Appendix H. Key Question #8 Summary of Findings Table for Systematic Reviews

Reference (type of evidence)	Number of Studies and Design	Study Features	Outcomes Assessed	Main Findings	Quality (Minimization of Risk of Bias) and Comments
McDaid 2011 *Continuous positive airway pressure devices for the treatment of obstructive sleep apnoea–hypopnoea syndrome: a systematic review and economic analysis*	One manufacturer (ResMed) submitted a full cost-effectiveness study. Two manufacturers (Fisher Paykel Ltd, ahd Respironics (UK) Ltd submitted partial economic evaluations. Four full economic evaluations were included in the cost-effectiveness review of published studies. Economic Model developed informed by this SR to evaluate cost-effectiveness of CPAP for treatment of OSAHS.	<u>The York Economic Model:</u> • A cost–utility analysis was undertaken that compared CPAP with use of dental devices and conservative management over a lifetime time horizon. • The costs of the use of these resources were reported related to 2005. • The health effects of OSAHS, and the impacts of alternative treatments, were expressed in terms of QALYs. Due to the paucity of HRQoL data estimates using other data was	• The base-case analysis compared the costs and QALYs of CPAP versus dental devices versus conservative management in a male aged 50 years. • Subgroup analyses were undertaken by gender, OSAHS severity (as measured by ESS) and other relevant baseline patient characteristics. • The model characterizes the patient's prognosis over his or her lifetime in terms of four health states: (1) OSAHS; (2) OSAHS post coronary heart disease (CHD); (3) OSAHS post stroke; and (4) death. • Yearly cycles were	The existing cost-effectiveness studies had several limitations that need to be addressed in order to assess the value for money of these technologies : • The cost-effectiveness studies did not use the full range of clinical trial evidence for estimating the impact of treatment on daytime sleepiness, blood pressure, HRQoL and other relevant outcomes. • There was a lack of trial-based evidence to compare the utility associated with different treatments for OSAHS. • There were limited data (in terms of quantity and quality) on the long-term impact of OSAHS on HRQoL, CVE, RTAs and other outcomes. • None of the evaluations examined all the comparators relevant to this review. In an attempt to make full use of all of the available evidence on therapies for the treatment of OSAHS and in order to overcome some of the limitations noted above, a new cost-effectiveness model was developed. <u>Results of York economic model:</u> <u>Base-case analysis:</u> • The base-case analysis is based on a	This study was rated "good" regarding minimizing bias. No conflicts of interests nor influence by funding sources were noted.

Reference (type of evidence)	Number of Studies and Design	Study Features	Outcomes Assessed	Main Findings	Quality (Minimization of Risk of Bias) and Comments
		required. Three clinical endpoints were related to QALYs: o ESS o Blood pressure o RTAs For expressing HRQoL utilities, the EQ-5D and SF-6D were used. <u>Additional model features included:</u> • Annual discount rate of 3.5% • Adults>16 yrs • Diagnosis of OSAHS by appropriate tool (e.g. AHI or arterial oxygen desaturation index and the ESS). • The model was run separately by age and sex, given the availability of age- and sex-specific mortality data and CVE risks. The	chosen for the current model.	hypothetical cohort of men aged 50 with specified CV risk factors. In this cohort CPAP was associated with both higher costs and higher QALYs in comparison with treatment with dental devices or conservative management. The incremental cost-effectiveness of CPAP compared with dental devices is estimated to be £ 4000 per QALY. CPAP might therefore be considered cost-effective at a cost-effectiveness threshold per QALY of £ 20,000. • For the base-case analysis the effect of CPAP on ESS has an ICER below a cost-effectiveness threshold of £ 20,000 for moderate and severe OSAHS. The effect of CPAP on blood pressure, for the economic model, the implications of this treatment effect for clinical events need to be estimated. The Framingham risk equations provide a link between risk factors such as blood pressure and the incidence of fatal and non-fatal CVEs. The relative risk reduction for CVE implied by the difference in SBP with CPAP compared with usual care is estimated to be relatively low using the Framingham risk equations (RR ≈ 0.98 for mean reduction in SBP of 1.06 mmHg).	

Reference (type of evidence)	Number of Studies and Design	Study Features	Outcomes Assessed	Main Findings	Quality (Minimization of Risk of Bias) and Comments
		base-case analysis is based on a male aged 50.			

Appendix I. Key Question #8 Summary of Findings Table for Individual Studies

Reference	Type of Evidence	Population, Setting, Follow-up	Intervention	Outcomes Assessed	Main Findings	Quality (Minimization of Risk of Bias) and Comments
Deutsch 2006^ *Cost-Effectiveness of Split-Night Polysomnography and Home Studies in the Evaluation of Obstructive Sleep Apnea Syndrome*	Cost Utility Analysis-An Economic Model	Hypothetical cohort of persons aged 30 to 64 years of whom 85% were men (i.e. excluding elderly subjects). All had symptoms highly suggestive of OSAS, specifically, excessive daytime somnolence, persistent snoring, and witnessed apneas during sleep. Note: An OSAS pretest probability of 82% was selected to be consistent with published studies that provided the chance-node values in the decision tree model. The pretest probability is determined by the case mix among patients selected for OSAS evaluation.	An OSAS diagnostic evaluation followed by CPAP auto-titration using full-night PSG, split-night PSG, or unattended home partial sleep monitoring (UHPSM). For full-night PSG and split-night PSG, an apnea-hypopnea index of 10 or greater or, for home studies, a respiratory disturbance index of 10 or greater was required for a diagnosis of OSAS. It was assumed that, in this highly symptomatic cohort, CPAP treatment would be considered for all patients who met these criteria. <u>Note:</u> Probabilities and test characteristics were	Cost estimates were based on the 2004 Medicare Fee Schedule. Survival rates were taken from National Center for Health Statistics data and published studies. Effectiveness was measured as quality-adjusted life years. The analytical time horizon used was 5 years, consistent with the period over which data regarding long-term CPAP is currently available. The cost analysis was performed from the perspective of third party payers, and only direct healthcare costs were considered. Although patients with untreated OSAS utilize more healthcare	Trade-offs of overall costs versus effectiveness were identified. The home-studies strategy was less costly and less effective than split-night PSG and full-night PSG, as was split-night PSG compared with full-night PSG. Costs to attain additional quality-adjusted life years were below commonly accepted thresholds. A probabilistic analysis suggested that the home-studies approach was most cost-effective at the lowest amounts of third-party willingness to pay, whereas split-night PSG or full-night PSG was most cost-effective at higher amounts. Cost-effectiveness ratios of all 3 strategies indicate increasing cost and effectiveness as split-night PSG is substituted for home studies and as full-night PSG is substituted for split-night PSG. The costs for additional QALYs incurred by full-night PSG and split-night PSG over home	Good This study targeted a cohort of symptomatic individuals at moderate to high risk for OSAS, which did not include children or elderly persons. The results may not apply to asymptomatic patients or groups at lower risk and should not be considered valid for pediatric or geriatric populations. Cost estimates did not include indirect costs such as healthcare and non-healthcare costs arising from complications of untreated OSAS, which are known to be considerable. Other treatments

Reference	Type of Evidence	Population, Setting, Follow-up	Intervention	Outcomes Assessed	Main Findings	Quality (Minimization of Risk of Bias) and Comments
		This analysis targeted a population at moderate to high risk for OSAS.	derived from data from the published literature.	services than does the general population the indirect costs have not been measured in the United States and the effect of CPAP treatment is unknown. Reimbursements were discounted at a rate of 3.0% annually. Health outcomes were expressed as quality-adjusted life years (QALYs), the product of the utility and life expectancy for the health state. A diagnostic strategy was considered dominant over another if the total costs were lower and QALYs were the same or higher. Strategies that were more costly and more effective, in terms of QALYs, were assessed according to the incremental cost-effectiveness ratio	studies, and even by full-night PSG over split-night PSG, compare favorably with cost-utility estimates for a variety of widely accepted healthcare interventions.	options were not studied in this model. For instance, the combination of a full-night PSG followed by home auto-titration of CPAP for patients found to have OSAS has been suggested as a potentially cost-effective approach. No conflicts of interests nor influence by funding sources were noted.

Reference	Type of Evidence	Population, Setting, Follow-up	Intervention	Outcomes Assessed	Main Findings	Quality (Minimization of Risk of Bias) and Comments
				(cost per QALY gained).		
Jennum 2011 *Health, social and economical consequences of sleep-disordered breathing: a controlled national study*	Cost Analysis-direct and indirect costs, (no measure of benefits such as QALY, etc.)	Using data from the Danish National Patient Registry (1998-2006), 12,045, 19,438 and 755 patients were identified with a diagnosis of snoring, SA and OHS, respectively. For every patient, four age-, sex- and socioeconomic-matched citizens were randomly selected (48,180, 77,752 and 3,020, respectively) from the Danish Civil Registration System Statistics. This study includes subjects with SA of whom 10% are <20 years of age. The evidence and study design are unique, therefore, an	Direct costs were extracted from the Danish Ministry of Health, Danish Medicines Agency and National Health Security. Indirect costs were based on data derived from the Coherent Social Statistics.	Direct illness costs included the costs of hospitalization and outpatient visits weighted by use according to diagnosis-related groups (DRG). Specific outpatient direct illness costs were based on data from the Danish Ministry of Health. The use and costs of drugs were based on data from the National Danish Medicine Agency which includes the retail price of the drug (including dispensing costs) multiplied by the number of transactions. The frequencies and costs of consultations with general practitioners and other specialists were based on data from the National Health Security.	*Note: The snoring and OHS patient groups were not of interest to this report, therefore the findings presented pertained only to the SA patient group and their controls.* More patients than control subjects received social services. Fewer patients with SA than control subjects received income from employment. Employment rates for patients with SA, were significantly lower up to 8 years before a diagnosis was established and further decreased after a diagnosis had been made compared with control subjects. The corresponding expenses in total direct and indirect costs were increased before a diagnosis of SA was made and further increased afterwards. Direct net health costs (GP services, hospital services and medication) and indirect costs (loss of labour market income) for patients compared with control subjects were as follows: SA, €5257 vs €1396	Good This study, which evaluated the direct and indirect objective socioeconomic impact of SDB in a complete national sample, found that SA, has a significant socioeconomic impact compared with a random population-based sample controlled for SES. These effects are present several years before a diagnosis is established. Patients with SA had medication and hospital costs 2-3 times higher than controls, total health costs that were more than twice as high and employment rates that were more than 30% lower.

Reference	Type of Evidence	Population, Setting, Follow-up	Intervention	Outcomes Assessed	Main Findings	Quality (Minimization of Risk of Bias) and Comments
		exception is made to include this study (inclusion criteria for Balk [AHRQ] 2011) was adults >16).		Indirect Costs: Estimate the production loss related to disease-related work disability measures by loss of income using the human capital approach. Indirect costs were based on income data from the Coherent Social Statistics. We estimated the economic consequence of SDB by determining the annual cost of illness per patient diagnosed with snoring (ICD DG065), SA (ICD DG473) and OHS (ICD DG662) and compared the calculation with the cost in a matched control group. The health cost was divided into annual direct and indirect healthcare costs.	(p<0.0001). These results correspond with an annual mean excess health-related cost for each patient with SA of €3860. Influence of CPAP and surgery on mortality, direct and indirect costs: Patients with SA had significantly higher mortality rates compared with controls 25.4% vs 6.8%, p<0.001, (adjusted for age, sex and social status). In the database, 4054 patients with SA were reported to be treated with CPAP for a period of at least 2 years with annual follow-up. CPAP reduced mortality in patients with SA (5.5% vs 5.5%, p<0.01). Further analysis of the influence of factors that influence mortality: Age <40 years, female gender and CPAP treatment were significantly associated with a better prognosis for patients with SA. Surgery (uvulopalatopharyngoplasty,	Limitations in this study include: (1) the accuracy of the diagnosis and management are sensitive to the diagnostic criteria used by the reporting doctors; (2) the local management of treatment, especially CPAP, may be underreported; (3) detailed information regarding CPAP usage and effect on SDB are not included; and, (4) 10% of SA patients were under 20 years of age. No conflicts of interests nor influence by funding sources were noted.

Reference	Type of Evidence	Population, Setting, Follow-up	Intervention	Outcomes Assessed	Main Findings	Quality (Minimization of Risk of Bias) and Comments
				Costs were measured on a yearly basis and adjusted to 2006 prices using the health sector price index for health sector costs, and the general price index was applied to non-medical costs. All costs were measured in DKK and converted into euros (€1=DKK7.45).	UPPP) had no influence on mortality among 727 patients with SA. The direct and indirect costs were all higher in CPAP-treated patients with SA in the 2-year follow-up period compared with 2 years before the diagnoses.	
Masa 2011 *Effectiveness of home respiratory polygraphy for the diagnosis of sleep apnoea and hypopnoea syndrome <SAHS>*	Multicentre, randomized, blinded crossover study to determine the diagnostic efficacy of home respiratory polygraphy (HRP) compared with PSG in the hospital setting, estimating the costs of HRP at the same level	Included: Patients between 18 and 70 years old, referred for pulmonary consultations to eight centres in Spain for suspected SAHS caused by snoring, observed apnoeas, sleepiness (Epworth sleepiness scale >10) or non-refreshing sleep. Excluded: Patients with other suspected sleep disorders, severe	All patients underwent PSG and HRP in random order. Observers were blinded to patient information and previous study results. HRP: Measurements included oxygen saturation, airflow through a nasal cannula, and thoracic and abdominal movements measured by piezoelectric bands,	359 patients who completed the protocol (both branches of the study), PSGs were repeated once in nine patients (2.5%), HRPs once in 51 patients (14%), and an additional time in 34 patients. 11 patients could not produce a valid HRP after repetitions.	ROCs were calculated for HRP with the different PSG cut-off points (>=5, >=10, and >=15) for SAHS diagnosis. All AUCs were statistically significant (p<0.001), expressing a high level of diagnostic accuracy. The best and worse AUCs were obtained using PSG cut-off points of AHI >=5 and AHI>=15 respectively. The best receiver operating characteristic curve was obtained with a PSG cut-off of the apnoea-hypopnoea index (AHI)>=5. The sensitive HRP AHI cut-off point (<5) had a sensitivity of 96%, a specificity of 57% and a negative likelihood	Good Large RCT comparing costs of PSG and HRP of equal efficacy. Only patients with high pre-test probabilities of OSA were included, however. Costs were reported in 2009 Euros without conversion or discounting. No conflicts of interests nor influence by funding sources were noted.

Reference	Type of Evidence	Population, Setting, Follow-up	Intervention	Outcomes Assessed	Main Findings	Quality (Minimization of Risk of Bias) and Comments
	of diagnostic efficacy as PSG.	and unstable heart disease or who were unable to set up the HRP instrument in a trial.	which also measured body position. The HRP device collected this information in a data card which was telecommunicated to a central website. The hospital technician downloaded the data file from the website and scored the raw data using a manual scoring protocol. <u>PSG in the hospital:</u> Studies were analysed manually at each participating centre, according to standard protocol. The scoring of respiratory events with the same criteria as for HRP.		ratio (LR) of 0.07. The cost of HRP was half that of PSG. The cost of achieving an HRP efficacy equal to that of PSG was three times higher than the test cost without equal efficacy, but half the cost of PSG.	
Sadatsafav 2009^ *Cost-effectiveness of oral appliances*	Cost Utility Analysis. A model was designed to simulate the costs and	The model was stratified on four age groups (25–34, 35–44, 45–54 and 55–64 years) and gender (male vs.	A discrete state Markov model was created to simulate the Natural course of moderate/severe OSAH [apnoea–	The primary outcome was the incremental cost-effectiveness ratio (ICER) in terms of costs per one quality-adjusted life year	<u>Relative efficacy of OA versus CPAP:</u> AHI was decreased by 18.3 (95% CI 14.1–22.0) in the CPAP group and by 9.7 (95% CI 6.4–12.8) in the OA group, and	Good This study has several limitations. While the model analyzes patients with

Reference	Type of Evidence	Population, Setting, Follow-up	Intervention	Outcomes Assessed	Main Findings	Quality (Minimization of Risk of Bias) and Comments
in the treatment of obstructive sleep apnoea–hypopnoea	benefits of treatment of OSAH with OA or CPAP based on their effects on quality of life, motor vehicle crashes, and cardio-vascular effects.	female). The weights assigned to each age group reflect the demographic characteristics of patients with moderate to severe OSAH in our centre which are comparable to that in the USA.	hypopnoea index (AHI) ≥15 events per hour] and the impact of different strategies (no treatment, OA and CPAP) on disease outcomes over a 5-year period. Mild OSAH was not chosen because several fundamental parameters of the model such as the impact of OSAH on MVC, efficacy of CPAP and adherence to treatment have only been evaluated in moderate to severe OSAH. Cardio-vascular and cerebro-vascular (CV) events were also modeled.	(QALY) gained 5 years after treatment.	the *relative efficacy of OA versus CPAP based on their ability to reduce* AHI was estimated to be 0.53 (95% CI 0.38–0.77). CPAP reduced the ESS score by 3.91 (95% CI 2.29–8.10), whilst OA reduced ESS by 2.20 (95% CI 0.69–6.84). In this model, OA and CPAP are both highly cost-effective treatments for OSAH when compared to no treatment, with CPAP being the best option. These results corroborate the current recommendations on the use of CPAP as the primary treatment for moderate/severe OSAH, with OA the preferred treatment in patients unwilling or unable to use CPAP. In the USA, it is currently recommended that treatments that result in less than $50,000 costs per one additional QALY be adopted. Based on these standards, the ICER of $2,984 for OA and	moderate to severe OSAH, OAs are used in patients with mild disease more typically. Given lack of evidence on many aspects of the model, assumptions were made regarding the effect of OA using indices of disease severity as a surrogate. Another limitation was that the estimated effect of OSAH on CV was based on an observational study, which could be prone to selection bias due to difference between patients who seek treatment and those who do not. The authors acknowledge that the assumptions and the uncertainty in the evidence may limit

Reference	Type of Evidence	Population, Setting, Follow-up	Intervention	Outcomes Assessed	Main Findings	Quality (Minimization of Risk of Bias) and Comments
					$13,698 for CPAP versus no treatment are highly favourable.	the generalisability of the findings. No conflicts of interests nor influence by funding sources were noted.
Tarasiuk 2008 *The Effect of Obstructive Sleep Apnea on Morbidity and Health Care Utilization of Middle-Aged and Older Adults*	Case-control study between January 2001 and April 2003.	158 elderly and 1,166 middle-aged (aged 67–89 and 40–64, respectively) patients with OSA were matched 1:1 with healthy controls according to age, sex, geographic area, and primary physician. Conducted in two sleep–wake disorders centers. All subjects were enrollees of Clalit Health Care Services (CHS), the largest health maintenance organization in Israel, providing medical services to	PSG results: Obstructive apnea was defined as an episode of complete cessation of breathing of 10 seconds or longer with continuing inspiratory effort. A hypopnea was scored when a reduction of at least 50% in airflow accompanied continuing inspiratory effort, resulting in an arousal or oxygen desaturation of at least 4%. AHI was calculated per hour of sleep. Epworth Sleepiness Scale Functional	Healthcare utilization was obtained from the CHS computerized databases. All costs were combined, and the 2 years before the PSG diagnosis and similar time periods were used for the control subjects. Indicators of healthcare utilization included hospitalization (days and costs), emergency department visits (number and costs), visits to specialists (category of specialty, number of visits, and cost per encounter), and prescriptions (number, category, 20 and cost).	Healthcare Utilization: The 2-year total costs were 2.02 and 1.81 times as high in elderly and middle-aged patients with OSA, respectively, as in their controls (P<.001). Healthcare costs were 1.93 times as high in elderly subjects with OSA as in middle-aged subjects with OSA (P <.001). Elderly and middle-aged subjects with OSA had more consultations with otolaryngologists, pulmonologists and other specialists (e.g., dermatologist, cardiologist, orthopedist, neurologist, gastroenterologist, urologist) than controls (P<.01 and <.001 respectively for age strata). Costs for drugs for elderly and	Good Large, case-control study of healthcare utilization in the 2 years prior to OSA diagnosis in middle-age and elderly patients. As the authors point out, costs are not normally distributed among patients with OSA, a small group of elderly and middle-aged patients with OSA who were the most ill and most costly consumed more than 70% of all healthcare resources used by patients with OSA during the 2-year

Reference	Type of Evidence	Population, Setting, Follow-up	Intervention	Outcomes Assessed	Main Findings	Quality (Minimization of Risk of Bias) and Comments
		approximately 60% of the population. Patients and controls with chronic obstructive pulmonary disease, hypoventilation, genetic disorders, cancer, or autoimmune disorders; patients hospitalized more than 20 days during the 2 years before PSG; and residents of nursing homes or hospitals were excluded.	Outcomes of Sleep Questionnaire (FOSQ): Self-rated health status was evaluated by asking a single question (''Define the level of satisfaction with your health status'') with five possible answers ranging from very satisfied to very much not satisfied. Medical diagnoses for all subjects were obtained from the CHS database, documented by physicians during patient visits (community and hospital) using the International Classification of Diseases, Ninth Revision (ICD-9) codes.		middle-aged patients with OSA were 1.73 and 1.91 times as high, respectively, as for controls (P<.001). The main drug category prescribed to elderly and middle-aged patients with OSA were for CVD and respiratory conditions. Elderly women had similar healthcare utilization as elderly men in the control and OSA groups. These findings are in contrast to those for middle-aged women with OSA, who are heavier users of healthcare resources than men. It is possible that, after menopause, the discrepancy between the sexes in utilization and morbidity disappears.	observation period. Nevertheless, in this study elderly and middle-aged patients with OSA consumed approximately two times as much in the way of healthcare resources as their paired controls. No conflicts of interests nor influence by funding sources were noted.

^ Model assumptions are provided in Appendix J

Appendix J. Economic Evaluation Studies using Models; Model Assumptions (Ayas 2010; Deutsch 2006; Sadatsafavi 2009)

Reference	Model Assumptions
Deutsch 2006 *Cost-Effectiveness of Split-Night Polysomnography and Home Studies in the Evaluation of Obstructive Sleep Apnea Syndrome*	Variable Value Chosen (from published references) <u>Chance Node Probabilities:</u> • OSAS pretest probability **0.82** • PSG sensitivity **0.97** • PSG specificity **1.00** • CPAP accepted • Full-Night PSG **0.93** • Split-Night PSG **0.89** • UHPSM **0.86** • Split-night PSG specificity **0.90** • Split-Night PSG sensitivity (after first 2 h) **0.93** • Second night needed for CPAP titration (after OSAS documented in first 2 h) **0.18** • Satisfactory UHPSM **0.80** • UHPSM sensitivity **0.95** • UHPSM specificity **0.73** • PSG follow-up after negative or unsuccessful home study procedure **0.77** • CPAP autotitration unsuccessful for patient with OSAS **0.13** <u>Cost Estimates (from 2004 Medicare Fee Schedule):</u> • Full-NightPSG (CPT 95810) $788.00 • Polysomnographic CPAP $852.00 • titration (CPT 95811) • Split-night PSG (CPT95811) $852.00 • UHPSM (CPT 95806) $218.00 • CPAP autotitration (CPT95806) $218.00 • CPAP rental and accessories • Year 1 $1600.00 • Year 2 $821.00

Reference	Model Assumptions
	• Years 3-5 $700.00 • Office visits (CPT 99214) $89.81 Utilities: • OSAS treated **0.55** • OSAS untreated **0.32** • No OSAS **0.435** • No OSAS treated **0.32** Cost Assumptions: Costs for all 3 pathways were adjusted with the assumption (from published literature) that 3.57% of PSG CPAP titrations would be repeated due to suboptimal initial procedures. Further costs for long-term CPAP use were estimated according to previous reports of long-term CPAP compliance, assuming CPAP usage to be 80% at 3 months, 74% at 1 year, and 71% at 5 years.
Sadatsafavi 2009 *Cost-effectiveness of oral appliances in the treatment of obstructive sleep apnoea–hypopnoea*	General Assumptions: • In each 1-year cycle of the model, patients could experience a MVC, CV event, die from other causes or remain event-free. • MVCs can result in property damage without injury, injury or death. • Injury levels were stratified to five maximum abbreviated injury scale (MAIS) levels. • CV events included myocardial infarction (MI) and stroke (ischaemic and haemorrhagic) and could be fatal or non-fatal. Stroke was divided into mild/moderate versus severe. It was assumed that patients with severe injury due to MVC (MAIS 4 or 5) or severe stroke are unable to drive anymore and hence are no longer at risk of further MVCs. • Background mortality rates were taken from the US life tables in 2003. • Mortality due to MVC and CV events in this population was deducted from the all-cause mortality estimates. Assumptions using indirect evidence to estimate the effect of treatment with CPAP and OA on the events modeled in this analysis: • The impact of CPAP and OA on the AHI was used as a surrogate for their effectiveness on reducing other events due to OSAH. • Assumed that a reduction in the risk of all events for CPAP and OA is proportional to their effect on reducing AHI. • The report used data for CPAP adherence; the main analysis assumed that adherence to CPAP and OA are equal, as adherence data on OA's use has been studied mainly in mild OSAH patients and this population is in those with moderate to severe OSAH.

Appendix K. Guideline Summary Table

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
National Institute for Health and Clinical Excellence (NICE), 2007	1.1 Current evidence on soft-palate implants for obstructive sleep apnoea (OSA) raises no major safety concerns, but there is inadequate evidence that the procedure is efficacious in the treatment of this potentially serious condition for which other treatments exist. Therefore, soft-palate implants should not be used in the treatment of this condition.	Literature review and expert consensus	Good
National Institute for Health and Clinical Excellence (NICE), 2008	1. Continuous positive airway pressure (CPAP) is recommended as a treatment option for adults with moderate or severe symptomatic obstructive sleep apnoea/hypopnoea syndrome (OSAHS). 2. CPAP is only recommended as a treatment option for adults with mild OSAHS if: a. They have symptoms that affect their quality of life and ability to go about their daily activities, and b. Lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate. 3. The diagnosis and treatment of OSAHS, and the monitoring of the response, should be carried out by a specialist service with appropriately trained medical and support staff.	Literature review and expert consensus	Good
American Academy of Sleep Medicine, 2009	1. High risk patients with nocturnal symptoms of OSA should undergo sleep testing, including those who are obese and those with coronary heart disease, or significant tachyarrhythmias. 2. To ensure satisfactory therapeutic benefit from oral appliances (OA), patient with OSA should undergo PSG or an attended cardiorespiratory (type 3 PM) sleep study with the OA in place after final adjustments of fit have been performed.	Literature review and expert consensus	Fair
American Society of Anesthesiologists Task Force on Perioperative Management of Patients with OSA, 2006	1. **Preoperative evaluation:** A perioperative evaluation should include a comprehensive review of previous medical record, an interview with the patient and/or family, and a physical examination. The severity of the patient's OSA, the invasiveness of the diagnostic or therapeutic procedure, and the requirement for postoperative analgesics should be taken into account in determining whether a patient is at increased perioperative risk from OSA. The patient and patient's family should be informed of the potential implications of OSA on the patient's perioperative course. 2. **Preoperative preparation:** Preoperative initiation of continuous positive airway pressure should be considered, particularly is OSA is severe. For patients who do not respond adequately to CPAP noninvasive positive-pressure ventilation (NIPPV) should be considered. In addition, the preoperative use of mandibular advancement devices or oral appliances and preoperative weight loss should be considered when feasible. In patients at risk of perioperative complications from OSA, a preoperative determination must be made regarding whether surgery should be performed on an inpatient or outpatient basis.	Meta-analysis, systematic review and expert consensus	Good
American Academy of	**Diagnosis**	Meta-analysis,	Fair

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
Sleep Medicine , 2010	1. The presence and severity of obstructive sleep apnea (OSA) must be determined before initiating surgical therapy **(Standard)**. 2. The patient should be advised about potential surgical success rates and complications, the availability of alternative treatment options such as nasal positive airway pressure and oral appliances, and the levels of effectiveness and success rates of these alternative treatments **(Standard)**. **Treatment Objective** 1. The desired outcomes of treatment include resolution of the clinical signs and symptoms of obstructive sleep apnea and the normalization of sleep quality, the apnea-hypopnea index (AHI), and oxyhemoglobin saturation levels **(Standard)**. **Surgical Procedures** 1. Tracheostomy: Tracheostomy has been shown to be an effective single intervention to treat obstructive sleep apnea. This operation should be considered only when other options do not exist, have failed, are refused, or when this operation is deemed necessary by clinical urgency **(Option)**. 2. Maxillo-Mandibular Advancement (MMA): MMA is indicated for surgical treatment of severe OSA in patients who cannot tolerate or who are unwilling to adhere to positive airway pressure therapy, or in whom oral appliances, which are more often appropriate in mild and moderate OSA patients, have been considered and found ineffective or undesirable **(Option)**. 3. Uvulopalatopharyngoplasty (UPPP) as a single surgical procedure: UPPP as a sole procedure, with or without a tonsillectomy, does not reliably normalize the apnea-hypopnea index (AHI) when treating moderate to severe obstructive sleep apnea syndrome. Therefore, patients with severe OSA should initially be offered positive airway pressure therapy, while those with moderate OSA should initially be offered either positive airway pressure (PAP) therapy or oral appliances **(Option)**. 4. Multi-Level of Stepwise Surgery (MLS): Use of MLS, as a combined procedure or as stepwise multiple operations, is acceptable in patients with narrowing of multiple sites in the upper airway, particularly if they have failed uvulopalatopharyngoplasty as a sole treatment **(Option)**. 5. Laser Assisted Uvulopalatoplasty (LAUP): LAUP is not routinely recommended as a treatment for obstructive sleep apnea syndrome **(Standard)**. 6. 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	review of published meta-analyses, systematic review, and expert consensus	

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
	airway pressure therapy, or in whom oral appliances have been considered and found ineffective or undesirable **(Option)**. 7. Palatal Implants: Palatal implants may be effective in some patients with mild 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 **(Option)**.		
American Academy of Sleep Medicine, 2006	**Weight Reduction** Successful dietary weight loss may improve the apnea-hypopnea index (AHI) in obese obstructive sleep apnea (OSA) patients. **(Guideline)** *This parameter is based on one Level I, one Level II, and 2 Level III papers.* Dietary weight loss should be combined with a primary treatment for OSA. (Kushida 2005; Kushida 2006; American Sleep Disorders Association, 1996) **(Option)** Bariatric surgery may be adjunctive in the treatment of OSA in obese patients. **(Option)** **Pharmacologic Agents** Selective serotonergic uptake inhibitors (SSRIs) are not recommended for treatment of OSA. **(Standard)** *The above recommendation is derived from 2 Level II publications and one level V using paroxetine and fluoxetine.* Protriptyline is not recommended as a primary treatment for OSA. **(Guideline)** *Three Level II and one Level V papers form the basis of this recommendation.* Methylxanthine derivatives (aminophylline and theophylline) are not recommended for treatment of OSA. **(Standard)** *For this recommendation, there are 3 Level II publications, all of which report similar negative findings.* Estrogen therapy (estrogen preparations with or without progesterone) is not indicated for the treatment of OSA. **(Standard)** *This recommendation is based on the results of 4 Level I, 3 Level II, and one Level V publications.* Modafinil is recommended for the treatment of residual excessive daytime sleepiness in OSA patients who have sleepiness despite effective positive airway pressure (PAP) treatment and who are lacking any other identifiable cause for their sleepiness. **(Standard)**	Systematic review, expert consensus	Good

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
American Academy of Sleep Medicine, 2007	**Indications for Portable Monitoring (PM)** "…PM may be used as an alternative to polysomnography (PSG) for the diagnosis of OSA in patients with a high pretest probability of moderate to severe OSA. PM should not be used in the patient groups with comorbidities, other sleep disorders, or for screening, as follows: • PM is not appropriate for the diagnosis of OSA in patients with significant comorbid medical conditions that may degrade the accuracy of PM, including, but not limited to, moderate to severe pulmonary disease, neuromuscular disease, or congestive heart failure. • PM is not appropriate for the diagnostic evaluation of OSA in patients suspected of having other sleep disorders, including central sleep apnea, periodic limb movement disorder (PLMD), insomnia, parasomnias, circadian rhythm disorders, or narcolepsy. • PM is not appropriate for general screening of asymptomatic populations. PM may be indicated for the diagnosis of OSA in patients for whom in-laboratory PSG is not possible by virtue of immobility, safety, or critical illness. PM may be indicated to monitor the response to noncontinuous positive airway pressure (CPAP) treatments for OSA, including oral appliances, upper airway surgery, and weight loss. **Conclusions** PM use should be integrated into a comprehensive program of patient evaluation and treatment under the direction of a sleep specialist board certified in sleep medicine. PM should only be used in populations with substantive published data on specificity and sensitivity. PM should be regulated by policies and procedures that maximize the reliability and validity of the diagnostic process.	Systematic review, expert consensus	Fair
University of Texas at Austin, School of Nursing, 2006	**Objective Assessment/Physical Examination** • Vital signs, including blood pressure, pulse, respirations: OSA is a leading cause of hypertension (The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure [JNC-7], 2003) **(Strength of Recommendation: B; Quality of Evidence: Fair)** • Height, weight, body mass index (BMI) calculation; BMI 25-30 indicates overweight, BMI >30 indicates obesity **(Strength of Recommendation: B; Quality of Evidence: Fair)** • HEENT: assess upper airway airflow obstruction, nasal polyps, septal deviation, mucosal congestion, turbinate hypertrophy, enlarged tonsils, large tongue volume, small jaw (micrognathia)	Systematic review	Poor

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
	• Measurement of neck circumference: >16 (women), >17 (men) • Neck exam: assess for thyroid enlargement **(Strength of Recommendation: B; Quality of Evidence: Fair)** • Cardiovascular exam: assess for rhythm regularity, bruits, murmurs (high prevalence with cardiovascular disease [CVD], CHF, arrhythmias, and hypertension (Hamilton, Solin, & Naughton, 2004; American Heart Association, 2005; JNC-7, 2003; Shahar 2001 **(Strength of Recommendation: B; Quality of Evidence: Fair)** • Pulmonary exam: assess breath sounds and quality of respirations • Abdominal exam: waist-hip ratio to determine body fat distribution: >0.72 = abnormal • Musculoskeletal: deformities, swelling, or pain with movement • Neurological exam: sensory function, balance, deep tendon reflexes • Psychiatric exam: administration of depression screening form (Netzer 2003; Schroder, 2005; Elliot, 2001; Mansfield & Naughton, 2005; Hamilton, Solin, & Naughton, 2004; Stevenson, 2003) **(Strength of Recommendation: B; Quality of Evidence: Fair)** **Diagnostic Procedures** 1. Laboratory studies • Sleep questionnaire (e.g., Epworth Sleepiness Scale), screen for sleep abnormalities (Elliott, 2001) **(Strength of Recommendation: A; Quality of Evidence: Good)** 2. Diagnostic tests • NPSG Sleep Study: Nocturnal polysomnographic diagnostic testing (Netzer 2003; Schroder, 2005; Elliot, 2001; Mansfield & Naughton, 2005; Hamilton, Solin, & Naughton, 2004; Rodsutti 2004) **(Strength of Recommendation: A; Quality of Evidence: Good)**		
American Academy of Sleep Medicine, 2007	Auto-titrating continuous positive airway pressure (APAP) is not recommended to diagnose obstructive sleep apnea (OSA). (**Standard**) Patients with congestive heart failure, significant lung disease such as chronic obstructive pulmonary disease, patients expected to have nocturnal arterial oxyhemoglobin desaturation due to conditions other than OSA (e.g., obesity hypoventilation syndrome), patients who do not snore (either naturally or as a result of palate surgery), and patients who have central sleep apnea syndromes are not currently candidates for APAP titration or treatment. (**Standard**)	Systematic review and expert consensus	Fair

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
	APAP devices are not currently recommended for split-night titration. (**Standard**) Certain APAP devices may be used during attended titration with polysomnography to identify a single pressure for use with standard continuous positive airway pressure (CPAP) for treatment of moderate to severe OSA (**Guideline**) Certain APAP devices may be initiated and used in the self-adjusting mode for unattended treatment of patients with moderate to severe OSA without significant comorbidities (congestive heart failure [CHF], chronic obstructive pulmonary disease [COPD], central sleep apnea syndromes, or hypoventilation syndromes). (**Option**) Certain APAP devices may be used in an unattended way to determine a fixed CPAP treatment pressure for patients with moderate to severe OSA without significant comorbidities (CHF, COPD, central sleep apnea syndromes, or hypoventilation syndromes). (**Option**) Patients being treated with fixed CPAP on the basis of APAP titration or being treated with APAP must have close clinical follow-up to determine treatment effectiveness and safety. This is especially important during the first few weeks of positive airway pressure (PAP) use. (**Standard**) A reevaluation and, if necessary, a standard attended CPAP titration should be performed if symptoms do not resolve or if the APAP treatment otherwise appears to lack efficacy. (**Standard**)		
American Academy of Sleep Medicine (2008)	**General Recommendations for Conducting Positive Airway Pressure (PAP) Titration Studies in Pediatric or Adult Patients with Obstructive** Sleep Apnea **(OSA)** All potential PAP titration candidates (including those candidates prior to a diagnostic study where the clinical suspicion of OSA is high and a split-night study is a possibility) should receive adequate PAP education, hands-on demonstration, careful mask fitting, and acclimatization prior to titration. **(Standard)** Recording the airflow signal generated by the PAP device or estimating airflow by measurement of the pressure difference between the mask and the outlet of the machine using a pressure transducer, with or without square root transformation of the signal, are acceptable methods for detecting apneas or	Systematic review, expert consensus	Good

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
	hypopneas. **(Consensus)** Nasal airflow obtained from a thermistor or thermocouple placed under the PAP mask is not an acceptable method for detecting apneas or hypopneas. **(Consensus)** Respiratory effort–related arousals (RERAs) may be estimated by flattening of the inspiratory airflow profile associated with an arousal when airflow changes do not meet criteria for apneas or hypopneas. **(Consensus)** Sawtooth patterns in the unfiltered airflow or mask pressure tracings and/or detection of vibration by piezoelectric transducers or microphones applied to the neck are acceptable methods for detecting snoring. **(Consensus)** **<u>Recommendations for Conducting Continuous Positive Airway Pressure (CPAP) Titration Studies in Pediatric or Adult Patients with OSA</u>** **General Recommendations for CPAP Titration Studies** CPAP should be increased until the following obstructive respiratory events are eliminated (no specific order) or the recommended maximum CPAP is reached: apneas, hypopneas, RERAs, and snoring. **(Consensus)** The recommended minimum starting CPAP should be 4 cm H_2O in pediatric and adult patients. **(Consensus)** The recommended maximum CPAP should be 15 cm H_2O for patients <12 years and 20 cm H_2O for patients ≥12 years. **(Consensus)** Methodology to determine CPAP a priori has insufficient evidence, although a higher starting CPAP may be selected for patients with an elevated body mass index (BMI) and for retitration studies. **(Consensus)** **Full-night CPAP Titration Studies** CPAP should be increased by at least 1 cm H_2O with an interval no shorter than 5 min, with the goal of		

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
	eliminating obstructive respiratory events. **(Consensus)** CPAP should be increased (according to the criterion in previous recommendation) if at least 1 obstructive apnea is observed for patients <12 years or if at least 2 obstructive apneas are observed for patients ≥12 years. **(Consensus)** CPAP should be increased if at least 1 hypopnea is observed for patients <12 years or if at least 3 hypopneas are observed for patients ≥12 years. **(Consensus)** CPAP should be increased if at least 3 RERAs are observed for patients <12 years or if at least 5 RERAs are observed for patients ≥12 years. **(Consensus)** CPAP may be increased if at least 1 min of loud or unambiguous snoring is observed for patients <12 years or if at least 3 min of loud or unambiguous snoring are observed for patients ≥12 years. **(Consensus)** "Exploration" of CPAP above the pressure at which control of abnormalities in respiratory parameters is achieved should not exceed 5 cm H_2O. **(Consensus)** If the patient awakens and complains that the pressure is too high, the pressure should be restarted at a lower pressure, chosen as one that the patient reports is comfortable enough to allow return to sleep. **(Consensus)** "Down" titration is not required but may be considered as an option. **(Consensus)** **Split-night CPAP Titration Studies** The titration algorithm for split-night CPAP titration studies should be identical to that of full-night CPAP titration studies. **(Guideline)** Of note, there are insufficient data to make any recommendations for split-night CPAP titration studies in children <12 years. **Recommendations for Conducting Bilevel PAP (BPAP) Titration Studies in Pediatric or Adult Patients with**		

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
	OSA **General Recommendations for BPAP Titration Studies** If the patient is uncomfortable or intolerant of high pressures on CPAP, the patient may be tried on BPAP. If there are continued obstructive respiratory events at 15 cm H2O of CPAP during the titration study, the patient may be switched to BPAP. **(Consensus)** BPAP (inspiratory positive airway pressure [IPAP] and/or expiratory positive airway pressure [EPAP], depending on the type of obstructive respiratory event) should be increased until the following events are eliminated (no specific order) or the recommended maximum IPAP is reached: apneas, hypopneas, RERAs, and snoring. **(Consensus)** The recommended minimum starting IPAP and EPAP should be 8 cm H_2O and 4 cm H_2O, respectively, in pediatric and adult patients **(Consensus)**. In addition, when switching from CPAP to BPAP, the Task Force recommends that the minimum starting EPAP should be set at 4 cm H_2O or the CPAP level at which obstructive apneas were eliminated. The recommended maximum IPAP should be 20 cm H_2O for patients <12 years or 30 cm H_2O for patients ≥12 years. **(Consensus)** Methodology to determine IPAP or EPAP a priori has insufficient evidence, although a higher starting IPAP or EPAP may be selected for patients with an elevated BMI and for retitration studies. **(Consensus)** The recommended minimum IPAP-EPAP differential is 4 cm H_2O and the recommended maximum IPAP-EPAP differential is 10 cm H_2O. **(Consensus)** **Full-night BPAP Titration Studies** IPAP and/or EPAP (depending on the type of obstructive respiratory event) should be increased by at least 1 cm H_2O apiece with an interval no shorter than 5 min, with the goal of eliminating obstructive respiratory events. **(Consensus)** IPAP and EPAP should be increased (according to the criterion in the previous recommendation) if at least 1		

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
	obstructive apnea is observed for patients <12 years or if at least 2 obstructive apneas are observed for patients ≥12 years. **(Consensus)** IPAP should be increased if at least 1 hypopnea is observed for patients <12 years or if at least 3 hypopneas are observed for patients ≥12 years. **(Consensus)** IPAP should be increased if at least 3 RERAs are observed for patients <12 years or if at least 5 RERAs are observed for patients ≥12 years. **(Consensus)** IPAP may be increased if at least 1 min of loud or unambiguous snoring is observed for patients <12 years or if at least 3 min of loud or unambiguous snoring are observed for patients ≥12 years. **(Consensus)** "Exploration" of IPAP above the pressure at which control of abnormalities in respiratory parameters is achieved should not exceed 5 cm H_2O. **(Consensus)** If the patient awakens and complains that the pressure is too high, the pressure should be restarted at a lower IPAP, chosen as one that the patient reports is comfortable enough to allow return to sleep. **(Consensus)** A decrease in IPAP or setting BPAP in spontaneous-timed (ST) mode with backup rate may be helpful if treatment-emergent central apneas (i.e., complex sleep apnea) are observed during the titration study. **(Consensus)** "Down" titration is not required but may be considered as an option. **(Consensus)** **Split-night BPAP Titration Studies** The titration algorithm for split-night BPAP titration studies should be identical to that of full-night BPAP titration studies. **(Consensus)** Of note, there are insufficient data to make any recommendations for split-night BPAP titration studies in children <12 years.		

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
	Important Considerations for PAP Titration Studies in Pediatric or Adult Patients with OSA **Acceptable PAP Titration Study** The CPAP or BPAP selected for patient use following the titration study should reflect control of the patient's obstructive respiration by a low (preferably <5 per hour) RDI at the selected pressure, a minimum sea level oxygen saturation (SpO_2) above 90% at the pressure, and with a leak within acceptable parameters at the pressure. **(Consensus)** Grading system: An optimal titration reduces RDI <5 per hour for at least a 15-min duration and should include supine rapid-eye-movement (REM) sleep at the selected pressure that is not continually interrupted by spontaneous arousals or awakenings. **(Consensus)** Grading system: A good titration reduces the overnight RDI ≤10 per hour or by 50% if the baseline RDI <15 per hour and should include supine REM sleep that is not continually interrupted by spontaneous arousals or awakenings at the selected pressure. **(Consensus)** Grading system: An adequate titration is one that does not reduce the overnight RDI ≤10 per hour but does reduce the RDI by 75% from baseline (especially in severe OSA patients), or one in which the titration grading criteria for optimal or good are met with the exception that supine REM sleep did not occur at the selected pressure. **(Consensus)** **Repeat PAP Titration Study** A repeat PAP titration study should be considered if the initial titration does not achieve a grade of optimal or good and, if it is a split-night polysomnography (PSG) study, it fails to meet American Academy of Sleep Medicine (AASM) criteria. **(Consensus)** **Leak and Comfort** PAP mask refit or readjustment should be performed whenever any significant unintentional leak is observed. **(Consensus)** There is insufficient evidence for what constitutes a clinically significant leak given mask fit and other factors; however, in general, an unacceptable leak for PAP is one that is substantially higher than the leak		

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
	recorded at a given pressure from a well-fitted, applied, and secured interface. The acceptable leak will always exceed the intentional leak, which depends on the applied pressure and interface type. The intentional leak vs. pressure relationship is usually supplied by the manufacturer of each interface. **(Consensus)** Pressure waveform modification technologies may improve patient comfort and adherence with PAP. **(Consensus)** **Positional and Sleep Stage Factors** Ideally, the patient should be recorded in supine REM sleep for at least 15 min at the designated optimal pressure during the PAP titration study. If the patient is in REM sleep but not in the supine position while at the designated optimal pressure, the patient may be awakened and instructed to lie in the supine position. **(Consensus)** **Supplemental Oxygen** Supplemental O_2 should be added during the PAP titration when, prior to the PAP titration, the patient's awake supine SpO_2 while breathing room air is ≤88%. Supplemental O_2 may also be added during the PAP titration when SpO_2 is ≤88% for ≥5 minutes in the absence of obstructive respiratory events. In both instances, supplemental O_2 should be introduced at 1 L/min and titrated upwards to achieve a target SpO_2 between 88% and 94%. **(Consensus)** The minimum starting O_2 rate should be 1 L/min (both pediatric and adult patients). **(Consensus)** O_2 rate should be increased by 1 L/min, with an interval no shorter than 15 min, until SpO_2 is between 88% and 94%. **(Consensus)** Optimally, supplemental O_2 should be connected to the PAP device outlet (using a T-connector). **(Consensus)** "Weaning" down of O_2 supplementation by employing BPAP or by further increasing IPAP (if BPAP was already instituted and if the patient tolerates the higher inspiratory pressures) can be attempted.		

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
	(Consensus) **Adaptive Servoventilation** Adaptive servoventilation may be considered if the patient is observed to have Cheyne-Stokes respiration or if treatment emergent central sleep apnea (i.e., complex sleep apnea) during the titration study is not eliminated by down titration of pressure. **(Consensus)** **Follow-up After the PAP Titration Study** PAP usage should be objectively monitored to help assure utilization. **(Standard)** Troubleshooting of problems encountered while on PAP, management of side effects, and methods to increase adherence should be a part of the close follow-up of the patient on PAP. **(Standard)**		
American Society of Plastic Surgeons, 2009	Recommendations Supporting Evidence Grade Obstructive Sleep Apnea (OSA) Patient Selection **Patient selection** The physical examination should include an evaluation of the airway, nasopharyngeal characteristics, tonsil and tongue size, neck circumference, and body mass index (BMI). (Liistro 2003; Kheterpal 2006) Grade: B **Preoperative** Continuous positive airway pressure (CPAP) has been shown to be effective at treating OSA; preoperative CPAP may be beneficial, especially in patients who are already using home CPAP (Gupta 2001; Rennotte 1995; Ballester 1999; Jenkinson 1999; Spicuzza 2006) Grade: A, B If premedication, such as benzodiazepines, will be administered, patients must be monitored continuously for any signs of respiratory compromise; CPAP should be available for use if the patient becomes sleepy and cannot control his or her own airway. (Gupta 2001; Rennotte 1995; Hoijer 1994; Dolly & Block, 1982) Grade: B **Patient Selection** The medical history should include questions about current symptoms (e.g., cough, dyspnea, wheezing) and frequency of symptoms; intensity of treatment (did patient require therapy at a medical facility?); current medications; recent use of rescue medications; tolerance to aspirin, cold air, dust, or smoke; smoking history; and previous exposures to general anesthesia and endotracheal intubation. (Warner, 2000) Grade:	Systematic review, expert consensus	Fair

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
	D** A complete physical examination should be performed, including chest auscultation, assessment of skin coloration, and chest radiography when indicated. Patients should be free of symptoms and have optimal lung function. If a patient presents with symptoms, elective surgery should be postponed, if possible, pending resolution of symptoms. Patients with severe or uncontrolled disease, or those in which pulmonary status is uncertain, should be referred to a pulmonologist for assessment of pulmonary function. If patients have been on steroid therapy during the past 6 mo before surgery, additional steroid support may be necessary. **Preoperative** If endotracheal intubation is required, consider preoperative prophylaxis (corticosteroids, topical lidocaine, beta$_2$-adrenergic agonists). (Groeben 2000; Maslow 2000; Groeben "Both local anesthetics and salbutamol," 2002; Silvanus, Groeben, & Peters, 2004) Grade: A Consider preoperative sedation with benzodiazepines. (Expert opinion) Grade: D		
American Academy of Sleep Medicine, 2006	Treatment with continuous positive airway pressure (CPAP) must be based on a prior diagnosis of obstructive sleep apnea (OSA) established using an acceptable method **(Standard**). *This recommendation is based on previous American Academy of* **Sleep** *Medicine (AASM) practice parameters for the indications for polysomnography and related procedures (2005 update).* CPAP is indicated for the treatment of moderate to severe OSA **(Standard)**. *This recommendation is based on 24 randomized controlled trials meeting Level I or II evidence-based medicine criteria.* CPAP is recommended for the treatment of mild OSA **(Option)**. *This recommendation as an option is based on mixed results in 2 Level I and 3 Level II outcome*	Systematic review and expert consensus	Good

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
	studies in patients with mild OSA. CPAP is indicated for improving self-reported sleepiness in patients with OSA **(Standard)**. *This recommendation is based on 10 randomized controlled trials in which CPAP reduced* **sleep***iness more than control procedures in patients with OSA.* CPAP is recommended for improving quality of life in patients with OSA **(Option)**. *This recommendation as an option is based on inconsistent results from 2 Level I studies and 4 Level II studies with placebo control, and 1 Level II study with conservative therapy as the control.* CPAP is recommended as an adjunctive therapy to lower blood pressure in hypertensive patients with OSA **(Option)**. *This recommendation as an option is based on 9 clinical trials, 6 of which did not find changes in mean arterial pressure compared to placebo.* Full-night, attended polysomnography performed in the laboratory is the preferred approach for titration to determine optimal positive airway pressure; however, split-night, diagnostic-titration studies are usually adequate **(Guideline)**. *This recommendation is based on 1 Level II and 6 Level IV studies.* CPAP Usage should be objectively monitored to help assure utilization **(Standard)**. *This recommendation is based on overwhelming evidence at all levels indicating patients with OSA overestimate their positive airway pressure. Level I and Level II studies indicate that objectively-measured nightly CPAP "time on" ranges from 3.5 hours/night in minimally symptomatic new patients to 7.1 hours/night in established users.* Close follow-up for positive airway pressure (PAP) usage and problems in patients with OSA by appropriately trained health care providers is indicated to establish effective utilization patterns and remediate problems, if needed. This is especially important during the first few weeks of PAP use **(Standard)**. *This recommendation is based on 61 studies that examined management paradigms and collected acceptance, utilization, and adverse events; 17 of these studies qualified as Level I.* The addition of heated humidification is indicated to improve CPAP utilization **(Standard)**.*This recommendation is based on 3 Level I studies. There was 1 Level II study that did not find*		

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
	increased utilization with heated humidification. Three additional studies favored heated humidification over unheated or non-humidified CPAP. The addition of a systematic educational program is indicated to improve PAP utilization **(Standard)**. *This recommendation is based on 4 Level I studies, 1 Level II study, and 1 Level III study.* After initial CPAP setup, long-term follow-up for CPAP-treated patients with OSA by appropriately trained health care providers is indicated yearly and as needed to troubleshoot PAP mask, machine, or usage problems **(Option)**. *This recommendation as an option is based on task force and SPC member consensus.* CPAP and bi-level positive airway pressure (BPAP) therapy are safe; side effects and adverse events are mainly minor and reversible **(Standard)**. *This recommendation is based on more than 23 published reports.* While the literature mainly supports CPAP therapy, BPAP is an optional therapy in some cases where high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure or coexisting central hypoventilation is present **(Guideline)**. *This recommendation is based on 2 Level I studies which yielded no evidence that BPAP improves efficacy or adherence in the management of OSA compared to CPAP.* BPAP may be useful in treating some forms of restrictive lung disease or hypoventilation syndromes associated with daytime hypercapnia **(Option)**. *This recommendation as an option is based on 11 studies all graded at Level III or better that overall found improvement associated with BPAP therapy.*		

Recommending Body, Year Published	Guideline(s)	Evidence Base	Overall Quality
European Federation of Neurological Societies, 2007	1. Patients with neurologic diseases often have significant sleep disorders which may affect both nocturnal sleep and daytime function with increased morbidity and even mortality. Many of these disorders are potentially treatable. Therefore, increased awareness should be directed toward sleep disorders in patient with neurodegenerative, cerebrovascular and neuromuscular diseases. Despite that, there are practically no grade A or B studies in this area. 2. A polysomnography (PSG) is usually a diagnostic minimum for the diagnoses of the most commonly reported sleep disorders in patients with neurologic diseases. 3. In patients with nocturnal motor and/behavior manifestations, a full video-PSG/video-electroencephalography (EEG)-PSG should be considered. 4. Respiratory polygraphy has a moderate sensitivity and specificity in the diagnosis of obstructive sleep apnea syndrome (OSAS) without neurologic diseases, but its value for diagnosis of other sleep-related breathing disorder (SBD) or in patients with OSAS with neurologic diseases has not been evaluated compared to gold standard PSG. 5. Limited channel polygraphy oximetry has a poor to moderate sensitivity-specificity for the identification of OSAS in patients without neurologic diseases. Oximetry cannot differentiate between obstructive and central sleep apnea or is insufficient to identify stridor. It is possible that oximetry has a role for the screening of hypoventilation in patients with neuromuscular weakness. Furthermore, oximetry may be useful for the control of continuous positive airway pressure (CPAP) treatment. 6. Patients with sleep-disordered breathing and muscle weakness and/or cardiac or pulmonary co-morbidity may present a sleep hypoventilation syndrome (SHVS), which manifests early as increased CO_2, hence $PaCO_2$ should be considered and controlled in such cases during sleep recordings. 7. Fixed pressure CPAP/auto-adjusted CPAP is the most effective treatment of OSAS. This probably also includes patients with OSAS and neurologic diseases. However, there is a need for further evaluation of the effect of CPAP in patients with OSAS and neurologic diseases. 8. Bi-level PAP/variable PAP, noninvasive positive pressure ventilation (NIPPV) and volumetric ventilation is useful for SBD-like central apneas, Cheyne-Stokes breathing, and alveolar hypoventilation. 9. There is a clear need for further studies focusing on the diagnostic procedures and treatment modalities in patients with sleep disorders and neurologic diseases.	Meta-analyses review, systematic review, and expert consensus	Fair

***Individual Guideline Rating Keys**

Key to guideline rating systems

American Academy of Sleep Medicine

Classification of Evidence

Level I Randomized well-designed trials with low alpha and beta levels*
Level II Randomized trials with high alpha and beta levels*
Level III Nonrandomized concurrently controlled studies
Level IV Nonrandomized historically controlled studies
Level V Case series

*Alpha (type I error) refers to the probability that the null hypothesis is rejected when in fact it is true (generally acceptable at 5% or less, or $p<0.05$). Beta (Type II error) refers to the probability that the null hypothesis is mistakenly accepted when in fact it is false (generally trials accept a beta error of 0.20). The estimation of Type II error is generally the result of a power analysis. The power analysis takes into account the variability and the effect size to determine if sample size is adequate to find a difference in means when it is present (Power generally acceptable at 80-90%).

Levels of Recommendations

Standard This is a generally accepted patient-care strategy, which reflects a high degree of clinical certainty. The term standard generally implies the use of Level I Evidence, which directly addresses the clinical issue, or overwhelming Level II Evidence.
Guideline This is a patient-care strategy, which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence.
Option This is a patient-care strategy, which reflects uncertain clinical use. The term option implies either inconclusive or conflicting evidence or conflicting expert opinion.

University of Texas at Austin School of Nursing

Quality of Evidence (Based on U.S. Preventive Services Task Force Ratings)
Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes
Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.
Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

Strength of Recommendations (Based on U.S. Preventive Services Task Force Ratings)

A. There is good evidence that the recommendation improves important health outcomes. Benefits substantially outweigh harms.

B. There is at least fair evidence that the recommendation improves important health outcomes. Benefits outweigh harms.
C. There is at least fair evidence that the recommendation can improve health outcomes but the balance of benefits and harms is too close to justify general recommendation.
D. There is at least fair evidence that the recommendation is ineffective or that harms outweigh benefits.
I. Evidence that the recommendation is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

American Society of Plastic Surgeons
Evidence Rating Scale for Studies Reviewed

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, randomized controlled trial with adequate power; or a systematic review of these studies
II	Lesser-quality, randomized controlled trial; prospective cohort study; or a systematic review of these studies
III	Retrospective comparative study; case-control study; or a systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

Scale for Grading Recommendations

Grade	Descriptor	Qualifying Evidence	Implications for Practice
A	Strong Recommendation	Level I evidence or consistent findings from multiple studies of levels II, III, or IV	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
B	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preference.
C	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
D	Option	Level V; little or no systematic	Clinicians should consider all options in their decision-making and be alert to new

Grade	Descriptor	Qualifying Evidence	Implications for Practice
		empirical evidence	published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

*Evidence composed of only one level III or IV study; more than one study would be needed to assign a higher grade of recommendation.

**Evidence composed of only one level II, III, or IV study; more than one study would be needed to assign a higher grade of recommendation.

Appendix L. Quality Assessment of Selected Guidelines

Key Recommendations	Guideline Developer, Year												
	NICE, 2007	NICE, 2008	AASM, 2009	ASA, 2006	AASM, 2010	AASM, 2006a	AASM, 2007a	UTSN, 2006	AASM, 2007b	AASM, 2008	ASPS, 2009	AASM, 2006b	EFNS, 2007
Section 1: Primary Criteria													
Rigor of Development: Evidence	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good
Rigor of Development: Recommendations	Good	Good	Fair	Good	Fair	Fair	Fair	Poor	Fair	Good	Fair	Good	Fair
Editorial Independence	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good
Section 2: Secondary Criteria													
Scope and Purpose	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good
Stakeholder Involvement	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good
Clarity and Presentation	Good	Good	Good	Good	Good	Good	Good	Poor	Good	Good	Fair	Good	Good
Applicability	Fair	Good	Fair	Good	Fair	Fair	Good	Good	Fair	Fair	Fair	Fair	Fair
Section 3: Overall Assessment of the Guideline													
How well done is this guideline?	**Good**	**Good**	**Fair**	**Good**	**Fair**	**Good**	**Fair**	**Poor**	**Fair**	**Good**	**Fair**	**Good**	**Fair**

Appendix M. Quality Assessment Tools

MED PROJECT	Methodology Checklist: Systematic Reviews and Meta-analyses

Study citation (*Include last name of first author, title, year of publication, journal title, pages*)

MED Topic:	Key Question No.(s):
Checklist completed by:	Date:

SECTION 1: INTERNAL VALIDITY

	In a well conducted systematic review	***In this study the criterion is met:***			
1.1	The study addresses an appropriate and clearly focused question.	YES	NO	UNCLEAR	N/A
1.2	An adequate description of the methodology used is included, and the methods used are appropriate to the question.	YES	NO	UNCLEAR	N/A
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	YES	NO	UNCLEAR	N/A
1.4	The criteria used to select articles for inclusion is appropriate.	YES	NO	UNCLEAR	N/A
1.5	Study quality is assessed and taken into account.	YES	NO	UNCLEAR	N/A
1.6	There are enough similarities between the studies selected to make combining them reasonable.	YES	NO	UNCLEAR	N/A
1.7	Competing interests of members have been recorded and addressed.	YES	NO	UNCLEAR	N/A
1.8	Views of funding body have not influenced the content of the study.	YES	NO	UNCLEAR	N/A

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1	How well was the study done to minimize bias? *Code: Good, Fair or Poor*	GOOD	FAIR	POOR

2.2	If coded as fair or poor, what is the likely direction in which bias might affect the study results?	
2.3	Are the results of this study directly applicable to the patient group targeted by this key question?	YES NO UNCLEAR N/A
2.4	Other reviewer comments:	

MED Project 2009. Adapted from NICE and SIGN materials.

MED PROJECT	Methodology Checklist: Randomized Controlled Trials

Study identification (*Include author, title, year of publication, journal title, pages*)

MED topic:	Key Question No(s):
Checklist completed by:	Date:

SECTION 1: INTERNAL VALIDITY

	In a well conducted RCT study…	***In this study this criterion is met:***
RANDOM ALLOCATION OF SUBJECTS		
1.1	An appropriate method of randomization was used to allocate participants to intervention groups.	YES NO UNCLEAR N/A
1.2	An adequate concealment method was used such that investigators, clinicians, and participants could not influence enrolment or intervention allocation.	YES NO UNCLEAR N/A
1.3	The intervention and control groups are similar at the start of the trial. (The only difference between groups is the treatment under investigation.)	YES NO UNCLEAR N/A
ASSESSMENT AND FOLLOW-UP		
1.4	Investigators, participants, and clinicians were kept 'blind' about treatment allocation and other important confounding/prognostic factors. If the answer is no, describe any bias that might have occurred.	YES NO UNCLEAR N/A
1.5	The intervention and control groups received the same care apart from the intervention(s) studied.	YES NO UNCLEAR N/A
1.6	The study had an appropriate length of follow-up.	YES NO UNCLEAR N/A
1.7	All groups were followed up for an equal length of time (or the analysis was adjusted to allow for differences in length of follow-up).	YES NO UNCLEAR N/A

1.8	What percentage of the individuals or clusters recruited into each group of the study dropped out before the study was completed? What percentage did not complete the intervention(s)?	
1.9	All the subjects were analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	YES NO UNCLEAR N/A
ASSESSMENT AND FOLLOW-UP, Cont.		
1.10	All relevant outcomes are measured in a standard, valid and reliable way.	YES NO UNCLEAR N/A
1.11	The study reported only on surrogate outcomes. (If so, please comment on the strength of the evidence associating the surrogate with the important clinical outcome for this topic.)	YES NO UNCLEAR N/A
1.12	The study uses a composite (vs. single) outcome as the primary outcome. If so, please comment on the appropriateness of the composite and whether any single outcome strongly influenced the composite.	YES NO UNCLEAR N/A
CONFLICT OF INTEREST		
1.13	Competing interests of members have been recorded and addressed.	YES NO UNCLEAR N/A
1.14	Views of funding body have not influenced the content of the study.	YES NO UNCLEAR N/A
Section 2: Overall Study Assessment		
2.1	How well was the study done to minimize bias? *Code Good, Fair, or Poor*	GOOD FAIR POOR
2.2	If coded as Fair or Poor what is the likely direction in which bias might affect the study results?	
2.3	Are the results of this study directly applicable to the patient group targeted by this topic?	YES NO UNCLEAR N/A
2.4	Other reviewer comments:	

MED Project 2009. Adapted from NICE and SIGN materials.

MED PROJECT	Methodology Checklist: Cohort Studies

Study identification (*Include author, title, year of publication, journal title, pages*)

Review topic:	Key Question No.(s), if applicable:
Checklist completed by:	Date:

SECTION 1: INTERNAL VALIDITY

In a well conducted cohort study:		***In this study the criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	YES NO N/A
SELECTION OF SUBJECTS		
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	YES NO N/A
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.	YES NO N/A
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrollment is assessed and taken into account in the analysis.	YES NO N/A
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed?	
1.6	Comparison is made between full participants and those who dropped out or were lost to follow up, by exposure status.	YES NO N/A
ASSESSMENT AND FOLLOW-UP		
1.7	The study employed a precise definition of outcome(s) appropriate to the key question(s).	YES NO N/A
1.8	The assessment of outcome(s) is made blind to exposure status.	YES NO N/A

1.9	Where outcome assessment blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	YES NO N/A
1.10	The measure of assessment of exposure is reliable.	YES NO N/A
1.11	Exposure level or prognostic factor is assessed more than once.	YES NO N/A
1.12	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	YES NO N/A
1.13	The study had an appropriate length of follow-up.	YES NO N/A
1.14	All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up)	YES NO N/A
CONFOUNDING		
1.15	The main potential confounders are identified and taken into account in the design and analysis.	YES NO N/A
STATISTICAL ANALYSIS		
1.16	Have confidence intervals been provided?	YES NO N/A
CONFLICT OF INTEREST		
1.17	Competing interests of members have been recorded and addressed.	YES NO N/A
1.18	Views of funding body have not influenced the content of the study.	YES NO N/A
SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimize the risk of bias or confounding, and to establish a causal relationship between exposure and effect? *Code Good, Fair, or Poor*	GOOD FAIR POOR
2.2	If coded as Fair, or Poor what is the likely direction in which bias might affect the study results?	
2.3	Are the results of this study directly applicable to the patient group targeted by this topic?	YES NO N/A
2.4	Taking into account clinical considerations, your evaluation of the methodology used, and the	

	statistical power of the study, are you certain that the overall effect is due to the exposure being investigated?	YES NO N/A
2.5	Other reviewer comments:	

MED Project 2009. Adapted from NICE and SIGN materials.

MED PROJECT	Methodology Checklist: Economic Evaluation

Study citation (*Include last name of first author, title, year of publication, journal title, pages*)

MED Topic:	Key Question No.(s):
Checklist completed by:	Date:

Cost
Cost analysis (no measure of benefits)

Economic Evaluations (please circle):

Study Type	*Measurement of Benefits*
Cost minimization	Benefits found to be equivalent
Cost effectiveness analysis	Natural units (e.g., life years gained)
Cost utility analysis	Healthy years (e.g. quality adjusted life years, health years equivalent)
Cost-benefit analysis	Monetary terms

Section 1: applicability

In a well conducted economic study…		*In this study the criterion is met:*			
1.1	The results of this study are directly applicable to the patient group targeted by this key question.	YES	NO	UNCLEAR	N/A
If criterion 1.1 is rated no, the study should be excluded.					
1.2	The healthcare system in which the study was conducted is sufficiently similar to the system of interest in the topic key question(s).	YES	NO	UNCLEAR	N/A

SECTION 2: Study Design, Data Collection, and Analysis

In a well conducted economic study…		*In this study the criterion is met:*			
2.1	The research question is well described.	YES	NO	UNCLEAR	N/A
2.2	The economic importance of the research question is	YES	NO	UNCLEAR	N/A

	stated.				
2.3	The perspective(s) of the analysis are clearly stated and justified (e.g. healthcare system, society, provider institution, professional organization, patient group).	YES	NO	UNCLEAR	N/A
2.4	The form of economic evaluation is stated and justified in relation to the questions addressed.	YES	NO	UNCLEAR	N/A
Methods to estimate the effectiveness of the intervention					
2.5	*Circle one* a. Details of the methods of synthesis or meta-analysis of estimates are given (if based on a synthesis of a number of effectiveness studies). b. Details of the design and results of effectiveness study are given (if based on a single study).	YES	NO	UNCLEAR	N/A
2.6	Estimates of effectiveness are used appropriately.	YES	NO	UNCLEAR	N/A
2.7	Methods to value health states and other benefits are stated.	YES	NO	UNCLEAR	N/A
2.8	Outcomes are used appropriately.	YES	NO	UNCLEAR	N/A
2.9	The primary outcome measure for the economic evaluation is clearly stated.	YES	NO	UNCLEAR	N/A
2.10	Details of the subjects from whom valuations were obtained are given.	YES	NO	UNCLEAR	N/A
2.11	Competing alternatives are clearly described.	YES	NO	UNCLEAR	N/A
Methods to estimate the costs of the intervention					
2.12	All important and relevant costs for each alternative are identified.	YES	NO	UNCLEAR	N/A
2.13	Methods for the estimation of quantities and unit costs are described.	YES	NO	UNCLEAR	N/A
2.14	Quantities of resource use are reported separately from their unit costs.	YES	NO	UNCLEAR	N/A
2.15	Productivity changes (if included) are reported	YES	NO	UNCLEAR	N/A

	separately.				
2.16	The choice of model used and the key parameters on which it is based are justified.	YES	NO	UNCLEAR	N/A
2.17	All costs are measured appropriately in physical units.	YES	NO	UNCLEAR	N/A
2.18	Costs are valued appropriately.	YES	NO	UNCLEAR	N/A
2.19	Outcomes are valued appropriately.	YES	NO	UNCLEAR	N/A
2.20	The time horizon is sufficiently long enough to reflect all important differences in costs and outcomes.	YES	NO	UNCLEAR	N/A
2.21	The discount rate(s) is stated.	YES	NO	UNCLEAR	N/A
2.22	An explanation is given if costs and benefits are not discounted.	YES	NO	UNCLEAR	N/A
2.23	The choice of discount rate(s) is justified.	YES	NO	UNCLEAR	N/A
2.24	All future costs and outcomes are discounted appropriately.	YES	NO	UNCLEAR	N/A
2.25	Details of currency of price adjustments for inflation or currency conversion are given.	YES	NO	UNCLEAR	N/A
2.26	Incremental analysis is reported or it can be calculated from the data.	YES	NO	UNCLEAR	N/A
2.27	Details of the statistical tests and confidence intervals are given for stochastic data.	YES	NO	UNCLEAR	N/A
2.28	Major outcomes are presented in a disaggregated as well as aggregated form.	YES	NO	UNCLEAR	N/A
2.29	Conclusions follow from the data reported.	YES	NO	UNCLEAR	N/A
2.30	Conclusions are accompanied by the appropriate caveats.	YES	NO	UNCLEAR	N/A
SECTION 3: sensitivity Analysis					

In a well conducted economic study…		*In this study the criterion is met:*			
3.1	The approach to sensitivity analysis is given.	YES	NO	UNCLEAR	N/A
3.2	All important and relevant costs for each alternative are identified.	YES	NO	UNCLEAR	N/A
3.3	An incremental analysis of costs and outcomes of alternatives is performed.	YES	NO	UNCLEAR	N/A
3.4	The choice of variables for sensitivity analysis is justified.	YES	NO	UNCLEAR	N/A
3.5	All important variables, whose values are uncertain, are appropriately subjected to sensitivity analysis.	YES	NO	UNCLEAR	N/A
3.6	The ranges over which the variables are varied are justified.	YES	NO	UNCLEAR	N/A
SECTION 4: CONFLICT OF INTEREST					
In a well conducted economic study…		*In this study the criterion is met:*			
4.1	Competing interests of members have been recorded and addressed.	YES	NO	UNCLEAR	N/A
4.2	Views of funding body have not influenced the content of the study.	YES	NO	UNCLEAR	N/A
SECTION 5: OVERALL ASSESSMENT					
5.1	**How well was the study done to minimize bias?** ***Code: Good, Fair or Poor***	GOOD	FAIR	POOR	
5.2	If coded as fair or poor, what is the likely direction in which bias might affect the study results?				
5.3	Other reviewer comments:				

MED Project 2011. Adapted from BMJ, NICE, and the Consensus on Health Economic Criteria (CHEC).

MED PROJECT	Methodology Checklist: Guidelines

Guideline citation *(Include name of organization, title, year of publication, journal title, pages)*

MED Topic:	Key Question No.(s), if applicable:
Checklist completed by:	Date:

SECTION 1: PRIMARY CRITERIA

	To what extent is there	***Assessment/Comments:***
1.1	**RIGOR OF DEVELOPMENT: Evidence** • Systematic literature search • Study selection criteria clearly described • Quality of individual studies and overall strength of the evidence assessed • Explicit link between evidence & recommendations *(If any of the above are missing, rate as poor)*	GOOD FAIR POOR
1.2	**RIGOR OF DEVELOPMENT: Recommendations** • Methods for developing recommendations clearly described • Strengths and limitations of evidence clearly described • Benefits/side effects/risks considered • External review	GOOD FAIR POOR
1.3	**EDITORIAL INDEPENDENCE**[1] • Views of funding body have not influenced the content of the guideline • Competing interests of members have been recorded and addressed	GOOD FAIR POOR

If any of three primary criteria are rated poor, the entire guideline should be rated poor.

SECTION 2: SECONDARY CRITERIA

2.1	**SCOPE AND PURPOSE** • Objectives described • Health question(s) specifically described • Population (patients, public, etc.) specified	GOOD FAIR POOR

1 Editorial Independence is a critical domain. However, it is often very poorly reported in guidelines. The assessor should not rate the domain, but write "unable to assess" in the comment section. If the editorial independence is rated as "poor", indicating a high likelihood of bias, the entire guideline should be assessed as poor.

SECTION 2: SECONDARY CRITERIA, CONT.				
2.2	**STAKEHOLDER INVOLVEMENT** • Relevant professional groups represented • Views and preferences of target population sought • Target users defined	GOOD	FAIR	POOR
2.3	**CLARITY AND PRESENTATION** • Recommendations specific, unambiguous • Management options clearly presented • Key recommendations identifiable • Application tools available Updating procedure specified	GOOD	FAIR	POOR
2.4	**APPLICABILITY** • Provides advice and/or tools on how the recommendation(s) can be put into practice • Description of facilitators and barriers to its application • Potential resource implications considered Monitoring/audit/review criteria presented	GOOD	FAIR	POOR
SECTION 3: OVERALL ASSESSMENT OF THE GUIDELINE				
3.1	How well done is this guideline?	GOOD	FAIR	POOR
3.2	Other reviewer comments:			

[This tool is adapted from the Appraisal of Guidelines Research & Evaluation (AGREE) II tool. The full AGREE II tool is available from http://www.agreetrust.org/resource-centre/agree-ii/]

Description of Ratings: Methodology Checklist for Guidelines

The checklist for rating guidelines is organized to emphasize the use of evidence in developing guidelines and the philosophy that "evidence is global, guidelines are local." This philosophy recognizes the unique situations (e.g., differences in resources, populations) that different organizations may face in developing guidelines for their constituents. The second area of emphasis is transparency. Guideline developers should be clear about how they arrived at a recommendation and to what extent there was potential for bias in their recommendations. For these reasons, rating descriptions are only provided for the primary criteria in section one. There may be variation in how individuals might apply the good, fair, and poor ratings in section two based on their needs, resources, organizations, etc.

Section 1. Primary Criteria (rigor of development and editorial independence) ratings:

Good: All items listed are present, well described, and well executed (e.g., key research references are included for each recommendation).
Fair: All items are present, but may not be well described or well executed.
Poor: One or more items are absent or are poorly conducted

Appendix N. Summary of Federal and Private Payer Policies

Payer	Coverage summary
Medicare Effective: 3/13/2008	**Medicare National Coverage Determinations Manual Chapter 1, Part 4** ***240.4 – Continuous positive Airway Pressure CPAP Therapy for Obstructive Sleep Apnea (OSA) (Various Effective Dates)*** *(Rev. 96, Issued: 10-15-08, Effective: 03-13-08. Implementation: 08-04-08)* https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=226&ncdver=3&NCAId=204&NcaName=Continuous+Positive+Airway+Pressure+(CPAP)+Therapy+for+Obstructive+Sleep+Apnea+(OSA)&IsPopup=y&bc=AAAAAAAAIAAA& **Nationally Covered Indications** B. Nationally Covered Indications Effective for claims with dates of service on and after March 13, 2008, the Centers for Medicare & Medicaid Services (CMS) determines that **CPAP therapy when used in adult patients with OSA is considered reasonable and necessary under the following situations**: 1. The use of CPAP is covered under Medicare when used in adult patients with OSA. Coverage of CPAP is initially limited to a 12-week period to identify beneficiaries diagnosed with OSA as subsequently described who benefit from CPAP. CPAP is subsequently covered only for those beneficiaries diagnosed with OSA who benefit from CPAP during this 12-week period. 2. The provider of CPAP must conduct education of the beneficiary prior to the use of the CPAP device to ensure that the beneficiary has been educated in the proper use of the device. A caregiver, for example a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate the CPAP device. 3. A positive diagnosis of OSA for the coverage of CPAP must include a clinical evaluation and a positive: a. attended PSG performed in a sleep laboratory; or b. unattended HST with a Type II home sleep monitoring device; or c. unattended HST with a Type III home sleep monitoring device; or d. unattended HST with a Type IV home sleep monitoring device that measures at least 3 channels. 4. The sleep test must have been previously ordered by the beneficiary's treating physician and furnished under appropriate physician supervision. 5. An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criterion using the AHI or RDI are met: a. AHI or RDI greater than or equal to 15 events per hour, or b. AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart

	disease, or history of stroke. 6. The AHI or RDI is calculated on the average number of events of per hour. If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing must be at a minimum the number of events that would have been required in a 2-hour period. 7. 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.8. Coverage with Evidence Development (CED): Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1-7 above. A clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address one or more of the following questions: a. In Medicare-aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and Type II, III & IV HST in identifying subjects with OSA who will respond to CPAP? b. In Medicare-aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or Type II, III & IV HST, does CPAP cause clinically meaningful harm? c. The study must meet the following additional standards: d. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes. e. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use. f. The research study does not unjustifiably duplicate existing studies. g. The research study design is appropriate to answer the research question being asked in the study. h. The research study is sponsored by an organization or individual capable of executing the proposed study successfully. i. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is Food and Drug Administration-regulated, it also must be in compliance with 21 CFR Parts 50 and 56. j. All aspects of the research study are conducted according to the appropriate standards of scientific integrity. k. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards. l. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options. m. The clinical research study is registered on the ClinicalTrials.gov Web site by the principal sponsor/investigator prior to the enrollment of the first study subject. n. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured, including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within

24 months of the end of data collection. If a report is planned for publication in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than 3 years after the end of data collection.

o. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

p. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

C. Nationally Non-covered Indications

Effective for claims with dates of services on and after March 13, 2008, other diagnostic tests for the diagnosis of OSA, other than those noted above for prescribing CPAP, are not sufficient for the coverage of CPAP.

240.4.1 – Sleep Testing for Obstructive Sleep Apnea (OSA) (Effective March 3, 2009)

(Rev. 103, Issued: 07-10-09, Effective: 03-03-09, Implementation: 08-10-09)

http://www.cmms.hhs.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=330&ncdver=1&NCAId=227&NcaName=Sleep+Testing+for+Obstructive+Sleep+Apnea+(OSA)&IsPopup=y&bc=AAAAAAAAIAAA&

B. Nationally Covered Indications

Effective for claims with dates of service on and after March 3, 2009, the Centers for Medicare & Medicaid Services finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA, that the use of such sleep testing technologies demonstrates improved health outcomes in Medicare beneficiaries who have OSA and receive the appropriate treatment, and that these tests are thus reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

1. Type I PSG is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility. Type II or Type III sleep testing devices are covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
2. Type IV sleep testing devices measuring three or more channels, one of which is airflow, are covered when used to aid the

	diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility. 3. Sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility. C. Nationally Non-Covered Indications Effective for claims with dates of services on and after March 3, 2009, other diagnostic sleep tests for the diagnosis of OSA, other than those noted above for prescribing CPAP, are not sufficient for the coverage of CPAP and are not covered.
Medicare LCDs	L28606 (updated 2/9/11) (Alaska, Oregon, Washington – Region X) A custom fabricated mandibular advancement oral appliance (E0486) used to treat obstructive sleep apnea (OSA) is covered if criteria A - D are met. A. The patient has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for obstructive sleep apnea testing. B. The patient has a Medicare-covered sleep test that meets one of the following criteria (1 - 3): 1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or 2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of: a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or b. Hypertension, ischemic heart disease, or history of stroke., or 3. If the AHI > 30 or the RDI > 30 and meets either of the following (a or b): a. The patient is not able to tolerate a positive airway pressure (PAP) device, or b. The treating physician determines that the use of a PAP device is contraindicated. C. The device is ordered by the treating physician following review of the report of the sleep test. (The physician who provides the order for the oral appliance could be different from the one who performed the clinical evaluation in criterion A.) D. The device is provided and billed for by a licensed dentist (DDS or DMD). If all of these criteria (A-D) are not met, the custom fabricated oral appliance (E0486) will be denied as not reasonable and necessary. Custom fabricated appliances that achieve their effect through positioning of the tongue (E1399) will be denied as not reasonable and necessary. There is insufficient evidence to show that these items are effective therapy for OSA. A prefabricated oral appliance (E0485) will be denied as not reasonable and necessary. There is insufficient evidence to show that these items are effective therapy for OSA. Custom fabricated mandibular advancement devices that do not meet the requirements in the Coding Guidelines section of the Related Policy Article (E1399) will be denied as not reasonable and necessary.

L171 (updated 3/7/11) (Alaska, Oregon, Washington – Region X)
In this policy, the term PAP (positive airway pressure) device will refer to both a single-level continuous positive airway pressure device (E0601) and a bi-level respiratory assist device without back-up rate (E0470) when it is used in the treatment of obstructive sleep apnea.

I. An E0601 device is covered for the treatment of obstructive sleep apnea (OSA) if criteria A - C are met:
   - A. The patient has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for obstructive sleep apnea.
   - B. The patient has a sleep test (as defined below) that meets either of the following criteria (1 or 2):
     1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,
     2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
        - a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
        - b. Hypertension, ischemic heart disease, or history of stroke.
   - C. The patient and/or their caregiver has received instruction from the supplier of the device in the proper use and care of the equipment.

If a claim for an E0601 is submitted and all of the criteria above have not been met, it will be denied as not reasonable and necessary.

II. An E0470 device is covered for those patients with OSA who meet criteria A-C above, in addition to criterion D
   - D. An E0601 has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.

Ineffective is defined as documented failure to meet therapeutic goals using an E0601 during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings).
If E0470 is billed for a patient with OSA and criteria A-D are not met, it will be denied as not reasonable and necessary.
A bi-level positive airway pressure device with back-up rate (E0471) is not reasonable and necessary if the primary diagnosis is OSA. If an E0471 is billed with a diagnosis of OSA, it will be denied as not reasonable and necessary.
If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 does not require a new initial face-to-face clinical evaluation or a new sleep test.
If an E0601 device has been used for more than 3 months and the patient is switched to an E0470, a new initial face-to-face clinical evaluation is required, but a new sleep test is not required. A new 3 month trial would begin for use of the E0470.
Coverage, coding and documentation requirements for the use of the E0470 and E0471 for diagnoses other than OSA are addressed in the Respiratory Assist Devices (RAD) Local Coverage Determination (LCD) and Policy Article (PA).

Continued coverage of a PAP device (E0470 or E0601) beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating physician must conduct a clinical re-evaluation and document that the

	beneficiary is benefiting from PAP therapy. For PAP devices with initial dates of service on or after November 1, 2008, documentation of clinical benefit is demonstrated by: 1. Face-to-face clinical re-evaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved; and 2. Objective evidence of adherence to use of the PAP device reviewed by the treating physician. Adherence to therapy is defined as use of PAP ≥ 4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage. If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as not reasonable and necessary. If the physician re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the patient is benefiting from PAP therapy as defined in criteria 1 and 2 above, continued coverage of the PAP device will commence with the date of that re-evaluation. Beneficiaries who fail the initial 12 week trial are eligible to requalify for a PAP device but must have both: 1. Face-to-face clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to PAP therapy; and 2. Repeat sleep test in a facility-based setting (Type 1 study). This may be a repeat diagnostic, titration or split-night study. If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 does not change the length of the trial unless there is less than 30 days remaining in the trial period. If more than 30 days remain in the trial period, the clinical re-evaluation would still occur between the 31st and 91st day following the initiation of an E0601 and objective documentation of adherence on the E0470 would need to occur prior to the 91st day following initiation of the E0601. If less than 30 days remain in the trial period, the clinical re-evaluation and objective documentation of adherence must occur before the 120th day following the initiation of the E0601. If an E0601 device was used for more than 3 months and the patient was then switched to an E0470, the clinical re-evaluation must occur between the 31st and 91st day following the initiation of the E0470. There would also need to be documentation of adherence to therapy during the 3 month trial with the E0470. If there is discontinuation of usage of a PAP device at any time, the supplier is expected to ascertain this and stop billing for the equipment and related accessories and supplies. For a PAP device dispensed prior to November 1, 2008, if the initial Medicare coverage criteria in effect at the time were met and the criteria for coverage after the first 3 months that were in effect at the time were met, the device will continue to be covered for dates of service on or after November 1, 2008, as long as the patient continues to use the device. REPLACEMENT: This section applies to PAP devices initially provided and covered while the beneficiary was in Medicare fee-for-service (FFS).

	If a PAP device is replaced during the 5 year reasonable useful lifetime (RUL) because of loss, theft, or irreparable damage due to a specific incident, there is no requirement for a new clinical evaluation, sleep test, or trial period. If a PAP device is replaced following the 5 year RUL, there must be a face-to-face evaluation by their treating physician that documents that the beneficiary continues to use and benefit from the PAP device. There is no requirement for a new sleep test or trial period. BENEFICIARIES ENTERING MEDICARE: For beneficiaries who received a PAP device prior to enrollment in fee for service (FFS) Medicare and are seeking Medicare coverage of either rental of the device, a replacement PAP device and/or accessories, both of the following coverage requirements must be met: 1. Sleep test – There must be documentation that the beneficiary had a sleep test, prior to FFS Medicare enrollment, that meets the Medicare AHI/RDI coverage criteria in effect at the time that the beneficiary seeks Medicare coverage of a replacement PAP device and/or accessories; and 2. Clinical Evaluation – Following enrollment in FFS Medicare, the beneficiary must have a face-to-face evaluation by their treating physician who documents in the beneficiary's medical record that: a. The beneficiary has a diagnosis of obstructive sleep apnea; and b. The beneficiary continues to use the PAP device. If either criteria 1 or 2 above are not met, the claim will be denied as not reasonable and necessary. In these situations, there is no requirement for a clinical re-evaluation or for objective documentation of adherence to use of the device. ACCESSORIES: Accessories used with a PAP device are covered when the Medicare coverage criteria for the device are met. If the Medicare coverage criteria are not met, the accessories will be denied as not reasonable and necessary. L30731 (updated 3/24/11) (40 states – includes Washington) A. Uvulopalatopharyngoplasty (UPPP) is covered for those patients who have all of the following: 1. Obstructive sleep apnea diagnosed (prior to any proposed surgery) in a certified sleep disorders laboratory (certification body recognized by the American Academy of Sleep Medicine); 2. A Respiratory Disturbance Index of 15 or higher 3. Failed to respond to Continuous Positive Airway Pressure therapy or cannot tolerate CPAP or other appropriate non-invasive treatment; 4. Documented counseling by a physician, with recognized training in sleep disorders, about the potential benefits and risks of the surgery; and 5. Evidence of retropalatal or combination retropalatal/retrolingual obstruction as the cause of the obstructive sleep apnea. B. Mandibular Maxillary Osteotomy and Advancement and /or genioglossus advancement with or without hyoid suspension is covered for those patients who have all of the following:

	1. Obstructive sleep apnea diagnosed (prior to any proposed surgery) in a certified sleep disorders laboratory (certification body recognized by the American Academy of Sleep Medicine); 2. A Respiratory Disturbance Index of 15 or higher; 3. Failed to respond to Continuous Positive Airway Pressure therapy or cannot tolerate CPAP or other appropriate non-invasive treatment; 4. Documented counseling by a physician, with recognized training in sleep disorders, about the potential benefits and risks of the surgery; and 5. Evidence of retrolingual obstruction as the cause of the obstructive sleep apnea, or previous failure of UPPP to correct the obstructive sleep apnea. Regarding the Mandibular Maxillary Osteotomy and Advancement operation: a. Separate repositioning of teeth would not be necessary except under unusual circumstances; but if necessary the dental work would be covered. b. Application of an interdental fixation device is occasionally necessary, and is a covered service (see Documentation Requirements). C. Tracheostomy is covered for obstructive sleep apnea that is in the judgment of the attending physician, unresponsive to other means of treatment or in cases where other means of treatment would be ineffective or not indicated. D. When obstructive sleep apnea is caused by discrete anatomic abnormalities of the upper airway (such as, but not limited to, enlarged tonsils or an enlarged tongue), surgery to correct these abnormalities is covered if medically necessary based on adequate documentation in the medical records supporting the significant contribution of these abnormalities to OSA. Submucous radiofrequency reduction of hypertrophied turbinates is covered as an appropriate treatment for nasal obstruction due to turbinate hypertrophy that significantly contributes to OSA or significantly compromises CPAP therapy. E. The following procedures are not covered at this time. 1. Laser-assisted uvulopalatoplasty (LAUP) is not covered at this time since it is not considered effective for OSA. LAUP must not be billed as 42145, Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty). This code is not appropriate for this procedure. If LAUP is billed for denial purposes, it should be coded as 42299, (unlisted procedure, palate, uvula) with "LAUP" listed in Item 19 on the CMS-1500 claim form or equivalent field for electronic claims. The claim will then be appropriately denied as not proven effective. 2. Somnoplasty™ is a trade name for palate reduction with the Somnoplasty™ System of Somnus Medical Systems. This is not a term recognized by this Contractor as a covered procedure under Medicare Part B. Therefore Somnoplasty™ must not be billed as 42145. This code is not appropriate for this procedure. If Somnoplasty™ is billed for denial purposes, it should be coded as 42299, (unlisted procedure, palate, uvula) with "Somnoplasty™" listed in Item 19 on the CMS-1500 claim form or equivalent field for electronic claims. This claim will then be appropriately denied as not proven effective. 3. The Pillar Procedure™ is a trade name for palatal implants. Palatal implants have not been shown effective for the treatment of

	obstructive sleep apnea and are not covered. This procedure should be billed by the physician as 42299 (unlisted procedure, palate, uvula) with "Pillar Procedure™" or "palatal implant" listed in Item 19 on the CMS-1500 claim form or equivalent field for electronic claims. This claim will then be denied as not proven effective. Hospital outpatient would use code C9727. 4. Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session. (41530) is not covered.
Washington Medicaid	http://hrsa.dshs.wa.gov/Download/Memos/2008Memos/08-43.pdf Continuous Positive Airway Pressure (CPAP) and Supplies What is covered? HRSA covers the rental and/or purchase of medically necessary CPAP equipment and related accessories when all of the following apply: 1. The results of a prior sleep study (polysonnogram) indicate the client has sleep apnea 2. The client's attending physician determines the client's sleep apnea is chronic 3. CPAP is the least costly, most effective treatment modality 4. The item is FDA-approved; and 5. The item requested is not included in any other reimbursement methodology such as, but not limited to, diagnosis-related group (DRG) HRSA covers the rental of CPAP equipment for a maximum of two months. Thereafter, if the client's primary physician determines the equipment is tolerated and beneficial to the client, HRSA will purchase it. CPAP Accessories and Services that are NOT covered: HRSA does not cover accessories/services not specifically identified in this document. Requires results of sleep study performed in an HRSA-approved sleep center. Rental Limit: 1 unit per month, maximum of 2 months rental. Purchase required after 2 months mandatory rental. Client compliance and effectiveness must be documented prior to purchase. Purchase limit: 1 unit per client, every 5 years with documentation of cost effectiveness prior to replacement. Purchase price is amount allowed after 2 months mandatory rental.
Aetna Last review: 03/25/2011	**Aetna Clinical Policy Bulletin Number 0004: Obstructive Sleep Apnea in Adults** http://www.aetna.com/cpb/medical/data/1_99/0004.html Aetna considers the diagnosis and treatment of obstructive sleep apnea (OSA) in adults age 18 and older medically necessary according to the criteria outlined below. I. Diagnosis Aetna considers *any* of the following diagnostic techniques medically necessary for members with symptoms suggestive of OSA (see Appendix B for definition of device types): A. Attended full-channel nocturnal polysomnography (NPSG) (Type I device) performed in a healthcare facility; *or*

	B. Attended or unattended sleep monitoring using a Type II device; *or* C. Attended or unattended sleep monitoring using a Type III device, *or* D. Attended or unattended sleep monitoring using a Type IV(A) device, measuring airflow and at least two other channels and providing measurement of apnea-hypopnea index (AHI); *or* E. Attended or unattended home sleep monitoring using a device that measures three or more channels that include pulse oximetry, actigraphy, and peripheral arterial tone (e.g., Watch-PAT device); *or* Split-night study NPSG in which the final portion of the NPSG is used to titrate continuous positive airway pressure (CPAP); Note: On occasion, an additional full-night CPAP titration NPSG may be necessary if the split-night study did not allow for the abolishment of the vast majority of obstructive respiratory events or prescribed CPAP treatment does not control clinical symptoms. F. Video-EEG-NPSG (NPSG with video monitoring of body positions and extended EEG channels) to assist with the diagnosis of paroxysmal arousals or other sleep disruptions that are thought to be seizure related when the initial clinical evaluation and results of a standard EEG are inconclusive. It may be necessary to perform repeat sleep studies up to twice a year for *any* of the following indications: G. To determine whether positive airway pressure treatment (i.e., CPAP, bilevel positive airway pressure (BiPAP), demand positive airway pressure (DPAP), variable positive airway pressure (VPAP), or auto-titrating positive airway pressure (AutoPAP)) continues to be effective; *or* H. To determine whether positive airway pressure treatment settings need to be changed; *or* I. To determine whether continued treatment with positive airway pressure treatment is necessary; *or* J. To assess treatment response after upper airway surgical procedures and after initial treatment with oral appliances. Aetna considers *any* of the following diagnostic techniques experimental and investigational in members with symptoms suggestive of OSA: K. Acoustic pharyngometry, or SNAP testing using fewer than three channels. See CPB 336 - Acoustic Pharyngometers and SNAP Testing System; *or* L. Actigraphy testing when used alone. Actigraphy, which consists of a small portable device that senses physical motion and stores the resulting information, has been used in research studies for the evaluation of rest-activity cycles. This technique, when used alone (single channel study), has not been validated as a method of diagnosing OSA. See CPB 710 - Actigraphy and Accelerometry; *or* M. Cephalographic X-rays for diagnosis of obstructive sleep apnea. Lateral cephalographic X-rays and orthopantograms may be medically necessary for evaluating persons for oral appliances; lateral cephalographic X-rays may also be necessary to evaluate persons for obstructive sleep apnea surgery; *or* N. Laryngeal function studies; *or*

O. Sonography; *or*
P. The static charge sensitive bed; *or*
Q. Tomographic X-ray; *or*

R. X-rays of the temporomandibular joint or sella turcica.

I. Treatment

Treatment of snoring alone, without significant OSA, is *not* considered medically necessary.

. Oral Appliances

Custom-fitted and prefabricated oral appliances to reduce upper airway collapsibility are considered medically necessary for members with OSA who meet the medical necessity criteria for CPAP. Oral appliances to reduce upper airway collapsibility are considered experimental and investigational for indications other than OSA.

Oral appliances for OSA that are available over-the-counter without a prescription are *not* considered medically necessary because they have not been shown to be as effective as prefabricated or custom-fitted oral appliances in the treatment of OSA.

Note: Dental rehabilitation services (dentures, bridgework, etc.) as treatment for OSA, even if medically necessary, are not available benefits under standard Aetna health insurance plans. Members should review their dental benefits plan, if any.

A. Continuous Positive Airway Pressure (CPAP)

It is expected that members receive lifestyle advice where applicable (i.e., helping people to lose weight, stop smoking and/or decrease alcohol consumption).

Aetna considers CPAP medically necessary DME for members with a positive facility-based NPSG*, or with a positive home sleep test* including Type II, III, IV(A) or Watch-PAT devices, as defined by *either* of the following criteria:

1. Member's AHI is greater than or equal to 15 events per hour with a minimum of 30 events; *or*
2. AHI greater than 5 and less than 15 events per hour with a minimum of 10 events and at least one of the following is met:

a. Documented history of stroke; *or*
b. Documented hypertension (systolic blood pressure greater than 140 mm Hg and/or diastolic blood pressure greater than 90 mm Hg); *or*
c. Documented ischemic heart disease; *or*
d. Documented symptoms of impaired cognition, mood disorders, or insomnia; *or*
e. Excessive daytime sleepiness (documented by either Epworth greater than 10 or Multiple Sleep Latency Test (MSLT) less than 6); *or*
f. Greater than 20 episodes of oxygen desaturation (i.e., oxygen saturation of less than 85%) during a full night sleep study, or any one episode of oxygen desaturation (i.e., oxygen saturation of less than 70%).

		The sleep study is based on a minimum of 2 hours of continuous recorded sleep or shorter periods of continuous recorded sleep if the total number of recorded events during that shorter period is at least the number of events that would have been required in a 2 hour period. Notes: The AHI is equal to the average number of episodes of apnea and hypopnea per hour of sleep. The respiratory disturbance index (RDI) is equal to the episodes of apnea and hypopnea per hour of measurement. For purposes of this policy, 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 percent reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4 percent oxygen desaturation. Leg movement, snoring, respiratory event related arousals (RERAs), and other sleep disturbances that may be included by some polysomnographic facilities are not considered to meet the AHI and/or RDI definition in this policy. Although AHI and RDI have been used interchangeably, some facilities use the term RDI to describe a calculation that includes these other sleep disturbances. Requests for CPAP will be considered not medically necessary if based upon an index that does not score apneas and hypopneas separately from other sleep disturbance events. Only persons with an AHI and/or RDI, as defined in this policy that meets medical necessity criteria may qualify for a CPAP device. Aetna considers CPAP experimental and investigational for the treatment of persons with upper airway resistance syndrome (UARS) or for the improvement of seizure control in persons with epilepsy . BiPAP without a backup rate feature, DPAP, VPAP, and AutoPAP are considered medically necessary DME for members who are intolerant to CPAP. These alternatives to CPAP may also be considered medically necessary for OSA members with concomitant breathing disorders, which include restrictive thoracic disorders, COPD, and nocturnal hypoventilation. An oral pressure appliance (OPAP) is considered medically necessary DME only on an exception basis for members who are unable to tolerate a standard nasal/face mask due to facial discomfort, sinus pain, or claustrophobia from masks. A BiPAP device with a backup rate feature (e.g., adaptive servoventilation, VPAP Adapt SV) is considered experimental and investigational for obstructive sleep apnea (see CPB 452 - Noninvasive Positive Pressure Ventilation). The following accessories and supplies are considered medically necessary for members who meet criteria for positive airway pressure devices: ▪ Chinstrap ▪ Disposable or non-disposable filters ▪ Full face mask with positive airway pressure device ▪ Headgear ▪ Heated or non-heated humidifier ▪ Nasal interface (mask or cannula type) for positive airway pressure device ▪ Oral interface for positive airway pressure device

- Replacement cushions and pillows for nasal application device
- Replacement interface for full face mask
- Tubing Heated or non-heated humidifier.

* Nasal interface (mask or cannula type) may be used with positive airway pressure device, with or without head strap is an alternative to full face mask. However, upgraded face mask is considered medically necessary only if there is documentation that the member needs a different mask because he/she cannot maintain CPAP pressures or that in order to get the pressure the mask needs to be so tight as to generate pressure sores.

Note: Aetna follows Medicare DME MAC rules with respect to the usual medically necessary quantity of supplies for positive airway pressure devices.

Upon individual review, positive airway pressure devices are considered a medically necessary form of noninvasive ventilation for members with lung disease without OSA. Requests for these devices for noninvasive ventilation of members with lung disease are subject to medical review.

B. Uvulopalatopharyngoplasty (UPPP)

Uvulopalatopharyngoplasty is used to treat OSA by enlarging the oropharynx; it is considered medically necessary for OSA members who meet the criteria for CPAP (see above), but who are intolerant to CPAP. The medical records must document that the member has attempted CPAP before considering surgery.

Uvulopalatopharyngoplasty has been found to be most reliably effective in OSA members who have adequately responded to a trial of CPAP. If CPAP is unsuccessful in relieving a member's symptoms, this indicates that apnea is not due to obstruction. Aetna considers this procedure experimental and investigational for persons who do not respond to CPAP because this surgical approach has not been shown to be effective in non-obstructive apnea.

C. Uvulectomy and Laser Assisted Uvuloplasty (LAUP)

Cold knife uvulectomy and laser assisted uvuloplasty (LAUP, laser uvulectomy) are considered experimental and investigational for OSA because they have not been shown to be as effective as UPPP for this indication. However, Aetna may consider these procedures medically necessary, upon individual case review, for members with severe OSA who have other medical conditions that make them unable to undergo UPPP and have failed a trial of CPAP or the use of an oral appliance or device. Note: Uvulectomy is considered medically necessary as an emergent treatment for acute edema of the uvula causing acute respiratory distress. Uvulectomy is considered experimental and investigational as a treatment for recurrent throat infections and for all other indications.

D. Somnoplasty and Coblation

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 obstructive sleep apnea because there is inadequate scientific evidence to validate the effectiveness of these procedures for this indication. Please see CPB 592 - Radiofrequency Ablation of Hypertrophied Nasal Turbinates. E. The Repose System Aetna considers the Repose system, a minimally invasive technique involving tongue base suspension, experimental and investigational. This procedure has been used for treating sleep disordered breathing (SDB) caused by tongue base collapse. No specific criteria exist regarding the diagnosis of tongue base collapse in SDB. Preliminary short-term studies of surgery targeted to alleviate tongue base collapse in SDB have shown subjective improvements in snoring and statistically significant decreases in mean RDI. However, the reported rates of success have been inconsistent among studies, and larger controlled studies with long-term follow-up are necessary to determine whether the Repose system is safe and effective. F. Pediatric Obstructive Sleep Apnea Syndrome (OSAS): Tonsillectomy and Adenoidectomy See CPB 752 - Obstructive Sleep Apnea in Children. G. Jaw Realignment Surgery (i.e., hyoid myotomy and suspension, mandibular osteotomy, genioglossal advancement) Aetna considers jaw realignment surgery medically necessary for persons who fail other treatment approaches for OSA. Although jaw realignment surgery may be considered medically necessary on an individual case basis, because of the extent of surgery, these cases may be subject to review by Aetna's Oral and Maxillofacial Surgery Unit to assess medical necessity. Note: According to the medical literature, persons undergoing jaw realignment surgery must usually also undergo orthodontic therapy to correct changes in occlusion associated with the surgery. Orthodontic therapy (i.e., the placement of orthodontic brackets and wires) is excluded from coverage under standard Aetna medical plans regardless of medical necessity. Please check benefit plan descriptions for details. Benefits for orthodontic therapy may be available under the member's dental plan, if any. H. Tracheostomy Aetna considers tracheostomy medically necessary for those members with the most severe obstructive sleep apnea not manageable by other interventions. Requests for tracheostomy for OSA are subject to medical review. I. Cardiac (Atrial) Pacing Aetna considers cardiac (atrial) pacing for treatment of sleep apnea experimental and investigational because the effectiveness of this procedure for obstructive sleep apnea has not been established. J. Injection Snoreplasty Aetna considers injection snoreplasty, injection of a sclerosing agent into the soft palate, experimental and investigational for the treatment of obstructive sleep apnea because its effectiveness for this indication has not been established.

	Treatment of snoring alone, without significant OSA, is not considered medically necessary K. Cautery-Assisted Palatal Stiffening Operation (CAPSO) Aetna considers cautery-assisted palatal stiffening operation (CAPSO) experimental and investigational for the treatment of OSA because its effectiveness for this indication has not been established. L. Pillar™ Palatal Implant System Aetna considers the Pillar Palatal Implant System (Restore Medical, Inc.) experimental and investigational for the treatment of OSA and all other indications because its effectiveness for this and other indications has not been established. M. Flexible Positive Airway Pressure Aetna considers flexible positive airway pressure (C-Flex, Respironics) experimental and investigational because its effectiveness has not been established. N. Transpalatal Advancement Pharyngoplasty Aetna considers transpalatal advancement pharyngoplasty experimental and investigational for the treatment of OSA because its effectiveness has not been established. O. Nasal Surgery Aetna considers nasal surgery (any technique) experimental and investigational for the treatment of OSA because its effectiveness has not been established. P. The Advance System Aetna considers the Advance System (an adjustable tongue-advancement device) experimental and investigational for the treatment of OSA because its effectiveness has not been established. Q. Tongue Base Reduction Surgery Aetna considers tongue base reduction surgery experimental and investigational for the treatment of OSA because its effectiveness has not been established. R. Partial Glossectomy Aetna considers partial glossectomy experimental and investigational for the treatment of OSA because its effectiveness has not been established. S. The Provent Sleep Apnea Therapy Aetna considers the Provent sleep apnea therapy experimental and investigational for the treatment of OSA because its effectiveness has not been established.
Blue Cross Blue Shield	**Regence Blue Shield** **POLICY/CRITERIA** http://blue.regence.com/trgmedpol/surgery/sur166.html

Note: Some member contracts have specific benefit limitations for orthognathic surgery.

I. Surgical Treatment of Snoring Alone
Surgical intervention for the treatment of snoring in the absence of documented obstructive sleep apnea is considered not medically necessary.

II. Surgical Treatment of Obstructive Sleep Apnea (OSA) and Upper Airway Resistance Syndrome (UARS)

A. Procedures

1. The following procedures may be considered medically necessary for the treatment of OSA and UARS when the criteria in either II.B and II.C or II.B and II.D below are met:
   a. Hyoid suspension
   b. Mandibular-maxillary advancement (MMA) when there is objective documentation of hypopharyngeal obstruction
   c. Uvulopalatopharyngoplasty (UPPP) with or without inferior sagittal osteotomy with hyoid suspension
2. All other procedures are considered investigational as treatments of OSA or UARS, including but not limited to:
   a. Uvulectomy
   b. Partial glossectomy
   c. Radiofrequency volumetric tissue reduction of the tongue base or palatal tissues
   d. Tongue base suspension procedures, including but not limited to the Repose™
   e. Laser-assisted palatoplasty (LAUP) or volumetric tissue reduction
   f. Palatal stiffening procedures, including but not limited to the following:
      i. Cautery-assisted palatal stiffening operation (CAPSO)
      ii. Injection of sclerosing agent
   g. Implantation of palatal implants (also known as the pillar procedure)

B. Failed Medical Therapy
All of the following medical therapies have failed to improve apnea/hypopnea including associated conditions such as excess daytime sleepiness:

1. Nasal CPAP – An adequate CPAP trial must include documentation of the following:
   a. A minimum of four hours per night for three weeks of CPAP usage
   b. Reasonable attempts to address any medical, mechanical, or psychological problems associated with CPAP (e.g., adjustment of pressure settings, appropriate medication and humidification, refitting of the mask)
   c. Reasonable attempts by patients with severe psychological aversion to CPAP to complete a conventional desensitization program

	i. Conventional desensitization programs include progressive steps intended to help the patient adapt first to the mask or nasal pillows, then to the air pressure. There may be more than one group or individual session, and the patient may work through the steps at home ii. Monitoring during desensitization programs (e.g., PAP-NAP) is considered **not medically necessary**. This monitoring may be reported using CPT code 95807 2. Maximal medical treatment of any underlying disease 3. Adjustment in sleep position 4. Avoidance of alcohol and sedative drugs C. Obstructive Sleep Apnea The patient has clinically significant OSA as defined below 1. An AHI equal to or greater than 15 per hour; OR 2. An AHI equal to or greater than 5 per hour with at least one of the following associated symptoms: a. Excessive daytime sleepiness that is not better explained by other factors b. Documented unexplained hypertension c. Ischemic heart disease or congestive heart failure d. History of stroke e. Obesity f. Diabetes and glucose intolerance g. Two or more of the following that are not better explained by other factors: i. Choking or gasping during sleep ii. Recurrent awakenings during sleep iii. Unrefreshing sleep with daytime fatigue iv. Impaired concentration or cognition v. Insomnia D. Upper Airway Resistance Syndrome The patient has clinically significant UARS defined as greater than 10 alpha EEG arousals per hour. **POSITION STATEMENT** Snoring in the absence of clinically significant obstructive sleep apnea (OSA) is not considered a medical condition. Therefore, any surgical intervention such as uvulopalatopharyngoplasty (UPPP), laser-assisted uvulopalatoplasty (LAUP), radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures, for snoring alone is considered not medically necessary. • There is sufficient evidence to determine that conventional uvulopalatopharyngoplasty (UPPP), hyoid suspension, and maxillofacial surgeries such as mandibular-maxillary advancement (MMA) may improve health outcomes for some patients with OSA.

	• There is insufficient evidence to support surgery as first-line treatment of OSA or upper airway resistance syndrome (UARS). Therefore, surgical treatments are considered only after failed medical therapy, including CPAP trials. • There is no evidence that monitored CPAP desensitization programs (e.g., PAP-NAP) result in equivalent or superior compliance rates compared to standard desensitization programs without monitoring in patients having difficulty adapting to their CPAP device. • There is insufficient evidence to determine the safety and efficacy of use of any other surgical interventions in the treatment of OSA including but not limited to uvulectomy, partial glossectomy, tongue base reduction and minimally invasive surgical procedures such as laser-assisted uvuloplasty (LAUP), radiofrequency tongue base or tissue volume reduction, pillar stiffening procedures and pillar implants.
Group Health	**Clinical Review Criteria: Pillar Implants for Obstructive Sleep Apnea and Snoring** *(Last revised 4/5/2011)* http://www.ghc.org/all-sites/clinical/criteria/pdf/pillar_implants_for_sa_and_snoring.pdf No criteria were developed at this time for Group Health Members. 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. **Clinical Review Criteria: Laser-Assisted Uvulopalatoplasty (PAUP), Somnoplasty, Repose Procedure, and Cautery-Assisted Palatal Stiffening operation (CAPSO)** *(Last revised 5/3/2011)* http://www.ghc.org/all-sites/clinical/criteria/pdf/laser_treatments_snoring_and_osa.pdf No criteria were developed at this time for Group Health Members as 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. No Group Health or Group Health Options Plan covers interventions for the treatment of snoring. **Clinical Review Criteria: Geniohyoid Advancement Myotomy Combined with Hyoid Re-Suspension or Maxillo-Mandibular Advancement for the Treatment of Obstructive Sleep Apnea** *(Last revised 5/3/2011)* http://www.ghc.org/all-sites/clinical/criteria/pdf/geniohyoid.pdf Medical necessity review is not required for this service **Clinical Review Criteria: Mandibular Advancement Devices for Treatment of Obstructive Sleep Apnea** *(Last revised 1/4/2011)* http://www.ghc.org/all-sites/clinical/criteria/pdf/madd.pdf Medical necessity review is no longer required for this service

Clinical Review Criteria: Sleep Apnea: Maxillomandibular Advancement Surgery
(Last revised 11/2/2010)
http://www.ghc.org/all-sites/clinical/criteria/pdf/ma_surgery.pdf;jsessionid=5ALVASPEWDHEVJCISQ4CHPQ
Covered when all of the following criteria are met:
1. Obstructive Sleep Apnea diagnosed (prior to the proposed surgery) in a sleep disorders laboratory
2. Has one of the following: AHI* of 15 events per hour AHI of 5 to14 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. Has failed to respond to CPAP therapy or cannot tolerate CPAP or other non-invasive treatment
4. Has been counseled by a physician, with recognized experience in sleep disorders, about the potential benefits and risks of the surgery; and
5.Has evidence of retrolingual and/or retropalatal obstruction as the cause of the OSA or previous failure of UPPP to correct OSA
* 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.

Clinical Review Criteria: Adaptive Servo-Ventilation Therapy (ASV) for Patients with Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency- VPAP
http://www.ghc.org/all-sites/clinical/criteria/pdf/asv.pdf;jsessionid=X2OLYIENNL03RJCISQ4CHPQ
(Revised 3/1/11)
No criteria were developed at this time for Commercial Members. 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.

Clinical Review Criteria: Positive Airway Pressure Device (PAP)
(2/10/2011)
http://www.ghc.org/all-sites/clinical/criteria/pdf/cpap.pdf;jsessionid=NQILG5ZXEIZ01JCISQ4CHPQ
For use with non-Medicare Group Health plan patients with PAP or DME benefit.
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 has:

	a. Completed a baseline Standford Sleepiness Score b. Completed a 3 night autotitration PAP c. Reported one of the following i. A positive response to initial autotitration* ii. A negative response to initial autotitration but has completed a polysomography test and met either of the two initial criteria above. *If there is a positive response to initial autotitration, 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. **For Medicare members, the policy refers to the Medicare National Coverage Determination manual.**

Appendix O. Summary of Payer Policy Coverage

Included Coverage Policies for OSA Sleep Tests and Treatments					
	Medicare	Washington Medicaid	Aetna	BCBS	GroupHealth
Sleep tests					
Type I PSG (attended)	Yes	Yes[1]	Yes		
Type II (attended or unattended)	Yes		Yes		
Type III (attended or unattended)	Yes		Yes		
Type IV measuring 3+ channels including air flow/AHI (attended or unattended)	Yes		Yes		
Device measuring 3+ channels including actigraphy, oximetry, and peripheral arterial tone (attended or unattended)	Yes		Yes		
Other diagnostic tests	No		Yes[2]		
Medical Therapy (require approved diagnosis unless otherwise noted)					
CPAP	Yes[3]	Yes[4]	Yes	Maybe	Yes
Oral appliances			Yes		Maybe
Provent Sleep Apnea Therapy			No		
Surgical treatment*					
Uvulopalatopharyngoplasty (UPPP)			Yes	Yes	
Uvulectomy and Laser Assisted Uvuloplasty (LAUP)			Yes	No	No
Tracheostomy			Yes		
Hyoid Suspension				Yes	
Mandibular-maxillary advancement			Yes	Yes	Yes[5]
Pillar Palatal Implant System			No	No	No
Cautery-Assisted Palatal Stiffening Operation (CAPSO)			No	No	No
Repose System			No	No	No
Partial Glossectomy			No	No	
Tongue Base Reduction Surgery			No	No	
Somnoplasty and Coblation			No		No
Nasal surgery			No		
Transpalatal Advancement Pharyngoplasty			No		
Flexible positive airway pressure			No		
Injection snoreplasty			No		
Cardiac (Atrial) pacing			No		
Adaptive Servo-Ventilation Therapy (ASV)					No

* Surgical treatments are only approved when medical therapies have failed.
1. Must be state approved sleep center
2. Other tests include split-night study PSG in which final portion is used to titrate CPAP or PSG with video monitoring of body positions and extended EEG channels to assist with diagnosis of sleep disruptions thought to be seizure related when a standard EEG are inconclusive
3. Requires 12 week 'trial period' to determine benefit, patient education
4. Physician must determine OSA as chronic; CPAP is the least costly and most effective treatment modality
5. OSA is diagnosed in sleep disorders laboratory, physician counseling on potential benefits and risks, evidence of retrolingual and/or retropalatal obstruction as a cause of OSA or previous failure of UPPP

Appendix P. Public Comments and Disposition

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OVERVIEW OF PUBLIC COMMENTS AND DISPOSITION

The Center for Evidence-based Policy is an independent vendor contracted to produce evidence assessment reports for the WA HTA program. For transparency, all comments received during the comments process are included in this response document. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only.

This document responds to comments from the following parties:

Key Questions

1. Eric J. Freer
2. Douglas Myers, MD
3. Kerilyn Nobuhara

Draft Report

1. Karen Anderson
2. Washington State Agency Medical Directors

The full version of each public comment received is available in the Public Comments section, beginning on page 390.

Table 1. Overview of Public Comments on Draft Key Questions

Submitted By	Cited Evidence	Overview of Public Comment
Eric J. Freer, GE Healthcare, Respiratory & Sleep, Home Care, Sales and Marketing Leader	▪ Cited evidence from eight reviews from The Cochrane Collaboration Database of Systematic Reviews, which included: o Surgery for Obstructed Sleep Apnea in Adults; o Continuous Positive Airways Pressure for Obstructed Sleep Apnea in Adults; o Lifestyle Modification in Obstructed Sleep Apnea; o Drug Therapy for Obstructed Sleep Apnea in Adults; o Pressure Modification for Improving Usage of Continuous Positive Airway Pressure Machines in Adults with Obstructed Sleep Apnea; o Oral Appliances for Obstructed Sleep Apnea; o Continuous Positive Airways Pressure Delivery Interfaces for Obstructed Sleep Apnea; and o Educational, Supportive and Behavioral Interventions to Improve Usage of Continuous Positive Airway Pressure Machines for Adults with Obstructed Sleep Apnea. ▪ Cited comparative effectiveness reviews from the Agency for Healthcare Research and Quality	▪ *Response to Key Question #1:* The severity of sleep apnea is typically quantified by the number of apneas and hypopneas per hour of sleep, defined as the AHI, measured during overnight monitoring. The American Academy of Sleep Medicine uses a threshold to define OSA of 15 events/hr (with or without OSA symptoms) or 5 events/hr with OSA symptoms. However, they found during their review, the minimum thresholds to diagnose sleep apnea in research studies vary from 5 to 20 events per hour by PSG. ▪ Polysomnography: the current diagnostic standard used in clinical practice is PSG. The formal diagnosis of sleep apnea requires a comprehensive, technologist-attended sleep study with multichannel PSG performed in specialized sleep laboratories. Laboratory-based PSG records a variety of neurophysiologic and cardiorespiratory signals that are read by trained technologist and interpreted by sleep physicians after a diagnostic sleep study has been completed. ▪ Portable Monitors: since in-laboratory PSG is costly, resource-intensive, and potentially inconvenience for the patient, other diagnostic tools have been developed, including portable testing and questionnaires for prescreening patients. Portable monitors vary in the type of neurophysiologic and respiratory information collected, and each synthesizes the accumulated data differently. Provided the American Sleep Disorders Association's classification of the different monitors that have been used into four categories. ▪ Pretesting Questionnaires and Other Tests: Questionnaires are used to prescreen patients for further testing or treatment. The most commonly used screening questionnaire in clinical practice is the Epworth Sleepiness Scale (ESS). The ESS focuses solely on sleepiness and not other signs and symptoms of OSA, thus is not specific to OSA. Another questionnaire commonly used in practice is the STOP questionnaire from the University of Toronto. In addition, researchers

Submitted By	Cited Evidence	Overview of Public Comment
		have created models to predict OSA based on demographic features, symptoms, head and neck anatomy and other variables. The value of the various questionnaires and other screening tools remain unclear. It is also unknown whether the tests can be accurately used to predict the clinical severity of patients' sleep apnea and the likelihood of clinically important sequelae. ▪ *Response to Key Question #5:* cited systematic reviews from the Cochrane Database. ▪ *Response to Key Question #6:* Cited a comparative effectiveness review from the Agency for Healthcare Research and Quality from July 2011. ▪ *Response to Key Question #7:* Cited a comparative effectiveness review from the Agency for Healthcare Research and Quality from July 2011.
Douglas Myers, MD, Vancouver, WA	No	▪ The diagnosis and treatment of sleep apnea requires a varied approach. ▪ In some instances, sleep studies represent an unnecessary expense and surgery is most cost effective; and in the other, the surgery is an unnecessary expense and sleep studies are most cost effective. ▪ Diagnostic evaluation and treatment must be individualized. ▪ The expertise to perform both diagnosis and treatment is available in most local medical communities, so that the added cost in time and transportation to regional centers is unnecessary. ▪ A common guideline for best practices would be helpful for use in community multispecialty discussions to establish diagnostic and surgical criteria.
Kerilyn Nobuhara, Senior Medical Consultant, Health	No	▪ Question: Will the cost effectiveness analysis include consideration of the morbidities associated with the different treatments?

Submitted By	Cited Evidence	Overview of Public Comment
Care Authority, WA		

Table 2. Public Comments on Draft Report and Disposition

Reviewer	Comment	Disposition
Karen Anderson	One of the concerns I have is that there are some vulnerable populations that were not "teased out" for evaluation. Specifically, patients with Down's Syndrome are notoriously afflicted with ENT issues and I had the unfortunate experience of dealing with one who was in heart failure, was evaluated and determined to have OSA, given CPAP which, despite her severe mental retardation, she avidly wore and improved immensely. I don't know how that fits in with the EBM eval but I do think that there may be some populations that have not been separately evaluated and who may benefit from treatment.	*Thank you for your comments and concerns. This report did not address patient populations which included Down syndrome. The sole source of evidence for this report, (Balk [AHRQ] 2011, p. 12-13) specifically excluded studies in which more that 20% of the participants had Down syndrome, among many other disorders…"This threshold (20 percent) was chosen arbitrarily to avoid excluding potentially relevant small studies that included some patients with conditions not of interest to the current report. This turned out to be a moot point since no eligible studies explicitly included patients with any of these conditions."*
	I did not see CHF findings or symptoms included in the pre/post rx evals. I think that is an important deficit.	*Thank you for your question involving CHF finding or symptoms in the treatment evaluations. This relates to KQ#5 (Comparative effective of different treatment for OSA).* *Congestive heart failure was discussed in KQ#5b in the comparison of "CPAP and Control" section (KQ#5b.) included 2 studies which "which included only patients with symptomatic, stable, and optimally-treated congestive heart failure." (CEbP Report, pg.79) The conclusion in that report section stated "A single study evaluated the impact of CPAP on the severity of symptoms of congestive heart failure and reported nonsignificant results." (CEbP Report, p. 82)*

Washington State Agency Medical Directors	The significance of the association between apnea-hypopnea index (AHI) and all-cause mortality is unclear, particularly given the uncertain association between AHI and cardiovascular mortality, stroke, hypertension, diabetes and other metabolic abnormalities, and quality of life. The draft report does comment on p. 5 "Thus the association between reductions in AHI by OSA treatment and improvements in long-term clinical outcomes remains theoretical."	*Thank you for your comments. Language has been inserted to clarify this issue (CEbP Report, p. 4-5).*
	In general, the wording of the report gives unsupported credence to a putative causal relationship between obstructive sleep apnea (OSA) and major morbidity and mortality.	*Thank you for your comment. This causal relationship (OSA and morbidity/mortality) was discussed and independently referenced (i.e. other than Balk) in p.12, paragraph 3, of the CEBP Report Background section.*
	Similarly, it is not sufficiently critical of the strength of evidence supporting the proposition that continuous positive airway pressure (CPAP) and other treatments for OSA improve major clinical outcomes.	*Thanks you for your comments. Several areas of this report discuss the evidence to support CPAP as an effective method for improving sleep indices and sleepiness symptoms. This point is reinforced in the Balk (CEbP Report, p. 149) conclusions "While the relevant trials are conclusive regarding the effects of CPAP on AHI and sleepiness measures, among over 40 trials of patients treated with CPAP or no treatment, none have reported long-term clinical outcomes." Further support for this perspective is found in Balk (CEbP Report, p.151) "Notably, little evidence exists across interventions supporting any OSA treatment as improving quality of life or neurocognitive function. Although trials did report improvements in these outcomes for CPAP, MAD, and surgical intervention, overall findings were inconsistent."*
	Regarding key question 4, the "relationships between… AHI and oxygen desaturation index… and other patient characteristics with long term clinical and functional outcomes" is further elaborated in the draft report, quoting from the AHRQ	*Thank you for your comments. These issues are discussed above. There appears to be confusion between the sleep indices (such as AHI) which is associated with all-cause mortality when high (and has been clarified in the text as*

	comparative effectiveness review on sleep apnea diagnosis and treatment, concluding, on p. 164 [CEbP Report, p. 149], "Unfortunately, as discussed below, there are almost no trial data to support that treatment of OSA and reduction of AHI improves clinical outcomes" and, on p. 165 [CEbP Report, p. 149] "While the relevant trials are conclusive regarding the effects of CPAP on AHI and sleepiness measures, among over 40 trials of patients treated with CPAP or no treatment, none have reported long-term clinical outcomes." Thus, it is contradictory and unclear what evidence is relied on for statements such as: p. 174 [CEbP Report, p.158], "Obstructive sleep apnea is a cause of significant morbidity and mortality, and is thus an important public health issue. In addition, the diagnosis and treatment of OSA have societal cost implications, making cost-effectiveness a concern in both of these aspects."	*above), and OSA, which is associated with significant morbidity/mortality as above.*
	On p. 7 of the draft report it is stated: "A moderate strength of evidence was found for the treatment of OSA with CPAP", a statement that in itself says little, but presumably intends to say that a moderate strength of evidence was found to support the effectiveness of treatment of OSA with CPAP. Subsequent statements qualify the statement, noting that there is relatively strong evidence that CPAP treatment improves sleep measures such as AHI, arousal index, and minimum oxygen saturation, and subjective report of daytime sleepiness on the Epworth Sleepiness Scale. Directly quoted from the AHRQ comparative effectiveness review on sleep apnea diagnosis and treatment, the draft report says on p. 7: "There is only weak evidence that that CPAP treatment may improve quality of life or neurocognitive measures, or other intermediate outcomes" and "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	*Thank you for your comments. Language has been inserted to clarify this statement (CEbP Report, p.7)*

	and symptoms was rated moderate."	
	The term "signs and symptoms" is not further specified, leaving it unclear exactly what beneficial effects of CPAP treatment are supported by evidence.	*"Signs and symptoms" is not further specified in the Balk report (CEbP Report, p.69).*
	It would be helpful to remind the reader at this point that any association between reductions "in AHI by OSA treatment and improvements in long-term clinical outcomes remains theoretical."	*Thank you…this language has been inserted in the draft (CEbP Report, p.7)*
	The discussion of cost effectiveness studies in both the Executive Summary and the body of the report fails to adequately emphasize that the "cost effectiveness" analysis assumes effectiveness of OSA treatment rather than basing the analysis on empirical findings of effectiveness, thus seriously undermining validity of "cost effectiveness" analyses. Such problems with the major "cost utility" study reported on (McDaid, 2009) are mentioned in the "Limitations" section on p. 174 [CEbP Report, pp. 158-9], yet the highly conjectural results of the cost utility study are reported with little in the way of caveat.	*Thank you…such language has been inserted in the Executive Summary (CEbP Report, p.8) and in the draft (CEbP Report, p. 155)*
	Similarly the cost-analysis studies of health care costs of persons with OSA compared to those without do not establish causality or evidence to support the expectation that diagnosis and treatment of OSA will reduce health care costs. Thus, in the "Policy context and cost information" discussion in the "Background" section of the draft report, on p. 17, it is surprising to see the statement "Undiagnosed OSA results in roughly a two-fold increase in health care utilization and costs, in the years preceding the diagnosis, due largely to the number of attendant comorbidities." The use of the words "results in" implies causality where it has not been established.	*Thank you…such language has been changed to reflect this comment in the draft (CEbP Report, p.17)*
	The draft report would do better to emphasize how much of the	*Thank you…such language has been inserted in the draft as*

	case for treatment of OSA is based on conjecture and extrapolation from associative relationships between sleep measures and clinical morbidity and the effects of OSA treatments on sleep measures and a few intermediate clinical outcome measures of uncertain clinical significance. In this context, "cost-effectiveness" studies of OSA treatment have little value other than as conjecture.	*above (CEbP Report, p. 155)*

PUBLIC COMMENTS – KEY QUESTIONS

1. Eric J. Freer

KQ1: How do different available tests compare to diagnose sleep apnea in adults with symptoms suggestive of disordered sleep?

Source:
Diagnosis and Treatment of Obstructive Sleep Apnea in Adults
Comparative Effectiveness Reviews, No. 32

Investigators: Ethan M Balk, MD, MPH, Denish Moorthy, MBBS, MS, Ndidiamaka O Obadan, MD, MS, Kamal Patel, MPH, MBA, Stanley Ip, MD, Mei Chung, PhD, MPH, Raveendhara R Bannuru, MD, Georgios D Kitsios, MD, PhD, Srila Sen, MA, Ramon C Iovin, PhD, James M Gaylor, BA, Carolyn D'Ambrosio, MD, MS, and Joseph Lau, MD.

Tufts Evidence-based Practice Center
Rockville (MD): Agency for Healthcare Research and Quality (US); July 2011.
Report No.: 11-EHC052

Diagnosis
In general, individuals with OSA experience repetitive cycles of upper airway obstruction and frequent nighttime arousals. Upper airway obstruction during sleep is most often due to anatomical anomalies of the nasopharyngeal or mandibular areas that cause narrowing of the respiratory passages, decreased pharyngeal muscle tone that reduces the cross-sectional area of the upper airway, and insufficient neuromuscular responses to airway obstruction.[5] This narrowing is often exacerbated by obesity-related peripharyngeal fat.[5] AHI, the count of the hourly apnea and hypopnea events during sleep, when combined with determinations of obstruction, is the primary measurement used for the diagnosis of OSA. It (or variations that measure oxygen desaturations or other measures of respiratory disturbance instead of apnea) can by measured by polysomnography (PSG) in a sleep laboratory or by (portable) monitors in other settings. Notably, though, AHI can vary from night-to-night or between settings and does not take into account symptoms, comorbidities, or response to treatment.[30]

The severity of sleep apnea is typically quantified by the number of apneas and hypopneas per hour of sleep, defined as the AHI, measured during overnight monitoring. The American Academy of Sleep Medicine uses a threshold to define OSA of 15 events/hr (with or without OSA symptoms) or 5 events/hr with OSA symptoms (unintentional sleep episodes during wakefulness; daytime sleepiness; unrefreshing sleep; fatigue; insomnia; waking up breath-holding, gasping, or choking; or the bed partner describing loud snoring, breathing interruptions, or both during the patient's sleep).[31,32] However, as we found during our review, the minimum thresholds to diagnose sleep apnea in research studies vary from 5 to 20 events per hour by PSG.

Polysomnography
The current diagnostic standard used in clinical practice is PSG. The formal diagnosis of sleep apnea requires a comprehensive, technologist-attended sleep study with multichannel PSG performed in specialized sleep laboratories.[4,33] Laboratory-based PSG records a variety of neurophysiologic and cardiorespiratory signals that are read by trained technologists and interpreted by sleep physicians after a diagnostic sleep study has been completed. The sleep study incorporates a number of assessments and measurements including: recordings of rapid eye movements, electroencephalogram to detect arousals, chest and abdominal wall monitors to evaluate respiratory movements, electrocardiogram, electromyogram, oximetry, and nasal and oral air flow measurements.[5] This process of diagnosing OSA by PSG in a sleep lab has some constraints including cost, inconvenience, and interlaboratory variation in hardware and assessment methods. Additionally, the current

clinical standard, which is the 16-channel, in-laboratory PSG has never been validated, and its true sensitivity and specificity in diagnosing OSA is not well documented.[26]

Portable Monitors

Since in-laboratory PSG is costly, resource-intensive, and potentially inconvenient for the patient, other diagnostic tools have been developed, including portable testing and questionnaires for prescreening patients. Portable monitors vary in the type of neurophysiologic and respiratory information collected, and each synthesizes the accumulated data differently.[34] There are different types (classes) of portable monitors. Each gathers different neurophysiologic and respiratory information and may synthesize the accumulated data differently. Portable monitors can be used in the home setting or sleep units.

The American Sleep Disorders Association has classified the different monitors that have been used in sleep studies into four categories, depending on which channels they record and evaluate.[34] As we did in the *2007 Technology Assessment of Home Diagnosis of Obstructive Sleep Apnea-Hypopnea Syndrome*,[26] we used the operational rules described in Table 1 to classify sleep monitors. Briefly:

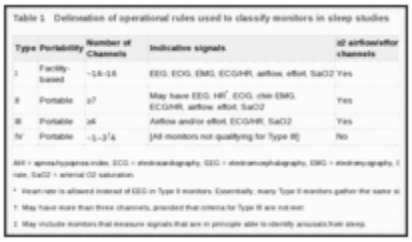

Table 1

Delineation of operational rules used to classify monitors in sleep studies.

- Type I is facility-based PSG.
- Type II monitors are portable and record the same information as Type I (perhaps with fewer channels). Type II monitors record signals that allow the reliable identification of (micro) arousals from sleep (e.g., electro-oculography, chin electromyography, electroencephalography) *and* at least two respiratory channels (two airflow channels or one airflow and one effort channel).
- Type III monitors are portable, but do not record the channels that differentiate between sleep and wake, but have at least two respiratory channels (two airflow channels or one airflow and one effort channel).
- Type IV are all other portable monitors that fail to fulfill criteria for Type III monitors. Therefore Type IV channels may include monitors that record more than two bioparameters.

Thus, portable monitors are classified as either Type II, III or IV. Please refer to our previous report for a more complete discussion of portable monitors.[26]

Pretesting Questionnaires and Other Tests

Questionnaires are used to prescreen patients for further testing or treatment. The most commonly used screening questionnaire in clinical practice is the Epworth Sleepiness Scale (ESS).[35] This questionnaire asks patients to rate how likely they are to fall asleep in certain situations, such as riding in the car on a long trip. The ESS focuses solely on sleepiness and not other signs and symptoms of OSA, thus is not specific to OSA. Another questionnaire commonly used in practice is the STOP questionnaire from the University of Toronto.[36] In addition, researchers have created models to predict OSA based on demographic features, symptoms, head and neck anatomy, and other variables.

The value of the various questionnaires and other screening tools remains unclear. It is also unknown whether the tests can be accurately used to predict the clinical severity of patients' sleep apnea and the likelihood of clinically important sequelae. If the screening tests are found to be sufficiently predictive of the results of full sleep testing, the question arises of how best to determine which patients should be prescreened (or sent directly for a sleep study), and, after screening, which should be treated for OSA, tested further, or considered to not have OSA.

References:

4. Practice parameters for the indications for polysomnography and related procedures. Polysomnography Task Force, American Sleep Disorders Association Standards of Practice Committee. Sleep. 1997;20:406–422. [PubMed: 9302725]

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33. Flemons WW, Littner MR, Rowley JA, et al. Home diagnosis of sleep apnea: a systematic review of the literature. An evidence review cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the Aerican Thoracic Society. Chest. 2003;124:1543–1579. [PubMed: 14555592]

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35. Johns MW. A new method for measuring daytime sleepiness: the Epworth sleepiness scale. Sleep. 1991;14:540–545. [PubMed: 1798888]

36. Chung F, Yegneswaran B, Liao P, et al. STOP questionnaire: a tool to screen patients for obstructive sleep apnea. Anesthesiology. 2008;108:812–821. [PubMed: 18431116]

a. How do the different tests compare in different subgroups of patients, based on: race, gender, body mass index (BMI), existing non-insulin dependent diabetes mellitus (NIDDM), existing cardiovascular disease (CVD), existing hypertension (HTN), clinical symptoms, previous stroke, or airway characteristics?

Source: The Effect of Race and Sleep-Disordered Breathing on Nocturnal BP "Dipping"

*Analysis in an Older Population

1. Sonia Ancoli-Israel, PhD,

2. Carl Stepnowsky, PhD,
3. Joel Dimsdale, MD,
4. Matthew Marler, PhD,
5. Mairav Cohen-Zion, MA and
6. Sherella Johnson, AA

CHEST October 2002 vol. 122 no. 4 1148-1155

In a study of randomly selected white and African-American elderly subjects, Ancoli-Israel et al,1 found that African Americans, when compared to white subjects, had twice the relative risk of severe sleep-disordered breathing (SDB) [defined as the presence of ≥ 30 respiratory events per hour of sleep] independent of age, gender, or body mass index (BMI). In a study of African-American families, Redline et al2 observed that the apnea index differed by race and age, finding a threefold risk for SDB in African Americans < 25 years old and a twofold greater risk in middle-aged African Americans (age range, 25 to 55 years). These data suggest that there may be a high rate of undiagnosed SDB among African Americans.

There is also a high rate of undiagnosed SDB among patients with hypertension.3 Approximately one third of all hypertensive subjects have SDB, and approximately one third of all patients with SDB have hypertension.45 Peppard et al6 found a dose-response association between SDB at baseline and hypertension 4 years later, suggesting that SDB may be a risk factor of hypertension and, consequently, of cardiac morbidity. Nieto et al,7 in one of the largest cross-sectional studies, found that the prevalence of hypertension increased with increasing levels of SDB. In addition, patients with severe SDB, defined as ≥ 30 respiratory events per hour of sleep, were one and a half times more likely to have hypertension than those with no or mild SDB. This association was significant in younger and older men and women, and in all ethnic groups.

References

1. Ancoli-Israel, S, Klauber, MR, Stepnowsky, C, et al (1995) Sleep-disordered breathing in African-American elderly. Am J Respir Crit Care Med 152,1946-1949

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3. Jeong, DU, Dimsdale, JE Sleep apnea and essential hypertension: a critical review of the epidemiological evidence for co-morbidity. Clin Exp Hypertens 1989;11,1301-1323

   CrossRef
4. Millman, RP, Redline, S, Carlisle, CC, et al Daytime hypertension in obstructive sleep apnea: prevalence and contributing risk factors. Chest 1991;99,861-866

   Abstract/FREE Full Text
5. Shepard, JW, Jr Hypertension, cardiac arrhythmias, myocardial infarction, and stroke in relation to obstructive sleep apnea. Clin Chest Med 1992;13,437-458

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   CrossRefMedlineWeb of Science
7. Nieto, FJ, Young, T, Lind, B, et al Association of sleep-disordered breathing, sleep apnea, and hypertension in a large community-based study: Sleep Heart Health Study. JAMA 2000;283,1829-1836

Treatment

KQ5: What is the comparative effect of different treatments for obstructive sleep apnea (OSA) in adults?

a. Does the comparative effect of treatments vary based on presenting patient characteristics, severity of OSA, or other pre-treatment factors? Are any of these characteristics or factors predictive of treatment success?

o Characteristics: Age, sex, race, weight, bed partner, airway and other physical characteristics, specific comorbidities

SO: Chai Ching Li, Pathinathan Anna, Smith Brian J. Continuous positive airway pressure delivery interfaces for obstructive sleep apnoea. Cochrane Database of Systematic Reviews: Reviews 2006 Issue 4

DOI: 10.1002/14651858.CD005308.pub2

CONTINUOUS POSITIVE AIRWAY PRESSURE DELIVERY INTERFACES FOR OBSTRUCTIVE SLEEP APNOEA IN ADULTS: Obstructive sleep apnoea (OSA) is a condition whereby patients experience obstruction of their airways and develop an irregular breathing pattern during their sleep. If untreated, OSA can cause a variety of health problems, including high blood pressure, heart problems, difficulty concentrating, excessive sleepiness and an increased risk of having a motor vehicle accident. One widely recommended form of treatment for OSA is CPAP (continuous positive airway pressure), which consists of a pump which blows air into a patient's nose and/or mouth during sleep to hold open the airways and stop obstructions from occurring. The pump is connected to the patient via a connecting hose and an "interface" which rests on the patient's face. There are many different types of interface available for CPAP use, including masks which cover the nose, the mouth, both the nose and mouth, and even the entire face. Unfortunately, patients will often experience side effects related to their interface, which may make them want to stop their CPAP treatment. This review compares the different interface options for CPAP in patients with OSA. Four trials involving 132 people were included. Two studies compared nasal masks with an oral mask called the Oracle, and there did not appear to any significant differences between the two in terms of compliance, sleep study recordings, sleepiness or other symptoms of OSA. One study assessing nasal masks versus nasal pillows (consisting of prongs that rest within the nostrils) showed that patients using the nasal pillows had fewer overall side effects and reported greater satisfaction. The nose mask performed better than the face mask (which covers both the nose and mouth) with one study showing greater compliance and less sleepiness, and was the preferred mask in almost all patients. The choice of interface for a particular person will need to be tailored to the individual. Further trials comparing the many interfaces for CPAP in the treatment of OSA are needed.

SO: Giles Tammie L, Lasserson Toby J, Smith Brian, White John, Wright John J, Cates Christopher J. Continuous positive airways pressure for obstructive sleep apnoea in adults. Cochrane Database of Systematic Reviews: Reviews 2006 Issue 3

DOI: 10.1002/14651858.CD001106.pub3

CONTINUOUS POSITIVE AIRWAYS PRESSURE FOR RELIEVING SIGNS AND SYMPTOMS OF OBSTRUCTIVE SLEEP APNOEA: Obstructive sleep apnoea is the term used to describe the interruption in normal breathing of individuals during sleep. It is caused by collapse of the upper airways during sleep and is strongly associated with obesity. The mainstay of medical treatment is a machine used at night to apply continuous positive airways pressure (CPAP). The machine blows air through the upper air passages via a mask on the mouth or nose to keep the throat open. We searched and reviewed all randomised controlled trials that had been undertaken to evaluate the benefit of CPAP in adult patients with sleep apnoea. Some of the trials had methodological flaws, although more recent studies have begun to use appropriate forms of control. The overall results demonstrate that in people with moderate to severe sleep apnoea CPAP can improve measures of sleepiness, quality of life and associated daytime sleepiness. CPAP leads to lower blood pressure compared with control, although the degree to which this is achieved may depend upon whether people start treatment with raised blood pressures. Oral appliances are also used to treat sleep apnoea but, whilst some people find them more convenient to use than CPAP, they do not appear to be as effective at keeping the airway open at

night. Further good quality trials are needed to define who benefits, by how much and at what cost. Further trials are also needed to evaluate the effectiveness of CPAP in comparison to other interventions, particularly those targeted at obesity.

SO: Smith Ian, Lasserson Toby J, Wright John J. Drug therapy for obstructive sleep apnoea in adults. Cochrane Database of Systematic Reviews: Reviews 2006 Issue 2

DOI: 10.1002/14651858.CD003002.pub2

DRUG THERAPY FOR OBSTRUCTIVE SLEEP APNOEA IN ADULTS: Obstructive sleep apnoea (OSA) is caused by collapse of the upper airway. The mainstay of medical treatment is continuous positive airways pressure (CPAP) delivered through a mask during sleep. Drug therapy has been proposed for patients with mild OSA and those intolerant of CPAP. Many drugs have been tested as treatments for obstructive sleep apnoea (when breathing stops during sleep). Most have not been found to be effective. A few have been shown to reduce the number of apnoeic episodes during sleep but have not yet been shown to improve well-being during wakefulness. We searched and reviewed all randomised placebo controlled trials of drugs in adult patients with OSA . Most of the trials had methodological flaws. Of 21 drugs tested, eight had some impact on the severity of OSA (in terms of either markers of sleep quality or symptoms of sleepiness) although in most people changes were only modest. Physostigmine, Mirtazipine and nasal lubricant were only trialed on single night studies and the long-term effects are therefore unknown. Topical nasal steroid was tolerated, reduced the severity of sleep apnoea and improved subjective daytime alertness in a specific sub group with both OSA and rhinitis. Acetazolamide reduced the number of respiratory events per hour of sleep but did not reduce daytime sleepiness and was poorly tolerated long term. Paroxetine had only a small effect on the amount of OSA and while it was tolerated there was no useful effect on daytime symptoms. In contrast participants reported a symptomatic benefit from protriptyline, but there was no improvement in OSA suggesting a different mechanism for their improved sense of well-being.

SO: Smith Ian, Nadig Vidya, Lasserson Toby J. Educational, supportive and behavioural interventions to improve usage of continuous positive airway pressure machines for adults with obstructive sleep apnoea. Cochrane Database of Systematic Reviews: Reviews 2009 Issue 2

DOI: 10.1002/14651858.CD007736

DO EDUCATIONAL, SUPPORTIVE AND/OR BEHAVIOURAL INTERVENTIONS INCREASE USAGE OF CONTINUOUS POSITIVE AIRWAY PRESSURE MACHINES FOR ADULTS WITH OBSTRUCTIVE SLEEP APNOEA?: Continuous positive airway pressure (CPAP) treats obstructive sleep apnoea (OSA) effectively in the majority of people. Despite its efficacy in ameliorating symptoms resulting from OSA, CPAP usage has been reported as 65-80%. This review critically appraises studies involving educational and behavioural interventions and supportive strategies aimed at improving CPAP usage. After reviewing the literature, we have found some evidence that educational interventions and cognitive behavioural therapy increased CPAP usage. Short course education did not have a statistically significant effect on CPAP usage.

SO: Shneerson John, Wright John J. Lifestyle modification for obstructive sleep apnoea. Cochrane Database of Systematic Reviews: Reviews 2001 Issue 1 UK DOI: 10.1002/14651858.CD002875

DOI: 10.1002/14651858.CD002875

LIFESTYLE MODIFICATION STRATEGIES FOR MANAGING OBSTRUCTIVE SLEEP APNOEA: Obstructive sleep apnoea happens when breathing is either stopped or reduced during sleep because of a narrowing or blockage of the upper airway (passage to the lungs). It causes loud snoring and occasional apnoea (stopping breathing). It can lead to daytime sleepiness and may cause, hypertension, stroke and road accidents. Lifestyle modification, especially weight loss, sleep hygiene and exercise, are often recommended. These could help by

relieving pressure on the upper airway, and increasing muscle tone in the airway. However, the review found no trials to assess the effects of these strategies, and more research is needed.

SO: Lim Jerome, Lasserson Toby J, Fleetham John, Wright John J. Oral appliances for obstructive sleep apnoea. Cochrane Database of Systematic Reviews: Reviews 2006 Issue 1

DOI: 10.1002/14651858.CD004435.pub3

ORAL APPLIANCES FOR TREATING SLEEPINESS, QUALITY OF LIFE AND MARKERS OF SLEEP DISRUPTION IN PEOPLE WITH OBSTRUCTIVE SLEEP APNOEA/HYPOPNOEA (OSAH): OSAH is characterized by recurrent episodes of partial or complete upper airway obstruction during sleep, leading to a variety of symptoms including excessive daytime sleepiness. The current first choice therapy is CPAP that keeps the upper airway patent during sleep. However, this treatment can be difficult for some patients to tolerate and comply with on a long-term basis. OA are now widely used as an alternative to CPAP therapy. They are designed to keep the upper airway open by either advancing the lower jaw forward or by keeping the mouth open during sleep. This review found that OA should not be considered as first choice therapy for OSAH, where symptoms and sleep disruption are severe. There has not been a sufficient amount of research that examines the effects of OA compared with CPAP in terms of symptoms and quality of life. Although CPAP was clearly more effective at reducing the disruption to sleep, some people with OSAH may prefer using them if they are found to be tolerable and more convenient than CPAP. When an active OA was compared with an inactive OA , there were improvements in daytime sleepiness and apnoea/hypopnoea severity. OA may be more effective than corrective upper airway surgery. Further research should consider whether people with more distinctly severe symptoms respond in a similar way to those patients represented in the studies we have included in the review.

SO: Smith Ian, Lasserson Toby J. Pressure modification for improving usage of continuous positive airway pressure machines in adults with obstructive sleep apnoea. Cochrane Database of Systematic Reviews: Reviews 2009 Issue 4

DOI: 10.1002/14651858.CD003531.pub3

THE EFFECTS OF DIFFERENT PRESSURE DELIVERY INTERVENTIONS FOR IMPROVING USE OF CONTINUOUS POSITIVE AIRWAY PRESSURE IN THE TREATMENT OF OBSTRUCTIVE SLEEP APNOEA: Obstructive sleep apnoea (OSA) is caused by intermittent airway closure during sleep such that airflow stops despite continued efforts to breathe. Continuous positive airways pressure (CPAP) can be an effective treatment for this condition but requires regular use, and many people cannot tolerate it, or do not use it every night. Attempts to improve compliance with treatment have included changes to the mechanical devices used to deliver airway pressure, such as auto-CPAP, bi-level PAP, expiratory pressure relief and additional humidification. We examined the evidence for these different approaches. None led to large increases in hours of use, though when asked, most participants expressed a preference for the auto-CPAP machine rather than fixed pressure. When bi-level PAP and fixed CPAP were compared, initial patient acceptance was greater for bi-level PAP in one study, but long-term usage in those accepting treatment was similar for both devices. Expiratory pressure relief (C-flexTM) did not show improvement in hours of use and symptom scores. According to the evidence currently available, compliance with positive airway pressure therapy for OSA is similar, irrespective of the mode of delivery (e.g. fixed, auto-titrating or bi-level device).

SO: Sundaram Supriya, Lim Jerome, Lasserson Toby J. Surgery for obstructive sleep apnoea in adults. Cochrane Database of Systematic Reviews: Reviews 2005 Issue 4

DOI: 10.1002/14651858.CD001004.pub2

SURGERY FOR OBSTRUCTIVE SLEEP APNOEA/HYPOPNOEA SYNDROME: Surgery for obstructive sleep apnoea/hypopnoea syndrome aims to relieve obstruction by increasing the size of the airway in the throat,

bypassing the airway or removing a lesion. A limited number of trials assessing diverse surgical techniques were identified. There were inconsistent effects reported across the trials. The available evidence from these small studies does not currently support the widespread use of surgery in people with mild to moderate daytime symptoms associated with sleep apnoea.

o OSA severity or characteristics: Baseline questionnaire (etc.) results, formal testing results (including hypoxemia levels), Baseline QoL; positional dependency, REM dependency

o Other: specific symptoms

b. Does the comparative effect of treatments vary based on the definitions of OSA used by study investigators?

KQ6: In OSA patients prescribed non-surgical treatments, what are the associations of pre-treatment patient-level characteristics with treatment compliance?

Source:
Diagnosis and Treatment of Obstructive Sleep Apnea in Adults
Comparative Effectiveness Reviews, No. 32

Investigators: Ethan M Balk, MD, MPH, Denish Moorthy, MBBS, MS, Ndidiamaka O Obadan, MD, MS, Kamal Patel, MPH, MBA, Stanley Ip, MD, Mei Chung, PhD, MPH, Raveendhara R Bannuru, MD, Georgios D Kitsios, MD, PhD, Srila Sen, MA, Ramon C Iovin, PhD, James M Gaylor, BA, Carolyn D'Ambrosio, MD, MS, and Joseph Lau, MD.

Tufts Evidence-based Practice Center
Rockville (MD): Agency for Healthcare Research and Quality (US); July 2011.
Report No.: 11-EHC052

Preoperative Testing
The occurrence of both perioperative and postoperative complications in OSA patients has been documented with respect to either surgical intervention for OSA or other procedures.[37–39] In a study of patients undergoing hip or knee replacement surgery, 24 percent of 101 patients with OSA had major postoperative complications (respiratory or cardiac) compared with 9 percent of matched controls.[39] Other studies have highlighted the risk of anesthesia and analgesia-related adverse outcomes, such as perioperative airway collapse and postoperative oxygen desaturation.[37,39] Many surgical patients with OSA, however, remain undiagnosed at the time of surgery,[37–39] and may benefit from some type of preoperative assessment for OSA.[37] Finding patients with undiagnosed sleep apnea who are undergoing surgery could, in theory, allow for optimization of perioperative care to minimize problems with intubation, extubation, and other respiratory events. At present, the value of screening all or selected surgical patients, and what method of screening would be most effective and efficient, is unclear.

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KQ7: What is the effect of interventions to improve compliance with device (CPAP, oral appliances, positional therapy) use on clinical and intermediate outcomes?

Source:
Diagnosis and Treatment of Obstructive Sleep Apnea in Adults
Comparative Effectiveness Reviews, No. 32

Investigators: Ethan M Balk, MD, MPH, Denish Moorthy, MBBS, MS, Ndidiamaka O Obadan, MD, MS, Kamal Patel, MPH, MBA, Stanley Ip, MD, Mei Chung, PhD, MPH, Raveendhara R Bannuru, MD, Georgios D Kitsios, MD, PhD, Srila Sen, MA, Ramon C Iovin, PhD, James M Gaylor, BA, Carolyn D'Ambrosio, MD, MS, and Joseph Lau, MD.

Tufts Evidence-based Practice Center
Rockville (MD): Agency for Healthcare Research and Quality (US); July 2011.
Report No.: 11-EHC052

Eric J. Freer
GE Healthcare, Respiratory & Sleep, Home Care
Sales & Marketing Leader

2. Douglas Myers

The diagnosis and treatment of sleep apnea requires a varried approach. On one end of the spectrum is the child with an oropharynx obstructed by grossly enlarged tonsils for whom no diagnostic studies are beneficial and for whom tonsillectomy results in a cure. On the other end is the obese adult individual who would be helped by weight loss, smoking and alcohol cessation, and C-PAP, who requires sleep studies for monitoring and for whom surgery holds little benefit. In one instance sleep studies represent an unnecessary expense and surgery is most cost effective, and in the other the surgery is an unnecessary expense and sleep studies are most cost effective. Diagnostic evaluation and treatment must be individualized. The expertise to perform both diagnosis and treatment is available in most local medical communities, so that the added cost in time and transportation to regional centers is unnecessary. A common guideline for best practices would be helpful for use in community multispecialty discussions to establish diagnostic and surgical criteria.

Douglas Myers, M.D.

Vancouver, WA

3. Kerilyn Nobuhara

Will the cost effectiveness analysis include consideration of the morbidities associated with the different treatments? Ie we receive a number of PA requests for UPPP surgery, which is at best only 50% successful in treatment of sleep apnea, and patients frequently require CPAP even if they have had the surgery, which essentially negates any cost benefit for the surgical intervention.

Thanks.

Kerilyn Nobuhara
Senior Medical Consultant
Healthcare Authority

PUBLIC COMMENTS – DRAFT REPORT

1. Karen Anderson

Hi, Denise.
I have just finished reviewing the summary on the OSA eval. One of the concerns I have is that there are some vulnerable populations that were not "teased out" for evaluation. Specifically, patients with Down's Syndrome are notoriously afflicted with ENT issues and I had the unfortunate experience of dealing with one who was in heart failure, was evaluated and determined to have OSA, given CPAP which, despite her severe mental retardation, she avidly wore and improved immensely. I don't know how that fits in with the EBM eval but I do think that there may be some populations that have not been separately evaluated and who may benefit from treatment. Also, I did not see CHF findings or symptoms included in the pre/post rx evals. I think that is an important deficit.
thanks
Karen Anderson

2. Washington State Agency Medical Directors

Comments on Sleep Apnea Draft Evidence Report

The significance of the association between apnea-hypopnea index (AHI) and all-cause mortality is unclear, particularly given the uncertain association between AHI and cardiovascular mortality, stroke, hypertension, diabetes and other metabolic abnormalities, and quality of life. The draft report does comment on p. 5 "Thus the association between reductions in AHI by OSA treatment and improvements in long-term clinical outcomes remains theoretical."In general, the wording of the report gives unsupported credence to a putative causal relationship between obstructive sleep apnea (OSA) and major morbidity and mortality. Similarly, it is not sufficiently critical of the strength of evidence supporting the proposition that continuous positive airway pressure (CPAP) and other treatments for OSA improve major clinical outcomes.

Regarding key question 4, the "relationships between… AHI and oxygen desaturation index… and other patient characteristics with long term clinical and functional outcomes" is further elaborated in the draft report, quoting from the AHRQ comparative effectiveness review on sleep apnea diagnosis and treatment, concluding, on p. 164, "Unfortunately, as discussed below, there are almost no trial data to support that treatment of OSA and reduction of AHI improves clinical outcomes" and, on p. 165 "While the relevant trials are conclusive regarding the effects of CPAP on AHI and sleepiness measures, among over 40 trials of patients treated with CPAP or no treatment, none have reported long-term clinical outcomes." Thus, it is contradictory and unclear what evidence is relied on for statements such as: p. 174, "Obstructive sleep apnea is a cause of significant morbidity and mortality, and is thus an important public health issue. In addition, the diagnosis and treatment of OSA have societal cost implications, making cost-effectiveness a concern in both of these aspects."

On p. 7 of the draft report it is stated: "A moderate strength of evidence was found for the treatment of OSA with CPAP", a statement that in itself says little, but presumably intends to say that a moderate strength of evidence was found to support the effectiveness of treatment of OSA with CPAP. Subsequent statements qualify the statement, noting that there is relatively strong evidence that CPAP treatment improves sleep measures such as AHI, arousal index, and minimum oxygen saturation, and subjective report of daytime sleepiness on the Epworth Sleepiness Scale. Directly quoted from the AHRQ comparative effectiveness review on sleep apnea diagnosis and treatment, the draft report says on p. 7: "There is only weak evidence that that CPAP treatment may improve quality of life or neurocognitive measures, or other intermediate outcomes" and "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 term "signs and symptoms" is not further specified, leaving it unclear exactly what beneficial effects of CPAP treatment are supported by evidence. It would be helpful to remind the reader at this point that any association between reductions "in AHI by OSA treatment and improvements in long-term clinical outcomes remains theoretical."
The discussion of cost effectiveness studies in both the Executive Summary and the body of the report fails to adequately emphasize that the "cost effectiveness" analysis assumes effectiveness of OSA treatment rather than basing the analysis on empirical findings of effectiveness, thus seriously undermining validity of "cost effectiveness" analyses. Such problems with the major "cost utility" study reported on (McDaid, 2009) are mentioned in the "Limitations" section on p. 174, yet the highly conjectural results of the cost utility study are reported with little in the way of caveat.

Similarly the cost-analysis studies of health care costs of persons with OSA compared to those without do not establish causality or evidence to support the expectation that diagnosis and treatment of OSA will reduce health care costs. Thus, in the "Policy context and cost information" discussion in the "Background" section of the draft report, on p. 17, it is surprising to see the statement "Undiagnosed OSA results in roughly a two-fold

increase in health care utilization and costs, in the years preceding the diagnosis, due largely to the number of attendant comorbidities." The use of the words "results in" implies causality where it has not been established.

The draft report would do better to emphasize how much of the case for treatment of OSA is based on conjecture and extrapolation from associative relationships between sleep measures and clinical morbidity and the effects of OSA treatments on sleep measures and a few intermediate clinical outcome measures of uncertain clinical significance. In this context, "cost-effectiveness" studies of OSA treatment have little value other than as conjecture.

Department of Corrections
Dr. Steve Hammond

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