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Medical Policy

Subject:	Oral, Pharyngeal and Maxillofacial Surgical Treatment for Obstructive Sleep Apnea or Snoring		
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Description/Scope

This document addresses surgical treatments for obstructive sleep apnea (OSA), such as uvulopalatopharyngoplasty (UPPP), hyoid myotomy and jaw realignment surgery, laser surgery, radiofrequency ablation, palatal implants, and other procedures. This document does not address tonsillectomy, adenoidectomy or nasal surgery.

Note: For information related to other technologies utilized in the diagnosis and management of sleep-related disorders, please see:

- DME.00039 Prefabricated Oral Appliances for the Treatment of Obstructive Sleep Apnea
- DME.00042 Electronic Positional Devices for the Treatment of Obstructive Sleep Apnea
- MED.00002 Selected Sleep Testing Services
- CG-MED-79 Diaphragmatic/Phrenic Nerve Stimulation and Diaphragm Pacing Systems
- CG-SURG-30 Tonsillectomy for Children with or without Adenoidectomy
- CG-SURG-36 Adenoidectomy

Note: Please see the following document for the use of nasal surgery to treat snoring and OSA

- CG-SURG-87 Nasal Surgery for the Treatment of Obstructive Sleep Apnea and Snoring

Position Statement

Medically Necessary:

Uvulopalatopharyngoplasty (UPPP):

Uvulopalatopharyngoplasty (UPPP) is considered **medically necessary** when **ALL** of the following criteria (A-D below) are met:

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A. Documented OSA with apnea hypopnea index (AHI) or respiratory disturbance index (RDI) meeting any of the following:
   1. UPPP as **sole** procedure with AHI (or RDI) greater than 15 events per hour and less than 40 events per hour,
      or
   2. UPPP as **sole** procedure with AHI (or RDI) between 10-15 events per hour and **one or more** of the conditions listed below:
      a. Hypertension; **or**
      b. Cardiac arrhythmias predominately during sleep; **or**
      c. Pulmonary hypertension; **or**
      d. Documented ischemic heart disease; **or**
      e. Impaired cognition or mood disorders; **or**
      f. History of stroke; **or**
      g. Excessive daytime sleepiness, as documented by either a score of greater than **10** on the Epworth Sleepiness Scale or inappropriate daytime napping, (for example, during driving, conversation or eating) or sleepiness that interferes with daily activities.
      or
   3. UPPP as part of a **planned staged** or **combined** surgery aimed at also relieving retrolingual obstruction, (for example, genioglossal advancement, hyoid myotomy and suspension) with AHI (or RDI) greater than 15 events per hour,
      or
   4. UPPP as part of a **planned staged** or **combined** surgery aimed at also relieving retrolingual obstruction, (for example, genioglossal advancement, hyoid myotomy and suspension) with AHI (or RDI) between 10-15 events per hour and **one or more** of the conditions listed below:
      a. Hypertension; **or**
      b. Cardiac arrhythmias predominately during sleep; **or**
      c. Pulmonary hypertension; **or**
      d. Documented ischemic heart disease; **or**
      e. Impaired cognition or mood disorders; **or**
      f. History of stroke; **or**
      g. Excessive daytime sleepiness, as documented by either a score of greater than **10** on the Epworth Sleepiness Scale or inappropriate daytime napping, (for example, during driving, conversation or eating) or sleepiness that interferes with daily activities.

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and

B. Have failed treatment with CPAP as demonstrated by any of the following:
   1. Claustrophobia from CPAP; **or**
   2. Inability to breathe through the nose; **or**
   3. Pain or discomfort from CPAP; **or**
   4. User intolerance to CPAP; **or**
   5. Individuals at high pressures of CPAP (greater than 10 cm H_2O) complaining of pressure discomfort.

   and

C. Fiberoptic endoscopy suggests retro-palatal narrowing is the primary source of airway obstruction if UPPP is the **sole** procedure or a **contributing** source of airway obstruction if part of a planned staged or combined surgery aimed at also relieving retrolingual obstruction;

   and

D. The individual is 18 years of age or older, or there is documentation that skeletal growth is complete based on long bone x-ray or serial cephalometrics showing no change in facial bone relationships for at least the last three consecutive months.

Soft Tissue Reconstruction:

Hyoid myotomy and suspension, with or without mandibular osteotomy with genioglossus (tongue) advancement, for the treatment of OSA is considered **medically necessary** when **ALL** of the following criteria (A-D below) are met:

A. The treatment of OSA in the individual is **medically necessary** based on either 1) or 2) below:
   1. AHI or RDI greater than or equal to 15 events per hour;

   or

   2. AHI (or RDI) greater than or equal to 5 events per hour, and less than 15 events per hour with documentation demonstrating **any** of the following symptoms:
      a. Excessive daytime sleepiness, as documented by either a score of greater than **10** on the Epworth Sleepiness scale or inappropriate daytime napping, (for example, during driving, conversation or eating) or sleepiness that interferes with daily activities; **or**
      b. Impaired cognition or mood disorders; **or**
      c. Hypertension; **or**
      d. Ischemic heart disease or history of stroke; **or**
      e. Cardiac arrhythmias, **or**
      f. Pulmonary hypertension.

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and

B. The individual has failed treatment with CPAP as demonstrated by **any** of the following:
   1. Claustrophobia from CPAP; **or**
   2. Inability to breathe through the nose; **or**
   3. Pain or discomfort from CPAP; **or**
   4. User intolerance to CPAP; **or**
   5. Individuals at high pressures of CPAP (greater than 10 cm H_2O) complaining of pressure discomfort.

   and

C. There are significant soft tissue and/or tongue base abnormalities with airway collapse. (Objective evidence of hypopharyngeal obstruction may be documented by either fiberoptic endoscopy or cephalometric radiographs.); **and**

D. The individual is 18 years of age or older, or there is documentation that skeletal growth is complete based on long bone x-ray or serial cephalometrics showing no change in facial bone relationships for at least the last three consecutive months.

Jaw Realignment Surgery:

Jaw realignment surgery (that is, maxillomandibular advancement) is considered **medically necessary** when **ALL** of the following criteria (A-D below) are met:

A. The treatment of OSA in the individual is **medically necessary** based on either 1) or 2) below:
   1. AHI or RDI greater than or equal to 15 events per hour;
      or
   2. AHI (or RDI) greater than or equal to 5 events per hour, and less than 15 events per hour with documentation demonstrating **any** of the following symptoms:
      a. Excessive daytime sleepiness, as documented by either a score of greater than **10** on the Epworth Sleepiness scale or inappropriate daytime napping, (for example, during driving, conversation or eating) or sleepiness that interferes with daily activities; **or**
      b. Impaired cognition or mood disorders; **or**
      c. Hypertension; **or**
      d. Ischemic heart disease or history of stroke; **or**
      e. Cardiac arrhythmias, **or**
      f. Pulmonary hypertension.

   and

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B. The individual has failed treatment with CPAP as demonstrated by any of the following:
   1. Claustrophobia from CPAP; **or**
   2. Inability to breathe through the nose; **or**
   3. Pain or discomfort from CPAP; **or**
   4. User intolerance to CPAP; **or**
   5. Individuals at high pressures of CPAP (greater than 10 cm H_2O) complaining of pressure discomfort.

   and
C. The individual has failed surgical intervention with any of the following:
   1. UPPP; **or**
   2. Genioglossus advancement and/or hyoid myotomy with suspension; **or**
   3. Both of these surgical procedures.

   and
D. The individual is 18 years of age or older, or there is documentation that skeletal growth is complete based on long bone x-ray or serial cephalometrics showing no change in facial bone relationships for at least the last three consecutive months.

Jaw realignment surgery is also considered **medically necessary** for individuals with a documented severe jaw/facial bony abnormality that contributes to OSA, including, but not limited to, craniofacial abnormalities, micrognathia, retrognathia or small retro-positioned jaw with associated overbite and small mouth.

Note: Individuals undergoing jaw realignment surgery may also undergo orthodontic therapy. Orthodontic therapy (that is, placement of orthodontic brackets and wires) may not be a covered benefit under all member benefit plans.

Hypoglossal nerve stimulation

Hypoglossal nerve stimulation is considered **medically necessary** when **all** of the following criteria (A-E below) are met:
A. AHI or RDI greater than or equal to 15 events per hour and less than or equal to 65 events per hour; **and**
B. Central or mixed apneas make up less than 25% of total AHI or RDI score; **and**
C. Body Mass Index (BMI) of 32 or less; **and**
D. Absence of complete concentric collapse at the soft palate level during drug-induced sleep endoscopy; **and**
E. The individual has failed treatment with CPAP as demonstrated by any of the following:
   1. Claustrophobia from CPAP; **or**
   2. Inability to breathe through the nose; **or**

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3. Pain or discomfort from CPAP; **or**
4. User intolerance to CPAP; **or**
5. Individuals at high pressures of CPAP (greater than 10 cm H_2O) complaining of pressure discomfort.

Not Medically Necessary:

UPPP~~vulopalatopharyngoplasty~~, soft tissue reconstruction, ~~or~~ jaw realignment surgery, or hypoglossal nerve stimulation are considered **not medically necessary** when the criteria above are not met.

~~UPPP as a **sole** procedure with AHI/RDI under 10 events per hour is considered **not medically necessary.**~~

Treatment of snoring without OSA is considered **not medically necessary** including, but not limited to the use of the following treatment methods:

A. UPPP;
B. Radiofrequency Volumetric Tissue Reduction (RFVTR) of the soft palate and/or the base of the tongue, including Somnoplasty® and Coblation®;
C. Laser-Assisted Uvulopalatoplasty (LAUP);
D. Cautery Assisted Palatal Stiffening Operation (CAPSO) or Palatal Implants~~.~~
E. Hypoglossal nerve stimulation.

Investigational and Not Medically Necessary:

~~The use of palatal implants is considered **investigational and not medically necessary** including, but not limited to:~~
~~A. Injection snoreplasty;~~
~~B. The Pillar™ system.~~

~~UPPP is considered **investigational and not medically necessary** for UARS (upper airway resistance syndrome).~~

Other surgical treatments for OSA are considered **investigational and not medically necessary** including, but not limited to, the following:

A. Palatal Implants (for example, injection snoreplasty, The Pillar® system);
~~A.~~B. Cautery-assisted Palatal Stiffening Operation (CAPSO);
~~B.~~C. Laser-Assisted Uvulopalatoplasty (LAUP);
~~C.~~D. Radiofrequency Volumetric Tissue Reduction (RFVTR) of the soft palate and/or the base of the tongue including Somnoplasty and Coblation;

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~~D.~~E. Transpalatal advancement pharyngoplasty;
~~E.~~F. Bone-anchored tongue base suspension systems by permanent suture techniques (which include the AIRvance™ System [formerly the Repose® System] and the ENCORE™ Tongue Suspension System).
~~Hypoglossal nerve stimulation (Inspire® Upper Airway Stimulation system).~~

Rationale

General Considerations

In 2009, the American Academy of Sleep Medicine (AASM), formerly known as the American Sleep Disorders Association, released the Clinical Guideline for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. This guideline addressed several surgical treatments of OSA, including the following:

- Individuals with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances (OAs).
- Evaluation for primary surgical treatment can be considered in persons with mild OSA who have severe obstructing anatomy that is surgically correctible, (for example, tonsillar hypertrophy obstructing the pharyngeal airway).
- Although the specifics of sleep apnea surgeries are beyond the scope of this guideline, surgical procedures may be considered as a secondary treatment for OSA when the outcome of positive airway pressure (PAP) therapy is inadequate, such as when the individual is intolerant of PAP, or PAP therapy is unable to eliminate OSA.
- Surgery may also be considered as an adjunct therapy when obstructive anatomy or functional deficiencies compromise other therapies or to improve tolerance of other OSA treatments.
- Maxillary and mandibular advancement (MMA) can improve polysomnography (PSG) parameters comparable to CPAP in the majority of individuals.
- Most other sleep apnea surgeries are rarely curative for OSA but may improve clinical outcomes, (e.g., mortality, cardiovascular risk, motor vehicle accidents, function, quality of life (QOL), and symptoms).
- Laser-assisted uvulopalatoplasty (LAUP) is not recommended for the treatment of obstructive sleep apnea (Epstein, 2009).

In 2010, the AASM published practice parameters for Surgical Modifications of the Upper Airway for OSA in Adults (Aurora, 2010), which were based on a systematic review and meta-analysis of the evidence currently available (Caples, 2010). Authors of the systematic review/meta-analysis reported that the bulk of the published literature consisted of case series, with a few controlled trials. The studies were characterized by considerable

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heterogeneity, including varying approaches to pre-operative evaluation and postoperative follow-up. Using the change in AHI as the primary measure of efficacy, substantial and consistent reductions were observed following MMA, and adverse events were not commonly reported. Outcomes following pharyngeal surgeries were less consistent, and adverse events were more commonly reported.

The following is excerpted from the AASM practice parameters:

- MMA, UPPP as a sole procedure or multi-level, or stepwise surgery following failed UPPP as a sole treatment - all received a recommendation of "Option" (uncertain clinical use), due to the lack of rigorous data evaluating surgical modifications of the upper airway;
- Radiofrequency Ablation (RFA) also received a recommendation of "Option" for individuals with mild to moderate OSA who cannot tolerate or who are unwilling to adhere to CPAP, or in whom oral appliances have been found ineffective or undesirable;
- Palatal implants received a recommendation of "Option" for those with mild OSA who failed medical therapy;
- LAUP was not recommended as a routine treatment for OSA ("Standard").
- A recommendation of "Standard" was given for the determination of the presence and severity of OSA before initiating surgical therapy, discussion of success rates, complications, and alternative treatments with the individual, and a postoperative follow-up evaluation, which includes a clinical evaluation and an objective measure of the presence and severity of sleep-disordered breathing and oxygen saturation, although it was noted that little guidance was available in the medical literature to recommend any particular monitoring strategy nor optimal intervals and duration of follow-up (Aurora, 2010).

UPPP

There is widespread agreement in the published studies of UPPP, as to the definition of "success" of the procedure. This is defined as a reduction in pre-operative AHI/RDI or Apnea index (AI) by at least 50% with a post UPPP AHI/RDI of less than 20; or a post UPPP AI less than 10. Using these definitions, a person whose pre-operative AHI/RDI/AI is less than 10 is already (by definition) "cured" of their OSA and is, therefore, not an appropriate candidate for UPPP. Furthermore, there is no published literature that supports the value of UPPP for this group.

Studies evaluating UPPP or modified UPPP as a sole treatment of OSA have reported decreased AHI from baseline maintained in the long-term, although several studies have showed a declining therapeutic effect over time (Friberg, 2020; Neruntarat, 2011; Sundman, 2021). In a meta-analysis, He and colleagues (2019) analyzed the long-term outcomes (at least 34 months) of UPPP as a sole treatment of OSA. A total of 11 studies were included. The mean

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AHI at baseline was 39.9 ± 18.3 in 6 studies and 43.2 ± 17.7 in 4 studies. Compared with the short-term studies, long-term studies showed a mean AHI increase of 12.3. Despite a decreasing curative effect, the mean AHI remained improved over baseline.

There is ~~also~~ recognition in the literature that UPPP, when performed as the sole procedure, is less likely to be a success when severe OSA is present preoperatively. The AASM defines "severe" as an AHI/RDI greater than 30. There is evidence that UPPP, when performed for individuals with an AHI/RDI greater than 40, is unsuccessful in the vast majority of cases (Friedman, 2005; ~~Janson, 1997;~~ Millman, 2000). This may, in part, be related to the presence of unrecognized coexistent hypopharyngeal obstruction in persons with severe OSA that could not be expected to be adequately relieved by UPPP alone, which addresses only velopharyngeal (retropalatal) obstruction. Multilevel upper airway collapse, which is often present in those with OSA, may be only partially relieved by a single procedure (Yang, 2020). ~~In a retrospective chart review of 134 subjects having undergone UPPP alone, those whose preoperative AHI was greater than 40 failed to have a successful result (defined as a 50% reduction in AHI with postoperative AHI less than 20) in 73.5% cases. That is to say the success rate was only 26.5% (Friedman, 2005).~~

There are a limited number of studies assessing the efficacy of multilevel surgery. Yang and associates (2020) compared the efficacy of hyoid myotomy and suspension with uvulopalatopharyngoplasty to CPAP therapy in individuals with moderate to severe OSA. In the case series study (n=15), individuals who failed or refused CPAP therapy underwent surgery. The results of each type of therapy were compared in the same individuals. While there were improvements in OSA severity and oxygen desaturation following both treatments, the individuals showed improved sleep stage, and blood pressure control during CPAP therapy.

The decreased efficacy over time is thought to be related to multiple factors, such as the tendency to gain weight as well as increased laxity in the tissue with age. Given the invasive nature of UPPP and the decreased efficacy over time, it is reasonable to limit use of this treatment to those who have failed non-invasive treatment with positive airway pressure therapy.

Soft Tissue Reconstruction

Hyoid myotomy and suspension, and mandibular osteotomy with genioglossus advancement have been demonstrated in multiple case series studies to provide significant relief of symptoms for individuals suffering from OSA where hypopharyngeal ~~hypopharyngeal~~ (retrolingual) obstruction during sleep is a significant factor. These soft tissue reconstructive procedures have been shown to successfully alter the anatomy of persons with OSA

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sufficiently to prevent upper airway collapse. Not all individuals are appropriate for this procedure. Careful evaluation of the upper airway anatomy should take place prior to consideration of this procedure. As with UPPP, hyoid myotomy and suspension, and mandibular osteotomy with genioglossus advancement should not be used as first line treatments, and trials of conservative therapies, such as CPAP, should be attempted first. Hyoid myotomy and suspension, and mandibular osteotomy with genioglossus advancement may be performed, along with UPPP, in selected individuals where both velopharyngeal and hypopharyngeal ~~(retrolingual)~~ obstruction during sleep are thought to occur.

Jaw Realignment Surgery

The use of jaw realignment surgery in persons with OSA who are unresponsive to other therapies has been demonstrated to be an effective treatment. While the results of this procedure have been shown to significantly improve the symptoms of OSA, jaw realignment surgery involves extensive jaw reconstruction. Several articles in the peer-reviewed literature have proposed a stepwise approach to OSA therapy that requires the use of other conservative and surgical interventions, mainly CPAP and UPPP, prior to consideration of jaw realignment surgery.

A meta-analysis by Zaghi and colleagues (2016) evaluated the efficacy of maxillomandibular advancement as a treatment of OSA. A total of 45 studies with individual data from 518 participants were included. The primary outcomes were the changes in AHI and RDI following surgery. Following ~~surgery~~surgery, 98.8% (512/518) reported an improvement in AHI and RDI. Mean postoperative changes in AHI and RDI were -47.8 (25.0) and -44.4 (33.0), respectively. The majority of individuals had a history of prior surgery for OSA (197 of 268 [73.5%]). The authors ~~noted~~noted, "patients with a high residual RDI and AHI after failure of other surgical procedures for sleep apnea are highly likely to benefit from MMA."

This conservative approach is appropriate in all but the most extenuating circumstances involving severe maxillofacial malformations related to OSA. Studies have reported success rates of up to 100%, although most studies report a surgical success rate of approximately 80% and OSA cure rates of 30-40% (Buller, 2020; Romano, 2020). The literature on this procedure indicates that success varies with the experience of the surgeon and the facility, and care should be taken in their selection.

Radiofrequency Volumetric Tissue Reduction (RFVTR) or *Laser-Assisted Uvulopalatoplasty (LAUP)*

~~At this time, t~~There is inadequate evidence in the published medical literature demonstrating the efficacy of radiofrequency (RF) ablation techniques for the treatment of OSA. One particular technique, RFVTR which focuses on the base of the tongue and soft palate and includes two procedures marketed as Somnoplasty and This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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Coblation, has been described in the medical literature. In a multi-institutional study of 56 subjects with OSA treated with radiofrequency tongue base reduction, the mean pre-operative AHI index of 40.5 decreased only to 32.8 after treatment (Woodson 2001). A randomized controlled trial (RCT), involving 90 subjects with mild to moderate OSA, evaluated RFVTR of both tongue and palate in 30 individuals with comparisons to those receiving CPAP or sham radiofrequency treatment. Results showed that there was no significant reduction in either AHI or nocturnal oxygen desaturation in the RFVTR-treated group compared with the CPAP or sham groups (Woodson 2003). A systematic review and meta-analysis of 20 studies was done to evaluate the efficacy of temperature controlled radiofrequency tissue ablation (TCRFTA) in treating OSA. TCRFTA was categorized based on location: base of tongue, soft palate and multilevel. Analysis showed significant reductions in RDI, Epworth Sleep Scale (ESS), lowest oxygen saturation (LSAT) and snoring for procedures performed at the base of the tongue. TCRFTA at the soft palate showed limited efficacy, although there was a paucity of studies in this area. Multilevel TCFFTA did show a significant reduction in RDI, in the short term. Analysis of AHI was not completed as this outcome was not consistently reported within the studies. The authors reported that the studies were generally of low quality and there was significant heterogeneity which did not allow strong conclusions (Baba, 2015). Studies with longer-term outcomes would be useful in evaluating the benefits of this procedure.

LAUP has primarily been researched as a treatment of snoring without associated clinically significant OSA. ~~As referenced earlier in this document, in 2009, the AASM issued another document, the AASM Clinical Guidelines for the Evaluation, Management, and Long-term Care of OSA in Adults, in which they restated their position not to recommend LAUP (Epstein, 2009).~~ ~~In a recent study by~~ There are concerns that OSA may worsen following the LAUP procedure, or OSA may develop if LAUP is used to treat snoring (Camacho, 2017; Epstein, 2009; Franklin, 2009; Göktas, 2014). Camacho and associates (2017) performed a meta-analysis on the use of LAUP as a stand-alone treatment for OSA and concluded:

> Statement of Significance
>
> There are three important points. First, laser-assisted uvulopalatoplasty (LAUP) can potentially worsen obstructive sleep apnea (OSA; 44% of patients with individual data). Second, primary snoring patients who no longer snore after LAUP should be tested for OSA post-operatively if they develop signs and symptoms of OSA. Third, given that reflexogenic dilation of the pharyngeal airway is at least partially mediated by pharyngeal mucosa afferent nerve fibers, it is possible that by destroying the surface of the soft palate with a laser, that there may be blunting of the reflexogenic dilation of the pharyngeal airway. Therefore, LAUP should be performed with caution

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or not performed at all. Proper patient counseling is essential.
Göktas (2014) evaluating long-term results of LAUP for OSA, the authors followed up with 25 individuals who had LAUP an average of 11 years. The authors noted that a comparison between mean preoperative and postoperative AHI scores did not report statistically significant long-term therapeutic positive outcomes (25.95 versus 23.62). More significantly, a group of individuals showed an increase in AHI following LAUP. Of the 15 individuals considered non-responders, 12 had an increase in AHI by more than 5 events per hour. The authors concluded that LAUP is associated with significant risks of increased postoperative AHI and positive outcomes are not sustained long-term.

An updated search of the published literature identified a study by Franklin (2009) who conducted a systematic review to evaluate the efficacy and adverse effects of surgery for snoring and OSA. The review included four RCTs of surgery versus either sham surgery or conservative treatment in adults, and described outcome measures for daytime sleepiness, QOL, AHI, and snoring. Results of this review found that there was no significant effect on daytime sleepiness and QOL following LAUP or RFVTR. The authors concluded that these studies did not provide evidence of therapeutic effect from LAUP or RFVTR on daytime sleepiness, apnea reduction, QOL, or snoring (Franklin, 2009).

Cautery-assisted palatal stiffening operation (CAPSO)

Llewellyn and associates (2018) performed a meta-analysis to evaluate the clinical outcomes of CAPSO used to treat OSA. The meta-analysis included individuals who underwent CAPSO as the sole treatment (n=80), CAPSO with tonsillectomy (n=92) and CAPSO with expansion pharyngoplasty (n=78). Each group saw a decrease in mean AHI from baseline to post procedure; CAPSO alone showed a 41.1% decrease, CAPSO with tonsillectomy reported a 61.7% decrease, and CAPSO with expansion pharyngoplasty recorded a 52.1% decrease. While the study noted post-operative decreases in AHI, there was limited data regarding the length of time the participants were followed. Additional limitations of the meta-analysis include a limited number of studies and participants, the presence of significant heterogeneity, and the lack of randomized studies available.

CAPSO has been suggested as a treatment of snoring or mild OSA. Evidence from earlier studies were limited by a focus on snoring rather than OSA, small size and poor outcomes (Mair, 2000; Wassmuth, 2000). The limited evidence available does not support that CAPSO provides equivalent clinical benefit when compared to the established alternatives. A prospective non-randomized trial using a CAPSO procedure for the treatment of excessive snoring in 206 consecutive subjects reported a "success" rate of 92% initially, falling to 77% at 1 year. Of note is the fact that the subjects with features suggestive of OSA or with evidence of OSA on sleep studies were

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~~excluded from the trial (Mair, 2000). A small study involving 25 subjects with OSA reported a 40% success rate in terms of a reduction in AHI of 50% or more reaching to less than 10. The mean AHI improved from 25.1 to 16.6. There was no significant improvement in nocturnal oxygen desaturation, and the follow-up period was only 3 months (Wassmuth, 2000).~~

ENCORE Tongue Suspension System

Additional treatment methods proposed for OSA utilize the ENCORE Tongue Suspension System (Siesta Medical, Inc., Los Gatos, CA) or the AIRvance (formerly the Repose) Bone-anchored Suspension System (Medtronic, Inc., Minneapolis, MN), and also injection snoreplasty. To date, these treatments have not been evaluated in large controlled trials with long-term outcomes data. At this time, there is insufficient evidence to make any recommendation about the appropriate clinical use of either tongue base suspension systems or injection snoreplasty.

Pillar palatal implant system

~~To date, t~~The literature has been limited regarding the safety and efficacy of the Pillar palatal implant system for treating OSA. Friedman reported a single institution RCT involving 62 subjects with mild to moderate OSA who were selected based on "Friedman tongue position," soft palate size, and body mass index (BMI) less than 32. Only 29 participants actually received the palatal implant and follow-up analysis. A total of 26 participants underwent a "sham" procedure and analysis as the placebo group. Follow-up was performed at 3 months, and success was defined as an AHI reduction of at least 50% and a post-procedure AHI less than 20. On this basis, 13/29 subjects receiving the implants were a success (44.8%), compared to 0 in the placebo group. However, 4 of the 13 "successes" already had a pre-procedure AHI of less than 20, as did 9 of the 26 in the placebo group. In the implant group, the mean AHI fell from 23.8 to 15.9, this latter number still representing moderate OSA, (as defined by the AASM). In addition, the mean Epworth Sleepiness Scale score fell from 12.7 to 10.2, the latter continuing to represent excessive daytime sleepiness (greater than 10). No individual data were reported, and it is unknown if OSA was completely relieved (AHI less than 5) in any of the trial participants. Mean minimum O_2 saturation rose from 88.3% to 89.7% (significance unclear) with QOL responses following treatment that were measured using an SF 36 rather than a more specific sleep-related QOL measurement tool. Acknowledged limitations of the study by the authors were the short follow-up (which precludes conclusions regarding the durability of the implant procedure) and the potential challenge in generalizing results arising from a limited study population of non-obese, mild to moderate OSA subjects with specific oral physical characteristics where half of the participants evaluated did not qualify for the study (Friedman, 2008).

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~~Walker reported follow-up at approximately 15 months for 22 subjects out of an original 53 undergoing the Pillar palatal implant procedure for mild to moderate OSA at 4 sites in the U.S. Of these 22, 13 had experienced a mean decrease in AHI from 19.5 to 13 at 90 days post implant (an AHI of 13 represents mild OSA by AASM definition). Ten of these 13 (76.9%) maintained a mean AHI of 12.8 (persistent mild OSA) at approximately 15 months post-procedure. There was some concern about the finding that 9/22 subjects, who had not improved 90 days post-procedure, experienced an increase in mean AHI from 19.9 pre-procedure to 28.4 at 90 days post-procedure and 26.2 at extended follow-up. Whether this early and sustained deterioration was related to the failed implant procedure or to the natural history of OSA is unclear. As with the Friedman study, no individual data were reported, and no information was provided as to whether any participants had their OSA totally relieved by the implant procedure. Limitations of this case series study include the small sample size, lack of placebo control group, and the significant number of the original 53 subjects who were lost to follow-up which affected the generalizability of the results (Walker, 2007).~~

The available studies to date do not provide convincing evidence of the long-term efficacy of palatal implants ~~for~~ in persons with OSA. The studies are restricted by small size, missing data, limited follow-up and large numbers of drop-outs within the study (Friedman, 2008; Walker, 2007). Walker (2007) reported a substantial number of individuals who experienced an increase in mean AHI at 90 days post-procedure compared to pre-procedure. Larger randomized controlled trials with longer follow-up and more complete participant data post-procedure are required to establish the procedure's efficacy for OSA.

Transpalatal advancement pharyngoplasty (TAP or TPAP)

Another technique that has been proposed as a surgical alternative for the treatment of OSA is ~~T~~TAP or TPAP. This surgical procedure alters the retro-palatal airway by advancing the palate forward without requiring excision of the soft palate. This procedure pulls the palate forward and superiorly. Conceptually, similarities exist to maxillary advancement without the associated alterations in dentition. The TAP procedure has been purported for use alone or in combination with other soft tissue surgeries for individuals with narrowing in the retro-palatal airway, especially narrowing proximal to the point of palatal excision using traditional UPPP techniques. A transpalatal approach and advancement has also been proposed for individuals with obstructions in the nasopharynx, such as enlarged adenoids, that cannot be accessed through traditional techniques. In a meta-analysis and systematic review, Volner and colleagues (2017) evaluated the effect of TPAP on the AHI and lowest oxygen saturation (LSAT). Studies were included when TPAP was used to treat OSA and no other surgeries addressing other levels of obstruction were performed at the same time. A total of 5 studies dating from 1993 to 2014 with 199 participants were included. The relative reduction in AHI was 64.8% (mean ± standard deviation of 54.6 ± 23.0 [95 % CI 51.4, 57.8] to 19.2 ± 16.8

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[95 % CI 16.9, 21.5] events/hour. The mean LSAT difference improved from 81.9 ± 8.1 to 85.4 ± 6.9 with a mean difference of 3.55. However, only 70 participants had data available regarding the LSAT and when one study was removed from the analysis, the mean difference was 0.62. There were multiple limitations associated with analysis including the quality of the studies, the lack of comparison with other surgical procedures and the potential for author bias (the individual who developed the procedure authored 3 of the studies). ~~However, to date, there is very little published outcomes data for persons with OSA. One~~A retrospective review not included in the analysis described 30 subjects who underwent a TAP procedure; 20 of these study subjects also had various tongue-base procedures performed at the same time as TAP (Woodson, 2005). Only 10 had TAP alone. The results of postoperative AHI in these 30 subjects were better than a comparable group of 44 subjects undergoing UPPP, 26 of whom had UPPP as the sole procedure. Also, for the subjects in each group who did not have additional tongue base surgery, the AHI improved significantly more in the TAP treated group (n=10) than the UPPP treated group (n=26). ~~(Woodson, 2005.)~~ Larger studies are needed to establish the safety/efficacy of the TAP procedure, together with prospective comparisons with established palate-based surgical techniques.

Hypoglossal nerve stimulation (HNS)

~~A device for hypoglossal nerve stimulation, t~~The Inspire II Upper Airway Stimulation System (UAS) (Inspire Medical Systems, Maple Grove, MN) was approved by the FDA in April 2014. The Inspire UAS is approved~~proposed~~ for use in a subset of adults ~~aged 22 and over~~ with moderate to severe OSA with an AHI between ~~20~~15-65. In addition, evaluation must show that individuals do not have a complete concentric collapse at the soft palate level. Inspire UAS is considered a second level treatment and individuals must have failed or cannot tolerate PAP therapy as noted below:

> 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).

The label warned that individuals with a BMI of greater than 32 were not studied in the pivotal trial. BMIs greater than 32 may be associated with decreased treatment success and treatment with HNS is not recommended in this population. Other c~~C~~ontraindications include:

- Central + mixed apneas > 25% of the total apnea–hypopnea index (AHI)

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- 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~~ Individuals who are unable or do not have the necessary assistance to operate the sleep remote
- ~~Patients~~ Individuals who are pregnant or plan to become pregnant
- Patients who will require magnetic resonance imaging (MRI)
- ~~Patients~~ Individuals 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.

Previously the need for an MRI was a contraindication. The need for a MRI is now considered a conditional indication; MRIs can be performed under certain conditions if the appropriate precautions are followed.

In a prospective, multicenter single group design, Strollo and associates (2014) ~~reported on a case series to~~ evaluated the safety and effectiveness of upper airway stimulation using the Inspire Upper Airway Stimulation system (Stimulation Treatment for Apnea Reduction (STAR)). A total of 126 individuals with moderate to severe OSA, BMI of 32 or lower and low adherence to CPAP were included. Individuals were excluded if there was complete concentric collapse of the retropalatal airway observed during drug-induced sleep endoscopy. Primary outcome measures included AHI and oxygen desaturation index (ODI). ~~Results showed that at~~At 12 months of follow-up, 60% of participants achieved at least a 50% decrease in AHI ~~and 65% met the secondary outcome of reduction in the ODI score of 25% or more~~. The median AHI decreased 68%, from 29.3 to 9.0 events/hour (mean, 32.0-15.3). The first consecutive 46 participants who were treatment responsive were subsequently randomized to either continued therapy or withdrawal from therapy. After 7 days, AHI of the continued treatment group remained stable from a mean of 7.2 to 8.9 events per hour, while the mean AHI in the withdrawal group increased from 7.6 to 25.8. Two participants experienced serious adverse events associated with the device. ~~The STAR trial continued to follow participants to assess safety and efficacy beyond 12 months.~~

Researchers ~~Strollo and associates (2015)~~ continued to follow the STAR participants through 5 years post-procedure. ~~reported that~~ Aat 18 months, ~~,~~ the AHI ~~remained decreased from the baseline (29.3 to 9.7 [67.4%]), and the ODI also~~ maintained the decrease from baseline, with a median AHI of 9.7 at 18 months. ~~(25.4 to 8.6 [67.5%].)~~ There were no new safety concerns raised (Strollo, 2015). At 36 months, 92% (116/126) of participants completed a follow-up evaluation and 78% (98/126) underwent a follow-up polysomnogram. The median AHI was 6.2. The self-reported daily used was reported at 81% (Woodson, 2016). In 2018, Woodson and associates reported on the 5

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year outcomes of the STAR trial. With 78% (97/126) completing a follow-up evaluation, the mean AHI improvement was maintained (12.4 ± 16.3). After 5 years, 8 individuals (6%) had serious device-related AEs which required surgery to replace or revise the device. At 24 months, the Epworth Sleepiness Scale (ESS), intrusive snoring, and daytime function as measured by the Functional Outcomes of Sleep Questionnaire (FOSQ), were used as the outcomes measurements. A total of 111 of 126 participants (88%) completed the 24-month follow-up evaluation. At 24 months, the mean ESS, which decreased significantly from baseline to 12 months, remained unchanged from the 12-month level. The percentage of participants with an ESS score of less than 10 significantly increased from baseline to 12 months and 24 months (32.5%; 74.8% and 77.5% respectively). Both FOSQ and intrusive snoring measures supported that significant improvements shown at 12 months were maintained. Supplemental information published with the 2014 Strollo study provides insight beyond the group means reported in the main paper. These data show that 83 of the 126 subjects (66%) were classified as treatment responders; 43 (33%) were classified as non responders; and 7 subjects (5.6%) had a worsening of AHI by 15 or more events per hour. An additional 12 subjects had an AHI worsening of less than 15 events per hour. Four subjects experienced AHI worsening of more than 60 events per hour. The authors did not identify any baseline characteristics that might predict who might experience a worsening of AHI with HNS stimulation.

The 36-month outcomes from the STAR trial were published in 2016 (Woodson). The authors noted that the improvements noted at 12 months had persisted at 36 months. A total of 116/126 participants (92%) completed the follow-up evaluation, and 98 (78%) of these individuals underwent a follow-up polysomnogram. The mean AHI, which had decreased from baseline at 12 months, remained stable at 36 months. However, there were fewer 12-month non-responders who agreed to undergo a follow-up polysomnogram, potentially confounding the results. In addition to the stable AHI, this group showed a further small decrease in ODI compared to the 12-month results. The majority of the adverse effects were related to implantation of the device. While the results of these studies are promising, there have been no studies comparing hypoglossal nerve stimulation to other treatments of OSA. In a review of upper airway stimulation therapy, Soose and Gillespie (2016) note "Additional studies are needed to better understand which anatomical and pathophysiologic patient phenotypes are associated with treatment success".

Woodson and colleagues (2018) reported on the 5-year outcomes of the STAR trial. A total of 97 individuals (78%) completed the 5-year follow-up visit. The mean AHI and the oxygen desaturation index (ODI) decreased at the 1-year follow-up from baseline (mean ± SD: 15.3 ± 16.1 and 14.0 ± 15.6 versus 32.0 ± 11.8 and 28.9 ± 18.2, respectively). The results remained stable at 5 years (mean ± SD: 12.4 ± 16.3 and 9.9 ± 14.5, respectively). In addition to the objective results, the subjective measures on daytime sleepiness and functioning were evaluated

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using the Epworth Sleepiness Scale (ESS); and Functional Outcomes of Sleep Questionnaire (FOSQ) tools were used. The scores of these tools showed a slight decrease at 12 months and a continuing steady decline through 5 years. After 5 years, 8 individuals (6%) had serious device-related AEs which required surgery to replace or revise the device. The authors noted that there was a lack of diversity in the study group; the group was predominantly male, obese, CPAP intolerant, and of European descent. In addition, the group excluded individuals with comorbidities such as active cardiovascular disease. This calls into question the generalizability of the results.

Certal and colleagues published a systematic review and meta-analysis on hypoglossal nerve stimulation (2015). A total of six studies (five prospective case series and one case report) with 200 participants were included. A pooled, fixed results analysis demonstrated significant improvements in AHI at the 3-, 6- and 12-month timepoints (43.90 ± 17.61/hour (hr) to 20.03 ± 14.15/hr; 43.73 ± 16.55/hr to 18.91 ± 16.47/hr; and 35.45 ± 13.26/hr to 17.55 ± 16.94/ hr respectively). In addition, there were statistically significant reductions in ODI and ESS. There were no reported safety concerns, and none of the studies reported any serious adverse events. The authors note that the quality of the studies included was low, and higher quality evidence in the form of randomized, controlled trials are needed. In addition, there are no trials comparing hypoglossal nerve stimulation to other treatments of OSA.

The Adherence and Outcome of Upper Airway Stimulation for OSA International Registry (ADHERE), an industry sponsored cohort of individuals who received the Inspire device from multiple sites in the United States and Europe, was designed as a follow-up to the STAR trial (Boon, 2018). The registry included those who met the following criteria: moderate to severe OSA, intolerance or inadequate adherence to CPAP, favorable anatomic criteria (a lack of complete concentric collapse of the retropalatal airway observed during drug-induced sleep endoscopy), device implantation and a willingness to return for routine clinic visits as required. Data was collected retrospectively in those participants who underwent device implantation prior to the creation of the registry and chose to participate in the registry. Registry participation was purely observational; there were no required study specific procedures or treatment plans (Boon, 2018). The ADHERE registry anticipates enrolling a total of 2500 participants. A total of 1017 participants had been enrolled between October 2016 and February 2019 (Thaler, 2020). The registry is comprised of a collection of retrospective and prospective outcome measures, with the first set of data published in 2018 (Boon, 2018). Since that time, several studies have been published using the data from the ADHERE registry.

Boon and associates (2018) evaluated the objective and subjective treatment outcomes, adverse events, and patient and physician satisfaction levels in the first 301 participants enrolled in the ADHERE registry. The mean AHI decreased from 35.6±15.3 to 10.2±12.9. Withrow and associates (2019) used data from the ADHERE registry to

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evaluate the impact of age on safety, efficacy, and usage of upper airway stimulation. The study included the data from 600 individuals, which was 20% of the population which had been treated with HNS (600/3000) at the time. The clinical outcomes of participants younger than 65 years old were compared to the clinical outcomes of those aged 65 and older. Both groups showed a significantly lower AHI at 12 months post-procedure, the older group showed a greater reduction-. Heiser and colleagues (2018) reviewed the data of 508 participants to identify the predictors of success. The authors concluded that increasing age and reduced BMI were predictors of treatment response. In 2020, Thaler and colleagues reported on the results of 640 individuals who are enrolled in the ADHERE registry and have completed their 6-month follow-up post implantation. An additional 382 individuals have completed a 12-month follow-up. The median AHI was reduced from 32.8 at baseline to 9.5 at 12 months follow-up.

In the first comparative study between PAP and HNS, Walia and associates (2020) compared improvements in blood pressure, daytime sleepiness (ESS) and therapy usage. The clinical outcomes of a portion of ADHERE (HNS) participants were retrospectively compared against consecutive individuals treated with PAP therapy at a single institution. Following propensity score matching, there were 201 individuals in each group. The average follow-up was 108 days in the PAP group and 134 days in the HNS group. The PAP therapy group showed a greater improvement in blood pressure readings, with the improvement in diastolic readings reaching statistical significance. Both groups showed an improvement in ESS scores. The HNS group reported higher nightly usage rates.

~~While the ADHERE registry represents a large cohort of individuals who underwent implantation, there are concerns about the generalizability and quality of the data. Participation in the registry is voluntary, approximately 20% of the implanted population at all centers consented to participate (Withrow, 2019). The low participation rate raises concerns regarding selection bias. Also, the first 301 participants were primarily middle-aged (mean 59.2 ± 11.2), Caucasian (97%) and male (82%) (Boon, 2018). These demographics remained largely unchanged following enrollment of the first 1017 participants: average age 60 ± 11 years, 74% male and 96% Caucasian (Thaler, 2020). These demographics do not reflect the prevalence rates observed within the community. Petrov and colleagues (2015) noted that the prevalence rate of OSA was comparable between black men and white men and the prevalence rate was substantially larger among black women compared to white women. An estimated 24% of young-middle aged men and 9% of young-middle aged women are affected by sleep disordered breathing. In older adults, these rates rise to approximately 70% in men and 56% in women (Lin, 2008). Additional limitations of the ADHRE registry include the non-standardized scoring sets among the participating providers and data limited to one year post-implantation.~~

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Costantino and colleagues (2020) performed a systematic review and meta-analysis evaluating the clinical outcomes associated with the use of HNS in individuals with moderate to severe OSA and CPAP non-adherence. A total of 12 prospective studies were included in the systematic review and 9 prospective studies were included in the meta-analysis. All of the included studies were generally of high quality. When compared to baseline (pre-implantation), the 6-month AHI mean difference for the Inspire device was -17.74 (95% CI: - 24.73 to - 10.14, Z score = 4.97, p < 0.001). That improvement remained at 12 months (-17.50, 95% CI: - 20.01 to - 14.98, Z score = 13.64, p < 0.001). The ODI and ESS also showed significantly improved scores at 6 and 12 months. The 3 studies which evaluated long-terms outcomes, ranging from 18 to 60 months, were STAR trial follow-ups. The AHI mean was decreased at 18 months and remained decreased through the 36 and 60 month follow-up (32.0 ± 11.8/h to 14.1 ± 14.4/h (n = 123), 30.4 ± 10.4/h to 11.5 ± 13.9/h (n = 98), and 30.4 ± 9.4/h to 12.4 ± 16.3/h (n = 71), respectively). After 5 years, 6% of individuals were reported to have device-related complications requiring surgical repositioning or replacement. Self-reported device use remained steady at 1, 3 and 5 years (86%, 81% and 80%, respectively). The authors note the results are promising, given that this population, which has failed other therapies, may be more difficult to treat.

~~As more literature regarding upper airway stimulation is published, the primary concerns regarding the current evidence have not been addressed.~~ There are a large number of studies regarding HNS therapy ~~current evidence~~ consistings of prospective, retrospective, observational or case series studies~~, which did not include a comparative group~~ (Costantino, 2020; Gillespie, 2017; Heiser, 2017; Huntley, 2018; Huntley, 2019; Kompelli, 2018; Shah, 2018; Yu, 2019). There are some concerns about the overall evidence, including the limited number of studies comparing HNS to other OSA therapies as well as a lack of diversity within the studied population. However, HNS therapy has been generally accepted by the medical community as a surgical option in the treatment of OSA. ~~RCTs reporting long-term outcomes would provide the means to evaluate the net health outcomes of hypoglossal nerve stimulation compared to the standard established therapies.~~ ~~have ed~~

Background/Overview

Description of Sleep Apnea

OSA syndrome affects over 18 million people in the United States. Many of these people have never had a proper diagnosis. OSA is characterized by an interruption of breathing during sleep, due to extra or loose tissue in the upper airway that collapses into the air passage with the effort of inhalation. The obstruction may occur at one or at multiple levels such as retropalatal, retrolingual, or nasal ~~-~~cavity. OSA~~This~~ is often linked to obesity and decreased

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muscle tone due to ~~aging.~~ aging. When the airway becomes blocked, a drop in blood oxygen content can occur which is detected by the brain, causing the individual to wake just enough to tighten the airway muscles and allow breathing to then resume. This may occur several hundred times in one night. OSA can cause many symptoms, such as depression, irritability, sexual dysfunction, learning and memory difficulties, and falling asleep while at work or driving. OSA is recognized as a contributor or primary mediators in several cardiovascular conditions, including atrial fibrillation, stroke, myocardial infarction and sudden cardiac death. Continuous positive airway pressure (CPAP) is considered the gold standard treatment for OSA. However, compliance is an issue with an estimated 40-70% of individuals using CPAP less than a therapeutic amount of time (Soose, 2016). In addition, there is a subset of individuals wh~~ich~~o do not respond adequately to CPAP therapy. Surgical treatment is considered a second-line therapy following failure of PAP trial in most cases. The most appropriate surgical treatment requires that a thorough evaluation be done to locate the precise area of obstruction as obstruction can occur at the retropalatal or the retrolingual area or in both areas (Aurora, 2010).

Description of OSA Treatments

UPPP is a surgical procedure involving the removal of excessive tissue in the retropharyngeal area, including tonsils and uvula, to widen the area to increase airflow. Since its inception, a number of modifications have been developed including lateral pharyngoplasty, uvulopalatal flap, Z-palatopharyngoplasty, palatal advancement pharyngoplasty, expansion sphincter pharyngoplasty, relocation pharyngoplasty and zed-plasty. Complications of this surgery may include swelling, pain, infection, bleeding, reflux of secretions into the nose, and a nasal quality to the voice. This procedure typically requires an inpatient stay and is used for the treatment of severe OSA. This procedure can be used alone or when there is multilevel obstruction, as part of a staged procedure.

Hyoid myotomy is a surgical procedure that involves movement of the hyoid bone in the neck. The hyoid bone is a c-shaped bone located above the Adam's apple, to which the base of the tongue and other soft tissues of the throat are anchored. Hyoid myotomy involves the surgical detachment of these soft tissues from the hyoid bone and then reattachment in a manner that places increased tension on the tissues. This increased tension is intended to decrease soft tissue collapse of the upper airway that is characteristic of sleep apnea.

Genioglossus advancement is a surgical procedure that involves alteration of the anchor point for the genioglossus muscle of the tongue. This point is located on the inside of the lower jaw. During this procedure, the area of bone surrounding the anchor point is separated from the rest of the ~~jaw bone~~jawbone and pulled outward, drawing the tongue away from the back of the throat. This serves to prevent the base of the tongue from blocking the upper airway during sleep.

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Jaw realignment surgery is an extensive procedure, in which the upper and lower jaws are advanced several millimeters to improve airflow through the back of the throat. Maxillomandibular advancement (MMA) -involves bilateral sagittal split advancement of the mandible and a concurrent Le Fort I advancement of the maxilla. Several surgeries may be required. Persons undergoing jaw realignment surgery typically also undergo orthodontic therapy to correct changes in tooth alignment, associated with the surgery. Change in facial appearance is common in this type of surgery. Other side effects of the procedure include swelling, pain, dental mal-alignment requiring correction, and bleeding.

Many other surgical methods have been proposed for the treatment of OSA, which use various methods of removing or ablating excess tissue from the upper airway, predominantly the soft palate and in some cases the base of the tongue. Of these proposed methods, radiofrequency ablation techniques use high frequency radio waves to destroy tissue of the soft palate, nasal turbinates and/or base of the tongue to decrease excess tissues in the back of the throat. Radiofrequency ablative techniques include RFVTR, Coblation and Somnoplasty. Persons undergoing these procedures frequently require multiple treatments for adequate results. Another category of treatment that aims to remove excess tissue from the upper airway uses heat from either a laser or an electrocautery device to destroy tissue of the soft palate. The two approaches currently available that use this method are LAUP and CAPSO. CAPSO involves denuding the anterior aspect of the soft palate with a blended cautery followed by cauterization of that tissue to further stiffen the palate. CAPSO has been suggested as a less invasive and painful technique compared to other surgical procedures of the palate (Llewellyn, 2018).

Another surgical method proposed for the treatment of OSA is the AIRvance (formerly the Repose) system. This system involves the insertion of a bone screw into the inside of the lower jaw. A cable is then threaded through the base of the tongue and anchored to the bone screw. This system is used to prevent the base of the tongue from falling into the airway, which can be a cause of some OSA symptoms. Similar to the AIRvance System, the ENCORE Tongue Suspension System utilizes a suture loop which is created in the posterior section of the tongue base and is then tensioned and anchored with a bone screw placed midline on the infero-posterior surface of the mandible. The ENCORE System was cleared by the FDA on July 1, 2011 through the 510(k) approval process as an intraoral device for anterior advancement of the tongue base by means of a bone screw threaded with a suture. It is indicated for the treatment of mild or moderate OSA and/or snoring. The literature, to date, has been limited by small numbers of subjects, and a literature review conducted by the manufacturer of the ENCORE System concluded that the evidence currently available has been graded as ~~low-level~~low-level evidence regarding safety and efficacy (Sezen, 2011).

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Injection snoreplasty has been proposed as a treatment of both snoring and OSA. This procedure, frequently done in one to three separate treatments, involves injection of a chemical (Sotradecol) into the soft palate and uvula. Sotradecol is known as a sclerotherapy agent, and causes scarring via an inflammatory reaction in the tissues to which it is exposed. The scarring caused by Sotradecol causes the flabby loose tissue in the back of the throat to shrink and tighten, which is proposed to open the upper airway and decrease the symptoms of snoring and OSA.

The Pillar Palatal Implant System (Restore Medical, Inc. St. Paul, MN) consists of three narrow threads of braided polyester slightly less than an inch in length that are inserted under the skin of the soft palate, using a delivery tool. One is placed in the midline and one each in right and left lateral locations. The procedure can be performed in the physician's office under local anesthesia, and over the next few weeks, scar tissue grows around the threads further stiffening the palate. The implants are designed to be permanent structures but can be removed if necessary for reasons of infection or instability. Post-operative pain is claimed to be mild and short lived with rapid resumption of normal activities and diet (unlike LAUP and RFVTR). The Pillar system received market clearance from the U.S. Food & Drug Administration in 2003. Common complications include implant extrusion, pain, sensation of a foreign body, cellulitis and difficulty swallowing (Povolotski, 2020).

Hypoglossal nerve stimulation devices consist of three components: a pulse generator, a breathing sensor lead which monitors and senses breathing patterns, and a stimulation lead which delivers mild stimulation to the genioglossus nerve. This stimulation causes enlargement and stabilization of both the retrolingual airway and the retropalatal space and is designed to work in synchrony with respiration to allow for unobstructed inspiration. A small remote allows the individual to turn the device on each night and turn it off upon awakening. While the Inspire device is currently the only FDA approved device, a second device, THN Sleep Therapy (ImThera, San Diego, CA) is undergoing phase III clinical trials. ~~Limitations of this therapy include MRI incompatibility and the need for three external incisions during implantation (Soose, 2016).~~

~~*Proposed Benefits*~~

~~The goal of all sleep disorder diagnostic procedures is to correctly identify a specific sleep disorder(s), in order to render proper treatment(s). Such treatment may alleviate sleep disorder symptoms and/or causes and allow the individual to achieve healthy sleep patterns.~~

Potential Risks

The level of risk associated with the various methods of OSA treatment varies dependent upon the level of invasiveness. The use of oral appliances poses little risk, but proper fitting should be done to assure optimal

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efficacy. The risks associated with CPAP and its derivatives are not life threatening, but include disturbed sleep until the user is acclimated to the device.

Various surgical treatments for OSA all include the standard risks associated with all surgical treatments, including infection, bleeding, pain and discomfort. Not all procedures are guaranteed to be 100% successful, and results may vary. All of these surgeries result in permanent reconfiguration of the anatomical position of the upper airway, which may have unintended consequences. Persons undergoing jaw realignment should be especially aware that this surgery will most likely affect their appearance.

Definitions

Apnea-Hypopnea index (AHI) or Respiratory disturbance index (RDI): A measure of apnea severity defined by the total number of episodes of apnea or hypopnea during a full period of sleep divided by the number of hours asleep. For the purposes of this document, the terms AHI and RDI are interchangeable, although they may differ slightly in clinical use. An AHI/RDI greater than 30 is consistent with severe OSA. In some cases, respiratory effort-related arousals (or RERAS) are included in the RDI value. These RERA episodes represent EEG arousals associated with increased respiratory efforts but do not qualify as apneic or hypopneic episodes because of the absence of their defining air flow changes and/or levels of oxygen desaturation.

Central sleep apnea (CSA): A condition that is caused by decreased respiratory center output in the brain. This sleep apnea syndrome is not as common as OSA but may be associated with similar symptoms.

Continuous positive airway pressure (CPAP): This is a noninvasive treatment for OSA that involves delivery of pressurized air during sleep through a device that snugly covers the nose. The appropriate setting for standard CPAP treatment is determined during a titration sleep study.

Obstructive sleep apnea (OSA): This is a form of sleep disturbance, which occurs as the result of a physical occlusion of the upper airway during sleep, which interferes with normal breathing. The occlusion is usually in the back of the tongue and/or flabby tissue in the upper airway. This condition is associated with frequent awakening and often with daytime sleepiness.

Coding

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When services may be Medically Necessary when criteria are met:

CPT

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
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation
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 Schuchardt)
21685	Hyoid myotomy and suspension
42145	Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator [when specified as implantation of hypoglossal nerve stimulator]
0466T	Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator
0467T	Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator
0468T	Removal of chest wall respiratory sensor electrode or electrode array

HCPCS

C1767	Generator, neurostimulator (implantable), nonrechargeable [when specified as a component of an HNS]
C1778	Lead, neurostimulator (implantable) [when specified as a component of an HNS]

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C1787	Patient programmer, neurostimulator [when specified as a component of an HNS]
D7940	Osteoplasty - for orthognathic deformities
D7941	Osteotomy - mandibular rami
D7943	Osteotomy - mandibular rami with bone graft; includes obtaining the graft
D7944	Osteotomy - segmented or subapical
D7945	Osteotomy - body of mandible
D7946-D7947	LeFort I (maxilla total, segmented)
L8680	Implantable neurostimulator electrode, each [when specified as a component of an HNS]
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only [when specified as a component of an HNS]
L8688	Implantable neurostimulator pulse generator, dual array; non-rechargeable, includes extension [when specified as a component of an HNS]

ICD-10 Procedure

0CQ30ZZ	Repair soft palate, open approach
0CQM0ZZ	Repair pharynx, open approach
0CQM7ZZ	Repair pharynx, via natural or artificial opening
0CQN0ZZ	Repair uvula, open approach
0CS30ZZ	Reposition soft palate, open approach
0CS70ZZ	Reposition tongue, open approach
0CSN0ZZ	Reposition uvula, open approach
0NBR0ZZ-0NBS0ZZ	Excision of maxilla, open approach [right/left; includes codes 0NBR0ZZ, 0NBS0ZZ]
0NBT0ZZ-0NBV0ZZ	Excision of mandible, open approach [right/left; includes codes 0NBT0ZZ, 0NBV0ZZ]
0NQR0ZZ-0NQS0ZZ	Repair maxilla, open approach [right/left; includes codes 0NQR0ZZ, 0NQS0ZZ]
0NQT0ZZ-0NQV0ZZ	Repair mandible, open approach [right/left; includes codes 0NQT0ZZ, 0NQV0ZZ]
0NQX0ZZ	Repair hyoid bone, open approach
0NSR04Z-0NSRS0ZZ	Reposition maxilla, open approach [with/without fixation, right/left; includes codes 0NSR04Z, 0NSR05Z, 0NSR0ZZ, 0NSS04Z, 0NSS05Z, 0NSS0ZZ]
0NST04Z-0NSV0ZZ	Reposition mandible, open approach [with/without fixation, right/left; includes codes 0NST04Z, 0NST05Z, 0NST0ZZ, 0NSV04Z, 0NSV05Z, 0NSV0ZZ]
0NSX04Z	Reposition hyoid bone with internal fixation device, open approach
0NSX0ZZ	Reposition hyoid bone, open approach

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0NUR07Z-0NUR0KZ	Supplement maxilla, open approach [with autologous/nonautologous tissue or synthetic substitute~~, right/left~~; includes codes 0NUR07Z, 0NUR0JZ, 0NUR0KZ~~, 0NUS07Z, 0NUS0JZ, 0NUS0KZ~~]
0NUT07Z-0NUV0KZ	Supplement mandible, open approach [with autologous/nonautologous tissue or synthetic substitute, right/left; includes codes 0NUT07Z, 0NUT0JZ, 0NUT0KZ, 0NUV07Z, 0NUV0JZ, 0NUV0KZ]

ICD-10 Diagnosis

G47.10-G47.19	Hypersomnia
G47.30-G47.39	Sleep apnea
G47.411-G47.429	Narcolepsy and cataplexy
G47.8	Other sleep disorders
G47.9	Sleep disorder, unspecified

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above~~,~~ when criteria are not met, ~~; for the following diagnosis,~~ or when the code describes a procedure indicated in the Position Statement section as not medically necessary.

~~**ICD-10 Diagnosis**~~	
~~R06.83~~	~~Snoring~~

When services are also Not Medically Necessary:

CPT

41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session [e.g., Somnoplasty]
42145	Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)
42299	Unlisted procedure, palate, uvula [when specified as any of the following: ▪ Cautery-assisted palatal stiffening (CAPSO); ▪ Coblation; ▪ Palatal implants; ▪ Injection snoreplasty; ▪ The Pillar™ system]

HCPCS

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CHANGES

C9727	Insertion of implants into the soft palate; minimum of three implants
S2080	Laser-assisted uvulopalatoplasty (LAUP)

ICD-10 Diagnosis

R06.83	Snoring

When services are Investigational and Not Medically Necessary:
For the procedures listed above, for all other diagnoses, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

When services are Investigational and Not Medically Necessary:

CPT

41512	Tongue base suspension, permanent suture technique
42299	Unlisted procedure, palate, uvula [when specified as transpalatal advancement pharyngoplasty (TAP)]
~~64568~~	~~Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator [when specified as implantation of hypoglossal nerve stimulator]~~
~~0466T~~	~~Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator~~
~~0467T~~	~~Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator~~
~~0468T~~	~~Removal of chest wall respiratory sensor electrode or electrode array~~

~~**HCPCS**~~

	~~For the following codes when specified as components of an implanted hypoglossal nerve stimulator:~~
~~C1767~~	~~Generator, neurostimulator (implantable), nonrechargeable~~
~~C1778~~	~~Lead, neurostimulator (implantable)~~
~~C1787~~	~~Patient programmer, neurostimulator~~
~~L8680~~	~~Implantable neurostimulator electrode, each~~
~~L8681~~	~~Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only~~

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~~L8688~~	~~Implantable neurostimulator pulse generator, dual array; non-rechargeable, includes extension~~

ICD-10 Diagnosis

All diagnoses

~~**When services are also Investigational and Not Medically Necessary:**~~

~~**CPT**~~

~~42145~~	~~Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)~~

~~**ICD-10 Procedure**~~

~~0CQ30ZZ~~	~~Repair soft palate, open approach~~
~~0CQM0ZZ~~	~~Repair pharynx, open approach~~
~~0CQM7ZZ~~	~~Repair pharynx, via natural or artificial opening~~
~~0CQN0ZZ~~	~~Repair uvula, open approach~~
~~0CS30ZZ~~	~~Reposition soft palate, open approach~~
~~0CS70ZZ~~	~~Reposition tongue, open approach~~
~~0CSN0ZZ~~	~~Reposition uvula, open approach~~

~~**ICD-10 Diagnosis**~~

~~G47.8~~	~~Other sleep disorders [when specified as upper airway resistance syndrome (UARS)]~~

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Websites for Additional Information

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Repose System
RF Thermal Ablation
Somnoplasty System
Uvulopalatopharyngoplasty

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	05/13/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised position statements to note that hypoglossal nerve stimulation is medically necessary when criteria are met. Revised Not Medically Necessary" and "Investigational and Not Medically Necessary" to clarify statements without a change in intent. Updated Rationale, Background, Coding and References sections.
Reviewed	08/13/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections. Updated Coding section; added HCPCS codes C1767, C1778, C1787, L8680, L8681, L8688.

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Revised	08/22/2019	MPTAC review. Removed not medically necessary indication for nasal surgery. Updated Description, Rationale, References and Websites sections. Corrected Coding section, removed 64999 no longer applicable.
Reviewed	09/13/2018	MPTAC review. Updated Rationale, Coding, References and Websites sections.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date". Updated Discussion and References sections.
Revised	11/03/2016	MPTAC review. Clarified criteria regarding failed surgical interventions in jaw realignment surgery. Added not medically necessary statement when criteria are not met. Revised title to include snoring. Rationale, Background, References, Websites for Additional Information and Index sections were updated. Updated formatting in Position Statement section. Updated Coding section with 01/01/2017 CPT changes.
Reviewed	11/05/2015	MPTAC review. Revised Description/Scope, Rationale, Background, References and Websites for Additional Information sections. Removed ICD-9 codes from Coding section.
Revised	11/13/2014	MPTAC review. An investigational and not medically necessary statement was added to the criteria regarding hypoglossal nerve stimulation. Updated Rationale, Coding, and References sections.
Revised	11/14/2013	MPTAC review. Clarified position statement regarding tongue base suspension procedures/systems which are considered investigational and not medically necessary. Updated Rationale and References sections.
Reviewed	11/08/2012	MPTAC review. Updated Rationale and References sections.
Revised	11/17/2011	MPTAC review. The scope and title have been revised to address surgical treatments only. The criteria for medical treatment with oral appliances have been removed. A criterion has been added for each medically necessary surgical procedure regarding age (18 or older) or skeletal maturity, in order to meet medical necessity. The Rationale, Background, Definitions and References were updated. Updated Coding section to remove codes E0485, E0486.
Reviewed	08/18/2011	MPTAC review. The Rationale section and References were updated. Definitions were added.

CHANGES

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Reviewed	08/19/2010	MPTAC review. The Rationale section and References were updated.
Reviewed	08/27/2009	MPTAC review. The Rationale section and References were updated.
	01/01/2009	Updated Coding section with 01/01/2009 CPT changes; removed 0088T deleted 12/31/2008.
Revised	08/28/2008	MPTAC review. An additional statement was added regarding UPPP to clarify that this surgery as a sole procedure for treatment of OSA is considered not medically necessary for patients with an AHI/RDI under 10. Transpalatal advancement pharyngoplasty was added to the procedures considered investigational and not medically necessary. Rationale and Reference Sections were also updated.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Revised	08/23/2007	MPTAC review. The criteria for CPAP, APAP and related devices were removed and transferred into the new Clinical UM Guideline CG-DME-32 Continuous Positive Airway Pressure (CPAP) and Related Devices. No change to other medical necessity criteria for other treatments for OSA with the exception of jaw realignment surgery where the medical necessity language was clarified to indicate that failed use of CPAP *and either* UPPP *or* genioglossus advancement and/or hyoid myotomy with suspension or both would meet medical necessity. References and coding sections were also updated.
Reviewed	12/07/2006	MPTAC review. References and coding were updated.
Revised	09/14/2006	MPTAC review. The medical necessity criteria for non-surgical treatments (CPAP) and for surgical treatment with UPPP were revised to add reference to RDI as equivalent to AHI values within the criteria. Also, the title was changed to Treatment of OSA in Adults and the statements were clarified to pertain to adults only. Coding was also updated.
Revised	12/01/2005	MPTAC review. Revised: Added flexible positive airway pressure (PAP) (e.g., C-Flex) to investigational/not medically necessary statement. Included information in rationale related to flexible positive airway pressure (e.g., C-Flex).

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	11/18/2005	Added references for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	07/14/2005	MPTAC review. Revised: Revised medical necessity criteria for UPPP; specifically, revised parameters for AHI based on if UPPP is the sole procedure or part of a planned staged or combined surgery. . .
Revised	04/28/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization. Updated coding: Removed HCPCS codes K0531, K0183, K0189, K0268 (deleted 01/01/2003).

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	07/28/2004	MED.00002	Diagnosis of Sleep Disorders and Treatment of OSA
WellPoint Health Networks, Inc.	03/11/2004	2.03.01	LAUP or Radiofrequency Thermal Ablation as a Treatment of OSA
	06/24/2004	3.03.26	Cautery Assisted Palatal Stiffening Operation (CAPSO) and Palatal Implants (Restoration) for the Treatment of Snoring and Obstructive Sleep Apnea
	09/23/2004	Clinical Guideline	WLP adopted and revised Milliman Guideline: Uvulopalatopharyngoplasty (UPPP)
	09/23/2004	Clinical Guideline	Clinical Guidelines: CPAP, BiPAP, AUTO-PAP, and Oral Appliances for Treatment of OSA in Adults

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