



New England Comparative Effectiveness Public Advisory Council

Public Meeting – Hartford, Connecticut

Diagnosis and Treatment of Obstructive Sleep Apnea in Adults

December 6, 2012

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QUESTIONS FOR DELIBERATION

Introduction

Each public meeting of CEPAC will involve deliberation and voting on key questions related to the supplementary analysis of the AHRQ review being presented by ICER. Members of CEPAC will discuss issues regarding the application of the available evidence to guide clinical decision-making and payer policies. 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 that are most important in applying the evidence to practice and medical policy decisions.

About the Questions

Comparative Clinical Effectiveness

The general framework within which CEPAC discusses and votes on the evidence is shown below:

Given a health care “intervention A” for “patients with condition X,” we will compare its clinical effectiveness for these patients to that of a “comparator B” by voting on the following question:

Is the evidence “adequate” to demonstrate that “intervention A” is equivalent or superior to “comparator B” for “patients with condition X”?

Discussion and voting will highlight the following issues:

1. The evidence on risks and benefits to determine the *comparative* clinical effectiveness of management options for specific patient populations. 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 equivalent to or superior than another.

2. Issues related to individual patient preferences and values, provider training, volume, or other factors that should be considered in judging the evidence on clinical effectiveness and value.
3. Weighing the evidence on cost-effectiveness and projected budgetary impact to determine the comparative value of various management options for key patient populations.
4. Comments or recommendations related to broader considerations of public health, equity, disparities, and access.

Comparative Value

When a majority of CEPAC votes that the evidence is adequate to demonstrate that an intervention produces patient outcomes as good as or better than a comparator, the Council will also be asked to vote on whether the intervention represents a “high,” “reasonable,” or “low” value. The value “perspective” that CEPAC will be 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 will be provided, CEPAC will not be given prescribed boundaries or thresholds for budget impact or incremental cost-effectiveness ratios to guide its judgment of high, reasonable, or low value.

For each vote, Council members will be asked to identify which element of the information provided to them on “value” was most influential in their judgment, including: 1) information on the incremental cost for an additional benefit (or for reduction in risk); or 2) information on the budget impact of different care/payment scenarios. Council members will also be asked to describe briefly the rationale for their rating of comparative value.

Additional comments/recommendations

CEPAC will be invited to comment or make recommendations on the following after each vote for comparative clinical effectiveness and value:

Are there any factors related to the following that should also be considered?

1. Severity of OSA, other patient characteristics, or patient values
2. Appropriate threshold of AHI for the confirmation of a diagnosis of OSA

Questions for Obstructive Sleep Apnea (OSA)

Definitions:

1. Obstructive sleep apnea: According to the American Academy of Sleep Medicine (AASM), a diagnosis of OSA is established if a patient with polysomnography demonstrates an apnea/hypopnea index (AHI) of > 15 events/hour, or > 5 events/hours in patients who report any of the following: 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.
2. Polysomnography: Diagnostic test for obstructive sleep apnea that is performed overnight in a sleep laboratory whereby a technologist monitors the patient's patterns of physiological abnormalities during sleep.
2. Home monitors: Home monitors are portable machines used to diagnose OSA in the home environment without the attendance of a technologist. They are classified into 3 categories as described below:
 - a. Type II: have at least 7 channels for monitoring patients, including ECG-heart rate, EEG, airflow and respiratory effort.
 - b. Type III: minimum of 4 monitored channels, including airflow, heart rate and oxygen saturation.
 - c. Type IV: have 1-3 channels monitoring patients and do not meet the criteria of the other monitor types.
3. Questionnaires: The Berlin questionnaire, STOP, STOP-Bang, ASA Checklist, Epworth Sleepiness Scale, Hawaii Sleep questionnaires, and other questionnaires that focus on a patient's risk factors and chronic behaviors suggestive of OSA.
4. Clinical prediction rules: Algorithm that uses various criteria, such as questionnaires and morphometric data, to predict the diagnosis of OSA.
5. Continuous Positive Airway Pressure (CPAP): Machine used in patients with OSA to maintain a continuous level of positive airway pressure. Includes several variations, including: oral, nasal, autotitrating, bilevel, flexible bilevel, fixed, humidification, and C-Flex™.
6. "Usual care": Control arms of studies have used a variety of interventions to classify usual care, including: no specific treatment, placebo therapy, optimal drug treatment, and conservative measures, which entail sleep hygiene counseling along with participation in a weight loss program.
7. Mandibular Advancement Devices (MADs): Devices worn orally to treat OSA and snoring.
8. Adjunctive therapies: Specific therapies designed to improve CPAP compliance. Adjunctive therapies may include intensive support or literature, cognitive behavioral therapy, telemonitoring, and habit-promoting audio-based interventions.

Comparative Clinical Effectiveness and Value: Diagnosis of OSA in Adults

Comparative Clinical Effectiveness

Note: Type II monitors are excluded from consideration in these voting questions due to the lack of studies assessing Type II monitors, though this in no way implies that Type II monitors are ineffective in diagnosing OSA.

Voting Stipulations

Based on the findings of the AHRQ review, and time limitation of the CEPAC meeting, we will ask CEPAC for unanimous consent to the following stipulations. If there is dissent, then a formal vote will be taken.

- 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.

Voting Questions:

1. Is the evidence adequate to demonstrate that Type III-IV home monitors are equivalent to polysomnography in diagnosing OSA?
2. Is the evidence adequate to demonstrate that a phased diagnostic approach using the Berlin questionnaire to identify candidates for polysomnography is equivalent to using polysomnography alone in all patients in whom there is a clinical suspicion for the diagnosis of OSA?
3. Is the evidence adequate to demonstrate that a phased diagnostic approach using externally-validated clinical predication rules to identify candidates for polysomnography is equivalent to using polysomnography alone in all patients in whom there is a clinical suspicion for the diagnosis of OSA?

Comparative Value

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

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

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 also be considered in medical policies related to the use of portable home monitors, PSG, or phased diagnostic approaches in patients in which there is a clinical suspicion of the diagnosis of OSA?

Comparative Clinical Effectiveness and Value: Treatment of OSA in Adults

Comparative Clinical Effectiveness

Based on the findings of the AHRQ review, and time limitation of the CEPAC meeting, we will ask CEPAC for unanimous consent to the following stipulations. If there is dissent, then a formal vote will be taken.

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

Voting Questions

1. Is the evidence adequate to demonstrate that surgery is equivalent or superior to CPAP in particular patient subpopulations with OSA?
 - If yes, does the evidence suggest that:
 - Surgery is equivalent to CPAP in particular subpopulations?
 - Surgery is superior to CPAP in particular subpopulations?
2. Is the evidence adequate to demonstrate that MADs are superior to no treatment in treating adults with OSA?

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)?
 - If yes, does the evidence suggest that:
 - Mandibular advancement devices are equivalent to CPAP?
 - Mandibular advancement devices are superior than CPAP?

Comparative Value

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

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 also be considered in medical policies related to the use of surgery, MADs, or CPAP in patients in whom there is a clinical suspicion of the diagnosis of OSA?

Other Comments or Recommendations

Are there specific actions that patients, providers, or insurers could take to improve the quality and value of care for patients with suspected or confirmed OSA?

What research is needed to fill the most important evidence gaps on the diagnosis and treatment of OSA?