

The New England Comparative Effectiveness Public Advisory Council

An Action Guide for Obstructive Sleep Apnea: Next Steps for Patients, Clinicians, and Insurers

January 2013

Completed by:

The Institute for Clinical and Economic Review



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Introduction

About this guide

Evidence from clinical effectiveness reviews is critical to judgments that patients, clinicians, and health insurers must make about treatment choices and coverage policies. Yet that evidence is often not translated in a way that is helpful to inform healthcare decisions. This document is a companion policy guide designed to help patients, clinicians, and insurers make use of the results of two reports: 1) the evidence review on diagnostic and treatment options for adults with Obstructive Sleep Apnea (OSA) produced by the Agency for Healthcare Research and Quality (AHRQ)¹; and a supplementary report with additional data and analyses on OSA diagnosis and treatment options developed by the Institute for Clinical and Economic Review (ICER). These two reports were used to support the deliberations of the New England Comparative Effectiveness Public Advisory Council (CEPAC) – an independent body that provides objective guidance on how information from federally produced evidence reviews can best be used by regional decision-makers to improve the quality and value of healthcare services.²

CEPAC held its meeting on the diagnosis and treatment of OSA on December 6, 2012 in Hartford, Connecticut. A full report summarizing the discussion and votes taken is available on the <u>CEPAC</u> <u>website</u>. We have developed this Action Guide in order to provide a user-friendly overview of the CEPAC findings and an associated list of specific evidence-based action steps that patients, clinicians, and insurers can take to improve patient outcomes and the overall value of OSA services. This information is being provided for informational purposes only.

A note on CEPAC evidence voting

Each public meeting of CEPAC involves deliberation and voting on key questions on the comparative clinical effectiveness of various diagnosis and treatment options discussed. When a majority of CEPAC votes that the evidence is adequate to demonstrate that an intervention produces patient outcomes equivalent or superior to a reference option, council members are also asked to vote on whether the intervention represent a "high", "reasonable", or "low" economic value. The value perspective that members of CEPAC are asked to assume is that of a state Medicaid program making resource decisions within a fixed budget for care.

¹ The full AHRQ report can be accessed here: : Balk EM, Moorthy D, Obadan NO, Patel K, Ip S, Chung M, Bannuru RR, Kitsios GD, Sen S, Iovin RC, Gaylor JM, D'Ambrosio C, Lau J. Diagnosis and Treatment of Obstructive Sleep Apnea in Adults. Comparative Effectiveness Review No. 32. (Prepared by Tufts Evidence-based Practice Center under Contract No. 290-2007-10055-1). AHRQ Publication No. 11-EHC052-EF. Rockville, MD: Agency for Healthcare Research and Quality [http://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=683]

² For more information on CEPAC, visit: <u>http://cepac.icer-review.org/</u>

Diagnostic and Treatment Options for Adults with OSA

Background

Obstructive sleep apnea (OSA) is a chronic disorder, characterized by repetitive stops and starts in breathing during a night of sleep (Mayo Foundation, 2012). As muscles in the throat relax, partial (hypopnea) or complete (apnea) blockage of the airway occurs, leading to symptoms such as snoring, gasping or choking (Young, 2009). Other nighttime events associated with intermittent breathing interruptions include decreased oxygen saturation and arousals from sleep (Punjabi, 2008). Consequences of OSA include excessive daytime sleepiness, hypertension, chronic fatigue and insomnia (Mayo Foundation, 2012). Long-term health problems associated with OSA include cardiovascular disease (increased risk of heart failure and stroke), ocular disorders such as glaucoma, memory and cognitive problems, and changes in mood or development of depression (Mayo Foundation, 2012).

The economic burden of OSA is also substantial. Direct medical costs have been estimated to total as much as \$3.4 billion in the U.S. (Kapur, 1999). In addition, findings from a recent Canadian study indicate that patients referred for sleep testing are 4 times more likely to be hospitalized than those not referred (Ronksley, 2011).

Diagnostic Strategies for OSA

A multifaceted approach is typically taken to diagnose OSA. First, a comprehensive clinical evaluation is performed, including assessment of patient risk factors and a detailed sleep history (Epstein, 2009). As part of a comprehensive clinical evaluation in a patient suspected of OSA, various questionnaires may be utilized to evaluate symptoms and rate the likelihood that symptoms represent OSA. The most common instruments evaluate daytime sleepiness, snoring, blood pressure, and fatigue and fatigue symptoms, as well as demographic and anatomic information. Commonly used questionnaires include the Epworth Sleepiness Scale (ESS), the Berlin questionnaire (BQ), and the STOP-Bang.

Clinical Prediction Rules

Clinicians and researchers have also developed several algorithmic clinical prediction rules to assist in risk stratification of patients suspected of OSA. Often, these tools are based on objectively-measured clinical parameters, along with clinical observations that are used as inputs in a statistical prediction model. Examples of input variables are BMI, age, presence of hypertension, morphometric parameters (e.g., palatal height, neck circumference), and results of pulmonary function testing.

Sleep Testing

Following initial assessment, patients judged to be at risk of OSA can undergo objective sleep testing to measure the Apnea-Hypopnea Index (AHI): the sum of the number of apneas and hypopneas divided by the total hours of sleep (Ho, 2011). Hypopneas are defined as temporary reductions in breathing lasting at least 10 seconds; apneas are complete disruptions in breathing greater than 10 seconds, and lasting

as long as one minute (Ho, 2011). An alternative measure of breathing disturbance severity is the Respiratory Disturbance Index (RDI) which includes respiratory event-related arousals (RERAs) in addition to apneas and hypopneas (Ho, 2011)

Polysomnography

A full-night sleep evaluation conducted in an accredited sleep facility and attended by a certified sleep technician is considered the gold standard for objective confirmation of OSA. Several "channels" (i.e., measurements of objective clinical parameters) are required during a polysomnography (PSG): cardiac activity (via ECG), brain activity (via EEG), visual movements (via electrooculogram), muscle activity (via electromyogram), airflow rate, oxygenation, respiratory movement, and body position (Ho, 2011). The measurement and clinical documentation of these physical parameters provides data to calculate the AHI and/or RDI by an experienced, board-certified clinician (Epstein, 2009). Patients spend an entire night undergoing evaluation of their sleep and breathing patterns during the PSG. Split-night testing may be undertaken in patients with a confirmed OSA diagnosis in the initial 2 hours of the PSG: following documentation of the AHI/RDI, titration of positive airway pressure therapy for treatment is conducted in the remaining hours (Kushida, 2005). While PSG is often the preferred test for OSA diagnosis, factors such as scoring methodology, inter-rater agreement in scoring, and night-to-night variability may affect the reliability and validity of the results (Trikalinos, 2007).

Home Sleep Testing

As an alternative to facility-based testing, different types of portable home sleep testing monitors may be used in combination with clinical evaluation for the diagnosis of OSA. The amount of clinical data collected with the various monitors differs: the AASM recommends that at a minimum, airflow, respiratory effort and blood oxygenation should be recorded (Collop, 2007). Full-night PSG utilizes Type I monitors; Type II monitors measure the same information as Type I but are portable and/or unattended (Collop, 2007). Type III and IV devices utilize fewer channels and record less clinical data.

CEPAC Votes and Deliberation on the Diagnosis of OSA in Adults:

Home sleep testing vs. Polysomnography

- The majority of CEPAC voted that Type III and IV home monitors are equivalent to polysomnography in diagnosing OSA [12 yes; 2 no]
- CEPAC also voted that home-based pathways (e.g. home sleep testing + autoPAP) have high or reasonable value compared to in-lab pathways (split-night PSG + CPAP) [6 high; 6 reasonable; 2 low)
- Although a majority of CEPAC voted that home sleep monitors are functionally equivalent to polysomnography, council members did voice concern that expanding access to home sleep testing may enlarge the scope of diagnostic testing to patients with lower risks of OSA, increasing the potential for mis- or over-diagnosis.
- Payers on the stakeholder roundtable who cover portable monitors noted that there has been relatively slow take-up of home sleep testing in some markets in spite of positive coverage, and that enlarging the scope of diagnostic testing to lower risk patients has not been the experience.

Phased-diagnostic approaches

• CEPAC voted that the evidence is inadequate to demonstrate that phased diagnostic approaches using either the Berlin questionnaire or clinical prediction rules to identify candidates for polysomnography is equivalent to using polysomnography alone in all patients in whom there is a clinical suspicion for OSA.

Treatment Options

Several treatment options to alleviate obstruction of the airway are prescribed for patients with OSA. After consideration of lifestyle changes such as weight loss, smoking cessation and decreased alcohol consumption, first-line therapy typically involves positive airway pressure (PAP) devices (Epstein, 2009). For patients who do not respond to PAP, alternate approaches include dental appliances and surgery to alter the obstructive anatomy. For all of the treatment options described it is important to note that the evidence linking treatment to improvement in objective outcomes such as cardiovascular events is relatively weak (Pack, 2009); as such, effectiveness of these options is primarily described in terms of improvements in AHI and/or RDI alone.

Continuous Positive Airway Pressure (CPAP)

CPAP involves the continuous supply of pressurized air to a patient through a mask in order to keep the airway fully open during inhalation and exhalation. A titration process is undertaken to arrive at the maximum effective pressure able to be tolerated comfortably by the patient (Ho, 2011). Common side effects include claustrophobia, along with nasal and oral dryness (Balk, 2011), which may contribute to suboptimal compliance with therapy. Several modifications exist to decrease side effects of PAP such as heated humidification to combat dryness, and alternate modalities like auto-titrating PAP (autoPAP), bilevel PAP (BPAP) or variable PAP (VPAP). In patients who require very high pressures, these alternate modalities provide different inspiratory and expiratory pressures, which may increase tolerance as well as compliance with therapy. Treatment with PAP is long-term with annual evaluation to assess therapy response as well as any equipment difficulties (Epstein, 2009).

Mandibular Advancement Devices (MADs)

Oral devices, custom-fitted by specialized dentists, may be used to treat patients with mild-to-moderate OSA. MADs are the most prescribed form of oral appliances and may also be used in patients intolerant to PAP therapy (Ahrens, 2011). These devices work by advancing the lower jaw, thereby increasing the airway space during sleep (Ho, 2011). MAD use may be limited by insufficient dentition for anchoring of the appliance and the presence of jaw dysfunction (Epstein, 2009). Side effects may include jaw or tooth pain, and potential aggravation of temporomandibular joint disease (Epstein, 2009). Annual appointments and periodic sleep testing are recommended following initial titration to evaluate continued successful management of OSA.

Surgical Procedures

Reserved predominantly for patients with moderate-to-severe OSA who have failed PAP therapy, surgical techniques designed to alter the anatomic space of the mouth and throat are also potential treatment options. For patients with enlarged tonsils, tonsillectomy and/or adenoidectomy may provide relief. Other common invasive procedures include uvulopalatopharyngoplasty (UPPP), in which the soft palate and surrounding tissue in the back of the mouth are removed to relieve airway obstruction, and maxillomandibular advancement (MMA), in which the upper and lower jaws are repositioned (Mayo Foundation, 2012). Tracheostomy, in which an opening in the windpipe is made, is

a surgery typically reserved for patients who have failed all other treatment options. Following surgery, some patients may continue to require PAP therapy to effectively manage the symptoms of OSA. In addition to side effects that may occur with any surgical procedures (anesthesia risks, bleeding, infection risk and sudden death), other potential side effects of OSA surgery include speech or swallowing problems, taste alteration, and transient nerve paralysis (Balk, 2011).

Weight Loss Interventions

A less-invasive approach to the management of OSA involves the use of defined weight loss programs. As obesity is a significant cause of OSA in many patients, decreasing body fat may significantly improve AHI and associated symptoms of OSA. Potential interventions involve strict calorie control with or without structured physical exercise. Exercise alone may impact patients with OSA by decreasing AHI and improving sleep quality (Kline, 2011). Structured programs involve multiple weekly sessions with trainers and/or dieticians. Following significant weight loss (≥ 10% of body weight), patients will require reassessment of their OSA along with continued monitoring for maintenance of weight reduction and any re-emergence of symptoms (Epstein, 2009).

CEPAC Votes and Deliberation on Treatment Options for OSA:

СРАР

- CEPAC stipulated that there is insufficient evidence to demonstrate that any of the available intervention programs improve compliance with CPAP relative to usual CPAP care in adults with OSA.
- CEPAC also stipulated that there is insufficient evidence to demonstrate that other interventions such as medication, bariatric surgery, palatal implants, nasal dilator strips, etc. are more effective than CPAP.

CPAP vs. Surgery

• A majority of CEPAC voted the evidence is inadequate to demonstrate that surgery is equivalent or superior to CPAP in particular subpopulations with OSA. [2 yes; 12 no]

MADs

- CEPAC stipulated that there is insufficient evidence to demonstrate that any one MAD is more effective than any other.
- A majority of CEPAC voted that MADs are superior to no treatment in treating adults with OSA. [13 yes; 1 no]
- A majority of CEPAC also voted that MADs have reasonable value compared to no treatment [1 high; 8 reasonable; 4 low; 1 abstain]

MADs vs. CPAP

• CEPAC voted that the evidence is inadequate to demonstrate that MADs are equivalent or superior to CPAP in treating patients with mild-to-moderate OSA.

Action Steps for Patients

The following information is designed to help patients understand their options for the diagnosis or treatment of obstructive sleep apnea (OSA). These steps are based on the most up-to-date evidence, including information about risks and benefits, on what works best for diagnosing and treating OSA.

1. Understand your symptoms and risk factors for obstructive sleep apnea.

Common signs and symptoms of obstructive sleep apnea include excessive daytime sleepiness, loud snoring, unrefreshing sleep, insomnia, and episodes of breathing cessation during sleep. However, the presence of common symptoms does not necessarily mean you have OSA. The American Academy of Sleep Medicine (AASM) and American Sleep Apnea Association (ASAA) websites have helpful information to help identify your symptoms, as well as self-tests to help you understand your individual risk for OSA:

AASM self-tests: http://www.sleepeducation.com/sleep-disorders/sleep-apnea/overview-facts.

ASAA self-tests: <u>http://www.sleepapnea.org/diagnosis-and-treatment/test-yourself.html</u>.

2. Compile your sleep and medical history to share with your clinician.

Effective treatment begins with a comprehensive medical evaluation to help clinicians identify signs and symptoms that signify the presence of OSA. If you think you may have OSA, help your clinician determine if further sleep testing is necessary by compiling your sleep and medical history. Free online programs are available to help you track your sleep patterns and other symptoms that can be shared directly with your primary care physician: http://www.arbormedicus.com/.

The American Sleep Apnea Association has more information on how this web-based tool works: <u>http://www.sleepapnea.org/diagnosis-and-treatment/diagnosis/your-medical-history.html</u>.

3. Become an expert: learn as much as you can about the various diagnosis and treatment options for OSA.

This Action Guide outlines the major approaches to OSA diagnosis and treatment: polysomnography, home sleep testing, CPAP, MADs, weight loss, and surgery.

Other resources with information on the various diagnosis and treatment options for OSA, and the relative effectiveness of each include:

a. Treating Sleep Apnea: A Review of the Research for Adults (US Agency for Healthcare Research and Quality) http://effectivehealthcare.ahrq.gov/ehc/products/117/684/sleep_ap_consumer.pdf

This consumer summary provides an overview of the various treatment options

available for patients with OSA, including information on which procedures are proven to work best, their comparative costs, and other important considerations before making a decision.

b. American Academy of Sleep Medicine Sleep Education

http://www.sleepeducation.com/sleep-disorders/sleep-apnea/diagnosis The American Academy of Sleep Medicine website also provides a detailed overview of the various options available for OSA treatment and diagnosis.

c. American Sleep Apnea Association
 <u>http://www.sleepapnea.org/learn.html</u>
 The ASAA website has information on the comparative effectiveness of various diagnostic and treatment options for OSA, as well as information on how to access patient support groups.

 d. National Institutes of Health: Your Guide to Healthy Sleep

http://www.nhlbi.nih.gov/health/public/sleep/healthy_sleep.pdf This booklet provides up-to-date information on sleep disorders, including obstructive sleep apnea; information on how to assess your sleep health; a sample sleep diary to help you track your behavior; and information on how to access treatment.

4. Talk to your doctor about the various diagnosis and treatment options, identifying the pros and cons of each. Discuss which diagnostic/treatment approaches you are most likely to succeed with given your individual risk, severity, and preferences.

Your clinician can help you understand what tests and/or treatments work best for you, based on the medical evidence and your individual preferences, values, and goals. Talk to your clinician about ways to make treatments more comfortable to improve compliance, and which test and treatment options have greater value for money. Not all doctors are well-versed in information related to sleep disorders or expert in sleep medicine, so you may want to seek out a certified physician (more information below) and online education resources (provided above).

5. If undergoing sleep testing, use a provider or sleep center using an evidence-based approach. If receiving home testing, make sure your test results are interpreted by a clinician accredited or trained in sleep medicine.

To find an accredited sleep center offering polysomnography and/or home testing in your area, visit <u>http://www.sleepeducation.com/find-a-center</u>. These sleep centers are accredited through the American Academy of Sleep Medicine. Other centers may be qualified but have not received accreditation, or may be in the process of doing so. Several of the member boards of the American Board of Medical Specialties offer certification examinations for sleep medicine. To verify if your physician is certified in sleep medicine, visit the following websites:

American Board of Internal Medicine: <u>http://www.abim.org/services/verify-a-physician.aspx</u> American Board of Sleep Medicine: <u>http://absm.org/listing.aspx</u> American Board of Anesthesiology: <u>http://directory.theaba.org/</u> American Board of Family Medicine: <u>https://www.theabfm.org/diplomate/index.aspx</u> American Board of Pediatrics: <u>https://www.abp.org/MOCVerification/VerificationServlet</u> American Board of Psychiatry and Neurology: <u>https://application.abpn.com/verifycert/verifycert.asp</u> American Board of Otolaryngology: <u>http://www.aboto.org/ABOInternet/VerifyPhysicianCertification</u>

About accredited centers: According to the American Academy of Sleep Medicine, each of these sleep centers "has demonstrated a commitment to the highest quality of care in the treatment and diagnosis of sleep disorders. In order to become accredited by the American Academy of Sleep Medicine, sleep centers must comply with the AASM Standards for Accreditation, the gold standard for patient care in the sleep medicine field. These requirements incorporate the latest advances in sleep medicine and guarantee quality care to meet the needs of patients and referring physician." The AASM Standards of Accreditation can be accessed here: http://www.aasmnet.org/accred_centerstandards.aspx.

6. Modify behaviors that may alleviate OSA symptoms.

For some patients, modifying lifestyle behaviors may reduce, or in some cases cure, OSA. Talk to your clinician about available programs and resources to change the following behaviors before or concurrent with receiving treatment:

- Losing weight if you are obese or overweight
- Not drinking alcohol before bed
- Not using sedative drugs
- Stopping tobacco use if you are a smoker
- Change your sleeping position to sleep on your side or in a semi-propped up position
- 7. If receiving OSA treatment, track any changes to your OSA symptoms overtime to help your clinician determine your progress with treatment and if other options should be pursued. If you are having difficulty complying with CPAP, discuss with your clinician techniques to improve compliance, the risks of noncompliance, and other treatment options that may be a better fit for you.

Action Steps for Clinicians

If you are a clinician treating or diagnosing a patient with OSA, the following steps are recommended to help you develop a care management plan that incorporates the best available evidence. This section contains steps specific to primary care physicians and specialists.

Primary Care Clinicians

1. Use an evidence-based approach to diagnosis, using appropriate diagnostic criteria including the ruling out of other sleep disorders such as central sleep apnea.

Clinical guidelines are available from the following medical societies, which outline evidencebased approaches to diagnosis and treatment for adults with OSA:

Diagnosis:

When diagnosing OSA, clinicians should perform a comprehensive evaluation that includes a patient's detailed sleep history and physical examination. Further sleep testing will depend on a patient's individual OSA risk and presence of symptoms.

Polysomnography

- American Academy of Sleep Medicine (2009)
 <u>http://www.aasmnet.org/Resources/clinicalguidelines/OSA_Adults.pdf</u>
- Institute for Clinical Systems Improvement (2008) <u>http://www.icsi.org/sleep_apnea/sleep_apnea_diagnosis_and_treatment_of_obst_ructive_.html</u>

Home testing

- American Academy of Sleep Medicine (2009): <u>http://www.aasmnet.org/Resources/clinicalguidelines/OSA_Adults.pdf</u>
- Institute for Clinical Systems Improvement (2008): <u>http://www.icsi.org/sleep_apnea_diagnosis_and_treatment_of_obst_ructive_.html</u>
- National Institute for Health and Clinical Excellence (2010) <u>http://www.nice.org.uk/nicemedia/live/11944/40085/40085.pdf</u>
- 2. Consider using a validated sleep apnea screening questionnaire as part of a comprehensive medical evaluation to help identify patients who should be referred to a specialist for further sleep testing.

Links to questionnaires are provided below.

- Berlin questionnaire: <u>http://www.edward.org/workfiles/sleep%20center%20Berlin%20Sleep%20Eval.pdf</u>
- Epworth Sleepiness Scale: <u>http://www.stanford.edu/~dement/epworth.html</u>
- STOP-Bang: <u>http://sleepapnea.org/assets/files/pdf/STOP-BANG%20Questionnaire.pdf</u>

 Refer a patient to home sleep testing instead of in-lab testing unless the patient has comorbidities or other factors that may diminish the accuracy of the results. If ordering a home sleep test, ensure that results are interpreted by a provider with appropriate training in sleep medicine.

Home sleep testing should not be used in patients who have major comorbid conditions, including moderate to severe pulmonary disease, neuromuscular disease, or congestive heart failure, or patients who are suspected of having another sleep disorder, such as central sleep apnea (Epstein, 2009). Home sleep testing should only be provided to patients who are functionally and developmentally able to use portable sleep monitor equipment.

- 4. When providing home testing, ensure that patients receive necessary guidance and follow-up to ensure the accuracy of results and troubleshoot any problems related to access.
- 5. Develop or use innovative delivery models such as telemedicine to ensure that patients undergoing home testing receive appropriate guidance on application and use of portable monitors, especially for patients without available direct home services.
- 6. Seek opportunities for collaborative co-management of patients between primary care and specialty care.
- 7. Discuss with your patient behavioral interventions that may alleviate OSA symptoms. For patients who are overweight or obese, screen for metabolic syndrome and enroll your patient in available counseling and weight loss programs. Enroll patients who smoke in cessation programs, and discuss with your patient the effects of positional therapy, and the impact of sedative and alcohol use on OSA.

Specialists

 Use an evidence-based approach to diagnosis and treatment, using appropriate diagnostic criteria including the ruling out of other sleep disorders such as central sleep apnea. Clinical guidelines are available from the following medical societies, which outline evidencebased approaches to diagnosis and treatment for adults with OSA:

Diagnosis:

When diagnosing OSA, clinicians should perform a comprehensive evaluation that includes a patient's detailed sleep history and physical examination. Further sleep testing will depend on a patient's individual OSA risk and presence of symptoms.

Polysomnography

 American Academy of Sleep Medicine (2009) <u>http://www.aasmnet.org/Resources/clinicalguidelines/OSA_Adults.pdf</u> Institute for Clinical Systems Improvement (2008) <u>http://www.icsi.org/sleep_apnea/sleep_apnea_diagnosis_and_treatment_of_obst_ructive_.html</u>

Home testing

- American Academy of Sleep Medicine (2009): <u>http://www.aasmnet.org/Resources/clinicalguidelines/OSA_Adults.pdf</u>
- Institute for Clinical Systems Improvement (2008): <u>http://www.icsi.org/sleep_apnea_diagnosis_and_treatment_of_obst_ructive_.html</u>
- National Institute for Health and Clinical Excellence (2010) <u>http://www.nice.org.uk/nicemedia/live/11944/40085/40085.pdf</u>

Treatment:

Positive airway pressure

- American Academy of Sleep Medicine (2009)
 <u>http://www.aasmnet.org/Resources/clinicalguidelines/OSA_Adults.pdf</u>
- Institute for Clinical Systems Improvement (2008) <u>http://www.icsi.org/sleep_apnea/sleep_apnea_diagnosis_and_treatment_of_obst_ructive_.html</u>
- National Institute for Health and Clinical Excellence (2010) <u>http://www.nice.org.uk/nicemedia/live/11944/40085/40085.pdf</u>

Mandibular advancement devices (MADs)

- American Academy of Sleep Medicine (2009)
 <u>http://www.aasmnet.org/Resources/clinicalguidelines/OSA_Adults.pdf</u>
- Institute for Clinical Systems Improvement (2008) <u>http://www.icsi.org/sleep_apnea_diagnosis_and_treatment_of_obst_ructive_.html</u>

Upper-airway surgery

- American Academy of Sleep Medicine (2010) <u>http://www.aasmnet.org/Resources/PracticeParameters/PP_SurgicalModifications</u> <u>OSA.pdf</u>
- Institute for Clinical Systems Improvement (2008) <u>http://www.icsi.org/sleep_apnea/sleep_apnea_diagnosis_and_treatment_of_obst_ructive_.html</u>

Behavioral strategies

- American Academy of Sleep Medicine (2009)
 <u>http://www.aasmnet.org/Resources/clinicalguidelines/OSA_Adults.pdf</u>
- Institute for Clinical Systems Improvement (2008) <u>http://www.icsi.org/sleep_apnea/sleep_apnea_diagnosis_and_treatment_of_obst_ructive_.html</u>
- National Institute for Health and Clinical Excellence (2010) <u>http://www.nice.org.uk/nicemedia/live/11944/40085/40085.pdf</u>

2. Consider using a validated sleep apnea screening questionnaire to monitor patient outcomes and response to treatment.

Links to questionnaires are provided below.

- Berlin questionnaire: http://www.edward.org/workfiles/sleep%20center%20Berlin%20Sleep%20Eval.pdf
- Epworth Sleepiness Scale: <u>http://www.stanford.edu/~dement/epworth.html</u>
- STOP-Bang: <u>http://sleepapnea.org/assets/files/pdf/STOP-BANG%20Questionnaire.pdf</u>
- 8. Use home sleep testing instead of in-lab testing unless the patient has comorbidities or other factors that may diminish the accuracy of the results.

Home sleep testing should not be used in patients who have major comorbid conditions, including moderate to severe pulmonary disease, neuromuscular disease, or congestive heart failure, or patients who are suspected of having another sleep disorder, such as central sleep apnea (Epstein, 2009). Home sleep testing should only be provided to patients who are functionally and developmentally able to use portable sleep monitor equipment.

- 3. When providing home testing, ensure that patients receive necessary guidance and follow-up to ensure the accuracy of results and troubleshoot any problems related to access.
- 4. Develop or use innovative delivery models such as telemedicine to ensure that patients undergoing home testing receive appropriate guidance on application and use of portable monitors, especially for patients without available direct home services.
- 5. Seek opportunities for collaborative co-management of patients between primary care and specialty care.
- 6. Make behavioral interventions a concurrent mode of OSA treatment.

Discuss with your patient behavioral modifications that may alleviate OSA symptoms. For patients who are overweight or obese, screen for metabolic syndrome and enroll your patient in available counseling and weight loss programs. Enroll patients who smoke in cessation programs, and discuss with your patient the effects of positional therapy, and the impact of sedative and alcohol use on OSA.

- 7. Use consistent outcomes measures throughout the course of treatment in order to evaluate your patient's response to treatment.
- 8. Educate patients on the benefits of treatment and importance of treatment compliance. Appropriately monitor and follow-up with patients to improve treatment adherence and ensure treatment response.

Action Steps for Payers

The following steps are designed to help payers develop policies that incentivize the use of evidencebased diagnosis and treatment options for OSA:

- **1.** Require that physicians who interpret home testing results are accredited through the American Board of Sleep Medicine or American Board of Internal Medicine.
- 2. Collaborate with providers to pilot-test the Epworth Sleepiness Scale, STOP-Bang, or Berlin questionnaire to help primary care providers and/or specialists appropriately identify patients most likely to benefit from formal sleep testing.

Questionnaires are not currently required by many medical policies or care management plans as a tool to help screen patients for OSA. Even though the evidence does not support their use as a replacement for sleep testing, they may still have value in clinical practice for primary care providers or specialists to appropriately identify patients that are most likely to benefit from further sleep testing.

- 3. Seek ways to reduce the administrative burden for clinicians referring patients for sleep testing for clinically appropriate reasons. For example, reduce prior authorization requirements for identified centers of excellence providing high quality, appropriate care.
- 4. Maintain or develop medical policies that encourage the use of home-based pathways (home testing + autoCPAP) over in-lab paradigms.

Based on the findings of the Agency for Healthcare Research and Quality (AHRQ) review and CEPAC votes on the comparative clinical effectiveness and value of home testing compared to polysomnography, payers may consider designing medical policies that require the use of home sleep testing as a default option for patients with clinical suspicion of OSA unless certain clinical criteria are present indicating the need for in-lab testing. Patients who undergo home-sleep testing should receive autoCPAP as opposed to fixed CPAP, as standard CPAP requires a splitnight study through polysomnography to achieve appropriate air pressure and titration. Patients that fail with home sleep testing or who do not titrate easily using APAP may require follow-up polysomnography.

Sample medical policies are provided below that encourage the use of home-based paradigms (home testing + autoCPAP).

5. Payers should not consider MADs as an equivalent treatment to CPAP for patients with moderate-to-severe OSA, and should only be approved for patients who cannot tolerate CPAP.

Multiple medical policies that encourage the use of home-based paradigms (home testing + autoCPAP) are provided below as a reference. These policies were selected a examples of evidence-based coverage as they currently require patients to try home sleep testing before polysomnography, unless certain clinical criteria are present that prevent the effective use of portable monitors.

Harvard Pilgrim Health Care

CareCore National Sleep Management Criteria

Home sleep testing	Criteria to be met:
	 A. High pre-test probability of moderate-to-severe OSA (e.g. patient reported excessive sleepiness or restless sleep, witnessed apneas or choking at night, two or more supporting signs or risk factors, and unexplained documented pulmonary hypertension) B. Persistent symptoms of OSA for at least 4 weeks in duration C. Absence of comorbidities that impair the accuracy of home sleep testing results D. Developmentally and functionally capable of following instructions for home sleep testing E. Comprehensive Sleep Evaluation with Epworth Sleepiness Scale evaluation or Berlin questionnaire completed
	Note: Polysomnography is approved for patients meeting certain criteria, including complicating factors or comorbidities that reduce home sleep testing accuracy, comorbid sleep disorder, or a previous home sleep testing with negative or inconclusive results in a patient with high pre-test probability for OSA in the past 6 months.
AutoPAP	APAP is reimbursed as a first-line treatment option if the following criteria are met:
	 Initial titration A. A face-to-face clinical evaluation by the treating physician following the diagnostic study and prior to the titration B. Positive diagnosis of OSA, determined by home sleep test or polysomnography (certain criteria must be met to determine diagnosis) C. Rendering site is registered and qualified site of service according to HPHC standards Repeat Titration A. Positive diagnosis of OSA measured by home sleep test or polysomnography B. Compliant with therapy C. Persistent symptoms or unimproved AHI in patient currently using APAP/CPAP must receive instruction from the treating physician or supplier of device on proper use, mask refitting or adjustment, and education of PAP accessories D. Rendering site is registered and qualified site of service according

to HPHC standards

Aetna, Inc.

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

Home sleep testing	Home sleep studies are considered medically necessary for patients with OSA symptoms when used as part of a comprehensive sleep evaluation.
	Note: Polysomnography is approved for patients meeting certain criteria, including complicating factors or comorbidities that reduce home sleep testing accuracy, comorbid sleep disorders, inability to use portable monitoring equipment, or a previous home sleep test with negative or inconclusive results
AutoPAP	APAP is reimbursed as a first-line treatment option if a patient has confirmed diagnosis of OSA with a positive polysomnography or home sleep test result. It is expected that members receive lifestyle advice, where applicable, as a part of treatment.

Humana

http://apps.humana.com/tad/tad_new/Search.aspx?criteria=apnea&searchtype=freetext.

Home sleep testing	Home sleep studies are considered medically necessary for patients who present symptoms for OSA and have appropriate mobility and cognitive function to use portable monitors. Home sleep testing must be provided in conjunction with a comprehensive sleep evaluation.
	Note: Polysomnography is approved for patients meeting certain criteria, including complicating factors or comorbidities that reduce home sleep testing accuracy, comorbid sleep disorders, inability to use portable monitoring equipment, or a previous home sleep test was indeterminante or technically inadequate in a patient with high pre-test probability for OSA.
AutoPAP	APAP is reimbursed as a first-line treatment option if a patient has confirmed diagnosis of OSA with a polysomnography or home sleep testing.

References

Aetna. Clinical policy bulletin: Obstructive sleep apnea in adults. <u>http://www.aetna.com/cpb/medical/data/1_99/0004.html</u>. Accessed October/November, 2012.

Ahrens A, McGrath C, Hägg U. A systematic review of the efficacy of oral appliance design in the management of obstructive sleep apnoea. *Eur J Orthod*. 2011;33(3):318-324.

American Academy of Sleep Medicine. Sleep Apnea – Diagnosis. <u>http://www.sleepeducation.com/sleep-disorders/sleep-apnea/diagnosis</u>. Accessed December, 2012.

American Sleep Apnea Association. Diagnosis and Treatment. <u>http://www.sleepapnea.org/diagnosis-and-treatment.html</u>. Accessed December, 2012.

Aurora RN, Casey KR, Kristo D, et al. Practice parameters for the surgical modifications of the upper airway for obstructive sleep apnea in adults. *Sleep*. 2010;33(10):1408-1413.

Balk EM, Moorthy D, Obadan NO, et al. Diagnosis and treatment of obstructive sleep apnea in adults. Comparative effectiveness review no. 32. Rockville, MD: Agency for Healthcare Research and Quality; 2011; 11-EHC052-EF.

Collop NA, Anderson WM, Boehlecke B, et al. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adults patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med*. 2007;3(7):737-747.

Epstein LJ, Kristo D, Strollo Jr. PJ, et al. for the Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med*. 2009;5(3):263-276.

Harvard Pilgrim Health Care. Sleep management criteria. <u>http://www.carecorenational.com/content/pdf/11/10F894F484F54D369FF678ED8ACBF8D2.pdf</u>. Accessed October, 2012.

Ho ML, Brass SD. Obstructive sleep apnea. Neurol Int. 2011;3(3):e15.

Humana. Medical coverage policies.

http://apps.humana.com/tad/tad_new/Search.aspx?criteria=apnea&searchtype=freetext. Accessed October, 2012.

Institute for Clinical Systems Improvement. Health Care Guideline: Diagnosis and treatment of obstructive sleep apnea.

http://www.icsi.org/sleep_apnea/sleep_apnea_diagnosis_and_treatment_of_obstructive_.html. Accessed October, 2012.

Kapur V, Blough DK, Sandblom RE, et al. The medical cost of undiagnosed sleep apnea. *Sleep*. 1999;22(6):749-755.

Kline CE, Crowley EP, Ewing GB, et al. The effect of exercise training on obstructive sleep apnea and sleep quality: a randomized controlled trial. *Sleep*. 2011;34(12):1631-1640.

Kushida CA, Berry RB, Blau A, et al. Positive airway pressure initiation: a randomized controlled trial to assess the impact of therapy mode and titration process on efficacy, adherence, and outcomes. *Sleep*. 2011;34(8):1083-1092.

Mayo Foundation for Medical Education and Research. Healthy lifestyle: Obstructive sleep apnea. <u>http://www.mayoclinic.com/health/obstructive-sleep-apnea/DS00968</u>. Accessed November, 2012.

National Institute for Health and Clinical Excellence (NICE). Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome. http://www.nice.org.uk/nicemedia/live/11944/40085/40085.pdf. Accessed October, 2012.

National Institutes for Health (NIH). Your guide to healthy sleep. <u>http://www.nhlbi.nih.gov/health/public/sleep/healthy_sleep.pdf</u>. Accessed December, 2012.

Pack AI, Gislason T. Obstructive sleep apnea and cardiovascular disease: a perspective and future directions. *Prog Cardiovasc Dis*. 2009;51(5):434-451.

Punjabi NM. The epidemiology of adult obstructive sleep apnea. *Proc Am Thorac Soc*. 2008;5(2):136-143.

Ronksley PE, Hemmelgarn BR, Heitman SJ, et al. Excessive daytime sleepiness is associated with increased health care utilization among patients referred for assessment of OSA. *Sleep*. 2011;34(3):363-370

Trikalinos TA, Ip S, Raman G, et al. Home diagnosis of obstructive sleep apnea-hypopnea syndrome. Technology assessment. Rockville, MD: Agency for Healthcare Research and Quality. <u>http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id48TA.pdf</u>. Accessed October, 2012.

White E, Workman T, Sharafkhaneh A, Fordis M. Treating sleep apnea: a review of the research for adults. Consumer Summary. Rockville, MD: Agency for Healthcare Research and Quality. <u>http://effectivehealthcare.ahrq.gov/ehc/products/117/684/sleep_ap_consumer.pdf</u>. Accessed December, 2012.

Young T, Palta M, Dempsey J, Peppard PE, Nieto FJ, Hla KM. Burden of sleep apnea: rationale, design, and major findings of the Wisconsin Sleep Cohort Study. *WMJ*. 2009;108(5):24