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Addendum: Aducanumab *(Aduhelm)* for Alzheimer's Disease

In June 2021, the FDA approved the IV amyloid beta-directed monoclonal antibody aducanumab *(Aduhelm)* for treatment of Alzheimer's disease. The approval did not restrict use of the drug to patients with mild cognitive impairment or mild dementia, which was the population enrolled in the clinical trials. Now, Biogen, with the permission of the FDA, has made an addition to the labeling of the drug that says: *Treatment with Aduhelm 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. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied.*

As we said in our article (Med Lett Drugs Ther 2021; 63:105), aducanumab was approved based on evidence that it reduces amyloid beta plaques in the brains of patients with mild cognitive impairment or mild dementia due to Alzheimer's disease. Whether it improves clinical outcomes remains to be established.