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IN BRIEF

Once-Monthly Lecanemab *(Leqembi)* for Alzheimer's Disease

The amyloid beta-directed monoclonal antibody lecanemab-irmb (*Leqembi* – Eisai/Biogen)[1] has now been approved by the FDA for once-monthly use for treatment of Alzheimer's disease (AD) in patients with mild cognitive impairment (MCI) or mild dementia. It was previously approved only for administration once every 2 weeks. Now, lecanemab can be given every 4 weeks after an 18-month initiation phase of biweekly administration.

CLINICAL STUDIES — FDA approval of the new regimen was based on modeling simulations from one phase 2 and one phase 3 trial (Clarity AD; trials are from the original FDA approval) and their open-label extensions in patients with confirmed amyloid pathology and MCI or mild dementia.[2,3] Modeling predicted that after 18 months of biweekly lecanemab treatment, transitioning to every 4 weeks would maintain biomarker and clinical effects. The phase 2 trial and its extension found that stopping lecanemab was associated with reaccumulation of amyloid protofibrils and reversion back to the rate of clinical decline observed with placebo.[4]

ADVERSE EFFECTS — The most common adverse effects of lecanemab given every 2 weeks in clinical trials were infusion-related reactions, headache, and amyloid-related imaging abnormalities (ARIA), with edema (ARIA-E), and with hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis. Most cases of ARIA have been detected by scheduled MRIs in asymptomatic patients. The risk of ARIA is greater in patients who are APOE4 homozygotes (~15% of AD patients). Whether administering lecanemab less frequently reduces the risk of ARIA is unknown.

DOSAGE AND COST — The recommended dosage of lecanemab is 10 mg/kg infused intravenously over about 1 hour. One dose of *Leqembi* for a 70-kg patient costs $897.[5] Reducing the number of doses by half would result in a significant cost savings. ■

1. Lecanemab (Leqembi) for Alzheimer's disease. Med Lett Drugs Ther 2023; 65:17.
2. E McDade et al. Lecanemab in patients with early Alzheimer's disease: detailed results on biomarker, cognitive, and clinical effects from the randomized and open-label extension of the phase 2 proof-of-concept study. Alzheimers Res Ther 2022; 14:191.
3. CH van Dyck et al. Lecanemab in early Alzheimer's disease. N Engl J Med 2023; 388:9.
4. D Selkoe. Does the current evidence for the lecanemab mechanism support a rationale for continued lecanemab dosing? Alzheimer's Association International Conference (AAIC) 2024; Philadelphia, PA, USA and online; July 28-August 1, 2024. Available at: https://bit.ly/4kz5GhR. Accessed March 27, 2025.
5. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. March 5, 2025. Reprinted with permission by First Databank, Inc. All rights reserved. ©2025. www.fdbhealth.com/policies/drug-pricing-policy.

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