KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Treatments of Sleep Apnea (Surgical & Non-Surgical)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (240.4)
Local Coverage Determinations (LCD)	Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718) Oral Appliances for Obstructive Sleep Apnea (L33611) Surgical Treatment of Obstructive Sleep Apnea (OSA) (L34526) Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38312)
Local Coverage Article	Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea - Policy Article (A52467) Oral Appliances for Obstructive Sleep Apnea (A52512) Surgical Treatment of Obstructive Sleep Apnea (OSA) (A56905) Billing and Coding: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (A57949)
Kaiser Permanente Medical Policy	For services that are not covered by the above NCD, LCD, or other coverage guidance, Kaiser Permanente 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. Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Laser Treatments for Snoring & Sleep Apnea***", for medical necessity determinations. Use the Non-Medicare criteria below. Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Uvulopalatopharyngoplasty***", for medical necessity determinations. Use the Non-Medicare criteria below.

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For Non-Medicare Members

Non-Surgical Treatments	Criteria Used
Positive Airway Pressure Devices (PAP Devices)	Has one of the following indications: 1) AHI of 15 events or greater per hour 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. 3) A Sleep Apnea Clinical Score (SACS) greater than 15 and meets all of the following: a) Completed a baseline Stanford Sleepiness Score b) Completed a 3-night auto titration PAP c) Reported one of the following: i) A positive response to initial auto titration* ii) A negative response to initial auto titration but has completed a polysomnography test and met either of the two initial criteria above. **If there is a positive response to initial auto titration, subsequent polysomnography is only covered if documentation in the medical records indicates the study is medically necessary.* 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). 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. 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.
Mandibular Advancement Devices for Treatment of Obstructive Sleep Apnea	Medical Necessity review is not required for this service.
Nasal Expiratory Positive Airway Pressure for Obstructive Sleep Apnea (Included but not limited to the following devices: Provent® Sleep Apnea Therapy, Ventus Medical Inc., Bongo) **Oral Pressure Therapy (OPT) for the treatment of Obstructive Sleep Apnea** (Including but not limited to the following devices: Winx System, iNAP)	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.

Surgical Treatments	Criteria Used
Hypoglossal Nerve Stimulation, Implantable	**Hypoglossal Nerve Stimulation, Implantable** FDA-approved hypoglossal nerve neurostimulation is considered medically

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Surgical Treatments	Criteria Used
	reasonable and necessary for the treatment of moderate to severe obstructive sleep apnea when all of the following criteria are met: 1. Patient is 22 years of age or older; and 2. Body mass index (BMI) is less than 32 kg/m2; and 3. A polysomnography (PSG) is performed within 24 months of first consultation for HGNS implant; and 4. Patient has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); and 5. AHI is 15 to 65 events per hour; and 6. Patient has documentation that demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than 4 hours per night, 5 nights per week or the CPAP has been returned) including shared decision making that the patient was intolerant of CPAP despite consultation with a sleep expert: and 7. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; and 8. No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale). **Limitations** 1. The following are considered not reasonable and necessary and therefore will be denied: 2. Hypoglossal nerve neurostimulation is considered not medically reasonable and necessary for all other indications. 3. Non-FDA-approved hypoglossal nerve neurostimulation is considered not medically reasonable and necessary for the treatment of adult obstructive sleep apnea due to insufficient evidence of being safe and effective. • Hypoglossal nerve neurostimulation is considered not medically reasonable and necessary when any of the following contraindications are present: • Patient with central and mixed apneas that make up more than one-quarter of the total AHI. • Patient with an implantable device could experience unintended interaction with the HGNS implant system. • Neuromuscular disease • Hypoglossal-nerve palsy • Severe restrictive or obstructive pulmonary disease • Moderate-to-severe pulmonary arterial hypertension • Severe valvular heart disease • New York Heart Association class III or IV heart failure • Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months) • Persistent uncontrolled hypertension despite medication use • An active, serious mental illness that reduces the ability to carry out Activities of Daily Living (ADLs) and would interfere with the patient's ability to operate the HNS and report problems to the attending provider. • Coexisting nonrespiratory sleep disorders that would confound functional sleep assessment • Patients who are, or who plan to become pregnant. • Patients who require Magnetic resonance imaging (MRI) with model 3024. • Patients, who require Magnetic resonance imaging (MRI) with model 3028, can undergo MRI on the head and extremities if certain conditions and precautions are met. Please refer to the Manufacturer Guidelines for this model and future models for more information. • Patients who are unable or do not have the necessary assistance to operate the sleep remote.

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Surgical Treatments	Criteria Used
	• Patients with any condition or procedure that has compromised neurological control of the upper airway.
Uvulopalatopharyngoplasty (UPPP)	Kaiser Permanente has elected to use the MCG* Uvulopalatopharyngoplasty (KP-0245) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
Drug-Induced Sleep Endoscopy (DISE) (CPT 42975)	**If being requested for anything besides Sleep apnea or HGNS review is not required.* The Drug-Induced Sleep Endoscopy (DISE) is considered medically reasonable and necessary for the workup of Hypoglossal nerve stimulator in patient with moderate to severe obstructive sleep apnea when all of the following criteria are met: 1. Patient is 22 years of age or older; and 2. Body mass index (BMI) is less than 32 kg/m2; and 3. A polysomnography (PSG) is performed within 24 months of first consultation for HGNS implant; and 4. Patient has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); and 5. AHI is 15 to 65 events per hour; and 6. Patient has documentation that demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than 4 hours per night, 5 nights per week or the CPAP has been returned) including shared decision making that the patient was intolerant of CPAP despite consultation with a sleep expert: and 7. No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale).
Maxillo-mandibular Advancement Surgery for Sleep Apnea **Geniohyoid Advancement Myotomy Combined with Hyoid Re-Suspension**	Kaiser Permanente has elected to use the Maxillomandibular Osteotomy and Advancement Surgery (A-0248) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access. **If requesting this service, please send the following documentation to support medical necessity:** • For sleep related issues, please send initial sleep study and all follow up notes. • For congenital malformation, submit all cranial facial clinic notes (oral surgeon, ENT, Orthodontist)
Laser Treatments for Snoring and Sleep Apnea • Cautery-Assisted Palatal Stiffening Operation (CAPSO) • Laser-Assisted Uvulopalatoplasty (LAUP) • Repose Procedure • Somnoplasty	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe and/or provides better long-term outcomes than current standard services/therapies. These treatments are found to be effective in the treatment of snoring; however, no Kaiser Permanente or Kaiser Permanente Options, Inc. plan covers interventions for the treatment of snoring.
Pillar Implants for	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard

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Surgical Treatments	Criteria Used
Obstructive Sleep Apnea and Snoring	services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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, Kaiser Permanente 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.

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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 protrusion muscle. Electrical stimulation of the hyoglossus muscle my 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
Laser Treatments for Snoring and Sleep Apnea
Uvulopalatopharyngoplasty (UPPP)
Laser Treatments for Snoring and 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

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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. REFRENCES 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), mandibular-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 hypercapnia 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/hypopnea syndrome. Treatment is indicated when there is documented sleep-related apnea/hypopnea 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 hypopnea 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 hypopnea: 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. Sleep1993 Aug; 16(5):403-408, Significance and treatment of non-apneic 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.

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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 non-apneic 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 protrusion muscle. Electrical stimulation of the hyoglossus muscle my 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*.

07/08/2019: MTAC REVIEW
Hypoglossal Nerve Stimulation
Evidence Conclusion:

- Although hypoglossal nerve stimulation surgery with the implantable device Inspire improves AHI, ODI, FOSQ, ESS in patients with moderate-to-severe obstructive sleep apnea (OSA) who failed or intolerant to CPAP, the evidence is insufficient to draw conclusions on its effectiveness and safety.
- Comparative studies with higher quality are warranted.

Articles: PubMed was searched from inception through April 23, 2019 with the following search terms (Hypoglossal OR (upper AND airway)) AND (neurostimulation OR neurostimulator OR stimulation OR stimulator OR inspire)) AND ((obstructive sleep apnea OR sleep apnea) OR (sleep AND apnea)). The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. PubMed search was performed for the comparison between hypoglossal nerve stimulation and uvulopalatopharyngoplasty or mandibular advancement devices or maxillomandibular advancement surgery or preimplantation measures. See Evidence Table.

The use of the Hypoglossal Nerve Stimulation 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

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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 difficultly, 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		
	Device-off	Device-on	Device-off	Device-on	P-value*
	Median (25th to 75th 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 an 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.

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.

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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, Heln 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

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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 stabile 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

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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
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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.

The use of the Maxillomandibular Advancement Surgery does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Laser Treatments for Snoring and Sleep Apnea
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 have 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.

Methods of treating OSA include weight loss, nasal continuous positive airway pressure (CPAP), surgical or laser resection of the uvula, tonsils or soft palate, or tracheostomy when all other treatments fail. Surgical treatment approach varies, and the results are affected by age, cause of obstruction, and severity of the disease. The best method of treatment remains controversial.

08/08/2001: MTAC REVIEW
Cautery-Assisted Palatal Stiffening Operation (CAPSO)
Evidence Conclusion: Only a single small case series is available to evaluate CAPSO for treating obstructive sleep apnea. This represents insufficient evidence to draw conclusions about the effect of CAPSO on health outcomes related to sleep apnea.
Articles: The search yielded 113 articles. Most of the articles were on uvulopalatopharyngoplasty or glossectomy. There were two empirical articles on CAPSO, both were case series. One of the case series (n=25) included patients with obstructive sleep apnea, while the other, report (n=206) included patients who complained of excessive habitual snoring, no attempt was made to diagnose sleep apnea. An evidence table was created for the case series with sleep apnea patients. Wassmuth Z, Mair E, Loube D, Leonard D. Cautery-assisted palatal stiffening operation for the treatment of obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg 2000; 123: 55-60. See Evidence Table.

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The use of cautery-assisted palatal stiffening operation (CAPSO) in the treatment of sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

08/08/2001: MTAC REVIEW
Repose Procedure
Evidence Conclusion: The existing scientific evidence does not permit conclusions about the efficacy of the Repose procedure on health outcomes. The best evidence is a case series of 16 individuals with data available on 14 of these. This report is subject to the limitations of case series (selection and observation bias likely).
Articles: The search yielded 113 articles. Most of the articles were on uvulopalatopharyngoplasty or glossectomy. There were three articles on the Repose procedure, one review/discussion piece and two small case series (n=9 and n=15). Because it was the best available evidence, an evidence table was created for the larger case series. DeRowe A, Gunther E, Fibbi A, Lehtimake K, Valatalo K., Maurer J, Ophir D. Tongue-based suspension with a soft tissue-to-bone anchor for obstructive sleep apnea: Preliminary clinical results of a new minimally invasive technique. Otolaryngol Head Neck Surg 2000; 122: 100-3. See Evidence Table.

The use of repose procedure in the treatment of sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

04/14/1999: MTAC REVIEW
Somnus Somnoplasty System
Evidence Conclusion: Evidence identification was conducted by searching MEDLINE from 1990 to February 1999 using the terms: somnoplasty, sleep apnea and radiofrequency. The Somnus Company was aware of only one published article related to the use of the Somnoplasty system for obstructive sleep apnea. This article (summarized below) reports data from a single case series of 22 patients treated for snoring, daytime sleepiness and mild obstructive sleep apnea. Results from this study show no changes in Respiratory Distress Index (RDI*) following somnoplasty, statistically significant improvements in partner report of snoring and an improvement of 3.3 points (24-point scale) in self-report of sleepiness.
Articles: Powell, NB, et al *Chest,* 1998:113:1163-74. See Evidence Table

The use of the Somnus Somnoplasty System for the treatment of obstructive sleep apnea has been approved by the FDA and therefore meets *Kaiser Permanente Medical Technology Assessment Criteria.*

08/08/2001: MTAC REVIEW
Base of Tongue Somnoplasty in the Treatment of Sleep Apnea
Evidence Conclusion: The evaluated study does not provide sufficient evidence to determine the efficacy of base of tongue somnoplasty, in the treatment of sleep apnea, due to its small sample size, together with the other limitations of case series.
Articles: The search yielded 113 articles. Most of the articles were on uvulopalatopharyngoplasty or glossectomy. There was a pilot study done for base of tongue somnoplasty on humans, and another study made on animals. *The best available article for critical appraisal was the pilot study:* Powell N B, Riley R W, et al. Radiofrequency Tongue Base Reduction in Sleep- Disordered Breathing: A Pilot Study. *Otolaryngol Head Neck Surg* 1999: 120: 656-64. See Evidence Table.

The use of base of tongue somnoplasty in the treatment of sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/05/2005: MTAC REVIEW
Radiofrequency Tissue Ablation (Somnoplasty)
Evidence Conclusion: There is insufficient evidence on single level base of tongue somnoplasty to draw conclusions about the efficacy of the procedure compared to placebo or the standard treatment, CPAP. There were no RCTs on single level somnoplasty. One non-randomized comparative study did not find significant between-group differences on subjective outcomes. There is evidence from one RCT that multilevel (base of tongue and soft palate) does not improve outcomes compared to sham treatment or placebo. The RCT did not identify significant between-group differences in two of three primary outcomes including the objective outcome, slowest reaction time. Findings from case series suggest that there is a relatively low complication rate, at least in institutions with extensive experience with the technology.
Articles: See Evidence Table. Stewart DL, Weaver EM, Woodson BT. Multilevel temperature-controlled radiofrequency for obstructive sleep apnea: Extended follow-up. Otolaryngol Head Neck Surg 2005; 132; 630-

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635. Woodson BT, Nelson L, Mickelson S et al. A multi-institutional study of radiofrequency volumetric tissue reduction for OSAS. Otolaryngol Head Neck Surg 2001; 125: 303-311. See Evidence Table. Kezirian EJ, Powell NB, Riley RW, Hester JE. Incidence of complications in radiofrequency treatment of the upper airway. Laryngoscope 2005; 115: 1298-1304. See Evidence Table. Stuck BA, Starzak K, Verse T et al. Complications of temperature-controlled radiofrequency volumetric tissue reduction for sleep-disordered breathing. Acta Otolaryngol 2003; 123: 532-535. See Evidence Table.

The use of Radiofrequency tissue ablation (somnoplasty) in the treatment of sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

eXciteOSA® for Snoring and Mild Obstructive Sleep Apnea (OSA)
12/2022: MTAT REVIEW
Evidence Conclusion: A Hayes, Inc. evidence review (Dec. 2022) identified three single-arm studies of poor or very poor quality that suggested the intervention may be associated with reduced snoring. Device-related adverse events were typically mild and self-limiting. A key limitation of the identified studies was a maximum follow-up period of six weeks. The INTC consented to no further review of eXciteOSA®. The Hayes report can be referenced to inform KP decision-making on eXciteOSA® at this time. The INTC may review the topic again should more substantial evidence become available. Two ongoing randomized controlled trials (RCTs) are in progress. Written clinical input was not obtained from PMG experts from across the KP program. However, clinical experts within KP have noted they are still exploring the technology at medical professional society meetings in 2023.

Uvulopalatopharyngoplasty (UPPP)

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 have 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.

Methods of treating OSA include weight loss, nasal continuous positive airway pressure (CPAP), surgical or laser resection of the uvula, tonsils or soft palate, or tracheostomy when all other treatments fail. Surgical treatment approach varies, and the results are affected by age, cause of obstruction, and severity of the disease. The best method of treatment remains controversial.

Uvulopalatopharyngoplasty (UPPP) is a surgical procedure used to treat sleep apnea or snoring. It removes excess tissue in the throat in an attempt to widen the airway. The soft tissue removed may include the uvula, tonsils, adenoids, tongue or roof of the month. It takes 2 to 3 weeks to recover from the surgery.

1997 Literature Search
Articles: Based on the literature below there is limited evidence of the value of LAUP or UPPP in the treatment of OSAS (Obstructive Sleep Apnea Syndrome). While there is strong evidence supporting the value of CPAP in the treatment of OSAS, compliance in the use of the CPAP device remains a problem. Anand-V-K, Ferguson-P-W, Schoen-I-S, Obstructive sleep apnea: comparison of continuous positive airway pressure and surgical treatment, Otolaryngology-Head-Neck Surgery. Sept: 105(3) 382-90. Retrospective review, 400 cases of patients diagnosed with OSA (Obstructive Sleep Apnea). A comparative analysis with polysomnography revealed superior cures with CPAP, although long term compliance remains problematic. Conclusion was use of CPAP as initial therapy in- patients with no clinically apparent causes for obstruction: nasal polyps, deviated nasal septum, or obstructive tonsillar hypertrophy. Mickelson, SA., Laser-Assisted Uvulopalatoplasty for Obstructive Sleep Apnea, Laryngoscope: 106(I Pt 1): 10-3, 1996 Jan. Study Size 34, Consecutive prospective patients; Improved RDI by at least 50% in 53.8% of the study group. Snoring was reduced by 92.3%. Conclusion: Results suggest that LAUP MAY be efficacious in management of OSAS. Vaidya AM. Petruzzelli GJ., McGee D., Gopalsami C., Identifying obstructive sleep apnea in patients presenting for laser-assisted uvulopalatoplasty, Laryngoscope: 106(4): 431-7 1996 Apr. 850 patients with snoring evaluated. While body mass index, falling asleep while driving, snoring every night, and stopping breathing during sleep were found to correlate strongly with increasing RDI (Respiratory Disease Index), it was strongly recommended that a

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referral for PSG (polysomnography Study) be initiated if there is any suspicion of OSAS. Walker RP. Grigg-Damberger MM. Gopalsami C, Totten MC., Laser-assisted uvulopalatoplasty for snoring and obstructive sleep apnea: results in 170 patients, Laryngoscope. 105(9 Pt 1): 938-43, 1995 Sept July 1993 - December 1994, 541 consecutive patients referred for treatment of snoring. 274 had LAUP treatments. As of January 1995 LAUP, treatment courses were completed for 170 patients.105 had diagnosis of snoring and 65 had diagnosis of OSAS based on preoperative polysomnography. Of the 65 OSAS patients 16 cases achieved success as measured on post-op polysomnography. Conclusion: LAUP may be a viable surgical option for patients with snoring and mild sleep apnea. Schecthtman KB. Sher AE., Piccirillo JF., Methodological and statistical problems in sleep apnea research: the literature on Uvulopalatopharyngoplasty. Sleep 18(8): 659-66 1995 Oct. A comprehensive review of the literature on surgical treatment of sleep apnea found 37 appropriate papers (total n = 992) on UPPP. Problems identified: 1) There were no randomized studies and few (n=4) with control groups. 2) Median sample size was only 21.5; thus statistical power was low and clinically important associations were routinely classified as "not statistically significant". 3) Only one paper presented the confidence bounds that might distinguish between statistical and clinical significance. 4) Because of short follow-up times and infrequent repeat follow-ups, little is known about whether UPPP results deteriorate in time. 5) In at least 15 papers, bias caused by retrospective designs and nonrandom loss to follow-upraised questions about generalizability of results. 6) Few papers associated polysomnography data with patient-based quality of life measures. 7) Missing data and inconsistent definitions were common. 8) Baseline measures were often biased because the same assessment was inappropriately but routinely used for both screening and baseline. LU SJ. Chang SY., Shiao GM., Comparison between short-term and log-term post-operative evaluation of sleep apnea after Uvulopalatopharyngoplasty. Journal of Laryngology & Otology. 109(4): 308-12 1995 Apr.
Sample 15 OSAS patients who had UPPP with pre-operative, initial post-operative and long-term post-operative polysomnography studies (more than 5 years after surgery). The subjective improvement after operation is not adequately correlated to the PSG results. Suggestion that long- term follow-up for patients after UPPP is necessary. 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.

Applicable Codes

PAP Devices –
Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
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)
E0601	Continuous positive airway pressure (CPAP) device
D9947	Custom sleep apnea appliance fabrication and placement
D9948	Adjustment of custom sleep apnea appliance
D9949	Repair of custom sleep apnea appliance

Geniohyoid Advancement Myotomy –
Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)

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21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (eg, wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
Does not require medical review	
21125	Augmentation, mandibular body or angle; prosthetic material
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)

Maxillo-mandibular Advancement Surgery for Sleep Apnea-
Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
21198	Osteotomy, mandible, segmental;
21199	Osteotomy, mandible, segmental; with genioglossus advancement
21206	Osteotomy, maxilla, segmental (eg, Wassmund or Schuchard)

Hypoglossal Nerve Stimulation-

Medicare – Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare- Considered medically necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
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
42975	Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic

Nasal Expiratory Positive Airway Pressure- Considered not medically necessary

CPT® or HCPC Codes	Description
No specific codes	

Pillar Implants- Considered not medically necessary

CPT® or HCPC Codes	Description
C9727	Insertion of implants into the soft palate; minimum of three implants

Oral Pressure Therapy- Considered not medically necessary

CPT® or HCPC Codes	Description
No specific codes	

Mandibular Advancement Devices for Treatment of Obstructive Sleep Apnea-
Medicare – Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Medical review no longer required

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

Uvulopalatopharyngoplasty-
Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
42145	Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)

Laser Treatments of Snoring-
Considered not medically necessary-
Repose

CPT® or HCPC Codes	Description
41512	Tongue base suspension, permanent suture technique

Somnoplasty

CPT® or HCPC Codes	Description
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session

LAUP

CPT® or HCPC Codes	Description
42160	Destruction of lesion, palate or uvula (thermal, cryo or chemical)
42890	Limited pharyngectomy
S2080	Laser-assisted uvulopalatoplasty (LAUP)

CAPSO

CPT® or HCPC Codes	Description
42950	Pharyngoplasty (plastic or reconstructive operation on pharynx)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Dates Reviewed	Date Last Revised
04/01/1998	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 02/07/2012[MDCRPC], 10/02/2012[MDCRPC], 12/04/2012[MDCRPC],10/01/2013[MPC], 07/01/2014[MPC], 08/05/2014[MPC], 06/02/2015[MPC], 04/05/2016[MPC], 02/07/2017[MPC], 12/05/2017[MPC], 11/06/2018[MPC], 12/04/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC], 11/07/2023[MPC], 08/06/2024[MPC]	01/09/2024

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

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Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services
12/05/2017	Adopted Kaiser Permanente Policy for Mandibular Advancement Surgery for Sleep Apnea for Medicare
08/06/2019	Added MTAC review for Hypoglossal Nerve Stimulation
10/30/2019	Merged Laser Treatments for Snoring and Sleep Apnea criteria
01/07/2020	MPC approved to retain policy of non-coverage for Hypoglossal Nerve Stimulation in accordance with MTAC recommendation
09/09/2020	Added Medicare LCD L38312 and LCA A57949
10/06/2020	MPC approved to adopt MCG A-0973, Hypoglossal Nerve Stimulation.
09/08/2022	Removed deleted codes 0466T, 0467T and 0468T; Added new codes 64582, 64583, 64584 and 42975 under Hypoglossal Nerve Stimulation section.
10/26/2022	Updated applicable codes, including new codes released 01/01/22 and 04/01/22.
11/11/2022	Updated Medicare Links
11/20/2023	Added MTAT Review for eXciteOSA® for Snoring and Mild Obstructive Sleep Apnea (OSA)
12/27/2023	Merged Laser Treatments for Snoring and Uvulopalatopharyngoplasty (UPPP) criteria to *Obstructive Sleep Apnea- Surgical and Non-Surgical*
01/09/2024	MPC approved medical necessity criteria for hypoglossal nerve stimulation and DISE procedure. Requires 60-day notice, effective date June 1st, 2024.

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