

# Real-World Safety and Efficacy of Lecanemab in Alzheimer’s Disease: A Systematic Review and Single-Arm Meta-Analysis

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| INTRODUCTION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | METHODS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | RESULTS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | CONCLUSIONS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
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| Alzheimer’s disease (AD) is a progressive neurodegenerative disorder associated with cognitive decline and functional impairment. Lecanemab, a monoclonal antibody targeting aggregated amyloid-β, has recently been introduced into clinical practice. While randomized trials have reported efficacy outcomes, data from real-world clinical settings remain limited. This systematic review and single-arm meta-analysis aimed to synthesize available real-world evidence on the safety and efficacy of lecanemab in patients with AD. | A systematic search of PubMed, Scopus, Web of Science, Embase, and Cochrane databases was conducted from inception till December 2025 for real-world and observational studies evaluating lecanemab in Alzheimer’s disease. As most included studies did not include a comparable control group, a single-arm meta-analysis was performed. Cognitive efficacy was assessed using changes in Mini-Mental State Examination (MMSE) scores at 6 and 12 months. Safety outcomes included pooled incidence estimates of amyloid-related imaging abnormalities (ARIA), including ARIA-H and ARIA-E, symptomatic ARIA, and infusion-related adverse events. Pooled mean differences (MDs) and incidence estimates with 95% confidence intervals (CIs) were calculated using random-effects models. | Four real-world studies comprising 294 patients were included. Changes in MMSE scores at 6 months (-0.09 (95% CI: -0.81 to 0.64)) and 12 months (-0.93 (95% CI: -4.00 to 2.15)) did not demonstrate statistically significant improvement. The pooled incidence of overall ARIA was 0.16 (95% CI 0.12–0.21). ARIA-H and ARIA-E occurred in 8% (95% CI 0.05–0.12) and 5% (95% CI 0.02–0.09) of patients, respectively. Symptomatic ARIA was infrequent incidence 0.01; 95% CI 0.00–0.04). Infusion-related adverse events were reported in 12% of patients (95% CI 0.05–0.23). | In real-world clinical settings, lecanemab was not associated with significant short-to mid-term changes in MMSE scores and was associated with a measurable incidence of ARIA and infusion-related adverse events. Although symptomatic ARIA was uncommon, these findings emphasize the need for careful monitoring in routine practice. Further large-scale, longer-term real-world studies are warranted to better characterize the clinical effectiveness and safety of lecanemab across diverse patient populations. |