



Resmetirom and Obeticholic Acid for Non-Alcoholic Steatohepatitis (NASH)

Draft Questions for Deliberation and Voting: April 28, 2023 Public Meeting

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

Patient Population for all questions: Adults with Non-Alcoholic Steatohepatitis (NASH) with significant fibrosis (i.e., stage 2 and stage 3 fibrosis) and not cirrhosis.

Clinical Evidence

1. Given the currently available evidence, is the evidence adequate to demonstrate that the net health benefit of **resmetirom** is superior to that provided by **lifestyle management alone**?

Yes No

2. Given the currently available evidence, is the evidence adequate to demonstrate that the net health benefit of **Obeticholic Acid (Ocaliva)** is superior to that provided by **lifestyle management alone** for NASH patients with Stage 2 fibrosis?

Yes No

3. Given the currently available evidence, is the evidence adequate to demonstrate that the net health benefit of **Obeticholic Acid (Ocaliva)** is superior to that provided by **lifestyle management alone** for NASH patients with Stage 3 fibrosis?

Yes No

Contextual Considerations and Potential Other Benefits or Disadvantages

Please vote on the following contextual considerations:

When making judgments of overall long-term value for money, what is the relative priority that should be given to any effective treatment for NASH with fibrosis, on the basis of the following contextual considerations:

1= Very low priority; 2 = Low priority; 3 = Average priority; 4 = High priority; 5= Very high priority

4. Acuity of need for treatment of individual patients based on short-term risk of death or progression to permanent disability
5. Magnitude of the lifetime impact on individual patients of the condition being treated

Please vote on the following potential other benefits or disadvantages:

What are the relative effects of resmetirom versus lifestyle management alone on the following outcomes that inform judgment of the overall long-term value for money of resmetirom?

1= Major negative effect; 2 = Minor negative effect; 3 = No difference; 4 = Minor positive effect; 5 = Major positive effect

6. Patients' ability to achieve major life goals related to education, work, or family life
7. Caregivers' quality of life and/or ability to achieve major life goals related to education, work, or family life
8. Society's goal of reducing health inequities

What are the relative effects of Obeticholic Acid (Ocaliva) versus lifestyle management alone on the following outcomes that inform judgment of the overall long-term value for money of Obeticholic Acid (Ocaliva)?

1= Major negative effect; 2 = Minor negative effect; 3 = No difference; 4 = Minor positive effect; 5 = Major positive effect

9. Patients' ability to achieve major life goals related to education, work, or family life
10. Caregivers' quality of life and/or ability to achieve major life goals related to education, work, or family life
11. Society's goal of reducing health inequities

Long-Term Value for Money

12. 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 **resmetirom** versus **lifestyle management alone**?*
 - a. Low long-term value for money at current prices
 - b. Intermediate long-term value for money at current prices
 - c. High long-term value for money at current pricing

13. 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 **Obeticholic Acid (Ocaliva)** versus **lifestyle management alone**?†
 - a. Low long-term value for money at current prices
 - b. Intermediate long-term value for money at current prices
 - c. High long-term value for money at current pricing

*This vote will only be taken if a price becomes available for resmetirom.

†This vote will only be taken if a price becomes available for Obeticholic Acid (Ocaliva).