



Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Laser Treatments for Snoring and Sleep Apnea

- Cautery-Assisted Palatal Stiffening Operation (CAPSO)
- Laser-Assisted Uvulopalatoplasty (LAUP)
- Repose Procedure
- Somnoplasty

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	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.

For Non-Medicare Members

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.

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 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.

Evidence and Source Documents

[Sleep Apnea – Cautery-Assisted Palatal Stiffening Operation \(CAPSO\)](#)

[Sleep Apnea – Repose Procedure](#)

[Somnoplasty for Treating Obstructive Sleep Apnea](#)

Medical Technology Assessment Committee (MTAC)

Sleep Apnea – Cautery-Assisted Palatal Stiffening Operation (CAPSO)

BACKGROUND

Obstructive sleep apnea has been treated with uvulopalatopharyngoplasty (UPPP), a surgical procedure on the soft palate using a scalpel. Cautery-assisted palatal stiffening operation (CAPSO) is a procedure that was first used to treat palatal snoring and is proposed as a new treatment for obstructive sleep apnea. With CAPSO, a midline strip of soft palate mucosa is removed, and the wound is allowed to heal by secondary intention. This procedure stiffens the flaccid palate and causes a cessation of palatal snoring (Wassmuth, 2000). Other possible alternatives to UPPP are laser-assisted uvulopalatoplasty (LAUP) and somnoplasty (which uses radiofrequency energy). Possible advantages of CAPSO, LAUP and somnoplasty compared to UPPP are that it is performed under local anesthetic and can be done as an outpatient procedure (Laube, 1999).

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](#).

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*.

Sleep Apnea: Repose Procedure

BACKGROUND

The Repose system is one of several new treatments of obstructive sleep apnea (OSA). The Repose is a disposable surgical kit manufactured by Influence Medical Technologies, San Francisco. The kit contains: 1) a self-tapping screw with pre-attached double polypropylene No. 1 sutures; 2) a battery-operated screwdriver and; 3) a suture passer that aids passage of the suture through the tongue. The Repose procedure consists of anchoring the bone to soft-tissue to stabilize the base of the tongue (deRowe et al., 2000).

The Repose system is used under general anesthesia. A screw with pre-attached sutures is inserted at the base of the mandible. The sutures are passed through the tongue base; the two ends are tied together below the tongue mucosa and placed in the mouth floor that supports the tongue base. Tightness of the suspension is determined digitally.

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*.

Somnoplasty for Treating Obstructive 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. Temperature-controlled radiofrequency tissue ablation (Somnoplasty) may be a less morbid alternative to other invasive surgical procedures. Somnoplasty is performed under local anesthesia in an outpatient setting. The commercially available device made by Gyrus Medical delivers 460 kHz using a radiofrequency generator. Radiofrequency energy is delivered via 22-gauge electrodes with a 10-mm active tip. High frequency alternating current flows into the tissue, creating ionic agitation. This agitation heats the tissue and, when the temperature rises above 47°C, protein coagulation and tissue necrosis take place. The target temperature is between 80°C and 85°C, with a maximum of less than 90°C. The maximum lesion size is two-thirds the diameter of the radiofrequency electrode, or approximately 7mm. During the three weeks following the procedure, there is inflammation, fibrosis and tissue volume reduction (Troell, 2003). The Gyrus Somnoplasty system was cleared by the FDA in 1998 for treating obstructive sleep apnea. Single-level radiofrequency ablation refers to creation of lesions in one area only (base of tongue, soft palate or turbinates). Multi-level radiofrequency ablation refers to its use in more than one area.

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: *Efficacy of Multi-Level Base of Tongue and Soft Palate Procedure:* The best evidence is from a randomized controlled trial comparing radiofrequency ablation of the tongue and soft palate to CPAP and sham ablation (Woodson et al., 2003; Stewart et al., 2005). The three primary outcomes were slowest reaction time (SRT) and two quality of life (QOL) variables. There were no significant differences in the change in SRT in the radiofrequency ablation versus the placebo group, the CPAP group versus the placebo group or the radiofrequency ablation group vs. CPAP group. One of the two QOL variables improved significantly in the radiofrequency ablation group compared to placebo, but there was not a significant difference in QOL change in

the radiofrequency ablation group versus the CPAP group. Among patients in the radiofrequency ablation group, those who had long-term follow-up had significant improvement in SRT, but not QOL compared to baseline. The 2005 publication did not report long-term findings for the CPAP or placebo groups.

Efficacy of Single-Level Base of Tongue Procedure: There were no randomized controlled trials. The best evidence is from a prospective non-randomized study comparing a group of patients who received base of tongue Somnoplasty and peri-operative use of CPAP to a group of patients receiving CPAP only (Woodson et al., 2001). There were no significant between-group differences in the change in subjective self-report outcomes (e.g. sleepiness, SF-36). Objective outcomes were only reported for the radiofrequency ablation group. In the group of 73 patients receiving radiofrequency ablation, the apnea-hypopnea index decreased significantly pre- to post-treatment. This study is subject to selection bias since patients were not randomized to treatment group; there was no between-group comparison for the objective outcomes. **Complications: Single and Multi-level:** Two single-center case series were reviewed; one included 136 patients and was conducted at Stanford University (Kerzirian et al., 2005) and the other included 322 patients and was conducted in Mannheim, Germany (Stuck et al., 2003). Both studies found relatively low complications rates. The Kerzirian study did not identify any moderate or severe complications. The Stuck study found four moderate severity complications and one severe complication. Both of the studies included a combination of patients who received single-level and multi-level radiofrequency ablation, and both included patients who received treatment of the turbinates, as well as those with base of tongue or palate procedures. A limitation of both studies was that they were conducted at centers with extensive experience in somnoplasty and findings may not be generalizable to other institutions. **Overall Conclusions:** 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: One randomized controlled trial was identified in the literature search, a comparison of multilevel radiofrequency ablation, sham treatment, and CPAP. There were two publications on the RCT, initial outcomes (Woodson et al., 2003) and long-term follow-up of the active treatment group (Stewart et al., 2005). Both articles were critically appraised in the same evidence table. One other comparative study was identified and critically appraised. This was a non-randomized comparison of a patients receiving single-level base of tongue Somnoplasty and CPAP (Woodson et al., 2001). Several small case series (n<25) on the efficacy of Somnoplasty were identified, but not reviewed further. Two relatively large case series (n>100) on complications of Somnoplasty were identified; both were critically appraised (Kerzirian et al., 2005; Stuck et al., 2003). *The articles critically appraised were:* Woodson BT, Steward DL, Weaver EM et al. A randomized trial of temperature-controlled radiofrequency, continuous positive airway pressure, and placebo for obstructive sleep apnea syndrome. *Otolaryngol Head Neck Surg* 2003; 128: 848-861. 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: 630-635. 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](#). Kerzirian 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*.

Applicable Codes

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](#).

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03/1999	05/04/2010 ^{MDCRPC} , 03/01/2011 ^{MDCRPC} , 05/03/2011 ^{MDCRPC} , 08/2/2011 ^{MDCRPC} , 03/6/2012 ^{MDCRPC} , 06/5/2012 ^{MDCRPC} , 01/08/2013 ^{MDCRPC} , 11/05/2013 ^{MDCRPC} , 09/02/2014 ^{MPC} , 07/07/2015 ^{MPC} , 05/03/2016 ^{MPC} , 03/07/2017 ^{MPC} , 01/09/2018 ^{MPC} , 12/01/2020 ^{MPC} , 12/07/2021 ^{MPC} , 12/06/2022 ^{MPC}	06/08/2009

^{MDCRPC} Medical Director Clinical Review and Policy Committee

^{MPC} Medical Director Clinical Review and Policy Committee

Revision History	Description
01/09/2018	Adopted Kaiser Permanente criteria for MA members