HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: TREATMENT OF SLEEP APNEA IN ADULTS

Approved by HERC 1/9/2014

HERC COVERAGE GUIDANCE

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

CPAP is recommended for coverage 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 *(strong recommendations)*; or if between 5 and 14 events with additional symptoms *(weak recommendations)* including one or more of the following:
    - excessive daytime sleepiness (Epworth Sleepiness Scale score > 10), or
    - documented hypertension, or
    - 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.

Mandibular advancement devices (oral appliances) are recommended for coverage for those for whom CPAP fails or is contraindicated (weak recommendation).

Intensive weight loss programs (if provided in the benefit package) are recommended for coverage for patients with obesity and obstructive sleep apnea.

Surgery for sleep apnea for adults is not recommended for coverage *(weak recommendation)*.

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

The diagnosis as well as the treatment of OSA is complicated by the difficulty in defining the syndrome. There is controversy surrounding the parameters to be used in a clinical definition as well as which diagnostic method is most appropriate to detect OSA. The

current standard for diagnosing OSA is polysomnography (PSG) administered in a sleep study facility. The frequency of obstructed breathing events (i.e., the apnea-hypopnea index (AHI)), combined with multiple other clinical features of obstruction (e.g., oxygen desaturation, air flow, choking episodes) are recorded during sleep. A diagnosis of OSA is generally made when AHI is greater than or equal to 15 or greater than 5 with noticeable daytime symptoms.

When considering the diagnosis of sleep apnea and the relationship between apnea/hypopnea index (AHI) and long term outcomes, the WA HTA report limited inclusion criteria to longitudinal studies of at least 500 participants and a minimum of 1 year of follow-up. Eleven trials were included in total. Four evaluated AHI as a predictor of mortality, and of those, three evaluated AHI categories (mild, moderate, severe). All found that AHI > 30 had a significant increased risk of death compared to AHI < 5-10. Those with AHI between 10 and 30 had a non-significantly increased risk of death.

Other conditions for which a correlation with AHI has been examined include non-fatal cardiovascular disease, stroke, diabetes and hypertension. There was a significant positive correlation between AHI of > 30 and non-fatal cardiovascular disease in patients not treated with CPAP. A similar correlation was not seen for lower levels of AHI. For stroke, there was no overall increase in incident stroke over 12 years of follow-up in patients with AHI > 20. For incident hypertension, results were mixed. One study found that AHI was not an independent predictor of incident hypertension unless BMI was not controlled for in the analysis. The other study found a significant association between any AHI > 0 and the presence of hypertension at 4 and 8 years follow-up, with higher AHI having a stronger association. For type 2 diabetes, results were again mixed. One study found no association between AHI and the incidence of diabetes after four years, while another found a significant association after 2.7 years for AHI > 8, There was no association between baseline AHI and quality of life (QOL) in the one study that reported on it after 5 years.

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. When evaluating the effectiveness of CPAP, 22 trials were included that had a range of baseline AHI from 10 to 65. With regard to inclusion criteria:

- 9 required AHI >5
- 1 required AHI > 10
- 7 required AHI > 15
- 2 required AHI > 20
- 1 required AHI > 30
- 2 did not report baseline or required AHI

Only one of these evaluated an objective clinical outcome, and it found no significant effect of CPAP on CHF symptoms (baseline average AHI 27). When evaluating the Epworth Sleepiness Scale[1](ESS) as an outcome, a total of 14 trials were included. Of the seven that included patients with baseline AHI as low as 5, only three found a statistically significant benefit of CPAP on ESS. Of those three, only one had an average baseline AHI for the study population less than 15. All of the studies that were limited to patients with an AHI of at least 15 found statistically significant benefit of CPAP. Improvements in ESS range from 2 to 7 points. Of the 3 trials that allowed AHI as low as 5 and found a significant difference, the improvements in ESS were 3 points (2 trials, average baseline AHI = 19 and 10) and 4 points (average baseline AHI = 27). A 1 point change in ESS is considered clinically significant.

Seven studies evaluated blood pressure; none found statistically significant differences between CPAP and control (minimum baseline AHI ranged from >5 to >30). One evaluated HbA1c and also found no difference (minimum baseline AHI >15).Ten studies reported on 29 different QOL measures. Overall, 11 measures in 6 trials reached statistical significance. Of those, only one had an average baseline AHI of less than 15 (range for remaining studies was 19 to 58).

The reviewed studies report sufficient evidence supporting large improvements in sleep measures with CPAP compared with control (e.g., reducing apnea hypopnea index

[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.

(AHI), improving symptoms as measured by the ESS, 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 ESS, 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 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. Details of each study are presented below:

Back 2009 compared a single session of RFA surgery of the soft palate to sham surgery (simulated surgery with no energy administered). The study included 32 male patients with mild sleep apnea (AHI 5-15 events/hour) and habitual snoring following a failed trial of conservative treatment (weight loss, positional therapy, restriction of alcohol and sedatives). At 4 month follow-up, no statistically significant difference between groups in AHI, ESS, minimum oxygen saturation, and quality of life [as measured by the Short Form 36 questionnaire (SF-36)] were found.

Koutsourelakis 2008 randomized patients to either nasal surgery (submucous resection of the deviated septum and bilateral resection of inferior turbinates) or sham surgery (simulated nasal surgery under anesthesia). In addition to OSA (defined as AHI ≥5 events/hour), all patients had fixed nasal obstruction due to deviated nasal septum. The study was conducted on 49, predominately male patients with a mean baseline AHI of 31 events/hour. After 4 months follow-up, the study found no statistically significant difference between groups in AHI or on ESS.

Woodson 2003 conducted a three-arm RCT that included a comparison of multilevel temperature controlled RFA of the soft palate with sham surgery (simulated RFA with no energy delivered). The study was conducted in 51, predominately male patients. Notably, the age of participants between groups was significantly different at baseline. (49 years (RFA) versus 51 years (sham), P=0.04). The mean baseline AHI also differed among groups (21 (RFA) versus 15 (sham) events/hour; P=0.06, including the CPAP study group). After 8 weeks follow-up, the study found a significantly greater improvement in sleep quality as measured by Functional Outcomes of Sleep Questionnaire with RFA as compared to sham surgery (P=0.04), but no statistically significant difference in AHI, ESS, minimum oxygen saturation, or quality of life as measured by SF-36.

Ferguson 2003 randomized patients to either LAUP or no treatment. In LAUP, the uvula and a specified portion of the palate is vaporized under local anesthesia in an outpatient setting. The goal is to relieve obstruction in patients with mild OSA or snoring. The study included 44 mostly male patients with mild OSA (AHI 10-27 events/hour) and snoring. This study reported disparate follow-up durations of 15 months in the LAUP group and 8 months in the control group. A statistically significant improvement in AHI was observed following LAUP as compared with no treatment (net change -10.5 events/hour; P=0.04). However, there was no statistically significant difference between groups on the ESS or in quality of life as measured by Sleep Apnea Quality of Life Index.

Guilleminault 2008 was reported as a crossover study comparing several surgical combinations to cognitive behavioral therapy in 30 patients with insomnia and mild OSA (mean AHI 10 events/hour). Based on anatomy, disease severity, and comorbidity, patients received combinations of pharyngoplasty, tonsillectomy, adenoidectomy, genioglossal advancement septoplasty, and RFA of the inferior nasal turbinates. Only the first phase of the trial was evaluated. Results showed that surgery led to improvements in AHI (-6.2 events/hour; P=0.0001), ESS (-1.1; P=0.002), minimum oxygen saturation (4.4 percent; P=0.0001) and two other sleep measures as compared to cognitive behavioral therapy.

Lojander 1996 & 1999 compared UPPP with or without mandibular osteotomy to conservative treatment (weight loss, positional therapy, and avoidance of tranquilizers

and alcohol at bedtime). The study included 32, predominately male patients with a mean age of 47 years and a mean baseline BMI of 31 kg/m2. Baseline Oxygen Desaturation Index ranged from 10 to 72 events/hour. A significant improvement in daytime somnolence (net difference -25 on a visual analogue scale ranging from 0 (no somnolence) to 100 (worst); P<0.05) was observed after 12 months; no statistically significant difference was found between groups in cognitive function.

Li 2009, in a nonrandomized prospective study, compared correction of nasal septum and volume reduction of the inferior turbinates to conservative nasal treatments in patients with snoring, nasal obstruction, and OSA. The study included 66 patients, 44 of whom had surgery. The patients were almost all male, with a mean age of 38 years and a mean BMI of 26.2 kg/m2. Baseline AHI was 38 events/hour in the surgically treated group and 26 in the conservative treatment group (no significant difference), and baseline ESS was 10.6. The article did not report at what time point follow-up data were collected. The study found a statistically significant difference in ESS, favoring surgery (net difference -3.6; 95 percent CI -6.1, -1.1; P=0.02). The study found no difference in AHI, minimum oxygen saturation or two sleep measures.

Overall there was insufficient evidence with which to evaluate the efficacy of any of these surgical treatments. 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. There is more evidence for effectiveness in patients with higher (>15) AHI. 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]

COMMITTEE DELIBERATIONS – HTAS

At the May 21, 2012 meeting, subcommittee members requested to add CMS criteria for CPAP compliance (70% of nights and 4 hours per night). Members requested further information to guide the decision about whether to perform surgery. At its June 25, 2012 meeting the subcommittee added language allowing coverage for surgery under certain conditions, and requested that the report be put out for public comment. On November 26, 2012 the subcommittee reviewed public comment and added a recommendation for coverage for intensive weight loss and the inclusion of the Epworth Sleepiness Scale score > 10 as a requirement for a CPAP trial. It removed the reference to impaired cognition before referring the draft coverage guidance to HERC.

COMMITTEE DELIBERATIONS – VBBS

At its March 14, 2013 meeting, the Value-based Benefits Subcommittee discussed the draft coverage guidance and recommended changing it in order to allow coverage for surgery only after both CPAP and an oral appliance had failed.

HERC DELIBERATIONS

In its review May 9, 2013, the HERC requested that staff consider the evidence around coverage for surgeries, creating a GRADE-informed framework and HERC Guidance Development Framework for this service, as has been done for the newer coverage guidances. These have been added as Appendices A, B and C. They asked that if the recommendation comes down as “not recommended for coverage” that the coverage guidance and associated coverage and prioritization decisions for the Oregon Health Plan, be referred back to VbBS without the coverage guidance returning to HTAS.

At its August 8, 2013 meeting, HERC reviewed additional evidence on the effectiveness of CPAP and returned the draft coverage guidance to the HTAS for additional work on surgery and indications for CPAP coverage, indicating that the document should go out for public comment again if changes are made which don't result from public comment.

COMMITTEE DELIBERATIONS – HTAS

At its September 23, 2013 meeting, based on the additional evidence reported, the HTAS changed the draft coverage guidance to recommend coverage for CPAP for patients with AHI of at least 30, as well as for patients with specified symptoms and an AHI of at least 15. The subcommittee also changed its recommendation for surgery to a weak recommendation not to cover surgeries based on insufficient evidence to prove benefit.

At its November 25, 2013 meeting, after reviewing written comments and hearing public comments from sleep medicine physicians, HTAS changed the draft coverage guidance. The subcommittee eliminated the coverage recommendation on mandibular advancement devices because CPAP may be more cost effective for many patients. In addition, the subcommittee revised the draft to allow for coverage of CPAP for patients with an AHI of at least 15 without additional symptoms and for patients with an AHI of 5-14 with certain specified symptoms. The subcommittee based this decision on public testimony from sleep medicine physicians who testified that certain patients in this subgroup may benefit from CPAP.

HERC DELIBERATIONS

At its January 9, 2014 meeting, HERC reviewed the draft coverage guidance. The Commission discussed the evidence for CPAP for patients with AHI of 5 to 14 and how, which some of the evidence included patients with these levels of AHI, these studies also included patients with AHI >14, making it difficult to come to a conclusion regarding effectiveness. After discussion, the HERC decided to make the recommendation on CPAP for persons with AHI 5-14 and additional symptoms a weak recommendation, and to add a rationale for this in a footnote to the GRADE table. In addition, the HERC restored the recommendation for coverage for mandibular advancement devices but made it second line therapy because comparative studies showed inferior benefit to CPAP.

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
327.20	Organic sleep apnea, unspecified
327.21	Primary central sleep apnea

CODES	DESCRIPTION
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
31600	Tracheostomy
41512	Tongue base suspension, permanent suture technique
41530	Radiofrequency reduction of the tongue base
42145	Uvulopalatopharyngoplasty
42299	Unlisted procedure, palate, uvula (use for laser assisted uvulopalatoplasty (LAUP), somnoplasty, palatal implants)
HCPCS Codes	
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

CODES	DESCRIPTION
	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.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

Appendix A.GRADE-Informed Framework

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are four elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Balance between desirable and undesirable effects, and quality of evidence, are derived from the evidence presented in this document, while estimated relative costs, values and preferences are assessments of the HERC members.

Indication	Balance between desirable and undesirable effects	Quality of evidence*	Resource Allocation	Values and preferences	Coverage Recommendation
Surgery	Uncertain, but no certain benefit, and significant risk of surgery	Very low	Moderately costly	Moderate variability	Surgery for sleep apnea for adults is not recommended for coverage.
CPAP for patients with AHI 5-14 with symptoms/signs	No benefit on mortality or comorbid diseases (hypertension, diabetes, etc), minimal benefit on sleepiness/QOL, if any. No serious harms, but significant patient inconvenience.	Moderate[2]	Moderately costly	Moderate variability	CPAP coverage is recommended for coverage at AHI levels 5-14 with daytime sleepiness, hypertension, ischemic heart disease, or history of stroke..
CPAP for patients with AHI 15-29	No benefit on mortality or comorbid diseases (hypertension, diabetes, etc), moderate benefit	Moderate[2]	Moderately costly	Moderate variability	CPAP coverage is recommended at AHI levels between 15 and

[2] The authors of the AHRQ report say, “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 ESS, the strength of evidence that CPAP is an effective treatment to alleviate sleep apnea signs and symptoms was rated moderate.” The HERC notes that the studies were not stratified by AHI levels of 5-14 vs 15-30 but that studies which included patients with lower AHI showed less benefit and therefore recommends coverage only for patients with additional symptoms/signs.

Indication	Balance between desirable and undesirable effects	Quality of evidence*	Resource Allocation	Values and preferences	Coverage Recommendation
	on sleepiness/QOL. No serious harms, but significant patient inconvenience.				30.
CPAP for patients with AHI ≥ 30	Significant benefit on mortality/ comorbid diseases, moderate benefit on sleepiness/QOL. No serious harms, but significant patient inconvenience.	Moderate[2]	Moderately costly	Small variability	CPAP coverage is recommended at AHI levels≥ 30.
Mandibular advancement devices	Significant benefit. Inferior to CPAP on sleep study measures but minimal difference in compliance, treatment response, quality of life or neurocognitive measures	Moderate for benefit, inferiority to CPAP on sleep study. Low for minimal differences on other outcomes	Low to moderate cost	Moderate variability	Recommended for coverage as second line therapy based on initial cost and inferiority to CPAP *(weak recommendation)*.

*The Quality of Evidence rating was assigned by the primary evidence source, not the HERC Subcommittee

Note: GRADE framework elements are described in Appendix B

Appendix B. GRADE Element Descriptions

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted

Strong recommendation

In Favor: The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Against: The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Weak recommendation

In Favor: the subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Against: the subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Quality of evidence across studies for the treatment/outcome

High= Further research is very unlikely to change our confidence in the estimate of effect.

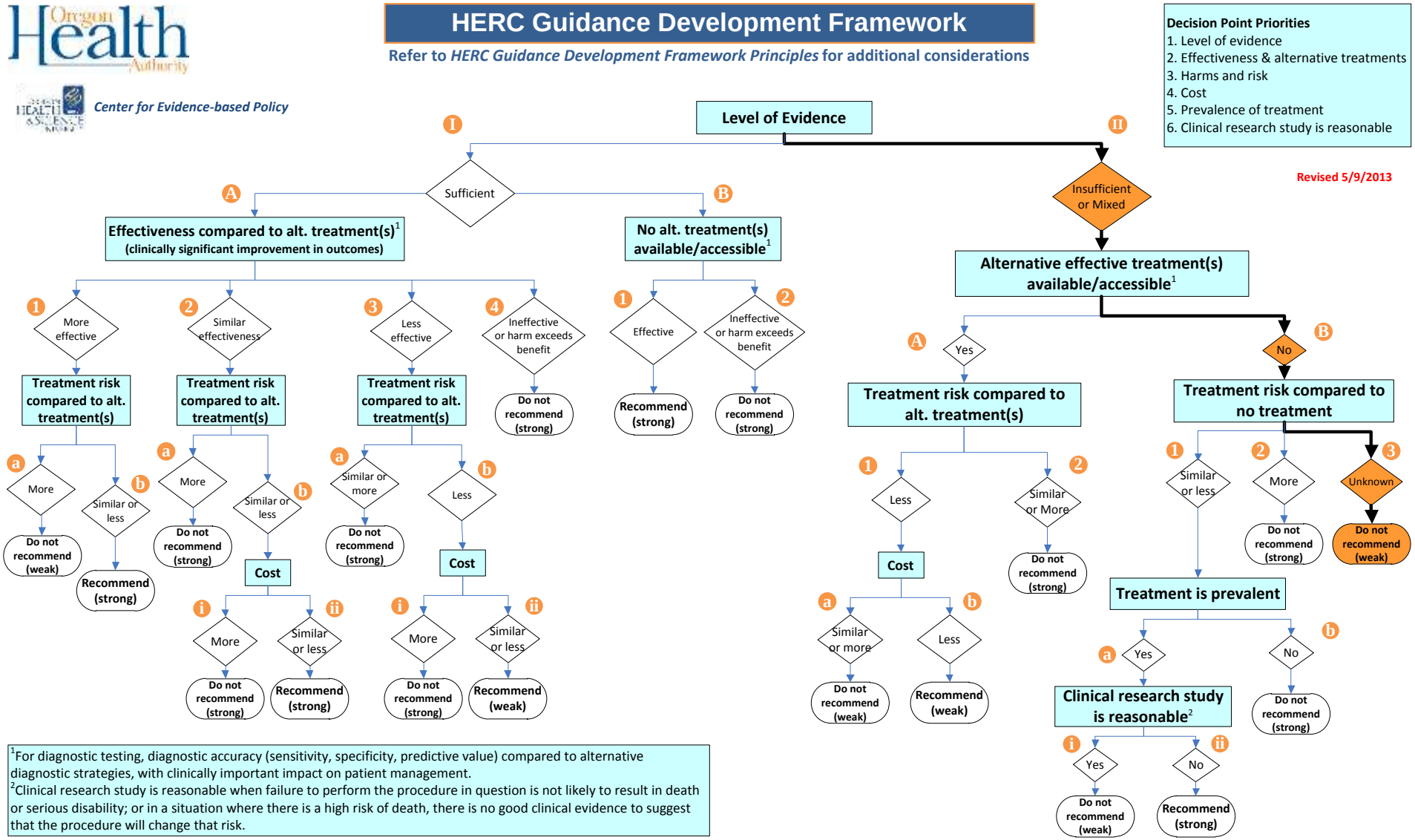
Moderate= Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low= Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low= Any estimate of effect is very uncertain.

Appendix C. HERC Guidance Development Framework

Surgery for treatment of sleep apnea in adults when both CPAP and/or other alternatives (e.g., oral appliances) have failed



[1]For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
[2]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

CPAP for Patients with AHI 5-14 with Symptoms/Signs

Oregon Health Authority

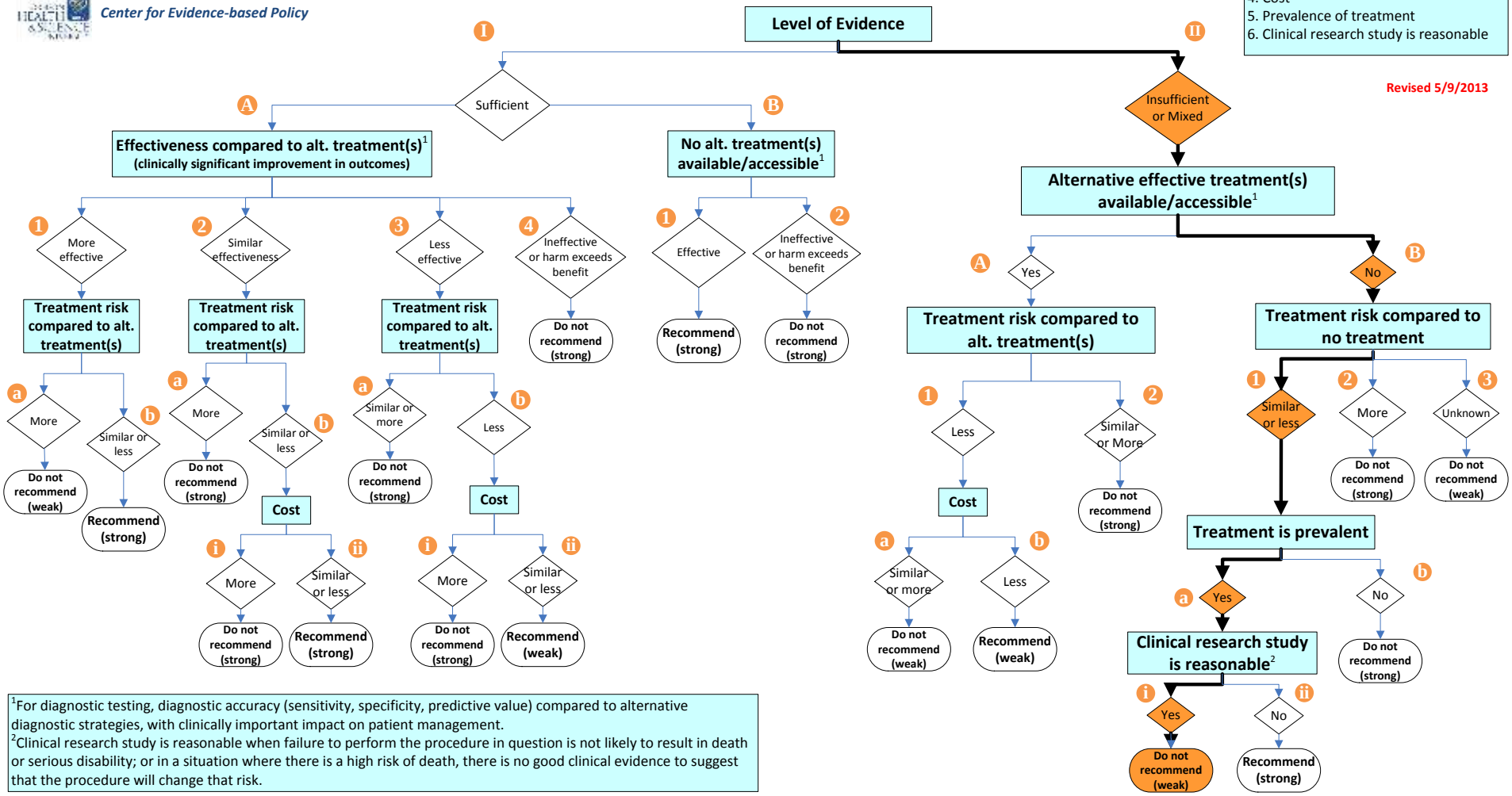
Center for Evidence-based Policy

HERC Guidance Development Framework

Refer to *HERC Guidance Development Framework Principles* for additional considerations

Decision Point Priorities
1. Level of evidence
2. Effectiveness & alternative treatments
3. Harms and risk
4. Cost
5. Prevalence of treatment
6. Clinical research study is reasonable

Revised 5/9/2013



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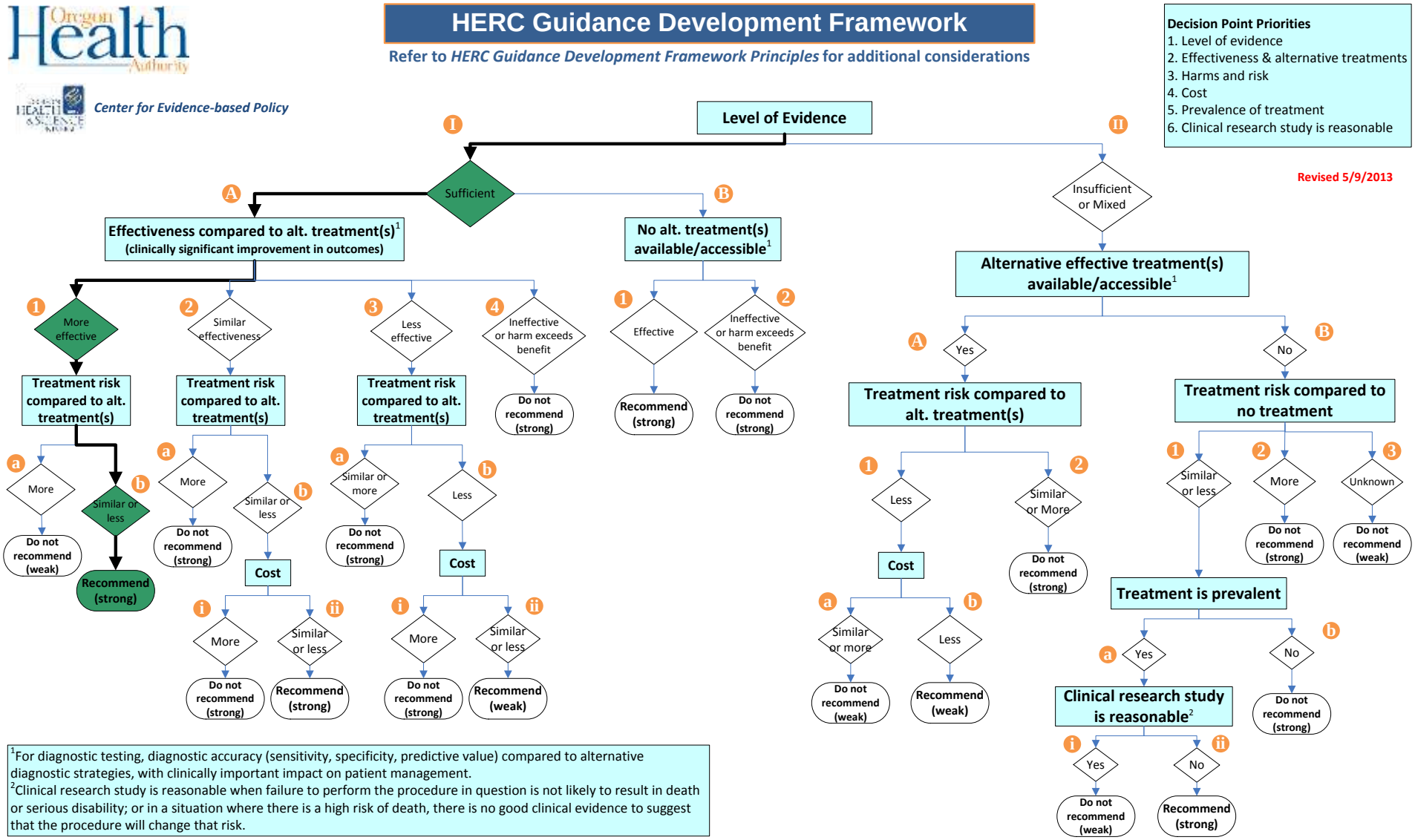
[2]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

CPAP for Patients with AHI 15-29; CPAP for Patients with AHI ≥ 30



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