

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: TREATMENT OF SLEEP APNEA IN ADULTS

(DRAFT as referred to HERC by HTAS on 4/22/2013, showing recommendations by VbBS)

HERC COVERAGE GUIDANCE

Coverage of treatment for Obstructive Sleep Apnea (OSA) in adults should be limited, as follows:

CPAP should be covered initially when all of the following conditions are met:

- 12 week 'trial' period to determine benefit. This period is covered if apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour, or if between 5 and 14 events with additional symptoms including excessive daytime sleepiness (Epworth Sleepiness Scale score > 10), or documented hypertension, ischemic heart disease, or history of stroke;
- Providers must provide education to patients and caregivers prior to use of CPAP machine to ensure proper use; and
- Positive diagnosis through polysomnogram (PSG) or Home Sleep Test (HST).

CPAP coverage subsequent to the initial 12 weeks should be based on documented patient tolerance, compliance, and clinical benefit. Compliance (adherence to therapy) is defined as use of CPAP for at least four hours per night on 70% of the nights during a consecutive 30 day period.

Coverage of mandibular advancement devices (oral appliances) should be provided.

Intensive weight loss programs (if provided in the benefit package) should be covered for patients with obesity and obstructive sleep apnea.

Surgery for sleep apnea for adults is only covered after a diagnosis of sleep apnea has been made, and there is documented failure or intolerance of both CPAP and an oral appliance (or other non-invasive treatment), and patients have been informed of the benefits and risks of surgery.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCE

Gleitsmann, K., Kriz, H., Thielke, A., Bunker, K., Ryan, K., Lorish, K., & King, V. (2012). *Sleep apnea diagnosis and treatment in adults*. Produced for the Washington HTA Program. Olympia, WA: Center for Evidence-based Policy, Oregon Health and Science University for the Washington Health Technology Assessment Program. Retrieved September 13, 2012, from http://www.hta.hca.wa.gov/documents/sleep_apnea_final_report.pdf

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Obstructive sleep apnea (OSA) refers to sleep-disordered breathing due to the recurrent collapse of pharyngeal tissues resulting in snoring, fitful sleep, and daytime somnolence. These episodes are characterized by either reduced airflow (hypopnea), or a complete obstruction (apnea), with a subsequent drop in oxygen saturation, interfering with gas exchange. Obstructive sleep apnea is a cause of significant morbidity and mortality and is associated with hypertension, neuropsychological impairment, motor vehicle accidents, stroke, cardiovascular disease, diabetes, and decreased quality of life. The prevalence of OSA is 2 to 7% in the general adult population. Prevalence increases steadily with age, to approximately 20% among people older than age 60. Risk factors for OSA include male gender, age, obesity, airway characteristics, familial/genetic predisposition, smoking, and alcohol consumption. The majority of

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patients with OSA are asymptomatic, unaware of their sleep disordered breathing and associated health risks.

There have been various modalities developed to treat OSA, most attempting to reduce the airway obstructive component. Continuous positive airway pressure (CPAP) is the first-line therapy for OSA and opens the airway with compressed air. However, the CPAP machinery required is poorly tolerated and compliance is a major concern. Various oral appliances, which attempt to splint open the airway, have been used as an alternative to CPAP. Surgical procedures, including various surgeries on the oropharyngeal anatomy to alter airway mechanics, are performed to treat OSA. Bariatric surgery may be performed to reduce the volume of obstructive tissues. Other interventions that have been used to treat OSA include: weight loss regimens; smoking cessation; caffeine and alcohol avoidance; positional therapy; oropharyngeal physical therapy to strengthen the musculature and reduce obstruction; arrhythmia treatment for nocturnal bradycardia; complementary and alternative medicine (e.g., acupuncture), and a variety of pharmacologic agents.

Evidence Review

Continuous Positive Airway Pressure

A moderate strength of evidence was found for the effectiveness of treatment of OSA with CPAP. However, there was insufficient evidence to determine which patients CPAP might benefit the most. The reviewed studies report sufficient evidence supporting large improvements in sleep measures with CPAP compared with control (e.g., reducing apnea hypopnea index (AHI), improving symptoms as measured by the Epworth Sleepiness Scale¹, reducing arousal index, and raising the minimum oxygen saturation). Weak evidence demonstrated no consistent benefit in improving quality of life, neurocognitive measures or other intermediate outcomes. Despite no or weak evidence for an effect of CPAP on clinical outcomes, given the large magnitude of effect on the intermediate outcomes of AHI and Epworth Sleepiness Scale, the strength of evidence that CPAP is an effective treatment to alleviate sleep apnea signs and symptoms was rated moderate. However, the link between AHI reduction and long term clinical outcomes is not directly proven. There was insufficient evidence regarding most comparisons of various different CPAP devices, including nasal vs. oral, bilevel vs. fixed, flexible bilevel vs. fixed and humidified vs. non-humidified. However, there was a low strength of evidence that C-Flex (a proprietary CPAP technology that reduces the pressure slightly at the beginning of exhalation) is not significantly different than fixed CPAP in compliance or other outcomes, and a moderate strength of evidence that autoCPAP and fixed CPAP result in similar compliance and treatment effects.

Other Treatments for Obstructive Sleep Apnea

Mandibular advancement devices (oral appliances) had moderate strength of evidence supporting their use as an effective treatment for OSA. However, as with CPAP, there was insufficient evidence to indicate which patients might benefit from their use. There

¹ A self-administered questionnaire that measures sleep propensity, total score ranges 0-24. Reference range is defined as ≤ 10 , with 1 point change considered clinically significant. Sensitivity 49% and specificity 80% for detecting OSA using an AHI cutoff of 5 events/hour, based on one high quality study. Coverage Guidance: Treatment of Sleep Apnea in Adults

was moderate evidence that the use of CPAP is superior to mandibular advancement devices with regard to improved sleep study measures, but weak evidence that there is minimal difference between the two for improving compliance, treatment response, quality of life or neurocognitive measures. There was insufficient evidence to compare the different oral devices, other than mandibular advancement devices.

Six surgical interventions for the treatment of OSA were reviewed (uvulopalatopharyngoplasty (UPPP), laser-assisted uvulopalatoplasty (LAUP), radiofrequency ablation (RFA), and combinations of pharyngoplasty, tonsillectomy, adenoidectomy, genioglossal advancement septoplasty, radiofrequency ablation of the inferior nasal turbinates, or combination nasal surgery) compared to sham, conservative therapy or no treatment. No surgical interventions were compared to each other. Overall there was insufficient evidence with which to evaluate their efficacy. When each modality was compared to CPAP, the evidence was insufficient to determine their relative merits. No evidence that met inclusion criteria was identified for any other surgical procedures.

Of the other treatments for OSA that were considered, only intensive weight loss programs were an effective treatment in obese patients with OSA with a low strength of evidence. The remainder of the other management modalities (e.g., atrial overdrive pacing, medications, palatal implants, oropharyngeal exercises, tongue-retaining devices with positional alarms either in isolation or in combination, bariatric surgery, acupuncture, and auricular plaster) had insufficient evidence to determine the effects of using them for treatment of OSA.

Compliance with Treatment

Compliance in OSA patients prescribed nonsurgical treatments had moderate strength of evidence that compliance was greater with CPAP use with more severe OSA and insufficient evidence regarding potential predictors of mandibular advancement devices compliance.

The strength of evidence is low for identifying any specific intervention which may improve CPAP compliance. No intervention type (e.g., education, telemonitoring) was more promising than others.

Overall Summary

CPAP is effective for improving sleep measures (e.g., reducing AHI, improving symptoms as measured by the Epworth Sleepiness Scale, reducing arousal index, and raising the minimum oxygen saturation), but there is no evidence of consistent benefit in improving quality of life, neurocognitive measures or other intermediate outcomes. AutoCPAP and fixed CPAP result in similar compliance and treatment effects. Mandibular advancement devices are effective treatment for OSA, although CPAP is superior to mandibular advancement devices with regard to improved sleep study measures. The evidence is insufficient to evaluate the efficacy of all surgical procedures and other treatments except intensive weight loss for obese patients with OSA.

[\[Evidence Source\]](#)

PROCEDURE

Continuous positive airway pressure

Uvulopalatopharyngoplasty

Mandibular maxillary osteotomy

Tracheostomy

DIAGNOSES

Obstructive sleep apnea

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
327.20	Organic sleep apnea, unspecified
327.21	Primary central sleep apnea
327.23	Obstructive sleep apnea (adult) (pediatric)
327.27	Central sleep apnea in conditions classified elsewhere
327.29	Other organic sleep apnea
780.5	Sleep disturbance, unspecified
780.51	Insomnia with sleep apnea, unspecified
780.53	Hypersomnia with sleep apnea, unspecified
780.54	Hypersomnia, unspecified
780.57	Unspecified sleep apnea
ICD-9 Volume 3 (Procedure Codes)	
21.31	Nasal surgery (remove polyps)
21.88	Other septoplasty
27.64	Insertion of palatal implant
27.69	Uvulopalatopharyngoplasty
28.2	Tonsillectomy
28.3	Tonsillectomy/adenoidectomy
28.6	Adenoidectomy
31.29	Tracheostomy
93.9	CPAP
CPT Codes	
21198	Osteotomy, mandible
21199	Osteotomy, mandible, with genioglossus advancement
21206	Osteotomy, maxilla
21685	Hyoid myotomy and suspension
24145	Uvulopalatopharyngoplasty
31600	Tracheostomy
41512	Tongue base suspension, permanent suture technique
41530	Radiofrequency reduction of the tongue base
42299	Unlisted procedure, palate, uvula (use for laser assisted uvulopalatoplasty (LAUP), somnoplasty, palatal implants)
HCPCS Codes	

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CODES	DESCRIPTION
A4604	Tubing with integrated heating element for use with positive airway pressure device
A7033	Pillow for use on nasal cannula type interface, replacement only, pair
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap
A7035	Headgear used with positive airway pressure device
A7036	Chinstrap used with positive airway pressure device
A7037	Tubing used with positive airway pressure device
A7038	Filter, disposable, used with positive airway pressure device
A7039	Filter, nondisposable, used with positive airway pressure device
A7524	Tracheostoma stent/stud/button, each
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0472	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment
E0601	Continuous airway pressure (CPAP) device

Note: Inclusion on this list does not guarantee coverage

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

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