

**Message to Stakeholders:
Update to “Beta-Amyloid Antibodies for Early Alzheimer’s Disease”**

August 30, 2022

As a result of additional information recently becoming available, ICER has decided to extend the timeline for its upcoming report on Alzheimer’s disease, “Beta-Amyloid Antibodies for Early Alzheimer’s Disease” and add lecanemab back into the report.

After reviewing information on lecanemab, including comments from a recent manufacturer’s quarterly earnings call, press coverage, and conversations with the developer, ICER has determined that there should be enough information between the expected readout on primary endpoints of the Phase 3 CLARITY AD trial in September and the availability of data in early December 2022 to add lecanemab back into the upcoming report by delaying publication of its Alzheimer’s draft report until late in December 2022. ICER recognizes that there is some possibility that donanemab could be granted accelerated approval before publication of the draft report, but it is likely that, were this to occur, there would only be a short gap in time between an approval decision and ICER’s draft report publication.

ICER will continue to evaluate changes to the timeline for this assessment if new information becomes available and will adjust the dates for key milestones as needed to ensure the timeliness of this assessment.