Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Description of Procedure or Service

Palatopharyngoplasty refers to several surgical approaches for management of the upper airway, including uvulopalatopharyngoplasty (UPPP), uvulopharyngoplasty (UPP), uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty and relocation pharyngoplasty. UPPP, one of the most commonly chosen approaches, involves surgical resection of the mucosa and submucosa of the soft palate, tonsillar fossa, and the lateral aspect of the uvula. The amount of tissue removed is individualized for each patient as determined by the potential space and width of the tonsillar pillar mucosa between the 2 palatal arches. The UPPP enlarges the oropharynx but cannot correct obstructions in the hypopharynx. Thus, patients who fail UPPP may be candidates for additional procedures, depending on the site of obstruction.

Implantable hypoglossal nerve stimulation is a procedure in which a stimulating electrode is placed around the hypoglossal nerve and the associated lead is tunneled beneath the platysma muscle and connected to the pulse generator, which is then placed subcutaneously above the pectoralis major muscle. The sensing lead, which is placed between the internal and intercostal muscles to monitor respirations, is also connected to the pulse generator. A neurostimulator detects inspiration through sensory leads, predicts the onset of inspiration using an algorithm, and delivers electric pulses to the hypoglossal nerve to activate and protrude the genioglossus muscle. This causes the base of the tongue to move forward, opening the obstructed airway.

Drug induced sleep endoscopy (DISE) is a procedure in which an infusion of a sedative with a short half-life induces a sleep state. DISE will indicate a flat, anterior-posterior collapse or complete circumferential oropharyngeal collapse. Concentric collapse is an exclusion criteria from the FDA due to research indicating decreased success of hypoglossal nerve stimulation in this event. The DISE procedure may also be performed after initiation of the hypoglossal nerve stimulator to monitor effectiveness and adjust settings.

Background

Uvulopalatopharyngoplasty has been found to be most reliably effective in obstructive sleep apnea (OSA) members who have adequately responded to a trial of continuous positive airway pressure (CPAP or auto-adjusting CPAP (AutoPAP)). If CPAP or AutoPAP is unsuccessful in relieving a member’s symptoms, this may indicate that apnea is not due to obstruction. Thus, this surgical approach has not been shown to be effective in non-obstructive apnea for persons who do not respond to CPAP or AutoPAP.

Uvulopalatopharyngoplasty (UPPP): The largest of the reviewed studies of UPPP (n=95) was in a randomized trial that evaluated UPPP versus nonsurgical treatment with a mandibular advancement device. This trial provides limited evidence that the mandibular advancement device is more effective than UPPP. Patients randomized to the device had statistically significant improvements in apnea index, apnea-hypopnea index, and blood oxygen saturation, relative to patients randomized to UPPP; however,
38% of patients in the device treatment group were lost to follow-up or withdrew from the study due to noncompliance before 4 years of follow-up were completed.

Another randomized trial of UPPP was conducted as part of two parallel, randomized studies in which patients were assigned to CPAP (n=44) or UPPP (n=32) by a team of medical experts. Patients were then randomized to treatment or no treatment. Although the results of this study suggest that UPPP and CPAP reduced symptoms of sleep apnea, the design of this study prevents direct comparison of results obtained with UPPP versus CPAP. Considering only the UPPP arm of the trial, this procedure was found to provide statistically significant improvements in daytime sleepiness and snoring but not in decreases in blood oxygen saturation levels during sleep.

One other randomized trial of UPPP met the criteria for detailed review and it compared UPPP with lateral pharyngoplasty for obstructive sleep apnea-hypopnea syndrome (OSAHS). This study found that lateral pharyngoplasty provided statistically significant improvements in daytime sleepiness and apnea-hypopnea index compared with UPPP; however, it was small (n=27) and involved only a mean 8 months follow-up.

Uvulopalatoplasty (UPP): Only three studies of UPP met the criteria for detailed review, a retrospective nonrandomized comparative study, a prospective case series, and a retrospective study. Outcome measures in these studies varied and included apnea index, blood oxygen saturation during sleep, daytime sleepiness, and snoring. In the nonrandomized comparative study, 63 patients with OSAHS underwent UPP or UPPP; patients with redundant pharyngeal folds were assigned to UPPP. Patients also underwent ablation of any redundant tonsillar tissue. Results of this study suggest that, when proper patient selection criteria are used, UPP and UPPP provide comparable improvements in daytime sleepiness and snoring. Snoring intensity decreased 67% after either treatment; however, daytime sleepiness decreased only 31% after UPP and only 33% after UPPP. The reviewed prospective and retrospective case series evaluating UPP do not provide conclusive evidence that this procedure is effective since they were uncontrolled. Although the larger of these two case series (n=76) reported that daytime sleepiness disappeared or decreased markedly for 66% of patients, the benefits of UPP seemed to diminish somewhat over time. In addition, the smaller case series reported that less than half of patients who underwent UPP had a > 50% improvement in apnea index.

Hypoglossal nerve stimulator: In a study published by Patrick Strollo in 2014, the hypoglossal nerve stimulator reduced the apnea-hypopnea index (AHI) by sixty-eight percent. The study included participants who were at least 22 years of age with moderate to severe obstructive sleep apnea. The participant body mass index was below 33 kg/m2. The study was limited to participants with no significant comorbidities, pronounced airway anatomic abnormalities and those with anterior-posterior predominant retropalatal collapse during drug induced sleep endoscopy.

Hypoglossal nerve stimulators are considered an effective second-line treatment of moderate to severe OSA in adult patients who are intolerant or unable to achieve benefit with positive airway pressure.

Patients with Down syndrome have a higher incidence of OSA than the general pediatric population, with rates up to 80%, resulting in increased morbidity and decreased quality of life for affected individuals. In children, adenotonsillar hypertrophy is often a contributing factor to OSA, and adenotonsillectomy (T&A) is the initial treatment of choice. Children with DS often undergo T&A for OSA; however, up to 67% will have persistent obstructive sleep patterns, which are attributed to
anatomic and physiologic differences in this population, including reduced muscular tone, macroglossia, maxillary hypoplasia, and lingual tonsil hypertrophy. These children often require positive-pressure airway support (continuous positive airway pressure [CPAP] or bilevel positive airway pressure), oromaxillofacial surgery, oxygen, or, in severe cases, tracheotomy for persistent airway obstruction. These treatments, although effective when used consistently, are often poorly tolerated (Diercks, et. al. 2018).

The study by Diercks et. al., (2018) included the following criteria and exclusions (not all inclusive): Children and young adults aged 10-21 years with a prior adentonsillectomy, BMI <95th percentile for age, moderate to severe OSA (AHI >10, AHI <50, no more than 25% AHI attributable to central events), tracheotomy or ineffectively treated with CPAP. Exclusion criteria included BMI>95th percentile for age, apnea hypopnea less than 10 or greater than 50, central or mixed apneas accounting for greater than 25% of the total AHI, anatomic finding that would compromise the performance of the stimulator, unstable co-morbidities and any condition that may require future MRI exams.

A follow up study was performed in which twenty non-obese children and adolescents (aged 10-21 years) with DS and severe OSA (apnea-hypopnea index [AHI] >10 and <50 events/hr) despite prior adenotonsillectomy were enrolled. Participants had failed a trial of continuous positive airway pressure therapy and underwent sleep endoscopy confirming surgical candidacy. The primary outcome was to assess safety and monitor for adverse events. Secondary outcomes included efficacy in reducing AHI (% reduction in AHI), adherence to therapy, and change in a validated quality-of-life instrument, the OSA-18 survey.

The result data suggests that pediatric hypoglossal nerve stimulation appears to be a safe and effective therapy for children with Down Syndrome and refractory severe obstructive sleep apnea (Caloway, C. et. al. 2019).

**Regulatory Status**

There are no regulatory specifics to note relevant to coverage of the titled procedures. However, there are several regulated therapies associated with surgical management of upper airway symptoms which may be mentioned in this coverage policy.

The FDA regulates hypoglossal nerve stimulator devices. The FDA granted premarket approval (PMA) on April 30, 2014, to the Inspire Upper Airway Stimulation (UAS) system (Inspire Medical Systems Inc.) (P130008), which includes the Model 3024 Implantable Pulse Generator, the Model 4063 Stimulation Lead, the Model 4323 Sensing Lead, the Model 2740 Physician Programmer, and the Model 3032 Patient Programmer.

**Benefit Application**

This medical policy relates only to the services or supplies described herein. Please refer to the member’s benefit booklet for availability of benefits.

Coverage for orthognathic surgery is only eligible in accord with the member’s benefit brochure which allows for the surgery only for the following conditions:

- Severe sleep apnea only after conservative treatment of sleep apnea has failed; or
• Cleft palate and Pierre Robin Syndrome.

Policy Statement

GEHA will provide coverage for palatopharyngoplasty procedures, including uvulopalatopharyngoplasty or uvulopalatoplasty, and hypoglossal Nerve Stimulator, when determined to be medically necessary because the medical criteria and guidelines as documented below have been demonstrated.

For non-surgical treatment of obstructive sleep apnea, refer to GEHA’s clinical coverage policy for obstructive sleep apnea at geha.com.

When Palatopharyngoplasty/Uvulopalatopharyngoplasty is covered:

• GEHA considers Uvulopalatopharyngoplasty (UPPP) or uvulopalatoplasty (UPP) medically necessary for the treatment of clinically significant (moderate to severe) obstructive sleep apnea syndrome or upper airway resistance syndrome (UARS) in patients who have tried and failed a good faith effort at treatment with continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP) and whose physical examination shows obstruction at the palatal level.

Clinically significant OSA is defined as those patients who have:

• An apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) of > 15 per hour, or
• An AHI or RDI of > 5 per hour in a patient with excessive daytime sleepiness or unexplained hypertension.

Clinically significant UARS is defined as greater than 10 alpha EEG respiratory arousals per hour. The presence of abnormally negative intrathoracic pressures (i.e., more negative than -10 cm) in conjunction with the EEG arousals supports the diagnosis. Measurement of intrathoracic pressures requires the use of an esophageal manometer as an adjunct to a polysomnogram. Objective evidence of hypopharyngeal obstruction is documented by either fiberoptic endoscopy or cephalometric radiographs.

• Uvulopalatopharyngoplasty may also be indicated in order to enhance CPAP or BiPAP effectiveness in patients who have tried and failed a good faith effort at pressure support.

When Palatopharyngoplasty/Uvulopalatopharyngoplasty is not covered:

GEHA considers the following procedures for the treatment of OSA to be experimental:

• Adult Lingual or Pharyngeal Tonsillectomy as an isolated procedure
• Trans-palatal Advancement Pharyngoplasty
• Expansion Sphincteroplasty
• Lateral Pharyngoplasty
- Laser-assisted Uvulopalatoplasty (LAUP)
- Radiofrequency Ablation of Palatal Tissues and the Tongue
- Tongue Base Suspension or Reduction
- Palatal Stiffening
- Cautery-Assisted Palatal Stiffening Operation (CAPSO)
- Palatal Implants
- Somnoplasty and Coblation
- Uvulectomy
- Injection snoreplasty
- All “minimally invasive” surgical procedures for OSA not specifically identified as covered above

**When Implantable Hypoglossal Nerve Stimulator is covered. (Member must meet ALL of the following):**

1. Only FDA approved hypoglossal nerve stimulator; AND
2. Age 22 years or older; AND
3. Body mass index is less than 32kg/m2; AND
4. Polysomnography performed within 24 months of first consultation for hypoglossal nerve stimulator; AND
5. Moderate to severe OSA with an AHI range from 15-65 and less than 25% central apneas; AND
6. Apnea hypopnea index (AHI) 15-65 events per hour; AND
7. Minimum of one month CPAP monitoring documentation that demonstrates CPAP failure (AHI greater than 15 with CPAP usage) or CPAP intolerance (less than 4 hours per night, 5 nights per week); AND
8. Absence of complete concentric collapse at the soft palate level as seen on a drug induced sleep endoscopy (DISE) procedure; AND
9. No other anatomical findings that might compromise performance of the hypoglossal nerve stimulator (enlarged tonsils size 3 or 4 per tonsillar hypertrophy grading scale)

Hypoglossal nerve stimulation may be considered medically necessary in adolescents or young adults with Down syndrome under the following conditions:

1. Age 10 to 21 years; AND
2. OSA with an AHI >10 and <50 with less than 25% central apneas after adenotonsillectomy; AND
3. Have a tracheotomy or are ineffectively treated with CPAP due to inconsistent or improper use, persistent symptoms despite compliance use, or refusal to use the device; AND
4. Body mass index less than or equal to the 95th percentile for age; AND
5. Non-concentric retropalatal obstruction on drug-induced sleep endoscopy
Replacement or revision of an implantable hypoglossal nerve stimulator (generator, leads and/or battery) is considered medically necessary for an individual who meets ALL the above criteria and the existing device is no longer under warranty and cannot be repaired.

After initiation of the implantable hypoglossal nerve stimulator, 1 drug induced sleep endoscopy OR polysomnography will be considered medically necessary to determine functionality effectiveness of device and adjust for maximum benefit.

**When Implantable Hypoglossal Nerve Stimulator Surgery is not covered:**

The following are contraindications to placement of an implantable HGNS, therefore HGNS will not be covered in these situations:

- Central + mixed apneas >25% of the total apnea-hypopnea index (AHI)
- 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
- Patients who are unable or do not have the necessary assistance to operate the sleep remote
- Patients who are pregnant or plan to become pregnant
- Patients who will require magnetic resonance imaging (MRI)
- Patients with an implantable device that may be susceptible to unintended interaction with the Inspire® system. Consult the device manufacturer to assess the possibility of interaction.

Hypoglossal nerve stimulation is considered experimental and investigational for all other indications not listed under the covered coverage criteria.

**Policy Guidelines**

Conservative measures must have been tried and failed prior to considering surgical management for OSA or Upper Airway Resistance Syndrome. Conservative medical therapy, when appropriate to the clinical situation, may include: weight loss, avoidance of alcohol, sedatives and caffeine consumption—especially before bedtime, allowing adequate sleep time, body position during sleep (side versus back), oral appliances, positive airway pressure devices and medically supervised smoking cessation programs.

GEHA considers positive airway pressure (e.g., CPAP, BiPAP) as the treatment of choice for obstructive sleep apnea based upon current medical practice standards. For this reason the general rule is that a good faith effort at positive pressure must be tried and failed prior to coverage of surgical treatment. Surgery is to be reserved for patients who have not responded to appropriate medical alternatives.

The American Academy of Otolaryngology-Head and Neck Surgery Foundation issued a position statement stating that it considers UAS via the hypoglossal nerve 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. Not all adult patients are candidates for UAS therapy; appropriate polysomnographic, age, body mass index, and objective upper airway evaluation measures are required for proper patient selection (Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea (OSA), 2016).

National Institute for Health and Care Excellence (NICE): NICE recommends that HGNS for moderate to severe OSA should be used only with special arrangements, as evidence on its efficacy and safety is limited in quantity and quality (NICE Interventional Procedures Guidance No. 598, 2017).

Activation of HGNS by Physician generally occurs 1 month after surgery. Post-operative HGNS follow up sleep study is performed and should be monitored by technician capable of adjusting the HGNS for optimal function.

**Physician documentation**

For any request for prior review of a surgical procedure, current polysomnogram data (including the initial sleep study, any CPAP titration data, and any other studies such as MSLT that have been performed) must be submitted for review with the supporting medical record documentation. Generally, the sleep study upon which approval is requested must be less than 18 months old.

Polysomnography data must include a summary with, at minimum, the following information:

- Total sleep time for the study;
- Total RDI or AHI for the study;
- Average and lowest recorded oxygen saturation;
- For any desaturations below 90%, the length of time at the abnormally low saturation level or range;
- Obstructive event indices for supine and non-supine positions, along with total sleep time spent supine;
- Periodic leg movement (PLM) index;
- A summary table of the polysomnogram results and titration data for all devices used.

A polysomnogram that does not distinguish between supine and non-supine obstructive events, to the extent that any possible positional predisposition to obstruction can be determined, may not be sufficient to support a request for surgery or pressure therapy; GEHA reserves the authority to seek clarifying information. GEHA may also require a repeat polysomnogram to support any request for additional surgical therapy after an approved surgical therapy based on an initial polysomnogram.

**Required documentation for the Implantable Hypoglossal Nerve Stimulator:**

- Demonstration of PAP failure with at least 1 of the following over a one month timespan:
  1. AHI greater than 15 with regular PAP usage; OR
  2. Intolerance of PAP therapy; less than 4 hours per night, 5 nights per week; OR
  3. Documented unwillingness to use PAP therapy; OR
4. Tracheostomy dependent at night for moderate or severe obstructive sleep apnea and unable to tolerate airway support therapy.
5. Drug Induced Sleep Endoscopy (DISE) to confirm absence of complete concentric collapse at the soft palate level.

The following codes are for reference purposes only and do not imply that the service is covered or non-covered. Applicable codes may include but are not limited to:

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Description</th>
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<tbody>
<tr>
<td>42145</td>
<td>Palatopharyngplasty (e.g. UPP, UPPP)</td>
</tr>
<tr>
<td>0466T</td>
<td>Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator</td>
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<tr>
<td>0467T</td>
<td>Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator</td>
</tr>
<tr>
<td>0468T</td>
<td>Removal of chest wall respiratory sensor electrode or electrode array</td>
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<tr>
<td>61886</td>
<td>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays</td>
</tr>
<tr>
<td>61888</td>
<td>Revision or removal of cranial neurostimulator pulse generator or receiver</td>
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<tr>
<td>64568</td>
<td>Incision for implantation of cranial nerve (eg, vagal or hypoglossal) neurostimulator electrode array and pulse generator</td>
</tr>
<tr>
<td>64569</td>
<td>Revision or Replacement of cranial nerve (e.g. vagus nerve) neurostimulator electrode array, including connection to existing pulse generator</td>
</tr>
<tr>
<td>64570</td>
<td>Removal of cranial nerve neurostimulator electrode array and pulse generator</td>
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<tr>
<td>64585</td>
<td>Revision or removal of peripheral neurostimulator electrode array</td>
</tr>
<tr>
<td>95971</td>
<td>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 spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional</td>
</tr>
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</table>

**Scientific references**


Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Radiofrequency volumetric tissue reduction for sleep-related breathing disorders. TEC Assessments. 2000; Volume 15, Tab 15


Strohl KP. Overview of obstructive sleep apnea in adults. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed November 2014.


Policy implementation and updates

2/2018 Revised to include expanded title and additional clarity around pre-surgical management of OSA.

2/2019 Changed name to reflect surgical procedures for snoring and OSA. Aligned with OSA clinical coverage policy for experimental and investigational technology.

9/2019 Added coverage and supporting content for HGNS