NEW ENGLAND CEPAC
COMPARATIVE EFFECTIVENESS PUBLIC ADVISORY COUNCIL
AN ICER PROGRAM

Obeticholic Acid for the treatment of Primary Biliary Cholangitis and Nonalcoholic Steatohepatitis

Questions for Deliberation

June 21, 2016

Comparative Clinical Effectiveness for PBC

1. For patients with PBC (primary biliary cholangitis or primary biliary cirrhosis), who fail to achieve an adequate reduction in alkaline phosphatase on ursodeoxycholic acid (UDCA) monotherapy, is the evidence adequate to demonstrate a net health benefit with the addition of obeticholic acid to continuing therapy with UDCA?

   Yes *No*

Comparative Value for PBC

Care Value for PBC

2. Given the available evidence for patients with PBC, what is the *care value** of adding obeticholic acid to UDCA alone?

   a. *Low* *b. Intermediate* c. *High*

Comparative Clinical Effectiveness for NASH

3. For patients with nonalcoholic steatohepatitis (NASH) and fibrosis, is the evidence adequate to demonstrate a net health benefit with the addition of obeticholic acid to usual care (e.g., lifestyle interventions, treatment with vitamin E, etc.)?

   Yes *No*

Comparative Value for NASH

Care Value for NASH

4. Given the available evidence for patients with NASH, what is the *care value** of adding obeticholic acid to usual care vs. usual care alone?

    a. Low b. Intermediate c. High

* ***Care value*** is determined by looking at four elements: comparative clinical effectiveness, incremental costs per outcomes achieved, other benefits or disadvantages, and contextual considerations. Care value represents the long-term perspective, at the individual patient level, on patient benefits and the incremental costs to achieve those benefits.