ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Message to Stakeholders: Update to "Beta-Amyloid Antibodies for Early Alzheimer's Disease"

August 9, 2022

As a result of a change in the expected timing of release of key clinical effectiveness information, ICER will be removing lecanemab from its upcoming report on Alzheimer's disease, "Beta-Amyloid Antibodies for Early Alzheimer's Disease".

The developer of lecanemab recently informed ICER that results from the Phase 3 CLARITY AD trial will be available in December 2022 prior to a PDUFA action date of January 6, 2023. These data will include key findings on the clinical outcomes of treatment, not just the impact on amyloid levels in the brain. It is unusual for the FDA to proceed with accelerated approval so close to the time when clinical data will be available.

Based on our previous assumption that clinical data would be available earlier, we scheduled the Draft Report for publication on November 21, 2022. Now, however, this date falls prior to the release of Phase 3 clinical data on lecanemab. If ICER were to postpone the Draft Report until after the CLARITY AD data become available, ICER's economic team would not have enough time to incorporate CLARITY AD data into the cost effectiveness model of lecanemab prior to its announced January 6 PDUFA date and would have to rely on older data that would likely rapidly become obsolete. This is in contrast to the review of donanemab, also being evaluated for accelerated approval, where new clinical data are not expected to be available close to the anticipated PDUFA date; a delay in the report would diminish the timeliness of the review of donanemab for decision-makers.

It is possible that ICER will evaluate lecanemab as part of a future report or as part of an update, or that lecanemab will be added back to the report if Phase 3 results become available earlier or the PDUFA date is extended.