



Beta-Amyloid Antibodies for Early Alzheimer’s Disease

Draft Questions for Deliberation and Voting: March 17, 2023 Public Meeting

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

Patient Population for all questions: Adults with early Alzheimer’s disease (i.e., Mild Cognitive Impairment due to Alzheimer’s disease and mild Alzheimer’s dementia).

Clinical Evidence

1. Given the currently available evidence, is the evidence adequate to demonstrate that the net health benefit of **lecanemab** in addition to **supportive care** is superior to that provided by **supportive care alone**?

Yes No

2. Given the currently available evidence, is the evidence adequate to demonstrate that the net health benefit of **donanemab** in addition to **supportive care** is superior to that provided by **supportive care alone**?

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 early Alzheimer’s disease with evidence of Alzheimer’s disease pathology, 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

3. Acuity of need for treatment of individual patients based on short-term risk of death or progression to permanent disability
4. 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 lecanemab in addition to supportive care versus supportive care alone on the following outcomes that inform judgment of the overall long-term value for money of lecanemab added to supportive care?

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

5. Patients' ability to achieve major life goals related to education, work, or family life
6. Caregivers' quality of life and/or ability to achieve major life goals related to education, work, or family life
7. Patients' ability to manage and sustain treatment given the complexity of regimen
8. Society's goal of reducing health inequities

What are the relative effects of donanemab in addition to supportive care versus supportive care alone on the following outcomes that inform judgment of the overall long-term value for money of donanemab added to supportive care?

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. Patients' ability to manage and sustain treatment given the complexity of regimen
12. Society's goal of reducing health inequities

Long-Term Value for Money

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 **lecanemab in addition to supportive care** versus supportive care 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 lecanemab.