



New England Comparative Effectiveness Public Advisory Council

Public Meeting – Durham, New Hampshire

Treatments for Attention Deficit Hyperactivity Disorder

June 1, 2012

DRAFT: May 2, 2012

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 RAPiD 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

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 on risks and benefits “adequate” to demonstrate that “intervention A” is as good or better for “patients with condition X” than “comparator B”?

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 as good or better 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.

Reasons for Voting “No”

When over half of the Council votes “no,” indicating that they believe the evidence is not adequate to demonstrate that an intervention is as good or better than a comparator, CEPAC members who voted “no” will be asked to choose from a set of reasons to explain the rationale for their vote:

1. Insufficient quantity of evidence (i.e. too few studies)
2. Risk of bias inherent in study designs
3. Uncertainty over validity of surrogate outcome measures
4. Uncertainty over duration of clinical benefit
5. Uncertainty over the rates or magnitude of clinical benefits
6. Uncertainty over the rates or severity of potential harms
7. Inconsistency of results of studies
8. Limited generalizability of the evidence to “real world” patients
9. Limited generalizability of the evidence to “real world” clinicians
10. There is adequate evidence that the intervention is inferior to the comparator

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: 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.

Questions for Attention Deficit Hyperactivity Disorder (ADHD)

Definitions:

1. *Pre-schoolers*: Children under six years of age.
2. *Patients with ADHD or DBD*: Patients who received a diagnosis of Attention Deficit Hyperactivity Disorder or Disrupting Behavior Disorder (including Oppositional Defiant Disorder and Conduct Disorder) by the Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD) criteria.
3. *Medication*: Pharmacological interventions used in the treatment of ADHD or DBD, including: methylphenidate (MPH), dextroamphetamine (DEX), mixed amphetamine salts (MAS), atomoxetine (ATX), and guanfacine extended release (GXR).
4. *Parent behavior training*: Manualized programs designed to help parents manage a child's problem behavior using rewards and non-punitive consequences.
5. *Usual care*: Care without medication or specific psychological/behavioral interventions, unless otherwise advised.
6. *Behavioral/psychosocial interventions*: Any one of a number of interventions aimed to assist the child and family through psychological and social therapies (e.g. psychoeducational, parent counseling, and social skills training).
7. *School-based interventions*: Interventions in which teachers are primary interveners and where the interventions take place in a classroom or school setting.
8. *Long-term outcomes*: Numerical or statistical results of any effectiveness or adverse event attributable to an intervention with a combined follow-up and treatment time equal to or greater than 12 months.

Comparative Clinical Effectiveness and Value: ADHD Treatment for Pre-Schoolers (children < 6 years of age)

Comparative Clinical Effectiveness

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

- Due to limitations of the available evidence, the evidence is not adequate to demonstrate that any other medication is as good as or better than methylphenidate (MPH) as a first-line treatment for preschoolers with either ADHD or DBD.
- Due to limitations of the available evidence, the evidence is not adequate to demonstrate that any branded parent behavior training (PBT) program is better than any other in preschoolers with ADHD or DBD.

Voting Questions:

1. Is the evidence on risks and benefits adequate to demonstrate that medication is as good as or better than usual care for treating pre-schoolers with ADHD or DBD?
 - a. If yes, does the evidence suggest that:
 - Medication is as good as (equivalent to) usual care without medication?
 - Medication is better than usual care without medication?

2. Is the evidence on risks and benefits adequate to demonstrate that parent behavior training is as good as or better than usual care for pre-schoolers with ADHD or DBD?
 - a. If yes, does the evidence suggest that:
 - Parent behavior training is as good as (equivalent to) usual care?
 - Parent behavior training is better than usual care?

3. Is the evidence on risks and benefits adequate to demonstrate that medication combined with psychosocial/behavioral interventions (including parent-behavior training) is as good as or better than using medication alone to treat pre-schoolers with ADHD or DBD?
 - a. If yes, does the evidence suggest that:
 - Medication combined with psychosocial/behavioral interventions is as good as (equivalent to) treatment with medication alone?
 - Medication combined with psychosocial/behavioral interventions is better than treatment with medication alone?

Comparative Value (TO BE ASKED IF >50% OF CEPAC VOTES IN FAVOR OF ADEQUACY OF EVIDENCE ON CLINICAL EFFECTIVENESS)

1. Based on reimbursement levels provided in this report, would you judge the comparative value of medication compared to usual care 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 PBT compared to usual care 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 medication combined with psychosocial/behavioral interventions (including PBT) compared to medication alone to be: 1) high value; 2) reasonable value; or 3) low value?

Comparative Clinical Effectiveness and Value: Long-Term Effectiveness of Treatments for ADHD in children 6 years and older

Comparative Clinical Effectiveness

Stipulation:

- There is sufficient evidence to demonstrate that medications are better than usual care for treating patients with ADHD over the age of 6.

Voting Questions

1. Is the evidence on risks and benefits adequate to demonstrate that any other medications are as good as or better than methylphenidate (MPH) in treating ADHD patients over the age of 6?
 - a. If yes, does the evidence suggest that:
 - Other medication(s) are as good as (equivalent to) MPH beyond 1 year?
 - Other medications are better than MPH beyond 1 year?
2. Is the evidence on risks and benefits adequate to demonstrate that parent behavior training (PBT) is as good as or better than usual care in treating ADHD patients over the age of 6?
 - a. If yes, does the evidence suggest that:
 - PBT is as good as (equivalent to) usual care beyond 1 year?
 - PBT is better than usual care beyond 1 year?
3. Is the evidence on risks and benefits adequate to demonstrate that medication combined with behavioral/psychosocial interventions is as good as or better than medication alone?
 - a. If yes, does the evidence suggest that:
 - Medication combined with behavioral/psychosocial interventions is as good as (equivalent to) medication alone beyond 1 year?
 - Medication combined with behavioral/psychosocial interventions is better than medication alone beyond 1 year?

Comparative Value (TO BE ASKED IF >50% OF CEPAC VOTES IN FAVOR OF ADEQUACY OF EVIDENCE ON CLINICAL EFFECTIVENESS)

1. Based on reimbursement levels provided in this report, would you judge the long-term comparative value of other medications compared to MPH 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 long-term comparative value of PBT compared to usual care 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 long-term comparative value of combined medications and behavioral/psychosocial treatments compared to medication alone to be: 1) high value; 2) reasonable value; or 3) low value?

Comparative Clinical Effectiveness and Value: School-Based Interventions for ADHD

1. Is the evidence on risks and benefits adequate to demonstrate that adding school-based interventions to treatment regimens including medication and/or all types of behavioral/psychosocial interventions is as good as or better than medication and/or behavioral/psychosocial interventions alone?
 - a. If yes, does the evidence suggest that:
 - Adding school-based interventions to medication and/or behavioral/psychosocial interventions is as good as (equivalent to) medication and/or behavioral/psychosocial interventions alone beyond 1 year?
 - Adding school-based interventions to medication and/or behavioral/psychosocial interventions is better than medication and/or behavioral/psychosocial interventions alone beyond 1 year?

Comparative Value (TO BE ASKED IF >50% OF CEPAC VOTES IN FAVOR OF ADEQUACY OF EVIDENCE ON CLINICAL EFFECTIVENESS)

1. Based on reimbursement levels provided in this report, would you judge the long-term comparative value of adding school-based interventions to medication and/or all types of behavioral/psychosocial interventions compared to medication and/or behavioral/psychosocial interventions alone 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 be considered in medical policies related to the use of medications, parent behavior training, or other psychosocial interventions for pre-schoolers and people 6 years old and over for the treatment of ADHD?