



Status

Active

Medical and Behavioral Health Policy

Section: Surgery

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TREATMENT OF OBSTRUCTIVE SLEEP APNEA AND SNORING IN ADULTS

Description: Obstructive sleep apnea (OSA) results from repetitive pharyngeal narrowing or collapse during sleep. Known contributors to OSA (and snoring) include relaxation of the soft palate, posterior displacement of the base of the tongue, and collapse of the hypopharyngeal airway. Several medical and surgical treatments have been developed to correct these causative factors and relieve symptoms.

Medical Management

Lifestyle modification and weight management

Weight loss can lead to improvement of OSA-related symptoms and severity. As a result, weight management is a first line treatment of OSA. Lifestyle changes and modifications to sleep position are also first lines of OSA management. Lifestyle changes include avoidance of alcohol, sedatives and stimulants, especially before bedtime. Sleep position changes, such as sleeping on one's side rather than back, and using pillows or other supports to maintain a more optimal position during sleep can also improve OSA.

Oral appliances can be broadly categorized as mandibular advancing/positioning devices or tongue-retaining devices. Oral appliances are available as "off the shelf" products or devices that are custom made for the patient by a dental laboratory or similar provider.

Positive airway pressure

- Continuous positive airway pressure (CPAP) involves the administration of air, usually through the nose, by an external device at a fixed pressure to maintain the patency of the upper airway.

- Bilevel Positive Airway Pressure (BiPAP) is similar to CPAP, but these devices are capable of generating two adjustable pressure levels.
- Auto-adjusting PAP (APAP or AutoPAP) adjusts the level of pressure based on the level of resistance. As a result, the device may administer a lower mean level of positive pressure during the night. APAP may also be used to initiate and titrate CPAP in adult patients with clinically significant OSA.

It has been hypothesized that both BiPAP and APAP are more comfortable for the patient, and thus might improve patient compliance or acceptance.

Nasal expiratory positive airway pressure (EPAP) is a single-use patch containing valves that are inserted into the nostrils and secured with adhesive that create a minimal amount of air pressure to improve airway patency during sleep. In 2010 a nasal expiratory resistance valve (Provent[®]) received marketing clearance for treatment of OSA through the U.S. Food and Drug Administration's 510(k) process.

Oral pressure therapy

Oral pressure therapy (OPT) provides light negative pressure to the oral cavity through a flexible mouthpiece connected to a bedside console. The device is proposed to increase the size of the retropalatal airway by pulling the soft palate forward and stabilizing the base of the tongue. One device, the Winx[™] System, received marketing clearance by the FDA in 2012. It is indicated for the home use of OSA treatment in adults.

Surgical Treatment

When medical management fails, surgical treatment may be indicated. A number of surgical procedures have been developed to address OSA or snoring.

Uvulopalatopharyngoplasty (UPPP) involves removing the uvula, a portion of the soft palate, and the palatine tonsils. The resulting scarring stiffens the soft palate, and is effective in reducing snoring, and to a lesser extent, relieving OSA. UPPP may be appropriate for patients with narrowing or collapse in the retropalatal (oropharyngeal) region.

Laser-assisted uvulopalatoplasty (LAUP) involves laser vaporization of the full length of the superficial layer of the soft palate on both sides of the uvula. The extent of surgery is typically different than standard UPPP since only part of the uvula and associated soft palate tissues are reshaped. The

procedure is performed to alleviate snoring but has not been proven to be effective for treatment of obstructive sleep apnea.

Surgeries in patients with narrowing or collapse in the retrolingual (hypopharyngeal) area

For patients with narrowing or collapse in the retrolingual (hypopharyngeal) area, inferior sagittal mandibular osteotomy and genioglossal advancement with or without hyoid myotomy and suspension may be appropriate. The procedure creates an enlarged retrolingual airway. In this procedure, the area of anterior attachment of the tongue is advanced by performing a mandibular osteotomy. The released segment of bone is drawn anteriorly with the attached tendon of the genioglossus and is fixed into position on the mandible. In some cases, the hyoid bone is advanced and suspended from the mandible by a fascial strip. For patients with both retropalatal and retrolingual obstruction, UPPP and inferior sagittal mandibular osteotomy and genioglossal advancement with or without hyoid myotomy and suspension may be performed.

Mandibular-maxillary advancement (MMA) may be another option for patients with narrowing or collapse of the retrolingual (hypopharyngeal) area. MMA involves simultaneous advancement of the maxilla and mandible through sagittal-split osteotomies which provides maximal enlargement of the retrolingual airway and some advancement of the retropalatal airway.

Radiofrequency volumetric tissue reduction (RFVTR) is a 30-minute procedure involving thermal ablation of excessive tissue in the area of the uvula, soft palate, tongue base, and turbinates to reduce severe snoring. The Somnoplasty® device has been cleared for marketing by the U.S. Food and Drug Administration (FDA) for radiofrequency ablation of palatal tissues for simple snoring and for the base of the tongue for OSA.

Tongue base suspension is intended to make it less likely for the base of the tongue to prolapse during sleep. In this procedure, the base of the tongue is suspended with a suture that is passed through the tongue and then fixated with a screw to the inner side of the mandible, below the tooth roots. Airvance®, formerly the Repose™ Bone Screw System was cleared for marketing through the FDA 510(k) process for the treatment of OSA and/or snoring. The Encore™ Tongue Suspension System (Siesta Medical) has received clearance citing the PRELUDE III Tongue Suspension System as a predicate device.

Palatal implants have been proposed as a method for managing snoring and for the treatment of mild to moderate

OSA. Palatal implants consist of narrow threads of braided polyethylene terephthalate which are slightly less than an inch in length. The cylindrical implants are inserted into the soft palate to increase the stiffness of the soft palate in order to reduce the vibrations. Two or three parallel implants are inserted in the soft palate using a special deployment device. The procedure is performed using local anesthetics. Scar tissue forms around the implants, further stiffening the palate. The implants are designed to be permanent, but they can be removed, if necessary. The Pillar™ Palatal Implant System is an implantable device that has been cleared for marketing through the FDA 510(k) process. The labeled indication of the device states that it is intended to reduce the incidence of airway obstructions in patients suffering from mild to moderate OSA.

Hypoglossal nerve stimulation uses an implantable pacemaker-like device capable of stimulating the nerve strongly enough to evoke a response keeping the airway open, but without disturbing sleep. Patients control therapy start and stop times with a handheld controller. The pulse generator processes information from the sensor and determines the most beneficial time in the breathing cycle to deliver the stimulation. The single lead pressure sensor provides real-time breathing cycle data throughout the night. In May 2014, the FDA granted premarket approval (PMA) to the Inspire II Upper Airway Stimulation System. The device is intended to treat a subset of patients with moderate to severe OSA (AHI of greater or equal to 20 and less than or equal to 65). Inspire is used in adult patients 22 years of age and older who have been confirmed to fail or cannot tolerate positive airway pressure (PAP) treatments and who do not have a complete concentric collapse at the soft palate level. PAP failure is defined as an inability to eliminate OSA (AHI of greater than 20 despite PAP usage) and PAP intolerance is defined as: 1) inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night); or 2) unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it).

Definitions:

Apnea Hypopnea Index (AHI) equals the average number of episodes of apnea and/or hypopnea per hour of sleep).

- Apnea is defined as the cessation of airflow for at least 10 seconds.
- Hypopnea is defined as a reduction in airflow equal to or greater than 30% with an associated fall in oxygen saturation of at least 4% or arousal. Hypopnea may also be defined as a reduction in airflow of 50% or greater with a fall in oxygen saturation of at least 3%.

Obstructive sleep apnea (OSA): A diagnosis of OSA syndrome is accepted when an adult patient has an AHI greater than 5 and symptoms of excessive daytime sleepiness or hypertension. It is

estimated that approximately 20% of adults have at least mild OSA. In adults, an AHI equal to or greater than 15 is typically considered moderate OSA, while an AHI greater than 30 is considered severe OSA. An estimated 7% of adults have moderate or severe OSA. Although there is poor correlation between AHI and OSA symptoms, an increase in mortality is associated with an AHI of 15 or greater in adults.

Respiratory Disturbance Index (RDI): is defined as the number of apneas, hypopneas, and respiratory event related arousals (RERAs) per hour of sleep. It may be referred to along with or instead of AHI.

Policy:

I. Medical Management

A. Oral Appliances

Oral appliances (e.g., mandibular advancing/positioning devices or tongue-retaining devices) may be considered **MEDICALLY NECESSARY** in patients with OSA confirmed by polysomnography.

B. Continuous Positive Airway Pressure (CPAP)

Continuous positive airway pressure (CPAP) may be considered **MEDICALLY NECESSARY** in patients with confirmed OSA with:

1. An AHI of 15 or greater;

OR

2. An AHI between 5 and 14 with any of the following associated symptoms:
 - a. Excessive daytime sleepiness
 - b. Impaired cognition
 - c. Mood disorders
 - d. Insomnia
 - e. Documented hypertension
 - f. Ischemic heart disease
 - g. History of stroke

C. Bi-level Positive Airway Pressure (BiPAP)

BiPAP may be considered **MEDICALLY NECESSARY** in patients who:

1. Meet the criteria for CPAP; **AND**
2. Have failed a prior trial of CPAP; **OR**
3. For whom BiPAP is found to be more effective than CPAP in the sleep laboratory.

D. Auto-Adjusting PAP (APAP)

APAP may be considered **MEDICALLY NECESSARY** in patients who:

1. Meet the criteria for CPAP above; **AND**
2. Have a contraindication to CPAP, have failed a prior trial of CPAP **OR** are undergoing a trial of APAP to titrate CPAP; **AND**
3. Have no evidence by history or physical examination of the following conditions:
 - a. Central sleep apnea

- b. Congestive heart failure
- c. Chronic pulmonary disease such as chronic obstructive pulmonary disease
- d. Pulmonary hypertension
- e. Obesity hypoventilation syndrome or other condition which may cause nocturnal arterial oxyhemoglobin desaturation

E. Expiratory Positive Airway Pressure (EPAP)

An EPAP device (ie, Provent[®]) is considered **INVESTIGATIVE** due to the lack of clinical evidence demonstrating its impact on improved health outcomes.

F. Oral Pressure Therapy Devices

Oral pressure therapy devices, including but not limited to the Winx[™] system, are considered **INVESTIGATIVE** due to the lack of clinical evidence demonstrating their impact on improved health outcomes.

G. Atrial Pacing

Atrial pacing is considered **INVESTIGATIVE** in the treatment of obstructive sleep apnea due to the lack of clinical evidence demonstrating its impact on improved health outcomes.

II. Surgical Management

A. Uvulopalatopharyngoplasty (UPPP)

UPPP may be considered **MEDICALLY NECESSARY** when all the following criteria are met:

1. Presence of significant, unexplained cor pulmonale or cardiac arrhythmia resulting from documented OSA;
OR
2. An AHI of 15 events per hour or greater; or an AHI between 5 and 14 with documented hypertension, ischemic heart disease, or history of stroke;
AND
 - a. BMI less than 40;
AND
 - b. Patient has not responded to or does not tolerate CPAP, BiPAP, or APAP following a minimum of 4 hours per night for three (3) months of PAP usage.

B. Maxillofacial Procedures

Maxillofacial surgical procedures, such as inferior sagittal mandibular osteotomy and genioglossal advancement with or without hyoid myotomy and suspension or mandibular-maxillary advancement (MMA) may be considered **MEDICALLY NECESSARY** when the following criteria are met:

1. Presence of significant, unexplained cor pulmonale or cardiac arrhythmia resulting from documented OSA;
OR
2. an AHI of 15 events per hour or greater; or an AHI between 5 and 14 with documented hypertension, ischemic heart disease, or history of stroke;

AND

- a. Objective evidence of hypopharyngeal obstruction documented by either fiberoptic examination or cephalometric radiographs;

AND

- b. Patient has not responded to or does not tolerate CPAP, BiPAP, or APAP following a minimum of 4 hours per night for three (3) months of PAP usage.

C. Other Surgical Procedures

All other surgical procedures are considered **INVESTIGATIVE** for the sole or adjunctive treatment of obstructive sleep apnea/upper airway resistance syndrome, including, but not limited to:

1. Uvulectomy
2. Laser-assisted uvulopalatoplasty (LAUP)
3. Radiofrequency volumetric reduction of the palatal tissues
4. Radiofrequency volumetric tissue reduction of the tongue, with or without radiofrequency reduction of the palatal tissues
5. Palatal stiffening procedures, including but not limited to, cautery-assisted palatal stiffening operation and the implantation of palatal implants
6. Tongue base suspension
7. Implantable hypoglossal nerve stimulators

III. Treatment of Snoring

Treatment of snoring is considered **NOT MEDICALLY NECESSARY** because simple snoring in the absence of documented obstructive sleep apnea is not considered a medical condition. Therefore, all procedures for the sole or adjunctive treatment of snoring are considered **NOT MEDICALLY NECESSARY**, including but not limited to:

- A. Uvulectomy
- B. Laser-assisted uvulopalatoplasty (LAUP)
- C. Radiofrequency volumetric reduction of the palatal tissues
- D. Radiofrequency volumetric tissue reduction of the tongue, with or without radiofrequency reduction of the palatal tissues
- E. Palatal stiffening procedures, including but not limited to, cautery-assisted palatal stiffening operation, and the implantation of palatal implants
- F. Tongue base suspension

Coverage:

Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is

subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Coding:

The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT:

21120 Genioplasty; augmentation (autograft, allograft, prosthetic material)

21121 Genioplasty; sliding osteotomy, single piece

21122 Genioplasty; sliding osteotomies, two or more osteotomies (e.g., wedge excision or bone wedge reversal for asymmetrical chin)

21123 Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)

21141 Reconstruction midface, LeFort I; single piece, segment movement in any direction (e.g., for Long Face Syndrome), without bone graft

21142 Reconstruction midface, LeFort I; two pieces, segment movement in any direction, without bone graft

21143 Reconstruction midface, LeFort I; three or more pieces, segment movement in any direction, without

21145 Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)

21146 Reconstruction midface, LeFort I; two pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (e.g., ungrafted unilateral alveolar cleft)

21147 Reconstruction midface, LeFort I; 3 or more pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted bilateral alveolar cleft or multiple osteotomies)

21193 Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft

21194 Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; with bone graft (includes obtaining graft)

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 Schuchard)

21685 Hyoid myotomy and suspension

41512 Tongue base suspension, permanent suture technique

41530 Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session

42140 Uvulectomy

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

42280 Maxillary impression for palatal prosthesis

42281 Insertion of pin-retained palatal prosthesis

42299 Unlisted procedure, palate, uvula

42950 Pharyngoplasty (plastic or reconstructive operation on pharynx)

61885 Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array

64568 Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator

HCPCS:

E0470 Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)

E0471 Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)

E0472 Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)

E0485 Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment

E0486 Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment

E0601 Continuous positive airway pressure (CPAP) device

S2080 Laser-assisted uvulopalatoplasty (LAUP)

L8679 Implantable neurostimulator, pulse generator, any type

L8680 Implantable neurostimulator electrode, each

L8682 Implantable neurostimulator radiofrequency receiver

L8683 Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver

L8685 Implantable neurostimulator pulse generator, single array, rechargeable, includes extension

L8686 Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension

ICD-9 Procedure:

27.64 Insertion of palatal implant

27.69 Other plastic repair of palate

27.72 Excision of uvula

27.73 Repair of uvula

27.79 Other operation on uvula

86.94 Insertion or replacement of single array neurostimulator pulse generator, not specified as rechargeable

86.96 Insertion or replacement of other neurostimulator pulse generator

86.97 Insertion or replacement of single array rechargeable neurostimulator pulse generator

Policy History:

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Most recent history:

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Cross Reference:

Sleep Disorder Testing In Adults, II-106

Orthognathic Surgery, IV-16

Sleep Studies/Polysomnograms in Children and Adolescents, II-128

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