Sleep Disorder Surgery

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COVERAGE CRITERIA 2
POLICY CROSS REFERENCES 4
POLICY GUIDELINES 5
REGULATORY STATUS 7
CLINICAL EVIDENCE AND LITERATURE REVIEW 8
BILLING GUIDELINES AND CODING 21
REFERENCES 24
POLICY REVISION HISTORY 27

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partnersas applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to OHA's prioritized list for the following coverage guidelines:

Hyoid Myotomy and Suspension: Guideline Note 173
Hypoglossal Nerve Stimulation: Guideline Note 27

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Note: With the exception of hypoglossal nerve stimulation, this medical policy does not address surgical treatments for sleep disorders in patients 17 years of age or younger, which may be considered medically necessary.

Surgical Treatments of Obstructive Sleep Apnea

UPPP, Hyoid Myotomy and Suspension, MMA

I. The following surgical treatments for obstructive sleep apnea (OSA) may be considered **medically necessary**:
- Uvulopalatopharyngoplasty (UPPP)
- Hyoid myotomy and suspension with or without osteotomy and/or genioglossus advancement
- Mandibular-maxillary advancement (MMA)

when **all** of the following (A.-D.) criteria are met:

A. The patient has been diagnosed with moderate or severe OSA (AHI or RDI ≥15 events per hour); **and**
B. Demonstrated inability to adhere to a minimum 3-month active trial of continuous positive airway pressure (CPAP or BiPAP) therapy or other appropriate non-invasive treatment, such as oral appliance*; **and**

C. A consult with a sleep specialist to ensure the conservative therapy trials were adequate and the potential benefits and risks of the surgery were discussed; **and**
D. Evidence of retropalatal or combination retropalatal/retrolingual obstruction as the cause of the obstructive sleep apnea.

*Note: An active trial of conservative therapy should include compliance monitoring, improvement in sleep hygiene, phone calls and visits with a provider or DME representative to make a concerted effort to improve adherence. An active CPAP or BiPAP trial should include mask and pressure adjustment.

II. When criterion I. above is not met, surgical treatments of sleep apnea are considered **not medically necessary**, including but not limited to the treatment of snoring without documented OSA.

Hypoglossal Nerve Stimulation

III. Hypoglossal nerve stimulation (e.g., Inspire Upper Airway System) for members 18 years of age and older with obstructive sleep apnea may be considered **medically necessary** when **all** of the following criteria are met (A.-H.):

A. Body mass index (BMI) is less than 40 kg/m^2; **and**
B. A polysomnography (PSG) is performed within 24 months of first consultations for Inspire implant; **and**
C. Apnea hypopnea index (AHI) is 15 to 100 events per hour; **and**
D. Member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); **and**
E. Demonstrated inability to adhere to a minimum 3-month active trial of continuous positive airway pressure (CPAP or BiPAP) therapy*; **and**
F. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; **and**
G. No other anatomical findings that would compromise performance of device (e.g. hypertrophied tonsils).

IV. Hypoglossal nerve stimulation (e.g. Inspire Upper Airway System) for members 17 years of age and younger with obstructive sleep apnea may be considered **medically necessary** in patients with unique congenital circumstances in which the patient has tried and failed standard pediatric surgical treatments.

*Note: An active trial of conservative therapy should include compliance monitoring, improvement in sleep hygiene, phone calls and visits with a provider or DME representative to make a concerted effort to improve adherence. An active CPAP or BiPAP trial should include mask and pressure adjustment.

V. Hypoglossal nerve stimulation (e.g. Inspire Upper Airway System) for obstructive sleep apnea is considered **not medically necessary** when criteria III. and IV. as above is not met.

Removal or Replacement of Hypoglossal Nerve Stimulator

VI. Removal of a hypoglossal nerve stimulator may be considered **medically necessary** for an individual that acquires one of the following (A.-C.) FDA contraindications after implantation:

A. Member requires magnetic resonance imaging (MRI); **or**
B. Member requires another implantable device that may be susceptible to unintended interaction with the HNS device; **or**
C. Member becomes pregnant.

VII. Replacement of a hypoglossal nerve stimulator may be considered **medically necessary** when **all** of the following (A.-B.) criteria are met:
A. Criteria III.A.-III.H. above are met; and
B. Member meets **at least one** of the following (1.-2.) criteria:
1. The battery of the existing device is depleted (results of the STAR trial indicate the minimum battery life to be 7 years and the average battery life to be 10.6 years); **or**
2. The device is malfunctioning, cannot be repaired, and is no longer under warranty (3 years from the date of implant)

VIII. Removal or replacement of a hypoglossal nerve stimulator is considered **not medically necessary** when criteria V. or VI. above are not met.

Non-covered Surgical Treatments of Obstructive Sleep Apnea

IX. Surgical treatments of obstructive sleep apnea not listed above are considered **not medically necessary**, including but not limited to the following:

A. Submucosal cryolysis therapy
B. Laser-assisted uvulopalatoplasty (LAUP)
C. Radiofrequency volume tissue reduction of the soft palate, uvula, tongue base or turbinates (e.g. Somnoplasty™)
D. Palatal stiffening procedures/palatal implants (e.g. the Pillar Procedure™)
E. Tongue suspension systems (e.g. AIRvance® or Encore™)

Link to Evidence Summary

POLICY CROSS REFERENCES

- Rhinoplasty and Other Nasal Surgeries, MP166
- Sleep Disorder Testing, MP60
- Sleep Disorder Treatment: Oral and Sleep Position Appliances, MP46
- Sleep Disorder Treatment: Positive Airway Pressure, MP56

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

Indications

Obstructive Sleep Apnea (OSA)

OSA occurs when muscles of the upper airway are not able to maintain an open airway when relaxed during sleep. Consequently, breathing stops and starts repeatedly during sleep. This can lead to a variety of health consequences including hypertension, depression, stroke, coronary and artery disease.[1]

Medically Necessary Procedures

Uvulopalatopharyngoplasty (UPPP)

UPPP is a surgical procedure in which tissue in the throat (e.g. tonsils, adenoids, uvula, soft palate) is remodeled and/or removed to improve airflow during sleep.

Mandibular Maxillary Advancement (MMA)

MMA is a surgical procedure in which the bones of the upper and lower jaw are repositioned to relieve airway obstruction. The attached pharyngeal airway muscles are suspended in an anterior position and pharyngeal soft tissue tension is increased.[2]

Hyoid Myotomy and Suspension

Hyoid myotomy and suspension, also known as hyoid advancement, is a surgical procedure in which the hyoid bone and muscle attachments to the tongue and airway are pulled toward the mandible, which may improve airway stability in the retrolingual and hypopharyngeal airway.

Mandibular Osteotomy

Mandibular osteotomy is a surgical procedure in which the lower jaw is moved into a new position and affixed with small metal plates and screws.

Genioglossal Advancement

Genioglossal advancement is a surgical procedure in which the tongue muscle is attached to the lower jaw and pulled forward, thereby rendering the tongue firmer and less likely to collapse during sleep.

Hypoglossal nerve stimulation (e.g. Inspire Upper Airway System)

Hypoglossal nerve stimulation refers to a surgical implanted system in which an implanted pulse generator stimulates the medial branch of the hypoglossal nerve, producing selective motor stimulation of the horizontal-longitudinal muscle fibers. These fibers draw the tongue forward, purportedly improving upper airway obstruction. The patient uses a remote control to activate the device before sleep.[1]

Procedures Considered Not Medically Necessary

Submucosal Cryolysis Therapy

Submucosal cryolysis therapy is a minimally invasive treatment for obstructive sleep apnea that uses controlled cold energy to reduce excess tissue at the base of the tongue, which can obstruct the airway during sleep. Delivered via a specialized probe, the therapy targets submucosal tissue without incisions, implants, or external devices. This approach aims to improve airflow and reduce apnea events, particularly in patients with moderate OSA.

Laser-Assisted Uvulopalatoplasty (LAUP)

LAUP is a surgical procedure that involves partial resection of the uvula and soft palate using a CO_2 laser, eliminating tissue obstruction contributing to sleep apnea.

Radiofrequency Volume Tissue Reduction (RFVTR)

Radiofrequency volumetric tissue volume reduction involves radiofrequency ablation of oropharyngeal tissue from the nasal turbinates, or the soft palate, uvula and tongue base so as to improve airflow.[3] Somnoplasty™ is a trade name for the Somnoplasty™ System of Somnus Medical Systems, which uses heat energy to modify the tissues of the uvula and soft palate.

Palatal stiffening procedures/Palatal implants (e.g. the Pillar Procedure)

Palatal stiffening involves the surgical placement of small polyester rods in the soft palate. The subsequent healing of tissue around the implants stiffens the soft palate, thereby reducing relaxation and vibration of the tissue during sleep.[4]

Tongue suspension systems (e.g. AIRvance® or Encore™)

Tongue suspension is a surgical procedure in which the tongue base is prevented from sliding toward the back of the throat during sleep. To this end, a screw is attached to the back of the jawbone below the roots of the front teeth, which is attached to a non-absorbable suture. The suture is passed through the left side of the tongue base and looped back to the front of the tongue base. The suturing process is then repeated to create a loop through the right side of the tongue base. The tension between the suture's left and right loops keeps the tongue in place.[5]

Expansion sphincter pharyngoplasty

Expansion sphincter pharyngoplasty (ESP) is a variation on uvulopalatopharyngoplasty that combines tissue removal and tissue repositioning to increase the size of the airway without affecting normal

functions of breathing, speaking, and swallowing. ESP consists of a tonsillectomy, expansion pharyngoplasty, rotation of the palatopharyngeus muscle, partial uvulectomy, and closure of anterior and posterior tonsillar pillars.[6]

Absorbable Nasal Implants (e.g. Latera®)

Absorbable nasal implants are soft absorbable tissue endoprostheses used to support the upper and lower cartilage inside the lateral wall of the nose. The device is intended to improve breathing in patients with nasal wall collapse.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

Device	Indications for Use	Contraindications
Somnoplasty System[7]	The Somnoplasty System is intended for the reduction of the incidence of airway obstructions in patients suffering from Upper Airway Resistance Syndrom (UARS) or Obstructive Sleep Apnea Syndrome (OSAS). This device is intended for use by qualified medical personnel trained in the use of electrosurgery.	n/a
AIRVance®[8]	The AIRvance™ Bone Screw System is intended for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with pre-threaded suture. It is indicated for the treatment of obstructive sleep apnea (OSA) and/or snoring. The AIRvance™ Bone Screw System is also suitable for the performance of a hyoid suspension procedure which can be used in combination with other procedures for the treatment of obstructive sleep apnea (OSA). It is indicated for the treatment of obstructive sleep apnea (OSA) and/or snoring.	n/a
Encore™ System[9]	The Siesta Medical, Inc. ENCORE Tongue Suspension System is intended to be used for anterior advancement of the tongue base by means of a bone screw threaded with suture. It is indicated for the treatment of mild or moderate obstructive sleep apnea (OSA) and /or snoring.	n/a

Pillar™ Palatal Implant System[10]	The PillarTM Palatal Implant System is intended for the reduction of the incidence of airway obstructions in patients suffering from mild to moderate OSA (Obstructive Sleep Apnea).	n/a
Inspire Upper Airway Respiratory (UAS) system (Inspire Medical Systems Inc.)[11]	Inspire Upper Airway Stimulation (UAS) is used to treat a subset of patients with moderate to severe Obstructive Sleep Apnea (OSA) (Apnea-hypopnea Index [AHI] of greater or equal to 15 and less than or equal to 100). Inspire UAS is used in adult patients 22 years of age and older who have been confirmed to fail or cannot tolerate Positive Airway Pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) and who do not have a complete concentric collapse at the soft palate level. PAP failure is defined as an inability to eliminate OSA (AHI of greater than 20 despite PAP usage) and PAP intolerance is defined as: 1. Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night), or 2. Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it).	Contraindications for the use of Inspire therapy include the following: • Central and mixed apneas make up over 1/4 of the total apnea-hypopnea index (AHI) • Patients with an implantable device that could experience unintended interaction with the Inspire system. Consult the device manufacturer to assess the possibility of interaction. • Patients who are, or who plan to become pregnant • Patients who require magnetic resonance imaging (MRI) • Patients who are unable or do not have the necessary assistance to operate the sleep remote • Any condition or procedure that has compromised neurological control of the upper airway (consult your doctor) • Any anatomical finding that would compromise the performance of upper airway stimulation.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of various surgical procedures for the treatment of sleep disorders. Below is a summary of the available evidence identified through July 2025.

Medically Necessary Procedures

Uvulopalatopharyngoplasty (UPPP)

- A 2019 systematic review and meta-analysis was conducted by He and colleagues on the long-term efficacy of UPPP in adults with obstructive sleep apnea (OSA). Eleven studies with 435 patients were included in the analysis, with mean follow-up of 34 to 87.5 months. There were randomized trials, 7 prospective studies, and 2 retrospective studies. The analysis found that both objective and subject sleep-related outcomes showed significant improvement long-term compared to baseline. Yet improvement declined short term results, with mean apnea-hypopnea index increasing 12.3 events/hour and surgical response decreasing from 67.3% to 44.35%. The authors conclude that although efficacy decreases over time, UPPP is an effective surgical method for treating adults with OSA.

- In 2018, Stuck and colleagues conducted a systematic review and meta-analysis comparing the efficacy of uvulopalatopharyngoplasty (UPPP) with or without tonsillectomy (TE) as a monotherapy for the treatment of adult obstructive sleep apnea (OSA).1 Independent investigators systematically searched the literature through January 2016, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 48 studies were included for review. Outcomes of interests included the frequency of respiratory events and success/response rates, mean scores of the Epworth Sleepiness Scale (ESS) and apnea=hypopnea index (AHI). Studies demonstrated significant improvement in all outcomes measured compared to baseline. Pooled data from two RCT's indicated an AHI mean difference (MD) of -18.59 (95% CI -34.14, -3.04) and an ESS MD of -5.37 (95% CI -7,03, -3.72). Data addressing effect of UPPP ± TE in comparison to baseline was available from three RCTs, indicated a significantly improved AHI from a mean 35.4 to 17.9 (49.5% reduction). Patients receiving UPPP with or without TE also reported improvements in sexual function, ventricular function, sleep stages, serum lipid, depressive disorder and driving performance.

  Limitations included a lack of prospective and randomized trials, small sample sizes, inadequate follow-up, non-representative patient group (i.e. predominantly white and male). Investigators concluded that evidence was sufficient to assert that UPPP with or without TE improves adult OSA with regard to respiratory events and daytime sleepiness. Authors called for additional research with long-term follow-up was to compare the effects of UPPPP with or without TE to CPAP, as well as the treatment's impact on patients' cardiovascular morbidity.

- In 2016, Choi and colleagues conducted a systematic review and meta-analysis of studies evaluating UPPP as a monotherapy for the treatment of OSA, to identify predictors of success after UPPP.2 Independent investigators systematically searched the literature through January 2015, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 15 retrospective case series were included for review. Age, body mass index (BMI), preoperative apnea-hypopnea index (AHI), Friedman stage and several cephalometric variables were compared between responders and non-responders. Pooled data suggested that Friedman

stage I was a strong predictor for success after UPPP, while Friedman stage III and low hyoid position were negative predictors. Age, BMI and preoperative AHI were found not to be predictors of surgical success. Study limitations included the retrospective case series included for review, the lack of RCTs, heterogeneous results and outcome measures constituting treatment success.

- In 2005 (updated 2009; archived 2011), Hayes conducted a systematic review evaluating the safety and efficacy of surgical treatments for sleep apnea.[12] Searching the literature through 2011, Hayes included 15 studies for review, of which 7 were RCTs. Three of these RCTs compared UPPP to either continuous positive airway pressure (CPAP), nonsurgical treatment with a mandibular advancement device, or lateral pharyngoplasty (n=198). Results across studies were mixed. One study, with significant attrition, found statistically significant improvements among patients receiving the mandibular advancement device compared to UPPP patients; a second study found significant improvements in daytime sleepiness and snoring but not in decreases in blood oxygen saturation levels during sleep; and a third study found that lateral pharyngoplasty significantly improved daytime sleepiness and AHI compared to UPPP. Findings' validity was limited by studies' small sample sizes and lack of long-term follow-up. Hayes ultimately assigned UPPP a "C" rating (potential but unproven benefit), due to a lack of controlled studies relative to CPAP.

<u>Hyoid Myotomy and Suspension, Surgical Modification of the Tongue, and/or Maxillofacial Surgery, Including Maxillomandibular Advancement (MMA)</u>

- In 2019, a meta-analysis was published on the long term results of maxillomandibular advancement to treat obstructive sleep agnea.[13] A total of 6 studies comprising of 120 patients were analyzed. Intermediate-term results showed a reduction in apnea-hypopnea index (AHI) from mean 48.3 events/h (95% CI, 42.1-54.5) pre-MMA to 8.4 (95% CI 5.6, 11.2) in the intermediate term for 31 patients. Fifty-four patients showed a reduction in AHI from a mean 65.8 events/h (95% CI, 58.8-72.8) pre-MMA to 7.7 (95% CI 5.9, 9.5) in the long term. Thirty-five showed a reduction in AHI from a mean 53.2 events/h (95% CI 45, 61.4) pre-MMA to 23.1 (95% CI 16.3, 29.9) in the very long term. This analysis concluded that patients with obstructive sleep apnea treated with MMA maintain improvements in the long-term, although regression does occur in the very long term.

- In 2018, John and colleagues conducted a systematic review and meta-analysis evaluating the efficacy of maxillomandibular advancement (MMA) for the treatment of OSA.[14] Independent investigators systematically searched the literature through December 2015, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 20 studies (13 retrospective cohort studies, 3 prospective cohort studies, 1 case series, 1 prospective RCT, 1 retrospective review) were included for review (n=462). Outcomes of interest included apnea-hypopnea index (AHI), respiratory disturbance index (RDI), Epworth Sleepiness Scale (ESS), lowest oxygen saturation (LSAT) and body mass index (BMI). Random-effects modeling was adopted for meta-analysis, except for BMI for which the fixed-effects model was used.

  The mean difference between the pre- and post- MMA AHI values was -44.76, representing a significant reduction in events per hour. Compared to baseline, an average change of 82.63% was reported, with 51% of patients (129 out of 251) experiencing an improvement of more than

80%. Surgical success was reported at 100%, with random-effects modeling confirming significant improvements among MMA patients. Investigators also reported statistical significance at the meta-analysis and study level for outcomes of RDI, ESS, LSAT and BMI, although only at the meta-analysis level for LSAT and BMI. All four prospective studies were assessed as having a low-risk of bias. Study limitations included reviewed studies' lack of information across studies regarding allocation or sequence generation, blinding, individual patient data, retrospective study design of most included studies, and attrition. Investigators concluded that MMA is a successful treatment for OSA, while also calling for additional RCTs, and studies evaluating MMA's efficacy when performed as an isolated primary procedure.

- In 2017, Tan and colleagues conducted a review of systematic reviews evaluating the effect of mandibular advancement with or without maxillary procedures on pharyngeal airways.[15] Independent investigators systematically searched the literature through April 2017, identified eligible studies, assessed study quality and extracted data. In total, 11 systematic reviews were included for review. MMA was found to significantly reduce patients' apnea-hyopnea index (AHI) and the respiratory disturbance index (RDI). Investigators concluded that MMA increases pharyngeal airway dimensions and improves outcomes for patients with OSA with a relatively high treatment success rate (>85%). Given the extensive evidence supporting the benefit of MMA on OSA patients, investigators called for future studies to investigate correlations between patients' pre-surgical clinical conditions, degree and direction of jaw movement and surgical success rates.

- In 2017, Noller and colleagues conducted a systematic review and meta-analysis evaluating the efficacy of mandibular advancement for patients with OSA who had not previously undergone surgical treatment.[16] Independent investigators systematically searched the literature through April 2017, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 11 studies were included for review (n=57). Meta-analysis showed an average AHI reduction of 87% from a mean of 45.89 ± 23.73 to 6.15 ± 10.144 events per hour. Sub-analysis using random effects modelling reported a mean difference of combined RHI/ADI -34.80 events per hour, and an LSAT rate of 13%. There was no heterogeneity and no inconsistency among findings, however, results were limited by the design of included studies (case reports and small case series). Authors nonetheless concluded that mandibular advancement or mandibular distraction osteogenesis significantly improves patient's OSA.

- In 2016, Song and colleagues conducted a systematic review and meta-analysis evaluating the safety and efficacy of hyoid surgery as a monotherapy for the treatment of OSA.[17] Independent investigators systematically searched the literature through September 2015, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 9 studies (2 case reports and 7 case series) were included for review (n=101). Outcomes of interest included AHI, oxygen saturation, quantitative sleepiness data. In patients undergoing isolated hyoid surgery, the AHI decreased from a mean 6 standard deviation of 37.3 ± 21.1 events per hour to 23.0 ± 18, corresponding to a 38.3% reduction ($p < .0001$). AHI reduced by 38.3% for hyoid myotomy with suspension, by 50.7% for hyothyroidopexy, and by 7.1% for hyoid expansion. Patients' Epworth Sleepiness Scale scores decreased by 3.2 points from 10.3 ±4.9 (95% CI: 8.8, 11.8) to 7.1 ± 4.2 (95% CI: 5.8, 8.4; $p = .0027$). Limitations included studies' retrospective design, heterogeneous outcome measures, small sample sizes and inadequate follow-up. Investigators concluded that while hyoid surgery improved patients' OSA severity and sleepiness, additional high-quality

studies were needed to establish the long-term safety and efficacy of hyoid myotomy as a monotherapy.

Hypoglossal Nerve Stimulation in Adults

- In 2022, Hayes conducted a systematic review evaluating the safety and efficacy of hypoglossal nerve stimulation (HGNS) for the treatment of obstructive sleep apnea (OSA).[1] In total, 26 publications base on 10 observational pretest/posttest studies were included for review. At 5-year follow-up, studies reported significant improvements in patients' airflow mechanics, and scores on indices of apnea-hypoxia and oxygen desaturation. All but one study also reported improvements in patient-reported outcome measures (i.e. Functional Outcomes of Sleep Questionnaire, Epworth Sleepiness Scale, Sleep Apnea Quality of Life Index, and Beck Depression Index). Three studies reported improvements in airflow mechanics. Studies reported conflicting results related to improvements in patients' sleep parameters, including changes in sleep efficiency and time spent in stage 1 non-rapid eye movement and rapid eye movement sleep. Evidence was insufficient to determine definitive patient selection criteria.

  Hayes assessed the overall quality of evidence as "low," (1 study rated as "fair quality;" 6 studies rated as "poor quality"; 3 studies rated as "very poor" quality) largely due to individual study limitations including pretest/posttest study design, potential for selection bias, unclear handling of missing data, loss to follow-up, and small sample sizes. Hayes assigned a "C" rating (potential but unproven benefit) for HGNS for the treatment of moderate-to-severe OSA in adults for whom CPAP therapy has failed to provide relief. Investigators concluded that while low-quality evidence suggests that HGNS may help lessen the severity of OSA and improve quality of life, more consistent high-quality findings were necessary to definitively establish efficacy and patient selection criteria for HGNS. Nonetheless, investigators also noted that higher-quality evidence may never be obtainable due to challenges in conducting high-quality studies in patients that fail or cannot tolerate CPAP.

- In 2019, a systematic review and meta-analysis was published on the long-term clinical outcomes of hypoglossal nerve stimulation in the treatment of moderate to severe obstructive sleep apnea (OSA).[18] Twelve studies totalling 350 patients were included in the analysis. Mean reduction in apnea-hypopnea index (AHI) was -17.50 to 24.20 at 12 months and -18.00 at 5 years. Epsworth sleepiness scale mean reduction was -5.27 at 12 months compared to -4.40 at 60 months. Six percent of patients reported serious device-related adverse events after 1 and 5-year follow up. The review had a number of limitations. Only one of the trials reviewed had follow up longer than 12 months and the trial that had 5 year follow up and poor patient adherence at 57%. The medical centers and patients may not be generalizable to the population effected, nonrandomzied data with high risk of bias were used, and there was moderate heterogeneity between trials.

- In 2018, Kompelli and colleagues conducted a systematic review and meta-analysis evaluating outcome of HGNS for the treatment of OSA.[19] Independent investigators systematically searched the literature through July 2017, identified eligible studies, assessed study quality, extracted data and pooled results. In total 16 studies were included for review, analyzing outcomes for 381 patients. Follow-up was 12 months. Patients experienced significant improvements in mean AHI, disability, and Epworth Sleepiness Scale score at 12-months follow-

up, but not quality of life. Adverse events were common, including pain (6.2%), tongue abrasion with or without lesions (11.0%), internal device malfunction (3.0%). Other adverse events were experienced by 7.0% of patients. Limitations included the lack of long-term follow-up and significant heterogeneity of data in studies included for review (I^2 = 64%, p <0.00001). Investigators concluded that while HGNS is a safe and effective treatment for OSA refractory to CPAP, further study comparing HGNS to other therapies are necessary to establish HGNS's place in clinical practice.

- In 2021, ECRI published an execute summary regarding the Inspire Upper Airway Stimulation (UAS) system indicating that the evidence was somewhat favorable for the use of HGNS as a treatment of moderate to severe OSA in adult patients.[20] The reviewed noted that long-term data are still lacking compared to surgical treatment. Limitations included risk of bias from retrospective design, lack of blinding, patient attrition (>15%), or single-center focus. Findings may not fully generalize to all patients with OSA because studies included few patients with obesity or age >65, which are common OSA risk factors. No studies reported on OSA-related morbidity (e.g., cardiovascular disease, accidents). Investigators concluded that evidence addressing the Inspire Upper Airway Stimulation system is "somewhat favorable," with demonstrated superiority to surgical approaches for improving sleep and reducing OSA symptoms at short-term follow-up.

Hypoglossal Nerve Stimulation in Children

Several small studies assessing hypoglossal nerve stimulation in children report that children with congenital syndromes, craniofacial abnormalities, mucopolysaccharidosis, or neuromuscular disorders may benefit from hypoglossal nerve stimulation.[21-23]

Non-Covered Procedures

Laser-Assisted Uvulopalatoplasty (LAUP)

- In 2017, Camacho and colleagues conducted a systematic review and meta-analysis evaluating the safety and efficacy of LAUP for the treatment of obstructive sleep apnea (OSA).[24] Independent investigators systematically searched the literature through October 2016, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 23 studies were included for review (n=717).

  Compared to baseline, LAUP patients experienced a 32% improvement in apnea-hypopnea index (AHI), with random effects modeling for 519 patients demonstrated an AHI mean difference of -6.56 (95% CI -10.14, -2.97) events per hour. Individual patient data analyses demonstrated a 23% success rate (≥50% reduction in AHI and <20 events/h) and an 8% cure rate. Lowest oxygen saturation (LSAT) rates also improved compared to baseline, albeit minimally. The overall success rate was calculated at 23% and a cure rate of 8%. In contrast, 44% of patients' AHI worsened after LAUP. Limitations included case series study design of most studies included for review, and a lack of randomized, controlled studies with long-term follow-up. Moreover, not all studies published individual patient data or sleep study data. The meta-analysis mostly showed insignificant heterogeneity but high inconsistency. In conclusion, investigators speculated that LAUP may blunt the reflexogenic dilation of the pharyngeal airway, there by negating any

potential improvements of OSA. As such, investigators recommended that LAUP be performed with caution or not performed at all given the unfavorable results of studies published to date.

- In 2005 (updated 2009; archived 2011), Hayes conducted an evidence review of surgical treatments of sleep apnea.[12] Searching the literature through September 2009, 15 studies were included for review of which 3 studies, all RCTs, that evaluated LAUP for the treatment of mild OSA. One RCT with 8 months' follow-up (n=45) evaluated LAUP versus no treatment. Although patients receiving multiple LAUP treatments experienced significant improvements in snoring and apnea-hypopnea index compared to the control group, improvements in daytime sleepiness and sleep apnea quality of life were not statistically significant. The benefits of LAUP were also limited, corresponding to a 44% decrease in mean snoring intensity and 35% decrease in apnea-hypopnea index. A second study, involved a randomized crossover design comparing LAUP to radiofrequency ablation of the palate (n=17). At 3-months' follow-up, patients receiving multiple LAUP treatments experienced significant reductions in other symptoms of sleep-disordered breathing (e.g. daytime sleepiness, upper airway collapse). A placebo-controlled study (n=25) reported no significant differences at 3-month follow-up between the control group (no treatment) and LAUP treatment group in snoring, daytime sleepiness, AHI, or quality of life measures. Hayes ultimately assigned a "C" rating (potential but unproven benefit) for LAUP in the treatment of sleep apnea.

<u>Radiofrequency Volume Tissue Reduction of the Soft Palate, Uvula, Tongue Base or Turbinates</u>

- In 2004, updated in 2020, ECRI published a clinical evidence assessment on radiofrequency ablation (RFA) for treating sleep apnea.[25] The review included one systematic review, 2 randomized controlled trials, one nonrandomized comparison study, and 4 before-and-after treatment studies. The systematic review and 2 before-and-after-studies reported a reduction in respiratory disturbance with RFA treatment compared to baseline and one RCT found improvement as well, but UPPP showed more substantial improvement at 6 months. The second RCT did not find improvement compared to sham treatment after 12 months. Daytime sleepiness and snoring also has mixed results, with some studies finding improvements from baseline, while other found no statistically significant improvements compared to sham or baseline.

  The systematic review consisted of 29 very small studies, totalling 940 participants. There was also high heterogeneity in both trial design, outcomes measures, and patient population. Other studies included were at high risk of bias due to small sample size, lack of long term follow up, single-center focus, and retrospective study design for all but the 2 RCTs. ECRI concluded that the evidence is inconclusive and of very low quality for RFA for treating OSA.

- In 2019, Mulholland and colleagues conducted a systematic review and meta-analysis evaluated the safety and efficacy of multilevel and tongue base surgical treatment of OSA.[26] Independent investigators systematically searched the literature through March 2017, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 46 studies were included for review, including 11 surgical subgroups and 1,806 patients. Two studies (1 prospective cohort study, 1 retrospective case controlled trial) examined UPPP with hyoid suspension and radiofrequency tongue-base reduction (RFTBR). Another study evaluated 472 patients receiving RFTBR alongside soft-palate surgery (e.g. UPPP). In this patient group, surgical

success ranged from 35.5% to 66.7%, with random-effects modelling reporting a superior decrease in AHI among patients receiving surgical treatment (-16.24, 95% CI -24.62 to -7.85, I^2 = 95%). The soft-palate procedure (SP), hyoid suspension and RFTBR, and SP and RFTBR groups showed decreases in AHI of -16.57 (95% CI: -21.11 to -12.04) and -18.09 (95% CI: -24.68 to -11.50) respectively. Limitations included the lack of large, prospective, randomized trials with follow-up beyond 9 months. On the basis of these data, investigators concluded that multilevel surgery conferred substantial clinical benefit, despite a need for additional, large controlled studies to better establish treatment safety and efficacy.

- In 2015, Baba conducted a systematic review and meta-analysis evaluating the safety and efficacy of temperature-controlled radiofrequency ablation (TCRFTA) at different sites for the treatment of obstructive OSA.[27] Independent investigators systematically searched the literature through April 2013, identified eligible studies, assessed study quality, extracted data and pooled results. Effectiveness was measured separately for application of RVTR at the base of tongue and soft palate, and for multi-level intervention. Outcomes of interest were the respiratory disturbance index (RDI), lowest oxygen saturation (LSAT), Epworth sleepiness scale (ESS), and visual analogue scale (VAS snoring). In total, 20 studies were included for review,

  In total, 29 studies were included for qualitative review, 20 of which were included for meta-analysis. Meta-analysis reported substantial and consistent improvement among TCRFTA patients in polysomnography (PSG) and subjective outcomes in the base of tongue and multilevel surgery groups only. Specifically, application of RVTR at the base of tongue was associated with significant improvements in RDI (RoM 0.60, CI 0.47-0.76), ESS (RoM 0.59, CI 0.51-0.67), and VAS snoring (RoM 0.48, CI 0.37-0.62) and improvements in LSAT RDI. Complication rates were low and rarely serious across all studies. Investigators concluded that RVTR appears clinically effective in the short-term in reducing RDI levels and symptoms of sleepiness in patients with OSA syndrome when directed at the base of tongue or as a multilevel procedure. Nonetheless, researchers called for long-term studies with less heterogeneity to determine patient selection criteria.

- In 2007 (updated 2011; archived 2012), Hayes conducted an evidence review evaluating the safety and efficacy of radiofrequency tissue volume reduction (RTVR) for the treatment of upper airway obstruction.[3] Searching the literature through February 2011, Hayes included 9 studies for review (8 controlled or comparative trials; 1 uncontrolled trial). Five of the controlled trials were RCTs, one of which was placebo-controlled. Studies focused on reduction of the soft palate, uvula and soft palate, tongue base, tongue base and soft palate and tonsils. Outcomes of interest included quality of life as assessed by questionnaires, respiratory distress index (RDI), apnea index (AI), hypopnea index (HI) and apnea hypopnea index (AHI).

  Results from the sole randomized placebo-controlled trial comparing tongue base and palate RFTVR with sham RFTVR and with nasal CPAP, indicated that CPAP-compliant patients experienced superior AI and AHI outcomes, and comparable quality of life improvements. Results from a small retrospective case-matched comparative trial and a prospective nonrandomized comparative study both reported comparable benefits among RFTVR and CPAP patients; however, neither study reported results at follow-up after the post-treatment assessment. Similarly, results of a parallel-arm study did not report the statistical significance of differences between the RFTVR and LAUP groups. While one randomized study reported

comparable improvements among snoring and OAS for patients undergoing RFTVR or palate and uvula compared to radiofrequency channeling, no data was reported beyond four months. RFTVR patients also experienced inferior-to-comparable- improvements relative to patients, receiving either UPPP, tonsillectomy/adenoidectomy, and conventional surgical treatments for sleep apnea. Patient selection criteria could not be determined.

Hayes ultimately assigned a "C" rating (potential but unproven benefit) for RFTVR of the tongue base or tongue base and palate and uvula for the treatment of mild to moderate OSA. Hayes assigned "D" rating (insufficient evidence) for RFTVR for the treatment of severe OSA. Limitations included the lack of long-term, prospective studies.

Palatal Stiffening Procedures/Palatal implants (e.g. the Pillar Procedure™)

Two systematic reviews were identified that conducted systematic reviews evaluating the safety and efficacy of palatal stiffening operations for OSA.[28,29] The first study assessed cautery-assisted palatal stiffening operations (CAPSO), and reported statistically and clinically significant improvements in patients' apnea-hypopnea index, oxygen saturation, sleepiness and snoring. Hayes conducted an evidence review assessing palatal implants, including 2 RCTs.[29] Hayes noted that the validity of the small-to-moderate benefit reported in these studies was limited by a lack of additional controlled trials, a small magnitude of benefit, and lack of long-term follow-up and patient selection criteria. Hayes ultimately assigned a "C" rating (potential but unproven benefit).

Tongue Suspension Systems (e.g. Repose or Encore)

- In October 2019, ECRI published a health technology assessment on Encore Suspension System by Siesta Medical Inc for treating OSA. The review identified one retrospective case series with 19 participants and the FDA 510k summary of 2 studies, totalling 45 participants. ECRI could not identify the studies references in the FDA summary. The case series was found to have major limitations, including small sample size, no control group, no randomization, retrospective design, no comparison groups, and no data on a number of patient-centered outcomes such as quality of life and adverse events. ECRI concluded that the evidence is inconclusive to determined efficacy of the Encore System.[30]

- Three systematic reviews were identified that evaluated the safety and efficacy of tongue-based suspension (TBS) procedures for hypopharyngeal obstruction in OSA.[5,31,32] Each review noted that while TBS success rates were comparable to UPPP, study findings were limited due to the lack of prospective, randomized and/or controlled studies available for review, small sample sizes for studies assessing TBS as a stand-alone procedure, and the lack of patient selection criteria. Two of the systematic reviews called for further controlled trials assessing efficacy at long-term follow-up.

Expansion sphincter pharyngoplasty (ESP)

- In 2016, Pang and colleagues conducted a systematic review and meta-analysis evaluating the safety and efficacy of expansion sphincter pharyngoplasty (ESP) for the treatment of OSA.[33] Searching the literature through March 2015, independent investigators identified eligible studies, assessed study quality, extracted data and pooled results. In total, 5 studies assessing a

total of 155 patients were included for review. Outcomes of interest were pre-operative and post-operative Apnea Hypopnea Index (AHI). Follow-up ranged from 6 months to 3 years. Investigators reported substantial and consistent improvement in PSG outcomes, with ESP patients experiencing significantly lower AHI than control group (SMD: -7.32. 95% CI -11.11, -3.52; p = 0.0002). Overall pro-rated pooled success rate (i.e. 50% reduction in pre-operative AHI and an AHI of less than 20) was 86.3%. Authors concluded that ESP was effective in the management of patients with OSA. Limitations included substantial heterogeneity between studies, lack of explicit systematic searching methodology, lack in prospective controlled trials included for review, small sample sizes and inadequate follow-up.

- In 2019, Hong and colleagues conducted a retrospective cohort study, evaluating indications for and outcomes of ESP for the treatment of obstructive sleep apnea.[34] In total, 63 patients diagnosed with OSA and lateral pharyngeal collapse underwent ESP combined with tonsillectomy, uvuloplasty or nasal surgery. The primary outcome of interest was the change in AHI after surgery. Secondary outcomes included differences in the surgical response rates, lowest oxygen saturation, subjective visual analog scale scores for snoring and apnea and Epworth Sleepiness Scale score. At 6-month follow-up, 42 of the 63 patients' (67%) lateral pharyngeal collapse was corrected with significant reduction in mean AHI from 35.5 to 17.3 (mean difference, 18.1; 95%CI, 16.3-20.0) and improvement of the lowest mean (SD) oxygen saturation measurement from 78.2% (21.3%) to 86.4% (10.6%) (mean difference, 8.60%; 95%CI, 6.60%-10.60%). The rate of post-operative complications (e.g. bleeding, pain, difficulty swallowing) was low. Limitations included the study's retrospective design, lack of patient-reported outcomes, small sample size, inadequate follow-up, lack of control group(s), and heterogenous treatments received (i.e. varying combinations of concurrent surgeries.) Authors concluded that while ESP "could be" a useful surgery for patients with intensive lateral pharyngeal collapse, additional RCTs with long-term follow-up were necessary to determine the procedure's efficacy.

- In 2018, Guler and colleagues retrospectively evaluated the efficacy of ESP among 67 patients with obstructive sleep apnea.[35] At 3-month follow-up, AHI decreased from 18.26 ± 2.23 to 8.01 ± 0.97 ($p<0.001$), with a reported surgical 67.2% success rate (i.e. 50% reduction in pre-operative AHI and an AHI of less than 20). Limitations included the small sample size, retrospective study design and lack of comparator group(s). Authors concluded that ESP appeared to be an effective surgery in selected patients with lateral pharyngeal and retropalatal narrowing, but called for larger, prospective studies with long-term follow-up to validate findings.

CLINICAL PRACTICE GUIDELINES

Medically Necessary Procedures

<u>Uvulopalatopharyngoplasty (UPPP)</u>

- In 2021, the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) issued a clinical practice guideline on the basis of expert opinion and a non-systematic review of evidence.[36] The body concluded that UPPP and its modifications reduced but does not normalize AHI, but remains an "effective therapies that result in important health and quality of life improvements in properly selected patients."[36]

- In 2013, the American College of Physicians issued an evidence-based clinical practice guideline addressing the management of OSA in adults.[37] Investigators concluded that evidence to date was insufficient to support the use of surgical interventions (including UPPP) over control treatment, CPAP or mandibular advancement devices.

- In 2010, the American Academy of Sleep Medicine issued an evidence-based clinical practice guideline addressing surgical modifications of the upper airway for OSA in adults.[38] The body concluded that UPPP should only be offered for patients who failed CPAP, given the inability of UPPP to normalize the AHI when treating moderate to severe OSA.

Mandibular Maxillary Advancement (MMA)

- In 2013, the American College of Physicians issued an evidence-based clinical practice guideline addressing the management of OSA in adults.[37] On the basis of low-quality evidence, the body issued a weak recommendation for mandibular advancement devices in adult OSA patients intolerant to CPAP. Investigators also concluded that evidence to date was insufficient to support the use of surgical interventions (including genioglossal advancement) over control treatment, CPAP or mandibular advancement devices.

- In 2010, the American Academy of Sleep Medicine issued an evidence-based clinical practice guideline addressing surgical modifications of the upper airway for OSA in adults.[38] The body stated that maxillomandibular advancement is indicated for surgical treatment of severe OSA in patients who cannot tolerate or who are unwilling to adhere to CPAP, which are more often appropriate in mild and moderate OSA patients.

Hyoid Myotomy and Suspension, Surgical Modification of the Tongue, and/or Maxillofacial Surgery, including Maxillomandibular Advancement (MMA)

- In 2014, the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) issued a clinical practice guideline on the basis of expert opinion and a non-systematic review of evidence.[39] The body concluded that "genioglossus advancement and hyoid myotomy/suspension, whether performed separately or combined, are considered effective and non-investigational with proven clinical results when considered as part of the comprehensive surgical management of symptomatic adult patients with mild OSA and adult patients with moderate and severe OSA assessed as having tongue base or hypopharyngeal obstruction."

Hypoglossal Nerve Stimulation

- In 2017, NICE issued a guidance stating that HGNS "should only be used with special arrangements" given the limited quantity and quality of research evaluating HGNS's safety and

efficacy.[40] NICE called for additional long-term research evaluating treatment safety, patient selection criteria, quality of life, and the position of the procedure in the treatment pathway.

- In 2019, the American Academy of Otolaryngology-Head and Neck Surgery issued a clinical practice guidance, stating that upper airway stimulation (UAS) via the hypoglossal nerve is an effective second-line treatment of moderate to severe obstructive sleep apnea in patients who are intolerant or unable to achieve benefit with positive pressure therapy. [41]

Expansion sphincter pharyngoplasty

- In 2021, the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) issued a position statement addressing surgical management of obstructive sleep apnea (OSA). On the basis of findings from a sole 2007 study assessing 45 adults, the statement included "expansion sphincter pharyngoplasty" on its list of procedures considered effective and not investigational when considered as part of a comprehensive approach in the medical and surgical management of adults with OSA.[36]

Non-Covered Procedures

Laser-Assisted Uvulopalatoplasty (LAUP)

- In 2013, the American College of Physicians issued an evidence-based clinical practice guideline addressing the management of OSA in adults.[37] Investigators concluded that evidence to date was insufficient to support the use of surgical interventions (including LAUP) over control treatment, CPAP or mandibular advancement devices.

- In 2010, the American Academy of Sleep Medicine issued an evidence-based clinical practice guideline addressing surgical modifications of the upper airway for OSA in adults.[38] The body concluded that LAUP should not routinely recommended as a treatment for OSA. This determination was made of the basis of "low quality" evidence (2 RCTs and 6 observational studies), reporting LAUP's inability to normalize patients' AHI and secondary outcomes.

Radiofrequency Volume Tissue Reduction of the Soft Palate, Uvula, Tongue Base or Turbinates

- In 2013, the American College of Physicians issued an evidence-based clinical practice guideline addressing the management of OSA in adults.[37] Investigators concluded that evidence to date was insufficient to support the use of surgical interventions (including radiofrequency ablation) over control treatment, CPAP or mandibular advancement devices.

- In 2010, the American Academy of Sleep Medicine issued an evidence-based clinical practice guideline addressing surgical modifications of the upper airway for OSA in adults.[38] The body concluded that radiofrequency ablation (RFA) may be effective in some patients with mild OSA who cannot or will not tolerate positive airway pressure therapy, or in whom oral appliances have failed. This recommendation was made on the basis of "very low quality evidence" (7 observational case series and 1 RCT), reporting improvements in sleepiness and quality of life. The guidance also noted that RFA may not be "predictably efficacious" and that long-term sequelae of RFA had not been published.

Palatal stiffening procedures/Palatal implants (e.g. the Pillar Procedure™)

- In 2010, the American Academy of Sleep Medicine issued an evidence-based clinical practice guideline addressing surgical modifications of the upper airway for OSA in adults.[38] The body concluded that palatal implants may be effective in some patients with mild OSA who cannot or will not tolerate positive airway pressure therapy, or in whom oral appliances have failed. This recommendation was made on the basis of "very low quality evidence" (2 case series and 1 RCT). The body also noted to that "it is difficult to predict if [palatal implants] will be ultimately found to be a reliably effective intervention."[38]

Tongue Suspension Systems (e.g. Repose or Encore)

- In 2021, the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) issued a clinical practice guideline on the basis of expert opinion and a non-systematic review of evidence.[42] Investigators concluded "tongue based suspension is effective and even comparable to genioglossus advancement. It should, therefore, not be deemed investigational when considered as part of a comprehensive approach in the medical and surgical management of symptomatic adult patients with mild OSAHS and adult patients with moderate and severe OSAHS who have evidence of tongue base or associated hypopharyngeal obstruction. Results appear to diminish in obese patients and this technique should receive a weaker recommendation for these patients."

EVIDENCE SUMMARY

Professional clinical organizations and low-quality but consistent evidence from clinical trials support the use of uvulopalatopharyngoplasty, hyoid myotomy and suspension with or without mandibular osteotomy with genioglossus (tongue) advancement, mandibular-maxillary advancement and hypoglossal nerve stimulation for the treatment of obstructive sleep apnea in select populations. Evidence does not support, however, the efficacy of laser-assisted uvulopalatoplasty, radiofrequency volume tissue reduction of the soft palate, uvula, tongue base or turbinates; palatal implants; or tongue suspension systems. Systematic reviews evaluating the latter treatments have noted a lack of long-term evidence from controlled, prospective trials, and called for additional studies to establish these procedures' safety and efficacy.

HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

BILLING GUIDELINES AND CODING

The following codes should not be used for surgical treatments of sleep apnea as they are related to other surgical procedures:

- 21121
- 21122
- 21248
- 21249
- 21199
- 30930

CPT codes 30140, 30801, 30802, 41530 and 42160 are considered not medically necessary when billed with OSA diagnosis codes. (G47.33, G47.39)

CPT codes 42225 and 42226 may be considered medically necessary when billed with the following cleft palate diagnosis codes:

Q35.1	Q37.0	Q37.5
Q35.3	Q37.1	Q37.8
Q35.5	Q37.2	Q37.9
Q35.7	Q37.3	
Q35.9	Q37.4	

Hypoglossal Nerve Stimulation (HNS)

In 2024, the FDA approved an updated model of the Inspire® system (Inspire V). While this next-In 2024, the FDA approved an updated model of the Inspire® system (Inspire V). While this next-generation model is similar to its predecessor (Inspire IV), it no longer includes the respiratory sensor lead. As a result of this difference between the two models, the manufacturer may advise providers to use CPT code 64582 when Inspire IV is used, and CPT 64568 when Inspire V is used.

- 64582 – Inspire IV
- 64568 – Inspire V

**Modifier(s) should also be used as appropriate.*

This coding information is consistent with Noridian LCA A57948.

Laser-assisted Uvulopalatoplasty

HCPCS code S2080 is not recognized as a valid code for claim submission as indicated in the relevant Company Coding Policy (HCPCS S-Codes and H-Codes, 22.0). Providers need to use alternate available CPT or HCPCS codes to report for the service. If no specific CPT or HCPCS code is available, then an unlisted code may be used. Note that unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. Thus, if an unlisted code is billed related to a non-covered service addressed in this policy, it will be denied as not covered. Note that CPT code 42145 (Palatopharyngoplasty [e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty]) is not appropriate for this procedure.

Somnoplasty

Somnoplasty is a trade name for palate reduction with the Somnoplasty System of Somnus Medical Systems. Somnoplasty must not be billed as 42145. This code is not appropriate for this procedure. If Somnoplasty is billed for denial purposes, the unlisted CPT code 42299 (Unlisted procedure, palate, uvula) should be used.

Pillar Procedure

The Pillar Procedure is a trade name for palatal implants. This procedure would be appropriately reported by the physician using CPT code 42299 (Unlisted procedure, palate, uvula). Hospital outpatient department services for this procedure would be reported using HCPCS code C9727.

CODES*		
CPT	0978T	Submucosal cryolysis therapy; soft palate, base of tongue, and lingual tonsil
	0979T	Submucosal cryolysis therapy; soft palate only
	0980T	Submucosal cryolysis therapy; base of tongue and lingual tonsil only
	21110	Application of interdental fixation device for conditions other than fracture or dislocation, includes removal
	21141	Reconstruction midface, LeFort I; single piece, segment movement in any direction (eg, for Long Face Syndrome), without bone graft
	21142	Reconstruction midface, LeFort I; 2 pieces, segment movement in any direction, without bone graft
	21143	Reconstruction midface, LeFort I; 3 or more pieces, segment movement in any direction, without bone graft
	21145	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)
	21146	Reconstruction midface, LeFort I; 2 pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted unilateral alveolar cleft)
	21147	Reconstruction midface, LeFort I; 3 or more pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted bilateral alveolar cleft or multiple osteotomies)

	21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft
	21194	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; with bone graft (includes obtaining graft)
	21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation
	21198	Osteotomy, mandible, segmental
	21199	Osteotomy, mandible, segmental; with genioglossus advancement
	21206	Osteotomy, maxilla, segmental (eg, Wassmund or Schuchard)
	21685	Hyoid myotomy and suspension
	30140	Submucous resection inferior turbinate, partial or complete, any method
	30801	Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (eg, electrocautery, radiofrequency ablation, or tissue volume reduction); superficial
	30802	Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (eg, electrocautery, radiofrequency ablation, or tissue volume reduction); intramural (ie, submucosal)
	41512	Tongue base suspension, permanent suture technique
	41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session
	42120	Resection of palate or extensive resection of lesion
	42140	Uvulectomy, excision of uvula
	42145	Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)
	41599	Unlisted procedure, tongue, floor of mouth
	42160	Destruction of lesion, palate or uvula (thermal, cryo or chemical)
	42225	Palatoplasty for cleft palate; attachment pharyngeal flap
	42226	Lengthening of palate, and pharyngeal flap
	42235	Repair of anterior palate, including vomer flap
	42299	Unlisted procedure, palate, uvula
	42950	Pharyngoplasty (plastic or reconstructive operation on pharynx)
	64568	Open implantation 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
	64999	Unlisted procedure, nervous system
HCPCS	C9727	Insertion of implants into the soft palate; minimum of three implants
	C8007	Open implantation of hypoglossal nerve neurostimulator array and pulse generator, not requiring insertion of a separate distal respiratory sensor electrode or electrode array
	C8008	Revision or replacement of hypoglossal nerve neurostimulator array including connection to existing pulse generator
	C8009	Removal of hypoglossal nerve neurostimulator array and pulse generator

	C8011	Open implantation of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver, including external power source and all system components
	C8012	Revision or replacement of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
	C8013	Removal of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
	S2080	Laser-assisted uvulopalatoplasty (laup)

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
12/2023	Annual update. Changed policy title. Changed denial type to “not medically necessary.”
9/2024	Interim update. “Billing Guidelines” updated.
10/2024	Annual update. Updated criterion III based on FDA indication changes. Removed expansion sphincter pharyngoplasty from criterion IX.
2/2025	Interim update. Added billing guideline.
7/2025	Q3 2025 code set update.
10/2025	Annual update. No changes. (10/23/2025: Replaced A57949 with A57948 due to Noridian JF consolidation with JE LCD policies)
1/2026	Interim update. Update coding for HNS.
4/2026	Q2 2026 code set update. New codes added