Protocol for Leqembi® (lecanemab-irmb)

Approved April 2023

Background: *Alzheimer's is a progressive disease beginning with mild memory loss and possibly leading to loss of the ability to carry on a conversation and respond to the environment.*

Leqembi *is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with Leqembi 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. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Leqembi. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.*

Criteria for approval:

1. Patient is ≥ 50 years of age; **AND**
2. Patient has a documented diagnosis of mild dementia or mild cognitive impairment (MCI) associated with Alzheimer's disease (AD)
3. Patient meets all the following testing requirements:
    a) Mini Mental State Examination (MMSE) score ≥ 22 and ≤ 30
    b) Clinical Dementia Rating (CDR) global score of 0.5 or 1 and Memory Box score of 0.5 or greater
    c) Documentation of positive amyloid Positron Emission Tomography (PET) scan OR a lumbar puncture (LP) for biomarkers such as amyloid or Tau
    d) Recent (within one year) brain MRI to evaluate for pre-existing Amyloid Related Imaging (ARIA); **AND**
4. Medication is prescribed by or in consultation with a neurologist, geropsychiatrist, geriatrician, or a prescriber who specializes in the treatment of Alzheimer's disease
5. Leqembi will not be used in combination with any other amyloid beta-directed antibodies (e.g., aducanumab).
6. Patient is not on anticoagulant therapy
7. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital

Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

8. Weight will be monitored

Initial Approval: 6 months

Continuation of therapy:

1. Documentation of follow-up MRIs to evaluate for ARIA-E, ARIA-H, and other structural changes prior to the 5th, 7th, and 14th infusions, (if radiographically observed ARIA occurs, treatment recommendations are based on type, severity, and presence of symptoms); **AND**
2. Patient has shown clinical benefit while on the medication (e.g., improvement, stability, or slowing in cognitive and/or functional impairment)
3. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence
4. Weight will be monitored

Renewal Approval: 6 months

References

1. Leqembi [prescription information]. Eisai Inc. Nutley, NJ. January 2023
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Press D, Alexander M; (2021). Treatment of Alzheimer disease. In J. Wilterdink (Ed.) UpToDate. Retrieved July 8, 2021, from https://www.uptodate.com/contents/treatment-of-alzheimer-disease?search=Aduhelm&source=search_result&selectedTitle=2~7&usage_type=default&display_rank=1#H2549013834
4. Delaby C, Alcolea D, Hirtz C, Vialaret J, Kindermans J, Morichon L, Fortea J, Belbin O, Gabelle A, Blennow K, Zetterberg H, Lleó A, Lehmann S. Blood amyloid and tau biomarkers as predictors of cerebrospinal fluid profiles. J Neural Transm (Vienna). 2022 Feb;129(2):231-237