



**Kaiser Foundation Health Plan of Washington**

**Clinical Review Criteria  
Treatments for Obstructive Sleep Apnea**

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**Criteria  
For Medicare Members**

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	<a href="#">Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA) (240.4)</a>
Local Coverage Determinations (LCD)	<a href="#">Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718)</a>  <a href="#">Oral Appliances for Obstructive Sleep Apnea (L33611).</a>  <a href="#">Surgical Treatment of Obstructive Sleep Apnea (OSA) (L34526)</a>  <a href="#">Non-Covered Services (L35008).</a>
Local Coverage Article	<a href="#">Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea - Policy Article (A52467)</a>  <a href="#">Oral Appliances for Obstructive Sleep Apnea (A52512)</a>
KPWA Policy	For services that are not covered by the above NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, "Treatments of Obstructive Sleep Apnea for Mandibular Advancement Surgery" for medical necessity determinations. Use the Non-Medicare criteria below.

**For Non-Medicare Members**

Treatment	Criteria Used
<b>Positive Airway Pressure Devices</b>	Has one of the following indications: <ol style="list-style-type: none"> <li>1) AHI of 15 events or greater per hour</li> <li>2) AHI between 5 and 15 events per hour with documented excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease or history of stroke.</li> <li>3) A Sleep Apnea Clinical Score (SACS) greater than 15 and meets all of the following:                             <ol style="list-style-type: none"> <li>a) Completed a baseline Stanford Sleepiness Score</li> <li>b) Completed a 3 night autotitration PAP</li> <li>c) Reported one of the following:                                     <ol style="list-style-type: none"> <li>i) A positive response to initial autotitration*</li> <li>ii) A negative response to initial autotitration but has completed a polysomnography test and met either of the two initial criteria above.</li> </ol> </li> </ol> </li> </ol> <p><i>*If there is a positive response to initial autotitration, subsequent polysomnography is</i></p>

Treatment	Criteria Used
	<p><i>only covered if documentation in the medical records indicates the study is medically necessary.</i></p> <p>The AHI (Apnea-Hypopnea Index) is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of 2 hours of sleep recorded by polysomnography using actual recorded hours of sleep (not projected or extrapolated).</p> <p>Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.</p> <p>Respiratory disturbance index is a term previously used for the measure to determine eligibility for PAP. It used the same parameters as the AHI. The more current term is AHI. Because some coverage requests are received with an RDI, the definition is included to help reviewers.</p>
<p><b>Hypoglossal Nerve Stimulation</b></p> <p><b>Nasal Expiratory Positive Airway Pressure for Obstructive Sleep Apnea</b></p> <p><b>Pillar Implants for Obstructive Sleep Apnea and Snoring</b></p> <p><b>Oral pressure therapy (OPT) for the treatment of obstructive sleep apnea</b></p>	<p>There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.</p>
<p><b>Laser Treatments for Snoring and OSA</b></p>	<p>See the <a href="#">criteria document for all laser treatments for snoring and OSA</a>.</p>
<p><b>Maxillo-mandibular Advancement Surgery for Sleep Apnea</b></p> <p><b>Geniohyoid Advancement Myotomy Combined with Hyoid Re-Suspension</b></p>	<p>Kaiser Permanente has elected to use the Maxillomandibular Osteotomy and Advancement Surgery (A-0248) MCG* for medical necessity determinations.</p> <p><b>If requesting this service, please send the following documentation to support medical necessity:</b></p> <ul style="list-style-type: none"> <li>• For sleep related issues, please send initial sleep study and all follow up notes.</li> <li>• For congenital malformation, submit all cranial facial clinic notes (oral surgeon, ENT, Orthodontist)</li> </ul>
<p><b>Mandibular Advancement Devices for Treatment of Obstructive Sleep Apnea</b></p>	<p>Medical Necessity review is not required for this service.</p>

The MCG Manuals are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

© The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

## Background

Sleep-disordered breathing includes a spectrum of disorders ranging from primary snoring to obstructive sleep apnea (OSA). Obstructive sleep apnea syndrome (OSAS) is defined as an apnea-hypopnea index of more than five events per hour, and often also has mental or physical effects such as excessive daytime sleepiness. Potential health consequences of OSAS are cardiovascular diseases, neuropsychiatric problems, injuries and increased mortality. Obstructive sleep apnea results from a combination of a structurally small upper airway and a loss of upper airway muscle tone.

Patients with primary snoring have an apnea-hypopnea index of fewer than five events per hour and no complaints of daytime sleepiness. Snoring is believed to be caused by loss of tissue integrity of the soft palate. Because tissues lack support, they stretch and collapse as muscles relax during sleep. This results in a narrowed airway and causes the soft palate to vibrate, causing snoring sounds. Primary snoring can be socially disruptive but is not harmful to the health of the patient.

There has been increasing recognition of a continuum of sleep disordered breathing disorders, ranging from simple snoring to obstructive sleep apnea (OSA). OSA refers to recurrent episodes of breathing cessation during sleep due to mechanical blockage of the airway. The diagnosis of OSA requires a minimum of 30 episodes of apnea, each lasting at least 10 seconds, during 6-7 hours of sleep. OSA patients are generally obese and the cardinal symptom is excessive daytime sleepiness. Upper airway resistance syndrome (UARS), a term first used in 1993, is a form of sleep-disordered breathing that is also associated with daytime sleepiness. Patients do not meet diagnostic criteria for OSA and are generally non-obese. Recent investigations suggest that UARS may have different pathophysiology than OSA, for example UARS patients may have increased airway collapsibility and craniofacial abnormalities. Common polysomnographic findings for UARS include apnea-hypopnea index (AHI) <5, minimum oxygen saturation >92%, increase in alpha rhythm and a relative increase in delta sleep (Bao & Guilleminault).

Continuous Positive Airway Pressure (CPAP) is widely used as first-line therapy for UARS, although there is a lack of high-grade evidence supporting its effectiveness. CPAP is also often used as a tool to diagnose UARS by seeing whether patients respond to a trial of CPAP treatment. Other treatment alternatives include oral appliances, septoplasty and radiofrequency reduction of enlarged nasal inferior turbinates. Classic surgical procedures used for OSA are considered by many clinicians to be too aggressive for treatment of UARS (Bao & Guilleminault).

Other methods of treating snoring and OSA include weight loss, nasal continuous positive airway pressure (CPAP), laser-assisted uvula palatoplasty (LAUP), uvulopalatopharyngoplasty (UPPP) and radiofrequency tissue ablation. Disadvantages of the surgical procedures are that they can be painful and are often associated with side effects. Radiofrequency ablation generally requires multiple treatment sessions.

A **CPAP** is defined as a device that provides constant air pressure to keep the airway open and allows patients to breathe unassisted. It is prescribed for patients with obstructive sleep apnea. The immediate clinical effectiveness of CPAP for patients with obstructive sleep apnea is well documented.

There are currently more than 35 different oral appliances on the market for OSA and/or snoring. The most widely used type of oral device is **mandibular advancement devices (MAD)** which act to keep the pharyngeal airspaces open by moving the mandible forward by advancing or downwardly rotating the mandible (Schoem, 2000).

**Hypoglossal nerve stimulation** is a new treatment for obstructive sleep apnea (OSA). It addresses the issue of tongue prolapse into the pharynx which causes airway blockage. Tongue prolapse may be due to decreased neuromuscular activity in the genioglossus muscle, the principal tongue protrusor muscle. Electrical stimulation of the hypoglossus muscle may result in activation of the genioglossus muscle, increasing tongue protrusion and opening the pharynx (Eisele, 1997).

A review article published in 1999 (Loube) mentioned that there is a multicenter clinical trial underway on the feasibility of a hypoglossal nerve stimulator (Inspire system; Medtronic), but that the trial has been slowed due to technical issues. The most recent entry on hypoglossal nerve stimulation on the Medtronic Web site was in 1997.

A **new nasal expiratory positive airway pressure device** (Provent® Sleep Apnea Therapy, Ventus Medical Inc.) has recently been approved by the FDA for the treatment of OSA. The Provent® Sleep Apnea Therapy device is a disposable, nightly-use device that consists of a one-way valve surrounded by a ring of soft foam. The device is placed just inside the nostrils and is held in place with adhesive. It works by limiting the airflow out of the nose during expiration, which increases pressure in the upper airway to keep it open for subsequent inspiration. During inspiration, the patient breaths freely through the nose and/or mouth (Kaiser 2010).

The **Pillar Palatal Implant System** (Restore Medical; St Paul, MN) is a treatment option for snoring and obstructive sleep apnea (OSA). Three implants made of braided polyester filaments are placed in the soft palate to help stiffen the soft palate and increase structural integrity. The implant system also includes a disposable delivery tool that is used for positioning and placement of the implant. Pillar implants are inserted during a single office visit under local anesthesia.

## Evidence and Source Documents

[CPAP](#)

[Hypoglossal Nerve Stimulation](#)

[Nasal Expiratory Positive Airway Pressure Device](#)

[Pillar implants for obstructive sleep apnea and snoring](#)

[Oral pressure therapy \(OPT\) for the treatment of obstructive sleep apnea](#)

[Mandibular Advancement Devices for Treatment of Obstructive Sleep Apnea](#)

[Maxillomandibular Advancement Surgery for Sleep Apnea](#)

## Medical Technology Assessment Committee (MTAC)

### **Positive Airway Pressure Device (CPAP)**

#### BACKGROUND

The criteria set previously used by Kaiser Permanente (from 1/1/92 through 3/96) were a direct adoption of the Medicare criteria. Changes in testing equipment have made it possible to test with greater specificity in a shorter testing period. In addition, many tests are now done using a split study, which uses half the test time for actual testing, and the other to titrate the most beneficial CPAP fit to affect the apnea previously documented. Since most of the Kaiser Permanente coverage contracts include a benefit for coverage of CPAP devices at 50-80% level, the existing criteria were reviewed and modified to allow for shorter testing periods and use of the in-home testing. Throughout 1996 and 1997 with experience in managing sleep anomaly cases, a new patient population has been identified that would benefit from the use of CPAP: the Upper Airway Resistance Syndrome (UARS). Dr. Jim DeMaine requested in April 1998 that the criteria be expanded to allow use of CPAP in such cases. Although there is no clinical evidence of benefit for such treatment, there is significant expert opinion and practice that would support such a change in the criteria. In addition, Kaiser Permanente Northwest has decided to cover CPAP for UARS as long as the patient has durable medical equipment coverage (DME). While the Kaiser Permanente plan criteria were modified in May 1998 to allow inclusion of UARS patients, this is not true for the private Medicare patients seen by Kaiser Permanente providers. It is still important to check coverage before ordering this treatment option so that the patient understands the financial obligation represented by the treatment option selected. A CPAP is defined as a device that provides constant air pressure to keep the airway open and allows patients to breathe unassisted. It is prescribed for patients with obstructive sleep apnea. The immediate clinical effectiveness of CPAP for patients with obstructive sleep apnea is well documented. REFERENCES Fairbanks, David N.F., Fairbanks, David W.: Obstructive Sleep Apnea: Therapeutic Alternatives. American Journal of Otolaryngology. 13: 265-270, 1992. Effective treatment of Obstructive Sleep Apnea is contingent on the establishment of a correct diagnosis and the identification of pathophysiologic conditions affecting the upper airway. CPAP is a forceful stream of air delivered to the collapsible oropharyngeal airway acting as a splint to keep the airway open. Almost all OSA patients can benefit from this treatment except those with obstructed nasal airways. Short-term compliance is 90%. Long-term compliance (2-4 yr.) is 50 - 80%. Over 300 devices are patented as "anti-snore" remedies: chin strap, whip-lash type collar, psychological conditioning devices, custom made orthodontic devices, and the tongue retaining device are examples of a few. Most of these have not been proven efficacious for sleep apnea. Surgical treatments include nasal surgery (often disappointing as a solitary treatment for severe OSA), uvulopalatopharyngoplasty, UPPP (Highly effective, 80-90%, for simple snoring in young patients, but if bulky tongue, receding chin, nasal airway obstruction, or pronounced obesity exists it is less effective a single therapy), mandibulo-maxillary advancement phase 1 and 2 (97% when combined with UPPP and nasal surgery), tongue surgery (limited studies but results are promising), and tracheostomies (most successful treatment but has been almost entirely replaced by CPAP). Watson, Robert K., Thompson, A. Siobhan: Treatment Outcome of Sleep Apnea. CONN Med. 56: 125-129, 1992. 101 patients. Interviewed over 12-24-month period. CPAP most often

treatment used with results of improved daytime alertness (84%). Patients with moderate OSA often had surgery which led to 85% improved daytime sleepiness, and patients with mild OSA were treated with sleep position change and weight loss with 64 - 66% improved daytime alertness. Kryger, Meir: Management of Obstructive Sleep Apnea. Clinics in Chest Medicine 13: 481-492, September 1992 Diagnosis with increased risk of death (chronic respiratory failure or obtundation) the patient should be hospitalized and monitored in ICU. Do Dx Sleep Study ASAP. O2 treatment may result in severe CO2 retention. If severe OSA Dx -- treat with urgent CPAP therapy. Mechanical ventilation recommended for patients with hypercapnea that are difficult to arouse or obtunded. BiPAP is used when all night treatment with CPAP is found to be ineffective. ATS Board of Directors: Indications and Standards for Use of Nasal Continuous Positive Airway Pressure (CPAP) in Sleep Apnea Syndromes. American Journal of Respiratory Critical Care Medicine 150: 1738-1745, 1994 Indications for CPAP: Effective in the treatment of patients with clinically important obstructive sleep apnea/hyponea syndrome. Treatment is indicated when there is documented sleep-related apnea/hyponea and evidence of clinical impairment. CPAP may be effective in the treatment of patients with clinically significant Cheyne Stokes respiration or central apnea with clinical impairment. Limited data to substantiate the later. CPAP is not routinely indicated in individuals with simple snoring that is not associated with pauses in respiration or with clinical impairment. CPAP is a safe, effective for therapy with rare contraindications. Relative contraindications include patients with bullous lung disease and recurrent sinus or ear infections. There are no absolute contraindications. Greater than 5-10 episodes of apnea or hyponea per hour is considered beyond the board limits of normal. Strollo, Patrick J. and Rogers, Robert M.: Obstructive Sleep Apnea. The New England Journal of Medicine 334: 99-104, 1996 Affects 2-4% of middle age adults.

Positive airway pressure, delivered through mask, is the initial treatment of choice in clinically important sleep apnea. The following are conditions associated with the varieties of Sleep Apnea:

Obstructive Sleep Apnea: Cessation of airflow for greater than or equal to 10 seconds despite continued ventilatory effort. 5 or more episodes per hour Usually associated with a decrease of greater than or equal to 4% in oxyhemoglobin saturation. Obstructive sleep hyponea: Decrease of 30-50% in airflow for greater than or equal to 10 seconds 15 or more episodes per hour of sleep May be associated with a decrease of greater than or equal to 4% in oxyhemoglobin saturation. Upper-airway resistance: No significant decrease in airflow (snoring is usual) 15 or more episodes of arousal per hour of sleep No significant decrease in oxyhemoglobin saturation Features Common to all three: Arousal associated with increasing ventilatory effort (as measured by esophageal balloon) Excessive daytime sleepiness Sleep 1996 Nov; 19(9 Suppl):S101-S110, Management of simple snoring, upper airway resistance syndrome, and moderate sleep apnea syndrome. Levy P, Pepin JL, Mayer P, Wuyam B, Veale D; Sleep and Respiration Unit, Grenoble University hospital, France. The spectrum of respiratory sleep disorders has been extended in the last years to include conditions that are less well defined than severe obstructive sleep apnea (OSA). Moderate OSA < snoring, and upper airway resistance syndrome (UARS) represent three clinical questions. Therefore, the therapeutic approach remains unclear. We have tried to define these entities and to review the respective indications and efficacy of pharmacological treatment, weight loss, sleep posture, oral appliances, upper airway surgery, and finally, continuous positive airway pressure (CPAP). From these data, we also aim to define strategies of treatment for moderate OSA, snoring, and UARS. However, these conditions are likely to be particularly appropriate for randomized trials comparing different modalities of treatment that may be the only way to validate these treatment strategies. Sleep 1993 Aug; 16(5):403-408, Significance and treatment of nonapneic snoring. Strollo PJ Jr, Sanders MH, Wilford Hall Medical Center, Lackland Air Force Base, Texas. Snoring has been associated with an increased risk of vascular morbidity and mortality and with the complaint of excessive daytime sleepiness. Much of this risk may be attributable to concomitant sleep apnea or hypopnea. Recent work suggests that in certain individuals, snoring without apnea or hypopnea can lead to sleep disruption. This appears to be due to augmented ventilatory effort in response to an increased "internal" resistive load that results in repetitive arousals from sleep. This condition has been termed the upper airway resistance syndrome (UARS). Identification of load-related arousals in patients with the UARS may require the addition of esophageal pressure monitoring to the diagnostic polysomnogram. Nasal continuous positive airway pressure (CPAP) effectively eliminates snoring, hypopnea and apnea and, therefore, may be useful in treating this form of sleep-disordered breathing. The diagnostic criteria and indications, if any, for chronic treatment of these nonapneic snorers with nasal CPAP as well as long-term compliance remain to be determined.

### **Sleep Apnea: Hypoglossal Nerve Stimulation**

#### **BACKGROUND**

Hypoglossal nerve stimulation is a new treatment for obstructive sleep apnea (OSA). It addresses the issue of tongue prolapse into the pharynx which causes airway blockage. Tongue prolapse may be due to decreased neuromuscular activity in the genioglossus muscle, the principal tongue protrusor muscle. Electrical stimulation of the hypoglossus muscle may result in activation of the genioglossus muscle, increasing tongue protrusion and opening the pharynx (Eisele, 1997). A review article published in 1999 (Loube) mentioned that there is a multicenter clinical trial underway on the feasibility of a hypoglossal nerve stimulator (Inspire system; Medtronic),

but that the trial has been slowed due to technical issues. The most recent entry on hypoglossal nerve stimulation on the Medtronic web site was in 1997.

**08/08/2001: MTAC REVIEW**

**Sleep Apnea: Hypoglossal Nerve Stimulation**

**Evidence Conclusion:** There is insufficient evidence on which to base conclusions about the effect of hypoglossal nerve stimulation on health outcomes associated with obstructive sleep apnea.

**Articles:** The search yielded 113 articles. Most of the articles were on uvulopalatopharyngoplasty or glossectomy. There was one empirical article on hypoglossal nerve stimulation. This was a small case series which included only 5 patients with sleep apnea (also included were 15 patients that were undergoing a surgical procedure involving the neck). Because of the small number of sleep apnea patients and a dearth of clinical outcomes, this study was not reviewed.

The use of hypoglossal nerve stimulation in the treatment of sleep apnea does not meet the Kaiser Permanente *Medical Technology Assessment Criteria*.

**Nasal Expiratory Positive Airway Pressure for Obstructive Sleep Apnea**

**BACKGROUND**

Obstructive sleep apnea (OSA) is a relatively common disorder that is characterized by recurrent episodes of complete (apnea) or partial (hypopnea) upper airway obstruction during sleep, with recurrent arousals and sleep fragmentation. Patients with OSA often experience daytime sleepiness, fatigue, or poor concentration, and have signs of sleep disturbance such as snoring and restlessness. If untreated OSA is associated with an increased risk of hypertension, cardiovascular complications, diabetes, and motor vehicle accidents (Balk 2012). A new nasal expiratory positive airway pressure device (Provent® Sleep Apnea Therapy, Ventus Medical Inc.) has recently been approved by the FDA for the treatment of OSA. The Provent® Sleep Apnea Therapy device is a disposable, nightly-use device that consists of a one-way valve surrounded by a ring of soft foam. The device is placed just inside the nostrils and is held in place with adhesive. It works by limiting the airflow out of the nose during expiration, which increases pressure in the upper airway to keep it open for subsequent inspiration. During inspiration, the patient breaths freely through the nose and/or mouth (Kaiser 2010).

**10/16/2012: MTAC REVIEW**

**Nasal Expiratory Positive Airway Pressure for Obstructive Sleep Apnea**

**Evidence Conclusion:** In 2010, Kaiser reviewed the safety and efficacy of a nasal EPAP device. Based on data from two case-series, Kaiser concluded that there was insufficient evidence to determine whether the device is a medically appropriate treatment for obstructive sleep apnea (Kaiser 2010).

A recent randomized controlled trial (RCT) evaluated the safety and efficacy of a nasal EPAP device compared to a sham device in 250 subjects with newly diagnosed or previously untreated obstructive sleep apnea. Polysomnography was performed on 2 non-consecutive nights (random order: device-on, device-off) at week1 and after 3 months of treatment. Results from this study suggest that after 3 months patients using the EPAP device had significantly greater improvements in Apnea Hypoxia Index (AHI) compared to the sham group. Adherence to treatment was determined by self-report and was approximately 88% in the EPAP group and 92% in the sham group. The most common device related adverse events were: nasal congestion, nasal discomfort, dry mouth, exhalation difficulty, and discomfort with the device. There was no serious device related adverse events. This study had several limitations: power was not assessed, the intent to treat analysis did not include all randomized patients, results are not generalizable to previously treated patients, and the study was funded by the manufacturer (Berry 2011).

**AHI results at week 1 and month 3 (Berry 011)**

	EPAP		Sham		P-value*
	Device-off	Device-on	Device-off	Device-on	
	Median (25 <sup>th</sup> to 75 <sup>th</sup> quartiles)				
Week 1	13.8 (5.3 to 22.6)	5.0† (1.7 to 11.6)	11.1 (4.8 to 21.8)	11.6 (4.0 to 21.0)	<0.001
Month 3	14.4 (5.5 to 21.4)	5.6† (2.1 to 12.5)	10.2 (3.4 to 19.3)	8.3 (4.2 to 20.6)	<0.001

\*P-value (EPAP vs. Sham).

†P<0.001 EPAP device-on vs. EPAP device off.

Conclusion: Results from a RCT that compared the safety and efficacy of a nasal EPAP device compared to a sham device found that after 3 months of use patients using the EPAP device had significantly greater

improvements in Apnea Hypoxia Index (AHI) compared to the sham group. This trial had several limitations. Additionally, the safety and efficacy of this device compared to CPAP is unknown.

**Articles:** The literature search revealed 6 studies (1 randomized controlled trial and 5 observational studies) that evaluated the safety and effectiveness of the EPAP device. Studies were excluded if they had severe methodological limitations, less than 25 subjects, or less than 30 days of follow-up. The following studies were selected for review: Berry RB, Kryger MH, Massie CA. A novel nasal expiratory airway pressure (EPAP) device for the treatment of obstructive sleep apnea: a randomized controlled trial. *Sleep*. 2011;34:497-485. See [Evidence Table](#). Kaiser Permanente. Provent Nasal Resistance Device for obstructive sleep apnea. September 2010. [http://pkc.kp.org/national/cpg/intc/topics/03\\_07\\_112.html](http://pkc.kp.org/national/cpg/intc/topics/03_07_112.html).

The use of nasal expiratory positive airway pressure for obstructive sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## **Pillar Implants for Obstructive Sleep Apnea and Snoring**

### **BACKGROUND**

Sleep-disordered breathing includes a spectrum of disorders ranging from primary snoring to obstructive sleep apnea (OSA). Obstructive sleep apnea syndrome (OSAS) is defined as an apnea-hypopnea index of more than five events per hour, and often also has mental or physical effects such as excessive daytime sleepiness. Potential health consequences of OSAS are cardiovascular diseases, neuropsychiatric problems, injuries and increased mortality. Obstructive sleep apnea results from a combination of a structurally small upper airway and a loss of upper airway muscle tone. Patients with primary snoring have an apnea-hypopnea index of fewer than five events per hour and no complaints of daytime sleepiness. Snoring is believed to be caused by loss of tissue integrity of the soft palate. Because tissues lack support, they stretch and collapse as muscles relax during sleep. This results in a narrowed airway and causes the soft palate to vibrate, causing snoring sounds. Primary snoring can be socially disruptive but is not harmful to the health of the patient. The Pillar Palatal Implant System (Restore Medical; St Paul, MN) is a treatment option for snoring and obstructive sleep apnea (OSA). Three implants made of braided polyester filaments are placed in the soft palate to help stiffen the soft palate and increase structural integrity. The implant system also includes a disposable delivery tool that is used for positioning and placement of the implant. Pillar implants are inserted during a single office visit under local anesthesia. Other methods of treating snoring and OSA include weight loss, nasal continuous positive airway pressure (CPAP), laser-assisted uvula palatoplasty (LAUP), uvulopalatopharyngoplasty (UPPP) and radiofrequency tissue ablation. Disadvantages of the surgical procedures are that they can be painful and are often associated with side effects. Radiofrequency ablation generally requires multiple treatment sessions. The Restore Medical Web site claims that pillar implants are cleared by the FDA for treatment of snoring and OSA. The review request noted that approval could not be confirmed on the FDA Web site.

### **12/05/2005: MTAC REVIEW**

#### **Pillar Implants for Obstructive Sleep Apnea and Snoring**

**Evidence Conclusion:** *Obstructive sleep apnea:* There is no published evidence on the effect of pillar implants on health outcomes for patients with obstructive sleep apnea. *Snoring:* The only published studies on the effectiveness of pillar implants for treating primary snoring were case series. The two studies with the largest sample sizes and longest follow-up periods were reviewed. The authors of the larger study (Kuhnel et al., 2005, n=106) did not clearly list their outcome variables and may have selectively reported positive outcomes. They reported a significant decrease in daytime sleepiness and a reduction in the snoring index after treatment. The smaller study (Maurer et al., 2005, n=40) reported a significant reduction in bed-partner-reported snoring and self-reported daytime sleepiness a year after treatment. There was no significant change when recordings of snoring were evaluated—recordings were available for only half of the patients. No serious adverse effects were reported in either study. The efficacy of the intervention compared to an alternative treatment or no treatment can be evaluated.

**Articles:** *Obstructive sleep apnea:* No empirical studies were identified. The Kaiser review stated “there were no studies published in the Medline literature reporting use of palatal implant in patients with obstructive sleep apnea.” *Snoring:* No randomized controlled trials or non-randomized comparative studies were identified. There were several case series. The two largest case series, which also had the longest follow-up, were critically appraised. The articles were by a similar team of German researchers, but there does not appear to be overlap in the patients included in the two studies. The two articles critically appraised are: Kuhnel TS, Hein G, Hohenhorst W, Maurer JT. Soft palate implants: a new option for treating habitual snoring. *Eur Arch Otorhinolaryngol* 2005; 262: 277-280. See [Evidence Table](#). Maurer JT, Hein G, Verse T. Long-term results of palatal implants for primary snoring. *Otolaryngology-Head and Neck Surgery* 2005; 133: 573-578. See [Evidence Table](#).

The use of Pillar implants in the treatment of obstructive sleep apnea and snoring does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## **Oral pressure therapy (OPT) for the Treatment of Obstructive Sleep Apnea**

### **BACKGROUND**

Obstructive sleep apnea (OSA) is a common medical condition that affects approximately 2-4% of middle-age men and women in the United States. It is characterized by recurrent episodes of partial or complete collapse or obstruction of the upper airways during sleep. This leads to repeated momentary cessation of breathing (apnea) or significant reductions in breathing amplitude (hypopnea) resulting in significant hypoxemia and hypercapnia. The apnea/hypopnea index (AHI) describes the total number of apnea/hypopnea episodes per hour of sleep which is usually <5 in normal individuals. AHI scores of 5-15, 15-30, and >30 categorize patients with sleep apnea as mild, moderate, and severe, respectively. OSA is often associated with loud snoring, increasing respiratory effort, intermittent arterial oxygen desaturation, observed apnea, and disrupted sleep. Other symptoms include excessive daytime sleepiness, sleep attacks, and non-restorative sleep. OSA is a serious disorder that may significantly increase morbidity and mortality. Its potential health consequences include hypertension, arrhythmia, cerebrovascular disease, neuropsychiatric problems. It may also be associated with motor vehicle accidents, as well as social and work-related problems (Farid-Moayer 2013, van Zeller 2013, Badran 2014, Jordan 2014, Ward 2014). Conservative treatments for OSA include weight loss, modification of the patient's sleep position, medications to relieve nasal obstruction, as well as avoidance of evening alcohol, sleep medications, and sedatives. For those who fail these measures, night-time continuous positive airway pressure (CPAP) via nasal or face mask is the recommended standard and effective treatment for OSA. This positive airway ventilation stabilizes the whole upper airway reduces the AHI, normalizes the oxyhemoglobin saturation, and reduces the cortical arousals associated with the apnea/hypopnea events. However, CPAP is not well tolerated by patients, is contraindicated in claustrophobic patients, and may be associated by a number of side effects. It was reported that up to 30% of OSA patients refuse CPAP treatment, and only 50% of those who accept it can tolerate its long-term use. When adherence is defined as more than 4 hours nightly use, 46-83% of patients have reported to be non-adherent (Sawyer 2011, Zeller 2013, Jordan 2014). Alternative therapies for cases who cannot tolerate or do not respond to CPAP therapy, include the use of oral and nasal appliances, surgical procedures, laser treatment, or tracheotomy when all other treatments fail. Despite the range therapeutic options available for managing OSA, there is no treatment that is both completely effective and fully tolerated by all patient (Farid-Moayer 2013, Colrain 2013). Oral pressure therapy (OPT) is a new concept for relieving airway obstruction to treat OSA. It is a novel noninvasive treatment modality that applies vacuum in the mouth to stabilize upper airway tissue in patients with OSA. The commercially available OPT system is composed of three components: an oral interface, a bedside console containing a pump, and tubing set. The oral interface is a mouthpiece that incorporates a lip seal and a connector. The pump applies continuous negative pressure to the oral interface and consists of a vacuum pump, a controller, and pressure measurement component. The tubing set connects the pump to the oral interface. The negative pressure in the oral cavity is intended to create a pressure gradient to draw the soft palate anteriorly into contact with the tongue to improve the airway flow during sleep. The patient breathes normally through the nose while sleeping, thus nasal patency to allow closed-mouth breathing is required for the use of that device (Colrain 2013, Farid-Moayer 2013). The Attune Sleep Apnea System and the Winx Sleep Therapy System (that has an additional data management software application) were approved by US Food and Drug Administration in 2012 for home use in the treatment of obstructive sleep apnea (OSA) in adults.

### **06/16/2014: MTAC REVIEW**

#### **Oral pressure therapy (OPT) for the Treatment of Obstructive Sleep Apnea**

**Evidence Conclusion:** The published studies on the oral pressure therapy for obstructive sleep apnea were conducted by the same group of investigators who had financial ties to ApniCure the manufacturer of the device, which also funded the studies. These were only observational studies where the patients acted as their own controls. The first (Farid-Moayer et al, 2013) was a feasibility study conducted among 71 patients from a single center, and the second (ATLAST study, Colrain et al, 2013) was a larger multicenter study initially, but included only a limited number of patients in the final analysis. The authors of ATLAST described the study as a prospective, randomized, crossover study. However, as they indicated, randomization was for the "first-night order of control versus treatment". The study did not have a control group, and OPT therapy was not compared to CPAP therapy, sham therapy, or any other treatment for OSA. The control subjects were those who underwent their baseline PSG before OPT while the treatment group had their PSG in the first treatment night. After the first night PSG, all participants received OPT for 28 days. The study included highly selected and motivated individuals with OSA, and only 14% of those who signed the consent were included in the analysis cohort. PSG was only performed at 2 nights at baseline and after 28 days of therapy. This does not allow for excluding the effect of the night to night variations in PSG or evaluating the long-term efficacy safety, or tolerability of the OPT. Conclusion:

There is insufficient published evidence to date to determine the safety, efficacy, long term effect, tolerability and compliance with the oral pressure therapy for the treatment of obstructive sleep apnea.

**Articles:** The literature search for studies on oral pressure therapy for the treatment of obstructive sleep study revealed two publications for a feasibility study, and a larger observational study. All were conducted by the same group of authors. The two published feasibility studies were conducted by the same group of investigators in the same center, with similar inclusion/exclusion criteria and patient characteristics, which makes it hard to determine if there is patient overlap between the studies. The authors indicate that in one study the mouthpiece was individually customized to the subjects, while it was only selected from 10 available fits in the other. The first feasibility study and the multicenter study were critically appraised. Colrain IM, Black J, Siegel LC, Bogan RK, A multicenter evaluation of oral pressure therapy for the treatment of obstructive sleep apnea. *Sleep Med*. 2013;14:830-837. [See Evidence Table](#). Farid-Moayer M, Siegel LC, Black J. A feasibility evaluation of oral pressure therapy for the treatment of obstructive sleep apnea. *Ther Adv Respir Dis*. 2013;7:3-12. [See Evidence Table](#).

The use of Oral pressure therapy (OPT) for the treatment of obstructive sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

### **Mandibular Advancement Devices for Treatment of Obstructive Sleep Apnea**

#### **BACKGROUND**

There has been increasing recognition of a continuum of sleep disordered breathing disorders, ranging from simple snoring to obstructive sleep apnea (OSA). OSA refers to recurrent episodes of breathing cessation during sleep due to mechanical blockage of the airway. The diagnosis of OSA requires a minimum of 30 episodes of apnea, each lasting at least 10 seconds, during 6-7 hours of sleep. OSA patients are generally obese and the cardinal symptom is excessive daytime sleepiness. Upper airway resistance syndrome (UARS), a term first used in 1993, is a form of sleep-disordered breathing that is also associated with daytime sleepiness. Patients do not meet diagnostic criteria for OSA, and are generally non-obese. Recent investigations suggest that UARS may have different pathophysiology than OSA, for example UARS patients may have increased airway collapsibility and craniofacial abnormalities. Common polysomnographic findings for UARS include Apnea-hypopnea index (AHI) <5, minimum oxygen saturation >92%, increase in alpha rhythm and a relative increase in delta sleep (Bao & Guilleminault). Continuous Positive Airway Pressure (CPAP) is widely used as first-line therapy for UARS although there is a lack of high-grade evidence supporting its effectiveness. CPAP is also often used as a tool to diagnose UARS by seeing whether patients respond to a trial of CPAP treatment. Other treatment alternatives include oral appliances, septoplasty and radiofrequency reduction of enlarged nasal inferior turbinates. Classic surgical procedures used for OSA are considered by many clinicians to be too aggressive for treatment of UARS (Bao & Guilleminault). There are currently more than 35 different oral appliances on the market for OSA and/or snoring. The most widely used type of oral device is mandibular advancement devices (MAD) which act to keep the pharyngeal airspaces open by moving the mandible forward by advancing or downwardly rotating the mandible (Schoem, 2000).

#### **12/13/2000: MTAC REVIEW**

#### **Mandibular Advancement Devices for Treatment of Obstructive Sleep Apnea**

**Evidence Conclusion:** There is insufficient evidence to permit conclusions about the effect of oral appliances on health outcomes. Since there are over 35 OAs, each needs to be considered separately. Only one commercially available oral appliance (Herbst device, Bloch RCT) was evaluated in the recent studies. The Bloch RCT was subject to threats to validity including small sample size, absence of a placebo controlled-group, no washout period between treatments, short intervention period (one week per treatment) and inappropriate p-value cut-off (i.e. did not adjust for multiple comparisons). The other new RCT, Wilhelmsson, used a custom-made oral appliance rather than a commercially available device. There were no long-term data on the effectiveness of any oral device. There were also no long-term data from RCTs on potential adverse effects associated with long-term use of oral devices. A cross-sectional study (Clark) suggests that there may be a high prevalence of adverse effects; this study was not able to measure the severity of complications.

**Articles:** Since the articles reviewed for the previous MTAC evaluation, there were two new RCTs (one was a cross-over trial), one cross-sectional study examining long-term use of an oral appliance and one case series. The randomized cross-over study compared two types of oral appliances and a no-treatment control group. The other RCT compared an oral appliance with uvulopalatopharyngoplasty (UPPP). *Evidence tables were created for two RCTs and the cross-sectional study:* Bloch KE, Jinnong AI, Zhang N, Kaplan V, Stohckli PW, Russi EW. A randomized, controlled crossover trial of two oral appliances for sleep apnea treatment. *Am J Respir Crit Care Med* 2000; 162: 246-51. See [Evidence Table](#). Clark GT, Sohn JW, Hong, CN. Treating obstructive sleep apnea and snoring: Assessment of an anterior mandibular positioning device. *JADA* 2000;131: 765-771. See [Evidence Table](#). Wilhelmsson B, Tegelberg A, Walker-Engstrom ML, Ringqvist M, Andersson L, Krekmanov L, Ringqvist I. A

prospective randomized study of a dental appliance compared with uvulopalatopharyngoplasty in the treatment of obstructive sleep apnea. See [Evidence Table](#).

The use of the Herbst, and Monbloc mandibular advancement devices for the treatment of obstructive sleep apnea meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

**06/06/2005: MTAC REVIEW**

**Mandibular Advancement Devices for Treatment of Obstructive Sleep Apnea**

**Evidence Conclusion:** There was only one empirical study evaluating the safety and efficacy of MAD for UARS, a case series with 32 patients (Yoshida, 2002). The investigators created an oral device for patients diagnosed with UARS. They assessed clinical variables using polysomnography at baseline, and 14-60 days after first use of the device. The investigators found statistically significant improvement in most of the polysomnography outcomes at follow-up, including a significant reduction in daytimes sleepiness according to the Epworth sleepiness scale. The study is limited by the small size and case series design—patients were not blinded and there was no comparison or control group. Improvement could have been due to the natural history of the condition or to a placebo effect. In addition, the performance of the devices may differ from other custom-made or commercially available mandibular advancement devices.

**Articles:** Only one empirical study was identified. This was a case series with 32 patients and was critically appraised: Yoshida K. Oral device therapy for the upper airway resistance syndrome patient. *J Prosthet Dent* 2002; 87: 427-30. See [Evidence Table](#).

The use of the Herbst, and Monbloc mandibular advancement devices for the treatment of upper airway resistance syndrome does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

**Maxillomandibular Advancement Surgery for Sleep Apnea**

**BACKGROUND**

Sleep apnea is characterized by repeated apnea or hypopnea during sleep. Apnea, which is the cessation of airflow for ten or more seconds, could be central or obstructive. If respiratory efforts persist despite cessation of airflow, the apnea is obstructive. Obstructive sleep apnea syndrome (OSAS) is defined by the presence of at least a minimum number of apneas or hypopneas per hour, and the presence of mental or physical effects or both. Potential health consequences of OSAS are cardiovascular diseases, neuropsychiatric problems, injuries, and increased mortality. Obstructive sleep apnea results from a combination of a structurally small upper airway and a loss of upper airway muscle tone. Methods of treating OSA include weight loss, nasal continuous positive airway pressure (CPAP), surgical or laser resection of the uvula, tonsils or soft palate, and tracheostomy when all other treatments fail. Surgical treatment approach varies and the results are affected by age, cause of obstruction, and severity of disease. The best method to of treatment remains controversial. Maxillomandibular advancement (MMA) pulls forward the anterior pharyngeal tissues attached to the maxilla, mandible, and hyoid to increase the posterior airway space. It is a currently accepted treatment for OSAS; however, its indication is unsettled and is often limited to the severe cases where other surgeries have failed.

**08/09/2001: MTAC REVIEW**

**Maxillomandibular Advancement Surgery**

**Evidence Conclusion:** Maxillomandibular advancement (MMA) may be successful, and safe for treating selected patients with OSA. However these series do not provide sufficient evidence to determine the efficacy of MMA in the treatment of obstructive sleep apnea. Case series offer the lowest grade of evidence and have several internal threats to their validity.

**Articles:** The search yielded 113 articles. Most of the articles were on uvulopalatopharyngoplasty or glossectomy. Three articles were found on maxillomandibular advancement (MMA). All three were case series, two small (n=19 and n=21), and a bigger series (n=50). *Critical appraisal was made for the following articles:* Hochban W, Brandenburg. et al. Surgical Treatment of Obstructive Sleep Apnea by Maxillomandibular Advancement. *Sleep* 1994; 17 (7): 624-629 [See Evidence Table](#). Nimkarn Y, Miles PG, Waite PD. Maxillomandibular Advancement Surgery in Obstructive Sleep Apnea Syndrome Patients: Long – Term Surgical Stability. *J Oral Maxillofac Surg* 1995; 53:1414-1418 [See Evidence Table](#). Prinsell JR. Maxillomandibular Advancement Surgery in a Site-Specific Treatment Approach for Obstructive Sleep Apnea in 50 Consecutive Patients. *Chest* 1999; 116: 1519-1529 [See Evidence Table](#).

Date Created	Dates Reviewed	Date Last Revised
04/01/1998	04/06/2010 <sup>MDCRPC</sup> , 02/10/2011 <sup>MDCRPC</sup> , 12/06/2011 <sup>MDCRPC</sup> , 02/07/2012 <sup>MDCRPC</sup> ,	07/01/2014

	10/02/2012 <sup>MDCRPC</sup> , 12/04/2012 <sup>MDCRPC</sup> , 10/01/2013 <sup>MPC</sup> , 07/01/2014 <sup>MPC</sup> , 08/05/2014 <sup>MPC</sup> , 06/02/2015 <sup>MPC</sup> , 04/05/2016 <sup>MPC</sup> , 02/07/2017 <sup>MPC</sup> , 12/05/2017 <sup>MPC</sup> , 11/06/2018 <sup>MPC</sup> , 12/04/2018 <sup>MPC</sup>	
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<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee  
<sup>MPC</sup> Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services
12/05/2017	Adopted KPWA Policy for Mandibular Advancement Surgery for Sleep Apnea for Medicare

## Codes

**PAP Devices: E0470, E0471, E0472, E0601**

**Hypoglossal Nerve Stimulation: 0466T, 0467T, 0648T**

**Nasal Expiratory Positive Airway Pressure: No specific codes**

**Oral Pressure Therapy: No specific codes**

**Pillar Implants: C9727**

**Mandibular Advancement Surgery for Sleep Apnea: 21198, 21199, 21206**

**Geniohyoid Advancement Myotomy – 21120, 21121, 21122, 21123 (21125 and 21127 do not need review)**