

AAN Public Comment to California Technology Assessment Forum on Institute for Clinical and Economic Review Report Aducanumab for Alzheimer's Disease: Effectiveness and Value

July 15, 2021

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 36,000 neurologists and clinical neuroscience professionals. Its members have specialized training in diagnosing, treating, and managing disorders of the brain and nervous system, including mild cognitive impairment and Alzheimer's disease.

AAN members are dedicated to promoting the highest quality patient-centered neurologic care by providing safe and effective treatments, but are unsure if aducanumab is the best option for their patients based on the current data. The AAN has been monitoring aducanumab's approval process and is concerned about implications relating to several considerations highlighted in the [Institute for Clinical and Economic Review's \(ICER\) report](#) including drug efficacy and costs to the health care system and patients.

The AAN appreciates many of the considerations included in the ICER report related to the ENGAGE and EMERGE clinical trials. The highly irregular clinical trial process leaves a plethora of questions about the efficacy patients and providers can expect from aducanumab as it begins to see widespread use. Many AAN members now face pressure for appropriate prescribing, given the uncertainties surrounding efficacy. The AAN also echoes ICER's concerns regarding the lack of racial and ethnic diversity in the clinical trial population, given the disproportionate impact of Alzheimer's disease on Black and Hispanic individuals. Given the current data, future clinical trials are needed to firmly establish or refute efficacy of aducanumab and to see if results are generalizable to other populations.

The AAN was heartened to see the FDA update the label to patients with mild cognitive impairment or mild dementia, as this is in line with the recommendations we sent to the FDA prior to aducanumab's approval. However as noted in ICER's revised evidence report, Biogen has set an annual price for aducanumab at \$56,000. Unfortunately, patients are likely to bear a significant amount of financial hardship given the rising out-of-pocket costs of many neurologic medications that has occurred over the last several years. Furthermore, the impact on Medicare Part B spending cannot be overstated as aducanumab could cost more than a trillion dollars before its clinical benefit is adequately demonstrated, depending on how many patients take the drug. The AAN agrees with ICER that due to the high systemic and out-of-pocket costs, aducanumab could only be administered to a very small number of patients before the need for federal policy changes to address access and affordability. The budget impact on the health care system and individual patients is very concerning, including factors not included in the ICER analysis such as ancillary costs associated with infusions and testing.

The AAN is grateful to ICER for conducting this thorough review of a drug that will have such an impact on neurologic patients and our health system broadly. We hope this report continues to inform stakeholder discussions on critical questions for aducanumab including the required Phase 4 clinical trial and insurance coverage.