and for members with Down syndrome ages 10 to 21 years. The coverage criteria are based on the inclusion criteria from the two clinical trials (Diercks, 2018; Woodson, 2018). We added contraindications from the device manufacturer.

In 2020, we updated the references and added new information. The new trial results warrant no coverage changes, but we modified the limitations to conform to the manufacturer's listed contraindications.

In 2023, we added several new studies with no policy changes warranted.

In 2024, we reorganized the findings and updated the references. We modified the coverage criteria based on new ADHERE registry data results (Bosschieter, 2022; Suurna, 2021) that also informed expanded regulatory approval to new subpopulations.

References

On June 28, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "Obstructive sleep apnea" (MeSH), "hypoglossal nerve stimulation," and "upper airway stimulation." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

10/2016: initial review date and clinical policy effective date: 1/2017

10/2017: Policy references updated.

11/2018: Policy references updated. Policy ID changed.

9/2019: Policy references updated. Policy changed from investigational to medically necessary and limitations added.

8/2020: Policy references updated.

8/2021: Policy references updated.

8/2022: Policy references updated.

8/2023: Policy references updated.

8/2024: Policy references updated. Coverage modified.