FDA Approves Lecanemab for Alzheimer's Disease

On January 6, 2023, the Food and Drug Administration granted Accelerated Approval to a new monoclonal antibody—lecanemab (brand name Leqembi)—directed against amyloid for the treatment of mild Alzheimer's disease (AD) and mild cognitive impairment (MCI). According to the FDA label, treatment with lecanemab should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. The initial sale price for lecanemab has been set at $26,500 per year, above the Institute for Clinical and Economic Review recommended price range of $8,500 to $20,600 based on their review of the efficacy data. Analysis of the results from lecanemab's phase three CLARITY AD trial published in the *New England Journal of Medicine* found that lecanemab was able to moderately slow decline on measures of cognition and function in patients with early AD and MCI relative to placebo at 18 months.

An existing National Coverage Determination (NCD) published by the Centers for Medicare & Medicaid Services (CMS) in April 2022 stipulates that monoclonal antibodies for the treatment of AD only receive coverage in the context of an approved clinical trial unless or until it was able to satisfy a variety of criteria as part of Coverage with Evidence Development. This means that lecanemab enters the market under this NCD and therefore access will be limited. In a statement released by CMS upon the approval of lecanemab the agency announced that they are, "examining available information and may reconsider its current coverage based on this review."

The AAN will continue its advocacy on this issue and is providing resources and education to help its members understand this new therapy. Please visit the Monoclonal Antibodies for Alzheimer's Resources page to stay up to date on the Academy's activity in this space.