Review Criteria
Georgia Region

KAISER PERMANENTE®

Title:	Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea			
Department:	QUALITY RESOURCE MANAGEMENT	Page:		1 of 4
Section:	UTILIZATION MANAGEMENT	Policy Number:		01-54
Type:	(X) New	Effective Date:		11/13/2020
	(X) Reviewed / Revised	Date:		1/21/2021 1/10/2022 2/28/2023

Purpose
This policy provides the indications and contraindications necessary for the Quality Resource Management staff to make the most appropriate decision related to the medical necessity of the procedure listed.

DIAGNOSIS/CONDITION: Hypoglossal Nerve Stimulator (HGNS) Therapy
CPT-4/ HCPCS CODE AND DESCRIPTION: INDICATORS:

0466T
0467T
0468T
31575

1.0 INDICATIONS/CHECKLIST
INCLUSION CRITERIA:

Clinical Parameters

- Age at least 22 years
- BMI ≤ 32
- AHI 15-65
- Member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); based on full night diagnostic sleep study (home sleep apnea test or polysomnography) within past 1 year of HGNS consultation with stable weight.
- Appropriate upper airway anatomy (sedation endoscopy reveals no complete concentric collapse at the level of the soft palate)

Clinical Management Parameters

1.1 PAP failure defined as nightly usage less than 4 hours nightly less than 30% of a minimum 3 month period while under management by a Permanente Sleep physician

1.2 Failure/Intolerance of or non-candidacy for oral appliance therapy/mandibular advancement device therapy (OAT/MAD) as defined by inability to use device for greater than 4 hours nightly less than 30% of a minimum 3 month period while under management by a sleep dentist and confirmed by a Permanente Sleep physician

1.3 Positional therapy is not an appropriate option.

1.4 Other potential therapies (e.g. nasal EPAP therapy) have been discussed.

1.5 Evaluation by a Permanente HNS surgeon with failure and/or non-candidacy of traditional surgical interventions for OSA

2.0 CONTRAINDICATIONS

EXCLUSION CRITERIA:

1. Enrollment in a Clinical Trial in which HGNS is being investigated
2. Chronic respiratory failure requiring oxygen supplementation and/or ventilatory support (eg, obesity hypoventilation syndrome requiring non-invasive ventilation)
3. Neuromuscular disorders
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 Hear Association Class III or IV heart failure
9. Recent MI or severe cardiac arrhythmias in the past 6 months
10. Uncontrolled HTN
11. Psychiatric or cognitive incompatibility with HGNS therapy
12. Pre-operative non-clearance by anesthesiology
13. Patients who are unable or do not have the necessary assistance to operate the sleep remote
14. Patients with an implantable device that may be susceptible to unintended interaction with the Inspire system
15. Patients who are pregnant or plan to become pregnant
16. Immunocompromised status, history of poor wound healing, uncontrolled diabetes, or other medical condition that may affect healing and/or be made worse by the presence of the inspire syste

3.0 Views of the Southeast Permanente Medical Group:

Hypoglossal Nerve stimulation may be a reasonable alternative to patients with moderate to severe OSA who have being managed by sleep medicine specialist and has tried and failed or intolerant to CPAP and failed or intolerant to oral appliances see clinical management parameters above.

4.0 LITERATURE SUMMARY/Reference:

SCAL MTDST Position & Deployment Strategy (July & September, 2018)

Due to the high burden of suffering, the SCAL Medical Technology Deployment Strategy Team (MTDST) supports limited deployment of Hypoglossal Nerve Stimulation (HGNS) for the treatment of Obstructive Sleep Apnea (OSA) as an adjunct treatment option for select patients who cannot tolerate Positive Airway Pressure (PAP) therapy. The MTDST supports initial internal deployment limited to Fontana where there is a sleep medicine program and clinical expertise. Outcome data should be tracked for all cases and conclusions on effectiveness and safety should be reported to the Procedural Outcomes Strategy Team (POST) prior to any further deployment of the service. Patients not able to travel to the internal center should be referred exclusively to an external institution with specific procedural expertise in HGNS. It is recommended the Regional Sleep Medicine team provide ongoing oversight of quality, safety and clinician proctoring for HGNS. Regionally developed indications for treatment and referral should be shared with the Chiefs of Head and Neck Surgery, Sleep and Pulmonary Medicine, and Neurology. An overview of the outcomes should be shared with the Procedural Outcomes Strategy Team (POST) prior to any further deployment of the technology.

Discussion participants (or provided comments):

1) American Academy of OtolaryngologyHead and Neck Surgery
11/13/2019 UAS via the hypoglossal nerve is considered to be an effective second-line treatment of moderate-to severe OSA in adult patients who are intolerant of or unable to achieve benefit with positive airway pressure.

The 2016Position Statement: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea (OSA)was updated November 13, 2019.

Veteran Affairs/Department of Defense (VA/DoD)
2019 Evaluation for surgical treatment with HGNS therapy is suggested for patients with OSA who cannot adhere to positive airway pressure therapy.
A new guideline was identified:VA/DoD Clinical Practice Guideline for the Management of Chronic Insomnia Disorder and Obstructive Sleep Apnea.

Aetna CPB

Aetna considers Food and Drug Administration (FDA)-approved hypoglossal nerve neurostimulation (e.g., Inspire II System, Inspire 3028 system for Upper Airway Stimulation (UAS) Therapy) medically necessary for the treatment of moderate to severe obstructive sleep apnea when *all* of the following criteria are met

1. Member is 18 years of age or older; *and*
2. Body mass index (BMI) is less than 32 kg/m^2; *and*
3. A polysomnography (PSG) is performed within 24 months of first consultation for Inspire implant; *and*
4. Member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); *and*
5. Apnea hypopnea index (AHI) is 15 to 65 events per hour; *and*
6. Member has a minimum of one month of CPAP monitoring documentation that demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than 4 hours per night, 5 nights per week); *and*
7. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; *and*
8. No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per tonsillar hypertrophy grading scale. See Appendix).

Hayes Update 9/2020- Hypoglossal Nerve Stimulation for OSA remains C rating.

MCG-24th Ed- role remains inconclusive

Expert Opinion : Dr. Blake Smith TSPMG ENT : 11/2020 – " I have attached the Permanente Medicine HGNS inclusion / exclusion criteria that are being used in SCAL and NCAL. These were provided by Dr. Mui from the NCAL Otolaryngology group during an inter-regional workshop we had this past December and are in keeping with the Aetna criteria and FDA indications. Implantations are being covered in their regions for qualifying patients.

Dr. Chung and I have been seeing patients in house for this treatment and implanted our first patient at EUHM in August. He has been activated and we are awaiting the results of his post op sleep study.
I think we (KPGA) should cover this treatment for patients meeting criteria"

Approval

	11/18/2020
Rhoda Sharp, MD, MBA **Physician Program Director, Quality Resource Management**	**Date**
	Date