POLICY STATEMENT:

I. Nasal Surgery
   Based upon our criteria and assessment of peer-reviewed literature, Septoplasty, Turbinate Reduction, and Polypectomy do not improve patient outcomes and are not medically necessary for obstructive sleep apnea (OSA). However, nasal surgery is considered medically appropriate to correct a nasal obstruction that prohibits the use of CPAP/BiPAP.

II. Upper Airway Surgery
   A. Palatopharyngoplasty (eg, uvulopalatopharyngoplasty(UPPP), uvulopharyngoplasty): Based upon our criteria and assessment of the peer-reviewed literature, UPPP, with or without inferior sagittal osteotomy (ISO) with hyoid suspension, for the treatment of OSA has been medically proven to be effective and therefore medically appropriate for the following indications:
      (Must meet criteria 1 AND 3 OR 2 AND 3)
      1. Documented OSA with an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) of 15 or greater events per hour regardless of symptoms; OR
      2. Documented OSA with an AHI or RDI of 5 to 14 events per hour accompanied by symptoms of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, or documented cardiovascular diseases, including hypertension and ischemic heart disease;
      AND
      3. Failure of all forms of medical management of OSA, including documented intolerance to positive airway pressure (e.g., CPAP, BiPAP).
   B. Radiofrequency ablation or Somnoplasty of palatal tissues: Based upon our criteria and assessment of the peer-reviewed literature, Somnoplasty does not improve patient outcomes and is not medically necessary for the treatment of OSA.
   C. Laser-assisted Uvulopalatoplasty (LAUP): Based upon our criteria and assessment of the peer-reviewed literature, LAUP does not improve patient outcomes and is not medically necessary for the treatment of OSA.
   D. Expansion sphincter pharyngoplasty/expansion sphincteroplasty (ESP): Based upon our criteria and lack of the peer-reviewed literature, ESP has not been proven medically effective and is considered investigational.
   E. Tonsillectomy and adenoidectomy (T&A): Based upon our criteria and assessment of the peer-reviewed literature, tonsillectomy and adenoidectomy has been medically proven to be effective and therefore medically appropriate for the treatment of OSA. T&A is also considered medically appropriate to correct an upper airway obstruction that prohibits the use of CPAP/BiPAP.
   F. Injection Snoreplasty: Based upon our criteria and assessment of peer-reviewed literature, injection snoreplasty has not been medically proven to be effective and is considered investigational for the treatment of OSA. Injection Snoreplasty for the treatment of snoring alone is considered not medically necessary.
G. Cautery-Assisted Palatal Stiffening Operation (CAPSO): Based upon our criteria and assessment of peer-reviewed literature, cautery-assisted palatal stiffening has not been medically proven to be effective and is considered investigational for the treatment of OSA. CAPSO for the treatment of snoring alone is considered not medically necessary.

H. Palatal Implant System (e.g., Pillar™ Palatal Implant): Based upon our criteria and assessment of peer-reviewed literature, the palatal implant system has not been medically proven to be effective and is considered investigational for the treatment of OSA. This implant as a treatment of snoring alone is considered not medically necessary.

III. Lower Airway Surgery

A. Jaw realignment Surgery (e.g., inferior sagittal mandibular osteotomy, genioglossal advancement, hyoid myotomy and suspension, maxillomandibular osteotomy and advancement): Based upon our criteria and assessment of the peer-reviewed literature, jaw realignment surgery has been medically proven to be effective and therefore medically appropriate for the treatment of OSA in patients who meet the criteria for UPPP, as stated in Policy Statement II A.

B. Tongue suspension suture system (e.g., Airvance® [formerly known as the Repose™ System], Encore™ System): Based upon our criteria and assessment of peer-reviewed literature, tongue suspension suture systems have not been medically proven to be effective and are considered investigational for the treatment of OSA.

C. Radiofrequency ablation or Somnoplasty of the base of the tongue: Based upon our criteria and assessment of the peer-reviewed literature, Somnoplasty does not improve patient outcomes and is not medically necessary for the treatment of OSA.

IV. Surgical Bypass of the Airway

Tracheostomy: Based upon our criteria and assessment of the peer-reviewed literature, tracheostomy has been medically proven to be effective and therefore, medically appropriate for treatment of severe, life-threatening OSA.

V. Hypoglossal Nerve/Upper Airway Stimulation (e.g., Inspire II Upper Airway Stimulation system)

Based upon our criteria and the lack of peer-reviewed literature, the use of implantable hypoglossal nerve stimulation is considered investigational in the treatment of OSA.

VI. Cardiac Pacing

Atrial overdrive pacing: Based upon our criteria and assessment of peer-reviewed literature, atrial overdrive pacing is considered investigational as a treatment of OSA.

VII. Based upon our criteria and assessment of peer-reviewed literature, treatment for snoring without polysomnographic evidence of OSA does not improve patient outcomes and is not medically necessary.

Refer to Corporate Medical Policy #1.01.06 regarding Positive Pressure Airway Devices.

Refer to Corporate Medical Policy#1.01.07 regarding Oral Appliances for the Treatment of Sleep-Related Breathing Disorders.

Refer to Corporate Medical Policy #2.01.28 regarding Sleep Studies.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

Refer to Corporate Medical Policy #7.01.05 Vagus Nerve Stimulation for vagus nerve stimulators used for other indications than Hypoglossal stimulation.
POLICY GUIDELINES:
I. Surgery is not the first treatment of choice for OSA. It is reserved for patients who have failed all forms of medical management of OSA, or are intolerant of CPAP and BiPAP, and/or oral appliances.

II. In severe OSA disease, surgery may not be curative and follow-up studies may be warranted post-operatively.

III. For those patients who have been found to have multiple levels or anatomical sites of obstructive sleep apnea (e.g., hypopharyngeal, retropalatal, and/or retrolingual) on clinical evaluation, a simultaneous combination of surgical procedures may be appropriate for the best surgical outcome and to minimize operative risk. Nasal surgery is not considered part of a multilevel surgery to correct OSA. If a nasal obstruction precludes the use of CPAP, then nasal surgery to allow the use of CPAP should be performed first.

IV. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:
Obstructive sleep apnea (OSA) is the cessation of airflow through the nose and mouth for at least 10 seconds with a respiratory effort noted, and is usually associated with a reduction in blood oxygen saturation. Features of OSA include daytime somnolence, disordered sleep, and a variety of clinical symptoms. It is also common to find decreased motor and perceptual skills while awake, which correlate with the severity of hypoxia during sleep. The syndrome is most common in middle-aged, obese, male smokers.

In patients with OSA, the normal pharyngeal narrowing is accentuated by anatomic factors, such as a short neck, elongated palate and uvula, or large tonsillar pillars with redundant lateral pharyngeal wall mucosa. OSA may also be associated with a wide variety of craniofacial abnormalities, including micrognathia, retrognathia or maxillary hypoplasia.

When patients with OSA are not able achieve benefit with non-invasive positive pressure therapy (PAP) or fail the gold standard of treatment in the form of continuous positive airway pressure (CPAP) a second-line treatment may be a surgical option. The AASM proposes the use of specific guidelines such as CPAP adherence for at least 4 hours of sleep for at least 70% of the days or an improvement in clinical symptoms. The Food and Drug Administration (FDA) defines failed compliance as using the CPAP less than 4 hours a night for less than 5 nights per week. Not all patients may be candidates for surgical options for appropriate polysomnographic, age, BMI and objective upper airway evaluation measures may be required for proper patient selection.

The goal of surgery is to enlarge the airway and prevent airway collapse and oxygen desaturation to prevent the clinical symptoms of OSA: excessive daytime sleepiness, impaired cognition, and mood disorders. Surgery is site specific, performed to enlarge a certain portion of the airway.

I. Nasal Surgery
   A. Septoplasty corrects a deviated septum, which may obstruct the nasal airway.
   B. Turbinate Reduction reduces the size of one of the 3 turbinates in each nostril, which can improve the size of the nasal airway. The surgery may be performed with lasers, cauterity or radiofrequency ablation.
   C. Polypectomy removes nasal polyps, which obstruct the nasal airways.
II. Upper Airway Surgery
   A. Uvulopalatopharyngoplasty (UPPP) removes the uvula and the lower edge of the soft palate is trimmed. The surgery may include several technical variations. All techniques include the basic UPPP procedure, but often additional surgery is performed, such as tonsillectomy. UPPP with inferior sagittal osteotomy with hyoid suspension is one variation proposed to improve the surgical outcome.

   B. Radio-frequency ablation of soft palate tissue, or Somnoplasty System, uses a device comprised of an electrosurgical (RF) generator and tissue coagulating electrodes, which ablate soft tissues in the palate or uvula.

   C. Laser-Assisted Uvulopalatoplasty (LAUP) involves the progressive removal of the back edge of the palate and a reduction in the size of the uvula. It is most frequently performed with a carbon dioxide laser and is typically performed over several surgical sessions in an outpatient setting.

   D. Expansion sphincter pharyngoplasty/expansion sphincteroplasty (ESP) is a modification of a UPPP in which the lateral pharyngeal wall is stiffened in order to prevent collapse. ESP consists of a tonsillectomy, expansion pharyngoplasty, rotation of the palatopharyngeus muscle, partial uvulectomy, and closure of the anterior and posterior tonsillar pillars.

   E. Tonsillectomy and Adenoidectomy. Enlarged tonsils may narrow the width of the upper airway; the adenoids are at the back of the nose and may obstruct the nasal airway. Removal of tonsils and adenoids are performed most often in children with sleep apnea. Adenoids usually shrink with age and only rarely require removal in adults.

   F. Injection Snoreplasty involves the injection of a sclerosing agent (tetradecyl Sulfate/Sotradecol) into the soft palate, which causes scarring and subsequent stiffening of the soft palate. This is thought to reduce the flutter of the soft palate, which is the cause of primary snoring.

   G. Cautery-Assisted Palatal Stiffening Operation (CAPSO) is a procedure where electrocautery is utilized to remove a portion of the soft palate and uvula. It is carried out under local anesthesia, on an outpatient basis.

   H. Palatal Implant System involves insertion of three narrow bands of braided polyester under the skin of the soft palate using a delivery tool. The implant has been proposed for the treatment of snoring and for the treatment of palate-related mild to moderate sleep apnea. Once in place, the implants stiffen the palate by mechanical means in addition to inducing a fibrotic response that incapsulates and secures the implants, further stiffening the palatal tissue. Palatal implants, though designed to be permanent, are removable. Implantation is carried out under local anesthesia.

III. Lower Airway Surgery
   A. Jaw realignment Surgery (e.g., inferior sagittal mandibular osteotomy, genioglossal advancement, hyoid myotomy and suspension, maxillomandibular osteotomy and advancement) is a more aggressive surgical procedure than UPPP. It has been used to relieve obstruction in OSA patients who meet the criteria for UPPP.

   B. A tongue suspension suture system (e.g., Airvance® [formerly known as the Repose™ System], Encore™ System) involves preventing the tongue from falling back during sleep. The Airvance® System uses a titanium screw in the chin attached to a permanent stitch through the tongue to pull it forward. The Encore™ System is similar to the Airvance® System but creates a suture loop within the tongue without having to create penetrations through the mucosal surface of the tongue.

   C. Radiofrequency ablation, or Somnoplasty System, uses a device, which is comprised of an electrosurgical (RF) generator and tissue coagulating electrodes that ablate soft tissues, creating volumetric tissue reduction of the tongue.

Proprietary Information of Excellus Health Plan, Inc.
IV. Surgical Bypass of the Airway

A tracheostomy bypasses the narrow segments of the airway that cause obstruction and create an opening in the neck that allows the patient to breathe unobstructed at night. This is done in severe, life-threatening cases of sleep apnea.

V. Hypoglossal Nerve/Upper Airway Stimulation

Electrical stimulation of the hypoglossal nerve has been proposed as a method to maintain upper airway patency by augmenting tone to the upper airway. The implant device consists of a pulse generator, a stimulation lead, and a sensing lead and is designed to detect the patient’s respiratory effort and maintain airway patency with mild stimulation of the hypoglossal nerve. Therapy settings are stored in the pulse generator and configured by the physician using an external programmer. The patient uses a remote to turn therapy on before they go to sleep and to turn therapy off when they wake up. The sleep remote also provides the ability to pause therapy and adjust stimulation amplitude within physician defined limits.

On April 30, 2014, the U.S. Food and Drug Administrations (FDA) granted pre-market approval for the Inspire® Upper Airway Stimulation (UAS) system (Inspire Medical Systems) for use in treating a subset of patients, age 22 years and older, with moderate to severe obstructive sleep apnea (apnea-hypopnea index [AHI] of 20 to 65) who have failed or cannot tolerate positive airway pressure (PAP) treatments and who do not have a complete concentric collapse, as seen during drug induced sleep endoscopy, at the soft palate level. Body Mass Index (BMI) greater than 32 was not studied as part of the pivotal trial. Based on data from the feasibility study, it may be associated with decreased likelihood of response to treatment. Use of Inspire UAS in higher BMI (>32) patients is not recommended due to unknown effectiveness and safety. Other devices under investigation include, but may not be limited to, the Aura™ 6000 System (Imthera Medical) and the HGNS® System (Apnex Medical).

VI. Atrial overdrive pacing

It has been found that bradycardia frequently occurs during episodes of apnea. Therefore, atrial overdrive pacing after implantation of a pacemaker has been proposed as a treatment to reduce the incidence of obstructive sleep apnea events.

RATIONALE:

Obstructive sleep apnea has been associated with significant co-morbidities. The gold standard of treatment has been non-invasive ventilation in the form of continuous positive airway pressure (CPAP). When anatomical obstructions exist, surgical intervention is used. The anatomical location for obstruction can occur at several different locations along the airway and, in specific circumstances, combined surgical procedures can offer a higher overall success rate than one single procedure alone. Because of the complexity of airway narrowing or collapse during sleep, any one surgical procedure may not eradicate the patient’s sleep apnea. Though procedures such as septoplasty, nasal turbinectomies or nasal polypectomies may be indicated for correction of a nasal airway obstruction, their role in treating multilevel OSA is very limited.

LAUP studies have shown that a large proportion of patients developed significant worsening of objective sleep parameters postoperatively. There are no data regarding the long-term efficacy and safety of injection snoreplasty as a treatment for OSA. The scientific evidence is insufficient to permit conclusions concerning the effect of CAPSO on health outcomes. Somnoplasty has been approved by the FDA only as a treatment for snoring. Current literature regarding radio-frequency/ somnoplasty does not support the efficacy or applicability of this procedure for OSA. Studies also fail to report long-term outcomes or recurrence rates.

There is insufficient evidence to support the safety and efficacy of the use of the Repose™ tongue suspension system in the treatment of OSA. Although preliminary studies have shown subjective improvements in snoring and decreases in the mean RDI, the overall surgical cure rate was only 20% (Miller, et al. 2002). Kuhnel, et al (2005) investigated the efficacy of tongue base suspension in modifying the posterior airway space in patients with OSA. The posterior airway
space was widened by at least 2 mm in 60% of cases. Daytime sleepiness improved subjectively in 67% of patients, and the respiratory disturbance index improved postoperatively in 55%. The correlation between posterior airway space widening and the improvements in daytime sleepiness and respiratory disturbance index was not significant. The authors concluded that surgical intervention in obstructive sleep apnea syndrome with the Repose System does not result in permanent anatomical change in the posterior airway space.

The Pillar™ Palatal Implant received FDA approval for the treatment of snoring in 2003 and subsequently, FDA approval as a treatment of OSA in September 2004. There is insufficient peer-reviewed evidence to support use of the Pillar implant as a treatment of OSA. The literature mainly consists of small case series investigating its use for snoring. Studies with OSA patients had very small sample sizes with limited follow-up and were vendor sponsored (Nordgard, et al. 2006; Friedman, et al. 2006).

Many patients with OSA also suffer from nocturnal bradycardia or tachyarrhythmias. It has been observed that in some patients, the use of a pacemaker to increase the heart rate and cardiac function during sleep could also reduce the incidence of apneic episodes. Although a clinical study by Garrigue, et al (2002) found that atrial overdrive pacing significantly reduced the number of episodes of central and obstructive sleep apnea, these positive findings have not been validated in any of the newer, well-designed studies. Atrial overdrive pacing has not been found to reduce the number of hypopnea-apnea events in patients with OSA (Krahn, et al. 2006; Unterberg, et al. 2005; Luthje, et al. 2005; Simantirakis, et al. 2005; Pepin et al. 2005).

Hypoglossal Nerve/Upper Airway Stimulation. In 2014, the STAR Trial Group (Funded by Inspire Medical Systems) reported 12-month outcomes from a multicenter single-arm study of 126 patients implanted with the Inspire® Upper Airway Stimulation system. Patients were included if the apnea hypopnea index (AHI) score from the screening polysomnogram (PSG) was at least 20 and no more than 50 events per hour. At 12 months after implantation 66% of the participants met the co-primary outcome of at least a 50% decrease in AHI with a final AHI of less than 20 events per hour and 75% met the co-primary outcome of a reduction in the oxygen desaturation index score of 25% or more. The median AHI decreased from 29.3 to 9.0 events per hour and the oxygen desaturation index score (ODI, number of times per hour that SO2 drops by 4% or more) decreased from 25.4 to 7.4 events per hour. The mean Epworth Sleepiness Scale (ESS) decreased from 11.6 to 7.0. The first 46 patients who responded to therapy were then 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, whereas the mean AHI in the withdrawal group increased from 7.6 to 25.8. Eighteen percent of participants had temporary tongue weakness and 21% reported tongue soreness, including abrasion, which resulted from stimulation-induced tongue motion over the lower teeth. (Strollo, et al.). Two participants experienced serious adverse events associated with the device. The lack of a control group limits the validity of the results of this study. This study was funded by Inspire Medical in which there was only a 12 month follow up and they concluded that while HGNFS demonstrated favorable safety, feasibility and efficacy and HNS may be a viable treatment option in OSA HNS it does not alleviate OSA in all subjects and there were no long term outcomes. This study is not adequate enough to approve implantable hypoglossal nerve stimulation.

In an editorial referencing the issue of the New England Journal of Medicine by Strollo et al, Malhotra acknowledged that the STAR study had many limitations. The population studied were carefully selected, and only a minority of screened patients underwent implantation. Second, some residual disease were seen during the therapy, as shown by a score on the apnea–hypopnea index (the number of apneas plus hypopneas per hour of sleep) of 9.0 events per hour at 12 months, leading to an interpretation that obstructive sleep apnea was reduced but not eliminated by hypoglossal nerve stimulation. The experimental design was an unblinded, prospective, open-label study, without a concomitant control group. Diet, exercise, or other unmeasured factors may have changed during the course of the study and could have contributed to the observed reduction in obstructive sleep apnea.

A series of 31 patients implanted with the Apnex hypoglossal nerve stimulation system (HGNFS®) was reported in 2014. There was a significant improvement (p less than 0.001) from baseline to 12 months in AHI (45.4±17.5 to 25.3±20.6
events/hour). Functional Outcomes of Sleep Questionnaire (FOSQ) score (14.2±2.0 to 17±2.4) as well as other polysomnogram and symptom measures outcomes were stable compared to 6 months following implantation. 3 serious device-related adverse events occurred: an infection requiring device removal and 2 stimulation lead cuff dislodgements requiring replacement. There were no significant adverse events w/ onset later than 6 months following implantation. The authors concluded HGNS demonstrated favorable safety, feasibility, and efficacy and HNS may be a viable treatment option in OSA, but because HNS does not alleviate OSA in all subjects, there is a potential for improvement in treatment selection or additional benefit from adjunctive interventions. (Kezirian, et al).

Due to the lack of high quality, peer-reviewed, published studies, with significant numbers of subjects in the studies that demonstrate improved long term patient outcomes past two years, the use of hypoglossal nerve stimulation in the treatment of obstructive sleep apnea has not been established as standard of care in published medical literature and is considered investigational.

**CODES:**

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<th>Number</th>
<th>Description</th>
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<td>Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract. CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.</td>
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<td>Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates. Code Key: Experimental/Investigational = (E/I), Not medically necessary/appropriate = (NMN).</td>
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<td>Jaw realignment surgery (code ranges)</td>
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<td>Tracheostomy, planned (separate procedure)</td>
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<td>Tongue base suspension, permanent suture technique</td>
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<td>age 12 or over</td>
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<td>0467T (NMN)</td>
<td>Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator</td>
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<td>0468T (NMN)</td>
<td>Removal of chest wall respiratory sensor electrode or electrode array</td>
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<td>64568 (E/I)</td>
<td>Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator (E/I for Hypoglossal Nerve/Upper Airway Stimulation (e.g., Inspire II UAS system) in the treatment of OSA)</td>
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<td>HCPCS:</td>
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<td>C9727 (E/I)</td>
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<td>S2080 (NMN)</td>
<td>Laser-assisted uvulopalatoplasty (LAUP)</td>
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ICD10:  
F51.8 Other sleep disorders not due to a substance or known physiological condition  
G47.00 Insomnia, unspecified  
G47.10 Hypersonnia, unspecified  
G47.20 Circadian rhythm sleep disorder, unspecified type  
G47.30-G47.39 Sleep apnea (code range)  
G47.69 Other sleep related movement disorders  
G47.8-G47.9 Other and unspecified sleep disorders (code range)

REFERENCES:  
BlueCross BlueShield Association Technology Evaluation Center (TEC). Radiofrequency volumetric tissue reduction for sleep-related breathing disorders. 2000 Dec;15(15).  


*key article
CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Neither a National nor a Regional Medicare coverage determination addressing surgical management of obstructive sleep apnea has been identified.