Medical Policy
Radiofrequency Tissue Volume Reduction
For Obstructive Sleep Apnea

Effective Date: February, 2008;
Revised [2/10; 1/12; 1/14]

Subject: Radiofrequency Tissue Volume Reduction for Obstructive Sleep Apnea

Overview: Radiofrequency tissue volume reduction (RFTVR) involves radiofrequency ablation (RFA) of tissue from the palate, uvula, and/or tongue base. Compared with other surgical methods for treatment of OSA, RFTVR causes less postoperative pain and can usually be performed as an outpatient procedure under local anesthesia.

Policy and Coverage Criteria:

Harvard Pilgrim Health Care does NOT cover radiofrequency tissue volume reduction for obstructive sleep apnea (OSA) as the procedure is considered investigational and unproven due to insufficient evidence of its efficacy and safety in current literature.

Exclusions: N/A

Supporting Information:

1. Technology Assessment: Radiofrequency volumetric tissue reduction (e.g., Coblation, Somnoplasty) is a procedure used to remove redundant tissue in the upper airway. Radiofrequency ablation of the soft palate aims to reduce the volume of the palatal tissue and to improve the texture of the remaining palate, so that it becomes more dynamically stable. The procedure is usually done on an outpatient basis using topical local anesthesia. An electrode delivery device is used to direct radiofrequency energy, commonly to the mid-portion of the palate from the uvular base to the posterior nasal spine. In addition, two lateral applications are often given at a reduced energy level.

2. Literature Review:

Radiofrequency ablation (RF) may be used to reduce and tighten excess tissues of the soft palate, uvula and tongue base (Somnoplasty) or nasal passages and soft palate (Coblation or Coblation channeling). Current literature does not support their efficacy for OSA. Studies are non-randomized, contain small, highly selected patient populations, and do not report long-term outcomes.

The most recent practice parameter for surgical treatment of OSA from the American Academy of Sleep Medicine (Aurora, 2010) notes, “RFA can be considered as a treatment in patients with mild to moderate obstructive sleep apnea who cannot tolerate or who are unwilling to adhere to positive airway pressure therapy, or in whom oral appliances have been considered and found ineffective or undesirable.” However, the article goes on to say the recommendation is based on very low quality evidence and that long term sequelae are not published.

Fibbi et al. (2009) compared and evaluated long term results of 24 patients with mild OSA who were treated with either lingual suspension or radiofrequency volume reduction. All patients had an apnea-hypopnea index between 10 and 20 and were assessed by the Epworth Sleepiness Scale, collection of anthropomorphic data, fiber-optic evaluation with Muller’s maneuver, cephalometric assessment, and polysomnography. Results were assessed at 6 and 24 months. At 6 months, success was found in 67% of lingual suspension patients and 75% of the RF patients. At 24 months the success rates dropped to 42% and 33%, respectively. The authors noted the effectiveness of both procedures drops after two years, but the RF procedure can be repeated over time.

Ceylan et al. (2009) presented results of a prospective nonrandomized clinical study comparing the effects of single-stage, multilevel, temperature-controlled radiofrequency tissue volume reduction to nasal CPAP. Data from
47 patients were reviewed. 26 patients underwent temperature-controlled RFTVR and 21 underwent CPAP. Baseline and 12-month post-treatment measurements were taken using the Epworth Sleepiness Scale and polysomnography. Results were not significant between the two treatment groups. Success rates were 52.4% for nasal CPAP and 53.8% for temperature-controlled RFTVR. These results led the researchers to conclude temp-controlled RFTVR to be a good alternative in primary treatment of mild to moderate OSA.

A 2004 report by Stuck et al. evaluated 20 patients with OSA and combined palatal and retrolingual obstruction treated with combined temperature-controlled RF volumetric reduction of the tongue base and soft palate. Functional parameters, daytime sleepiness, and quality of life were assessed using questionnaires before and at 12 weeks following the treatments. Polysomnography was also performed on two consecutive nights. Results showed no changes in functional parameters and a significant improvement in daytime sleepiness. 6 out of 18 patients were cured after a mean of 2.7 treatments. Based on the results of the 12 week follow-up the authors found the procedure to be a safe and effective treatment for OSA.

Woodson, et al. (2003) reported on the results of radiofrequency ablation of the turbinates and soft palate in patients with mild to moderate obstructive sleep apnea (AHI of 10 to 30 on screening sleep study). Ninety subjects were randomly assigned to radiofrequency ablation, CPAP, or sham-placebo. Subjects assigned to RF had a moderate decrease in AHI but the results were not significant. Compared with sham-placebo, RF patients reported statistically significant improvements in quality of life, airway volume, apnea index and respiratory arousal index. A number of subjects were lost to follow up, and data were incomplete on a quarter of study subjects.

Staid and Strome (2003) conducted a retrospective review of 39 patients that received RFVTR of the soft palate for snoring. Telephone interviews were used to collect long-term follow-up info on efficacy and sequelae. Average follow-up time was 14 months. All measures were self-reported. Snoring scores decreased an average of 52%. 67% of patients reported they were satisfied. No significant complications or long-term sequelae were reported. Based on these results the authors felt that RFVTR of the palate is a relatively safe and effective long-term treatment for snoring.

There is no enough evidence in the clinical literature to support the long-term safety and efficacy of this procedure for the treatment of OSA.

3. Benchmarks:

BCBS MA: The following minimally-invasive surgical procedures are investigational for the sole or adjunctive treatment of obstructive sleep apnea (OSA) or upper airway resistance syndrome (UARS):

- Radiofrequency volumetric tissue reduction of the tongue, with or without radiofrequency reduction of the palatal tissues, AND
- Laser-assisted palatoplasty (LAUP) or radiofrequency volumetric tissue reduction of the palatal tissues, AND
- Palatal stiffening procedures including, but not limited to, cautery-assisted palatal stiffening operation, injection of a sclerosing agent, and the implantation of palatal implants,
- Tongue base suspension, AND
- All other minimally-invasive surgical procedures not described above.

All interventions, including LAUP, radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures, for the treatment of snoring in the absence of documented OSAS, are NOT MEDICALLY NECESSARY. Snoring alone is not considered a medical condition.


Anthem BCBS NH: Other surgical treatments for OSA are considered investigational and not medically necessary including, but not limited to, the following:

- Cautery-assisted Palatal Stiffening Operation (CAPSO);
- Laser-Assisted Uvulopalatoplasty (LAUP);
- Radiofrequency Volumetric Tissue Reduction (RFVTR) of the soft palate and/or the base of the tongue including Somnoplasty® and Coblation®;
- Nasal surgery; (See SURG.00074 Nasal Surgery for the Treatment of Obstructive Sleep Apnea (OSA) and Snoring for further information.)
• Transpalatal advancement pharyngoplasty;
• The Repose® System (bone-anchored tongue base suspension system by permanent suture technique).

http://www.anthem.com/medicalpolicies/policies/mp_pw_a050503.htm

United HealthCare: Radiofrequency ablation of the soft palate and/or tongue base (e.g., Coblation® or Somnoplasty™) is proven for treating mild to moderate obstructive sleep apnea as Related documented by polysomnography (performed with Type 1 or Type 2 devices) or limited channel testing (performed with Type 3 devices or Type 4 devices with a minimum of 3 channels including heart rate, oxygen saturation and respiratory analysis).


CIGNA: CIGNA does not cover any of the following procedures or services for the treatment of OSA because they are considered experimental, investigational or unproven:
• laser-assisted uvulopalatoplasty (LAUP)
• cautery-assisted palatal stiffening operation (CAPSO)
• Pillar™ Palatal Implant System
• radiofrequency volumetric tissue reduction (RFVTR) of the soft palate, uvula, or tongue base (e.g., Coblation®, Somnoplasty®)
• tongue-base suspension using the Repose™ Bone Screw System
• Provent™ Professional Sleep Apnea Therapy Device
• electrosleep therapy
• injection Snoreplasty
• atrial overdrive pacing

http://www.cigna.com/assets/docs/health-care-professionals/coverage_positions/mm_0158_coveragepositioncriteria_obstructive_sleep_apnea_diag_trtment_svc.pdf

Aetna: Aetna considers radiofrequency ablation of the tongue base, uvula or soft palate (Somnoplasty) or of the nasal passages and soft palate (Coblation) experimental and investigational as a treatment for OSA because there is inadequate scientific evidence to validate the effectiveness of these procedures for this indication.

http://www.aetna.com/cpb/medical/data/1_99/0004.html

4. Professional/Governmental Agencies:

American Society Sleep Medicine: Practice Parameter for Surgery of OSA in Adults – “Radiofrequency ablation (RFA): RFA can be considered as a treatment in patients with mild to moderate obstructive sleep apnea who cannot tolerate or who are unwilling to adhere to positive airway pressure therapy, or in whom oral appliances have been considered and found ineffective or undesirable.”

http://www.aasmnet.org/Resources/PracticeParameters/PP_SurgicalModificationsOSA.pdf

CMS – No NCD

Codes:
CPT Codes:
41530 – Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session

References: