



**CEPAC Voting and Policy Implications Summary**  
**Diagnosis and Treatment of Obstructive Sleep Apnea in Adults**  
**December 6, 2012**

The New England Comparative Effectiveness Public Advisory Council (CEPAC) is an independent forum in which clinical and public policy experts publicly deliberate on evidence reviews of the clinical effectiveness and value of health care services. Through these deliberations, and summary votes held on key evidence questions, CEPAC provides guidance on how the existing evidence can best be applied to improve the quality and value of health care services across New England. CEPAC is comprised of 19 members, a mix of clinicians and public representatives from each New England state. Representatives of state Medicaid programs and of regional private payers are included as ex-officio members of CEPAC. CEPAC members are recruited through an open public nomination process, and are selected on the basis of their experience and training in the interpretation and application of medical evidence in health care delivery.

This public meeting of CEPAC discussed the diagnosis and treatment of obstructive sleep apnea (OSA) in adults. Staff from the Institute for Clinical and Economic Review (ICER) provided CEPAC with a supplementary evidence report that included the evidence review developed by the Agency for Healthcare Research and Quality (AHRQ), with additional material and analyses including: 1) updated information on the diagnosis and treatment of OSA published since the AHRQ review; 2) regional and national data on prevalence, utilization, and existing clinical guidelines and payer coverage policies; and 3) the results of budgetary impact and cost-effectiveness analyses developed to support discussion of the comparative value of different diagnostic and management options. Prior to the in-person CEPAC meeting, a conference call was held with three clinical experts in the treatment and diagnosis of OSA: Charles Atwood Jr., MD, FCCP, FAASM of the VA Pittsburgh Health System, B. Gail Demko, DMD of Sleep Apnea Dentists of New England and Lawrence Epstein, MD of Sleep HealthCenters. These experts discussed the diagnostic and treatment interventions available for OSA and responded to CEPAC member questions.

This summary includes the results of the votes of CEPAC on key evidence questions. In addition, we present policy considerations highlighted by CEPAC and by the roundtable of regional clinical experts and regional payers that discussed the implications of CEPAC votes for clinical practice, and payer policies. The meeting agenda and full attendance list, including roundtable panelists, are shown in Appendix A.

## SUMMARY OF VOTES AND RECOMMENDATIONS

Following the outline of the AHRQ review, CEPAC members voted on questions concerning the comparative clinical effectiveness and comparative value of diagnostic and treatment options for adults with OSA.

### Votes on Clinical Effectiveness

Each public meeting of CEPAC involves deliberation and voting on key questions related to the supplementary AHRQ report being presented by ICER. The key questions are developed by ICER with significant input from members of the CEPAC Advisory Board to ensure that the questions are framed to address the issues most important in applying the evidence to practice and medical policy decisions. In judging comparative clinical effectiveness, there are two interrelated questions: the relative magnitude of differences in risks and benefits; and the relative confidence that the body of evidence can provide in the accuracy of estimates of risks and benefits. Considering these two issues together is required in order to make a judgment of whether the evidence is “adequate” to demonstrate that one intervention is as good as or better than another.

#### Comparative clinical effectiveness: Diagnostic Strategies

*Based on the findings of the AHRQ review and time limitations of the CEPAC meeting, members of CEPAC were asked for their consent to the following stipulation.*

- **There is insufficient evidence to distinguish the diagnostic accuracy of Type III vs. Type IV home monitors, and available evidence suggests their sensitivity and specificity largely overlaps.**

CEPAC Vote:  Yes  No

#### *Voting Questions*

- **Is the evidence adequate to demonstrate that Type III-IV home monitors are “functionally” equivalent to polysomnography (PSG) in diagnosing OSA?**

CEPAC Vote:  Yes  No

- **Is the evidence adequate to demonstrate that a phased diagnostic approach using the Berlin questionnaire to identify candidates for PSG is equivalent to using PSG alone in all patients in whom there is a clinical suspicion for the diagnosis of OSA?**

CEPAC Vote:  Yes  No  Abstain

*Comments:* Although CEPAC voted that the evidence is inadequate to demonstrate that using a phased diagnostic approach with the Berlin questionnaire is equivalent to PSG alone, council members noted that questionnaires may still have utility in the diagnostic process, but not as a replacement for standard testing.

- **Is the evidence adequate to demonstrate that a phased diagnostic approach using externally-validated clinical prediction rules to identify candidates for PSG is equivalent to using PSG alone in all patients in whom there is a clinical suspicion for the diagnosis of OSA?**

CEPAC Vote: 2 Yes ☒ 12 No

#### Comparative clinical effectiveness: Treatment of OSA in Adults

*Based on the findings of the AHRQ review and time limitations of the CEPAC meeting, members of CEPAC were asked for their consent to the following stipulations.*

- **There is insufficient evidence to demonstrate that other interventions (e.g. medication, palatal implants, bariatric surgery, acupuncture, nasal dilator strips, etc.) are better than continuous positive airway pressure (CPAP) in treating adults with OSA.**

CEPAC Vote: ☒ 14 Yes 0 No

- **There is insufficient evidence to demonstrate that any one form of mandibular advancement device (MAD) is more effective than any other in treating OSA in adults.**

CEPAC Vote: ☒ 14 Yes 0 No

- **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 Vote: ☒ 14 Yes 0 No

#### *Voting Questions*

1. **Is the evidence adequate to demonstrate that surgery is equivalent or superior to CPAP in particular subpopulations with OSA?**

CEPAC Vote: 2 Yes ☒ 12 No

**2. Is the evidence adequate to demonstrate that MADs are superior to no treatment in treating adults with OSA?**

CEPAC Vote: ☒ 13 Yes    1 No

*Comments:* CEPAC votes were based on the patient inclusion criteria used for studies included in the AHRQ review. The council noted that certain patient subpopulations may benefit more than others from MADs. For example, patients with mild-to-moderate disease may experience improved outcomes with oral devices while patients with periodontal disease are contraindicated.

**3. Is the evidence adequate to demonstrate that MADs are equivalent or superior to CPAP in treating mild-to-moderate OSA (AHI 5-30 events/hour)?**

CEPAC Vote: 3 Yes    ☒ 11 No

*Comments:* CEPAC members who voted “no” stated that even though the evidence is inadequate to demonstrate that MADs are equivalent or superior to CPAP, that it is important to consider higher compliance rates observed with oral devices.

**Votes on Comparative Value**

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, the Council members are also asked to vote on whether the intervention represents a “high”, “reasonable”, or “low” value. The value perspective that members of CEPAC are asked to assume is that of a state Medicaid program that must make resource decisions within a fixed budget for care. While information about hypothetical budget tradeoffs are provided, CEPAC is not given prescribed boundaries or thresholds for budget impact, per member per month (PMPM) changes, or incremental cost-effectiveness ratios to guide its judgment of high, reasonable, or low value. Typically only those CEPAC members who vote that the evidence is adequate to demonstrate equivalent or superior clinical effectiveness are asked to vote on comparative value. However, under certain circumstances when one intervention is particularly cost-saving compared to another and a value consideration is deemed important in spite of insufficient evidence to support clinical equivalency, CEPAC members who voted “no” may also be asked to vote on value.

Comparative Value: Diagnostic Strategies

**1. Based on reimbursement levels provided with this report, would you judge the comparative value of a phased diagnostic approach using the Berlin questionnaire compared to PSG alone to be 1) high value; 2) reasonable value; or 3) low value compared to?**

*No vote taken: majority of CEPAC voted “no” on comparative clinical effectiveness.*

2. **Based on reimbursement levels provided with this report, would you judge the comparative value of a phased diagnostic approach using the externally-validated clinical prediction rules compared to PSG alone to be 1) high value; 2) reasonable value; or 3) low value?**

*No vote taken: majority of CEPAC voted “no” on comparative clinical effectiveness.*

3. **Based on reimbursement levels provided with this report, would you judge the comparative value of a home-based pathway (Type III-IV home monitor with auto-CPAP) compared to an in-lab pathway (split-night PSG plus CPAP) to be 1) high value; 2) reasonable value; or 3) low value?**

CEPAC Vote: 

6 High	6 Reasonable
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 2 Low

*Comments:* CEPAC members who voted that a home-based pathway had “high” value compared to an in-lab pathway emphasized the higher cost-benefit ratio for home-testing combined with autoCPAP. CEPAC members stated that since home-testing is less costly and functionally equivalent, a home-based paradigm represents “high” value and may increase access to services. CEPAC members noted the importance of considering the severity of the patient’s symptoms before determining the appropriate pathway, as home testing may be more effective for patients with high pre-test probability of OSA. One CEPAC member argued that in spite of variability of home testing accuracy, increasing access to home testing may result in improved studies and better standards for diagnosis and treatment of OSA.

CEPAC members who voted that a home-based pathway had “reasonable” value compared to an in-lab approach predominantly cited concerns for false positives and false negatives that may result in unnecessary treatment and increase costs. There was concern among CEPAC members that expanding access to home sleep testing may enlarge the scope of diagnostic testing to patients with lower risks of OSA, causing potential mis- or over-diagnosis. CEPAC members were also concerned with differences in outcomes that occur between clinical studies and a real world context, and that patients receiving home testing outside of a clinical trial may not experience the same quality of care and follow-up needed for successful diagnosis.

CEPAC members who voted that home-based pathways represent “low” value also voiced concerns with the specificity and sensitivity of portable monitors and felt that making home-testing more accessible may lead to over-screening that could potentially increase costs and result in a larger number of false positives.

### Comparative Value: Treatment

1. **Based on reimbursement levels provided with this report, would you judge the comparative value of MADs compared to no treatment to be 1) high value; 2) reasonable value; or 3) low value for patients with mild-to-moderate OSA (AHI 5-30 events/hour)?**

CEPAC Vote: 1 High **8 Reasonable** 4 Low 1 Abstain

*Comments:* The CEPAC member who voted that MADs have “high” value stated that MADs are worth the cost to improve the quality of life for a patient with symptomatic OSA versus no treatment at all. CEPAC members who voted that MADs have “low” value discussed concerns with overtreatment of OSA, in particular for patients with mild-to-moderate disease severity.

2. **Based on reimbursement levels provided with this report, would you judge the comparative value of MADs compared to CPAP to be 1) high value; 2) reasonable value; or 3) low value for patients with mild-to-moderate OSA (AHI 5-30 events/hour)?**

*No vote taken: majority of CEPAC voted “no” on comparative clinical effectiveness.*

### Broader Considerations of Public Health, Equity, and Access

**Are there any considerations related to public health, equity, disparities in access or outcomes for specific patient populations, or other social values that should be considered in medical policies related to the use of home monitors, PSG, or phased diagnostic approaches for patients in whom there is a clinical suspicion of OSA?**

*Comments:* Some CEPAC members voiced concern for equitable access to home sleep testing for the Medicaid population, as some vendors are unwilling to travel to inner-city or rural areas to assist patients in the application and use of portable monitors. If home sleep testing is to be covered as a preferred diagnostic option, council members suggested that programs should also be in place to help patients receive necessary guidance and follow-up when conducting a home sleep test to ensure equal access. Other CEPAC members feared that false negatives from home testing may prevent patients from further investigation even if they continue to have issues with sleep. In addition, patients who receive a false negative diagnosis through home testing may not have access to a sleep center for follow-up testing; senior populations are of particular concern.

## ROUNDTABLE DISCUSSION AND POLICY IMPLICATIONS

Following the CEPAC votes and deliberation, CEPAC engaged in a roundtable discussion with a panel composed of two representatives from the clinical expert community, one private payer, and one public payer (names shown in the meeting participant section of this report). A patient advocate was invited to serve on the roundtable but due to logistical reasons was unable to attend the in-person meeting. However, patient advocacy and support groups were contacted throughout the development of the supplementary report and CEPAC process to ensure that the patient perspective is represented. The goal of the roundtable was to explore the implications of CEPAC votes for clinical practice and payer policies. The topics discussed included:

### Future Research Needs

CEPAC members identified the following research areas needed to fill the most important evidence gaps in the diagnosis and treatment of OSA:

- Clarification of the prevalence of OSA given increases in obesity
- Better definition of OSA to improve value of clinical prediction rules and other screening approaches
- Effectiveness of using screening tools to identify appropriate patients for sleep testing in primary care settings, including any barriers to their optimal use
- Long-term impact of shifting patients from PSG to home-testing on sensitivity and specificity of testing, clinical outcomes and costs
- Long-term impact of treatment on patient satisfaction and quality of life outcomes, including the impact of weight loss on OSA symptoms
- Long-term risks and harms associated with untreated OSA
- Issues surrounding patient compliance, management, and follow-up for long-term use of CPAP
- Further consensus on outcomes and compliance reporting in order to better draw comparisons across studies
- Sub-group analyses in order to understand the impact of diagnostic and treatment interventions on specific patient populations, in particular how effectiveness varies by disease severity
- Additional cost-effectiveness analyses, in particular to address impact of OSA on socioeconomic outcomes, including job retention, wages, income, etc.

### Diagnosis of OSA

#### Home Sleep Testing vs. PSG

The majority of CEPAC supported the use of home testing over polysomnography for patients in whom there is a clinical suspicion for OSA and meet appropriate clinical criteria. Some CEPAC members remarked that the potential for false positives and false negatives from home testing requires quality

standards to ensure that qualified providers interpret results and determine whether a patient should be referred for follow-up PSG.

There was concern among CEPAC members that expanding access to home sleep testing may have the unintended consequence of mis- or over-diagnosis as more patients with lower risks of OSA receive testing. However, panelists noted that this has not been the experience for payers with positive coverage for home sleep testing. Payers mentioned that there has been low rise in utilization of home sleep testing regardless of coverage for portable monitors, though decreased utilization may be a product of regulations in certain markets that require providers to rule out other sleep disorders or specific contraindications that may require a patient to receive PSG. Some providers are exploring innovative delivery models such as telemedicine to increase access to home testing services.

### Role of Primary Care Physicians

CEPAC discussed with panelists the important role of primary care physicians in identifying patients at risk for OSA and referring patients for appropriate diagnostic testing. Providers noted that accreditation standards and quality benchmarking are important to ensure that providers administering home monitors are qualified to interpret results and appropriately refer patients to a sleep specialist for follow-up care. CEPAC also deliberated on the role of questionnaires and how screening tools can effectively be utilized by primary care providers to triage patients for further testing and improve quality of referrals. Clinical experts noted that questionnaires are not being used routinely in current practice but they represent a good starting point to ensure that patient sleep patterns are being appropriately evaluated. Some CEPAC members felt that the benefit of early intervention should be further clarified before screening with questionnaires is endorsed. Other CEPAC members cautioned that many primary care providers are already constrained with limited time to spend with patients, and expanding their scope to include OSA screening may not be beneficial or feasible.

### **Treatment of OSA**

#### Variations on CPAP

CEPAC discussed the available variations of CPAP therapy and cost differences among the various options. Panelists noted that most insurers require patients to fail therapy with autoCPAP or CPAP before receiving bi-level CPAP, so a patient using more expensive variations as a first-line treatment option is not a primary concern.

#### Compliance

CEPAC extensively discussed the issues surrounding patient compliance with various treatment interventions for OSA. Providers noted that patients who are symptomatic are typically more compliant, and that patients who are unaware of baseline sleeplessness or are asymptomatic may be unmotivated



to adhere to treatment. The major reason patients fail on CPAP is due to poor compliance, and roundtable panelists and CEPAC agreed that patient education is lacking to increase awareness of the treatment benefits, thus improving adherence to CPAP and other treatment regimens. Physician and payer panelists provided examples of how compliance is being monitored in clinical practice, and how current data reveal that many patients are not using CPAP effectively.

### Care Coordination

CEPAC members and panelists voiced concern that patients with OSA receive fragmented care and that further outreach with professional specialty societies is needed to develop new delivery models that improve care coordination. CEPAC recommended that reimbursement models shift to promote greater care coordination between primary care providers and specialists, and incentivize physicians to integrate care and track follow-up of patients receiving treatment for OSA. Clinical experts discussed how vendor contracts and other market dynamics for current practice are often barriers to care coordination.

### Behavioral Modifications

CEPAC and the roundtable considered stronger levers to incentivize patients to lose weight to help moderate the effects of OSA and reduce costs of treatment. When discussing the current tools available, panelists mentioned new requirements through the Patient Protection and Affordable Care Act (PPACA) for insurers to reimburse counseling and other behavioral interventions to promote weight loss, as well as other health promotion programs including financial incentives for employees participating in wellness programs or who achieve other health targets.

CEPAC members suggested that requiring patients to attempt lifestyle modifications before undergoing sleep testing may be an option, but that this may not be reasonable for patients with moderate-to-severe apnea. CEPAC members cautioned that obesity is a psychological, hormonal, and metabolic disease often without a straightforward solution. CEPAC members agreed, however, that patients should be educated on sleep management and undergo counseling before they receive sleep testing and that behavioral modifications should be a concurrent mode of treatment.

### Patient engagement

CEPAC generally supported the use of education campaigns to raise awareness of the symptoms and risks of OSA with information on how patients may communicate with their physician about testing. Some council members feared that widespread education campaigns could lead to overdiagnosis and overtreatment, and that patients may not change behavior on the basis of knowledge alone. Most CEPAC members agreed that patient education on behavioral modifications, treatment benefits, follow-up, and compliance should be a routine part of care.

## **SUMMARY: SUGGESTIONS FOR POLICY AND PRACTICE**

### **For clinicians**

- Use or develop innovative delivery models such as telemedicine to ensure that patients undergoing home testing have appropriate guidance on application and use of portable monitors, especially for patients without available direct home services.
- Collaborate with payers to pilot-test questionnaires to help primary care providers evaluate patients and appropriately identify patients for further sleep testing.
- Educate patients on the benefits of treatment and potential behavioral modifications, including positional therapy, weight loss, smoking cessation, reduced alcohol consumption, etc. Make behavioral interventions a concurrent mode of OSA treatment.
- Appropriately monitor and follow-up with patients to improve treatment compliance.
- Establish greater coordination between primary care providers and specialists to improve quality of care for patients with OSA.

### **For payers**

- Reimburse home sleep testing with autoCPAP. Only approve polysomnography for patients who meet certain clinical criteria, including conditions that prevent the use of portable monitors or comorbidities that diminish the accuracy of their results.
- Require that providers interpreting sleep testing results meet certain quality and accreditation standards to ensure quality of diagnosis and appropriate patient follow-up.
- Collaborate with providers to pilot-test questionnaires to help primary care providers and/or specialists conduct a comprehensive sleep evaluation and appropriately identify patients most likely to benefit from formal testing.
- Heighten efforts to reduce the administrative burden for clinicians referring patients for sleep testing for clinically appropriate reasons.
- Use global payment schemes and other innovative payment models that reward integrated care for patients with OSA.

### **For patients**

- Patient advocacy groups should continue to provide resources to help patients understand OSA symptoms, improve treatment compliance, and modify behaviors that could improve outcomes. A high-profile education campaign may help raise awareness of the comparative effectiveness and value of the various diagnostic and treatment options available for OSA.
- Modify behaviors that improve OSA symptoms, including stopping use of sedatives, reducing alcohol use before bed, positional therapy, weight loss, smoking cessation, etc.

## Appendix A



### **New England Comparative Effectiveness Public Advisory Council**

Public Meeting – Hartford, CT

December 6, 2012

10:00 AM – 4:00 PM

10:00 – 10:15 AM: Meeting Convened and Introductions (*Jeannette DeJesús, MPA, MSW and Steven Pearson, MD, MSc*)

10:15 – 11:00 AM: Presentation of the Evidence

11:00 AM – 12:00 PM: Q&A with ICER Staff and CEPAC Deliberation

12:00 – 1:00 PM: Lunch

1:00 – 1:30 PM: Public Comment

1:30 – 2:30 PM: Votes on Questions

2:30 – 3:50 PM: Roundtable Discussion on Implications of CEPAC Votes

3:50 – 4:00 PM: Close

## MEETING PARTICIPANTS

### CEPAC Members

Name	State	Organization	Disclosures
Ellen Andrews, PhD	CT	CT Health Policy Project	
Robert Aseltine, PhD	CT	University of Connecticut Health Center	
R. William Corwin, MD	RI	Miriam Hospital	
D. Joshua Cutler, MD	ME	MaineHealth and Maine Heart Center	
Teresa Fama, MD	VT	Central Vermont Rheumatology	
Austin Frakt, PhD	MA	Boston University School of Medicine and Boston University School of Public Health	
Claudia Gruss, MD (Vice Chair)	CT	Arbor Medical Group, LLC	Wellpoint shares held jointly with spouse in excess of \$10,000
Felix Hernandez, MD	ME	Eastern Maine Medical Center	
Joseph Kozachek, MD (ex-officio)	CT	Aetna	
Richard Lopez, MD (Chair)	MA	Atrius Health	
Lori Nerbonne, RN, BSN	NH	New Hampshire Patient Voices	
Sandhya Rao, MD	MA	Massachusetts General Physicians Organization	
Roger Snow, MD (ex-officio)	MA	Commonwealth of Massachusetts	
Keith A. Stahl, MD	NH	Family Health and Wellness Center	
Mitchell Stein, MBA	ME	Consumers for Affordable Health Care	
William Taylor, MD	MA	Harvard Medical School	Also employed by Harvard Pilgrim Health Care Institute (HPHCI), which receives funding from Harvard Pilgrim Health Care; Payments also received as a medical consultant to malpractice insurers
Members not in attendance:			
<ul style="list-style-type: none"> <li>Charles Eaton, MD, MS, Memorial Hospital of Rhode Island and Brown University</li> <li>William Cyrus Jordan, MD, MPH, Vermont Medical Society's Foundation for Research and Education</li> <li>Christopher Jones, PhD, University of Vermont College of Medicine</li> </ul>			

### Roundtable Panelists

- **Mark D'Agostino, MD**  
Section Chief, Otolaryngology
- **Lawrence Epstein, MD**  
Chief Medical Officer, Sleep HealthCenters
- **Robert McDonough, MD, JD, MPP**  
Head of Clinical Policy Research and Development, Aetna, Inc.
- **Robert Zavoski, MD, MPH**  
Medical Director, Division of Health Services, Connecticut Department of Social Services

### ICER

- Steve Pearson, MD, President
- Daniel Ollendorf, MPH, Chief Review Officer
- Sarah Emond, MPP, Chief Operating Officer
- Jennifer Colby, PharmD, Research Associate
- Swetha Sitaram, MS, Research Association
- Jessica Chubiz, MS, Research Associate
- Sarah Jane Reed, MSc, Program Coordinator