

MEDICAL POLICY

MEDICAL POLICY DETAILS	
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Policy Number	7.01.41
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Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit. • If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit. • If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. • If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY STATEMENT

I. Nasal Surgery

Based upon our criteria and assessment of the peer-reviewed literature, septoplasty, turbinate reduction, and polypectomy do not improve patient outcomes and, therefore, are considered **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 (e.g., 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, is considered **medically appropriate** for patients who meet **BOTH 1 and 3**, or **BOTH 2 and 3**, below:
1. Documented OSA with an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) of 15 or greater events per hour, regardless of symptoms;
 2. Documented OSA with an AHI or RDI of five 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;
 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, therefore, is considered **not medically necessary** for the treatment of OSA.

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- C. Laser-assisted uvulopalatoplasty (LAUP): Based upon our criteria and assessment of the peer-reviewed literature, LAUP does not improve patient outcomes and, therefore, is considered **not medically necessary** for the treatment of OSA.
- D. Expansion sphincter pharyngoplasty/expansion sphincteroplasty (ESP): Based upon our criteria and the lack of peer-reviewed literature, ESP has not been medically proven to be effective and, therefore, is considered **investigational**.
- E. Tonsillectomy and adenoidectomy: Based upon our criteria and assessment of the peer-reviewed literature, tonsillectomy and adenoidectomy have been medically proven to be effective and, therefore, are considered **medically appropriate** for the treatment of OSA, as well as to correct an upper airway obstruction that prohibits the use of CPAP/BiPAP.
- F. Injection snoreplasty: Based upon our criteria and assessment of the peer-reviewed literature, injection snoreplasty has not been medically proven to be effective and, therefore, 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 the peer-reviewed literature, CAPSO has not been medically proven to be effective and, therefore, 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 the peer-reviewed literature, the palatal implant system has not been medically proven to be effective and, therefore, is considered **investigational** for the treatment of OSA. Palatal implant for the 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, is considered **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 the peer-reviewed literature, tongue suspension suture systems have not been medically proven to be effective and, therefore, 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, therefore, is considered **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, is considered **medically appropriate** for the treatment of severe, life-threatening OSA.

V. Hypoglossal Nerve/Upper Airway Stimulation

- A. Based upon our criteria and assessment of the peer-reviewed literature, hypoglossal nerve upper airway stimulation (e.g., Inspire II Upper Airway Stimulation system) has been medically proven to be effective and, therefore, is considered **medically appropriate** for the treatment of moderate-to-severe OSA, when **ALL** of the following criteria are met for each listed age group.
 1. Adult patient (aged 18 years or older);

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- a. AHI described as greater than 15 and less than 65; and
- b. Unable to use or cannot tolerate CPAP; and
- c. All previous treatment measures exhausted/failed; and
- d. BMI less than 32.

B. Upper airway stimulation therapy is **contraindicated** when patient:

1. Has central and mixed apneas greater than 25% of the total AHI;
2. Has any anatomical finding that would affect the performance of upper airway stimulation, such as the presence of complete concentric collapse of the soft palate;
3. Has any condition or procedure that would affect neurological control of the upper airway;
4. Is unable or does not have the necessary assistance to operate the sleep remote;
5. Is pregnant or plans to become pregnant;
6. Will require magnetic resonance imaging (MRI); or
7. Has an implantable device that may have unintended interactions with the Inspire system.

VI. Cardiac Pacing

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

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

Refer to Corporate Medical Policy #1.01.06 Positive Airway Pressure Devices CPAP, BIPAP, APAP, and Noninvasive Positive Pressure Ventilators.

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

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

Refer to Corporate Medical Policy #7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy.

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, 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 (e.g., hypopharyngeal, retropalatal, and/or retro lingual) of OSA 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 multi-level 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.

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.

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When patients with OSA are not able to 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 American Academy of Sleep Medicine (AASM) proposes the use of specific guidelines, such as CPAP adherence for at least four hours of sleep for at least 70% of the days, or an improvement in clinical symptoms. The United States Food and Drug Administration (FDA) defines failed compliance as using the CPAP for fewer than four hours per night for fewer than five nights per week. Not all patients may be candidates for surgical options; 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 three turbinates in each nostril, which can improve the size of the nasal airway. The surgery may be performed with lasers, cautery or radiofrequency ablation.
- C. Polypectomy removes nasal polyps that obstruct the nasal airways.

II. Upper Airway Surgery

- A. Uvulopalatopharyngoplasty (UPPP) involves the removal of the uvula and trimming of the lower edge of the soft palate. 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 consisting of an electro-surgical (RF) generator and tissue-coagulating electrodes that 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 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 palatopharyngeal muscle, partial uvulectomy, and closure of the anterior and posterior tonsillar pillars.
- E. Tonsillectomy and adenoidectomy are, respectively, procedures to remove enlarged tonsils, which may narrow the width of the upper airway, and the adenoids, which are at the back of the nose and may obstruct the nasal airway. Removal of tonsils and adenoids is 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 in which 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 implant stiffens the palate by mechanical means and induces a fibrotic response that encapsulates 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.

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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, Medtronic, Inc) involves preventing the tongue from falling back during sleep. The Airvance System uses a titanium screw in the chin, which is 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 consisting of an electrosurgical (RF) generator and tissue-coagulating electrodes that ablate soft tissues, creating volumetric tissue reduction of the tongue.

IV. Surgical Bypass of the Airway

A tracheostomy bypasses the narrow segments of the airway that cause obstruction and creates 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 of maintaining upper airway patency by augmenting tone to the upper airway. The implant device, which consists of a pulse generator, a stimulation lead, and a sensing lead, 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 start therapy before going to sleep and to stop therapy when awakened. The sleep remote also provides the ability to pause therapy and to adjust stimulation amplitude within physician-defined limits.

On April 30, 2014, the FDA granted pre-market approval for the Inspire Upper Airway Stimulation (UAS) system (Inspire Medical Systems) for use in treating a subset of patients, aged 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 CPAP treatments; who do not have complete concentric collapse, as seen during drug-induced sleep endoscopy (DISE), at the level of the soft palate; and whose Body Mass Index (BMI) is less than 32. Other devices under investigation include, but may not be limited to, the Aura6000 System (Imthera Medical) and the HGNS System (Apnex Medical), although neither of these devices is FDA-approved. In 2020 the FDA granted approval of the Inspire® UAS device for use in patients between the ages of 18 and 21 years for whom specific criteria is met.

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. Obstruction can occur at any of 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. Due to 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 nasal airway obstruction, their role in treating multi-level OSA is very limited.

LAUP studies have shown that a large proportion of patients post-operatively developed significant worsening of objective sleep parameters. 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-

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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 Airvance 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 two mm in 60% of cases. Daytime sleepiness improved, subjectively, in 67% of patients, and the respiratory disturbance index improved post-operatively 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 OSA 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 as a treatment for OSA in September 2004. There is insufficient peer-reviewed evidence to support the use of the Pillar implant as a treatment for OSA. The literature mainly consists of small case series investigating its use for snoring. Studies with OSA patients had very small sample sizes and 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 apnea and/or hypopnea 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 (HGNS). In 2014, the STAR Trial Group (funded by Inspire Medical Systems, Inc.) reported 12-month outcomes from a multi-center, 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 they had 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), which is the 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 seven 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. In addition, this study had only a 12-month follow-up, and there were no long-term outcomes. The authors concluded that, while HGNS demonstrated favorable safety, feasibility, and efficacy, and HGNS may be a viable option in treating OSA, HGNS does not alleviate OSA in all subjects. This study is not adequate enough to approve implantable hypoglossal nerve stimulation.

In an editorial in the New England Journal of Medicine by Strollo et al. (2014), Malhotra acknowledged that the STAR study had many limitations. First, the population studied was carefully selected, and only a minority of screened patients underwent implantation. Second, some residual disease was seen during the therapy, as shown by a score on the AHI (the number of apneas plus hypopneas per hour of sleep) of 9.0 events per hour at 12 months, leading to an interpretation that OSA was reduced, but not eliminated, by HGNS. The experimental design was an unblinded, prospective, open-label study, without a concomitant control group. In addition, diet, exercise, or other unmeasured factors may have changed during the course of the study and could have contributed to the observed reduction in OSA.

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Upper airway stimulation (UAS) leads to significant reductions in the AHI, the ODI, and the ESS in older patients, despite higher age with multiple co-morbidities. Advanced age was not a limiting factor for surgical procedure or treatment outcomes. The main result of this study is a significant reduction of the AHI in younger and older subjects: 84% decrease in younger subjects and 80.8% decrease in older subjects where the AHI declined below a level of 15 events per hour (the generally accepted values that define mild sleep apnea). Furthermore, the level of daytime sleepiness also declined in 69.6% of younger and in 72% of older subjects where the value of ESS was below 10 points. (Zhu et al. 2018)

The largest cohort study done to date, which focused exclusively on UAS therapy outcomes, consisted of a study of 47 patients, 30 of whom had undergone a previous surgery and 16 of whom had not suffered from moderate-to-severe OSA, but were surgical candidates for HNS therapy. The study examined AHI and nadir oxyhemoglobin saturation (NOS) as measured by polysomnography; secondary measures included ESS. The study revealed an overall reduction in AHI by 90%, which translated to a success rate of 96% and cure rate of 81%. (Mahmoud et al. 2018)

Patients with moderate-to-severe OSA and an inability to adhere to positive pressure therapy, who underwent HGNS, were compared to a historical cohort of patients who were intolerant of CPAP who underwent UPPP. Data included BMI, as well as pre- and post-implant AHI. UAS resulted in an approximately 90% reduction in AHI, while traditional airway surgery resulted in an approximately 30% reduction in AHI. In addition, 65% of the patients in the UAS cohort demonstrated a reduction in AHI from the moderate-to-severe range into the normal range (AHI <5), compared to only 20% of the patients in the UPPP group. (Shah et al. 2018).

CODES

- 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.**
- 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).

CPT Codes

Code	Description
21141-21155, 21193-21206, 21244	Jaw realignment surgery (code ranges)
31600	Tracheostomy, planned (separate procedure)
41512 (E/I)	Tongue base suspension, permanent suture technique
41530 (NMN)	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session
42145	Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty)
42820	Tonsillectomy and adenoidectomy; younger than age 12
42821	Tonsillectomy and adenoidectomy; age 12 or over
64568	Open implantation cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array

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Code	Description
64583	Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator
64584	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

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Code	Description
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads
C9727 (E/I)	Insertion of implants into the soft palate; minimum of three implants
S2080 (NMN)	Laser-assisted uvulopalatoplasty (LAUP)

ICD10 Codes

Code	Description
F51.8	Other sleep disorders not due to a substance or known physiological condition
G47.00	Insomnia, unspecified
G47.10	Hypersomnia, 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)

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REFERENCES

- Algethami MR, et al. Perception of surgical treatments for obstructive sleep apnea among sleep medicine physicians: A cross-sectional study. J Family Med Prim Care. 2020 Aug 25;9(8):4401-4405.
- American Academy of Otolaryngology – Head and Neck Surgery. Nasal surgery and OSAS. Position statement. Revised 09/08/2017 <https://www.entnet.org/resource/position-statement-nasal-surgery-and-osas/> accessed 02/13/23.
- American Academy of Otolaryngology – Head and Neck Surgery. Surgical management of obstructive sleep apnea. Position statement. Revised 2014 Mar 2 [<https://www.entnet.org/resource/position-statement-surgical-management-of-obstructive-sleep-apnea/>] accessed 02/13/23.
- American Academy of Otolaryngology – Head and Neck Surgery. Uvulopalatopharyngoplasty. Position statement. Reaffirmed 2012 Dec 8. Revised 01/11/2019 [<http://www.entnet.org/node/896>] accessed 02/13/23.
- American Academy of Otolaryngology – Head and Neck Surgery. Tongue suspension. Position statement. 2012 Dec 8 [<https://www.entnet.org/resource/position-statement-tongue-suspension/>] accessed 02/13/23.
- American Academy of Otolaryngology-Head and Neck Surgery. 2016 Position Statement: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea (OSA). Revised 2019 Nov 11 [<https://www.entnet.org/resource/position-statement-hypoglossal-nerve-stimulation-for-treatment-of-obstructive-sleep-apnea-osa/>] Accessed 02/13/23.
- *American Academy of Sleep Medicine. Practice parameters for the use of laser-assisted uvulopalatoplasty. An update for 2000. 2001 Aug [http://www.aasmnet.org/Resources/PracticeParameters/PP_Uvulopalatoplasty.pdf] accessed 02/13/23.
- *Aurora RN, et al. Practice parameters for the surgical modifications of the upper airway for obstructive sleep apnea in adults. Sleep 2010 Oct 1;33(10):1408-13.
- *Baldassari CM, et al. Changes in central apnea index following pediatric adenotonsillectomy. Otolaryngol Head Neck Surg 2012 Mar;146(3):487-90.
- Bestouros D, et al. Adverse events associated with the Inspire implantable hypoglossal nerve stimulator: A MAUDE database review. American Journal of Otolaryngology 2020;41(6):102616.
- Bowe SN, et al. Modified surgical approach to hypoglossal nerve stimulator implantation in the pediatric population. The Laryngoscope 2018;128:1490.
- Bowen AJ, et al. Voice and swallowing outcomes following hypoglossal nerve stimulation for obstructive sleep apnea. American Journal of Otolaryngology-Head and Neck Medicine and Surgery 2018;39:122-126.
- *Epstein LJ, et al; Adult obstructive sleep apnea task force of the American academy of sleep medicine. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. J Clin Sleep Med 2009 Jun 15;5(3):263-76.
- *Garetz SL, et al. Quality of life and obstructive sleep apnea symptoms after pediatric adenotonsillectomy. Pediatrics 2015 Feb;135(2):e477-86.
- *Garrigue S, et al. Benefit of atrial pacing in sleep apnea syndrome. NEJM 2002 Feb 7;346(6):404-12.
- Heiser, et al. Technical tips during implantation of selective upper airway stimulation. The Laryngoscope 2018;128:756.
- *Holmlund T, et al. Effects of radiofrequency versus sham surgery of the soft palate on daytime sleepiness. Laryngoscope 2014 Oct;124(10):2422-6.
- Hong SN, et al. Indications for and Outcomes of Expansion Sphincter Pharyngoplasty to Treat Lateral Pharyngeal Collapse in Patients with Obstructive Sleep Apnea. JAMA Otolaryngol Head Neck Surg 2019;145(5):405-412.
- Jones JW, et al. Hypoglossal nerve stimulation for obstructive sleep apnea in a patient with previous tongue laceration. BMJ Case Rep 2018 Mar 28;2018:bcr2017222230.

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Kang KT, et al. Effect of sleep surgery on blood pressure in adults with obstructive sleep apnea: A systematic review and meta-analysis. Sleep Medicine Reviews 2022 Apr;62:101590.

*Krahn AD, et al. Physiologic pacing in patients with obstructive sleep apnea: a prospective, randomized crossover trial. J Am Coll Cardiol 2006 Jan 17;47(2):379-83.

*Lim J, et al. Adenotonsillectomy for obstructive sleep apnea in children. The Cochrane Library 2009 Issue 2, No. CD003136.

*Luthje L, et al. Atrial overdrive pacing in patients with sleep apnea with implanted pacemaker. Am J Respir Crit Care Med 2005 Jul 1;172(1):118-22.

Mahmoud AF and Thaler ER. Upper airway stimulation therapy and prior airway surgery for obstructive sleep apnea. The Laryngoscope 2018;128:1486-1489.

Mahmoud AF, et al. Outcomes of Hypoglossal Nerve Upper Airway Stimulation among Patients with Isolated Retropalatal Collapse. Otolaryngology– Head and Neck Surgery 2019;160(6):1124–1129.

*Marcus CL, et al; American Academy of Pediatrics. Diagnosis and management of childhood obstructive sleep apnea syndrome. technical report. Pediatrics 2012 Sep;130(3):e714-55.

Maresch KJ. Hypoglossal nerve stimulation: Effective long-term therapy for obstructive sleep apnea. AANA J. 2018 Oct;86(5):412-416.

*Miller FR, et al. Role of the tongue base suspension suture with the Repose System bone screw in the multilevel surgical management of obstructive sleep apnea. Otolaryngol Head Neck Surg 2002 Apr;126(4):392-8.

Neruntarat C, et al. Barb reposition pharyngoplasty versus expansion sphincter pharyngoplasty: a meta-analysis. Laryngoscope 2021 Jun;131(6):1420-1428.

*Nordgard S, et al. Soft palate implants for the treatment of mild to moderate obstructive sleep apnea. Otolaryngol Head Neck Surg 2006 Apr;134(4):565-70.

*Pepin JL, et al. Overdrive atrial pacing does not improve obstructive sleep apnea syndrome. Eur Resp J 2005 Feb;25(2):343-7.

Povolotskiy R, et al. Complications of Palatal Pillar Implants: An analysis of the MAUDE database and literature review. Am J Otolaryngol 2020;41:102303.

Shah J, et al. Uvulopalatopharyngoplasty vs CN XII stimulation for treatment of obstructive sleep apnea: A single institution experience. Otolaryngology 2018;39:266-270.

Shiffman HS, et al. Minimally invasive combined Nd:YAG and Er:YAG laser-assisted uvulopalatoplasty for treatment of obstructive sleep apnea. Photobiomodul Photomed Laser Surg. 2021 Aug;39(8):550-557.

*Simantirakis EN, et al. Atrial overdrive pacing for obstructive sleep apnea-hypopnea syndrome. NEJM 2005 Dec 15;353(24):2568-77.

Tabatabai GM, Karempelis P, Hsia JC. Hypoglossal nerve stimulator generator migration: INSPIRE device reimplantation with parallels to cardiac implantable electronic devices. Am J Otolaryngol. 2018 Sep-Oct;39(5):639-641.

*Unterberg C, et al. Atrial overdrive pacing compared to CPAP in patients with obstructive sleep apnoea syndrome. Eur Heart J 2005 Dec;26(23):2568-75.

U.S. Food & Drug Administration Inspire® Upper Airway Stimulation – P130008/S039 <https://www.fda.gov/medical-devices/recently-approved-devices/inspirer-upper-airway-stimulation-p130008s039> accessed 02/22/23.

Wischusen J, et al. Laser-assisted uvulopalatoplasty (LAUP) complications and side effects: a systematic review. Nature and Science of Sleep 2019;11:59–67.

Medical Policy: SURGICAL MANAGEMENT OF SLEEP DISORDERS

Policy Number: 7.01.41

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Withrow K. et al. Upper Airway Stimulation Response in Older Adults with Moderate to Severe Obstructive Sleep Apnea. Otolaryngology– Head and Neck Surgery 2019;161(4):714–719.

Zhu Z, et al. Selective upper airway stimulation in older patients. Respiratory Medicine 2018;140:77-81.

Zhu Z, et al. Improving surgical results in complex nerve anatomy during implantation of selective upper airway stimulation. Auris Nasus Larynx 2018;45:653-656.

*Key Article

KEY WORDS

Airvance, Atrial overdrive pacing, Aura6000 System, CAPSO, Encore, HGNS, Hypoglossal Nerve Stimulation, Inspire II Upper Airway Stimulation System, LAUP, Pillar, Repose, Snoreplasty, Somnoplasty, UPPP

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, surgical management of obstructive sleep apnea is not addressed in National or Regional Medicare coverage determinations or policies.