Obeticholic Acid for the Treatment of Nonalcoholic Steatohepatitis with Fibrosis

Draft Questions for Deliberation and Voting at the tentative August 2020 Public Meeting

*These questions are intended for the deliberation of the Midwest CEPAC voting body at the public meeting.*

**Patient Population for all questions:** Adult patients with a diagnosis of NASH.

**Clinical Evidence**

1. In patients with F3 fibrosis, is the evidence adequate to demonstrate a net health benefit for treatment with OCA compared to no treatment?

   Yes  No

2. In patients with F2 fibrosis, is the evidence adequate to demonstrate a net health benefit for treatment with OCA compared to no treatment?

   Yes  No

3. In patients with F2/F3 fibrosis, is the evidence adequate to distinguish the net health benefit of treatment with OCA compared to pioglitazone?

   Yes  No

   *If yes to q. 3, then proceed to question 3a.*

3a. If yes to Q. 3, which therapy has the greater net health benefit?

   a. OCA  b. Pioglitazone
Potential Other Benefits and Contextual Considerations

4. Does treating patients with OCA offer one or more of the following potential “other benefits” compared to no treatment? (select all that apply)
   a. This intervention will significantly reduce caregiver or broader family burden.
   b. This intervention offers a novel mechanism of action or approach that will allow successful treatment of many patients for whom other available treatments have failed.
   c. This intervention will have a significant impact on improving patients’ ability to return to work and/or their overall productivity.

There are other important benefits or disadvantages that should have an important role in judgments of the value of this intervention: ________________

5. Are any of the following contextual considerations important in assessing OCA’s long-term value for money? (select all that apply)
   a. This intervention is intended for the care of individuals with a condition of particularly high severity in terms of impact on length of life and/or quality of life.
   b. This intervention is intended for the care of individuals with a condition that represents a particularly high lifetime burden of illness.
   c. This intervention is the first to offer any improvement for patients with this condition.
   d. There is significant uncertainty about the long-term risk of serious side effects of this intervention.
   e. There is significant uncertainty about the magnitude or durability of the long-term benefits of this intervention.
   f. There are additional contextual considerations that should have an important role in judgments of the value of this intervention: __________________________.

Long-term Value for Money

*If the price of OCA is not available by the time of the public meeting, no value vote will be taken.*

6. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment at current pricing with OCA versus no treatment?
   a. Low long-term value for money
   b. Intermediate long-term value for money
   c. High long-term value for money