New Hampshire Medicaid Fee-for-Service Program Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease Criteria

Approval Date: November 21, 2024

Pharmacology

Aducanumab-avwa, lecanemab-irmb, and donanemab-azbt are humanized, immunoglobulin gamma 1 (IgG1) monoclonal antibodies directed against aggregated soluble and insoluble forms of amyloid beta. The accumulation of amyloid plaques and neurofibrillary/tau tangles are hallmark indicators of Alzheimer's disease.

Medications

Brand Name	Generic Name	Dosage Strengths
Aduhelm®	aducanumab-avwa	170 mg/1.7 mL and 300 mg/3 mL solution in single dose vial for IV infusion
Kisunla™	donanemab-azbt	350 mg/20 mL
Leqembi™	lecanemab-irmb	200 mg/2 mL and 500 mg/5 mL solution in single dose vial for IV infusion

Criteria for Approval

Will follow Medicare coverage decision for dual eligible beneficiaries.

1. Patient is ≥ 18 years of age; **AND**
2. Patient has mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or has mild Alzheimer's disease as evidenced by **all** of the following:
   a. Clinical Dementia Rating (CDR) – Global Score of 0.5 to 1; **AND**
   b. Objective evidence of cognitive impairment at screening; **AND**
   c. Mini-Mental Status Exam (MMSE) score between 22 and 30 (inclusive); **AND**
   d. Positron Emission Tomography (PET) scan is positive for amyloid beta plaque or cerebrospinal fluid (CSF) assessment of amyloid beta (1–42) is positive or FDA-approved test to confirm diagnosis; **AND**
3. Other conditions mimicking, but of non-Alzheimer's dementia etiology, have been ruled out (e.g., vascular dementia, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD], normal pressure hydrocephalus); **AND**

4. Patient has not had a stroke or transient ischemic attack (TIA) or unexplained loss of consciousness in the past 12 months; **AND**
5. Patient does not have any relevant brain hemorrhage, bleeding disorder, cerebrovascular abnormalities, or recent (within the prior year) cardiovascular condition (e.g., unstable angina, myocardial infarction, advanced congestive heart failure [CHF], or clinically significant conduction abnormalities); **AND**
6. Patient is not currently receiving anti-platelet agents, anticoagulants, or anti-thrombins (except for prophylactic aspirin at doses < 325 mg daily); **AND**
7. Drug must be prescribed by, or in consultation with, a specialist in neurology or gerontology; **AND**
8. Patient has received a baseline brain magnetic resonance imaging (MRI) prior to initiating treatment; **AND**
    a. Within 1 year prior unless the patient has a more recent exacerbation, traumatic event [e.g., falls], or co-morbidity necessitating an evaluation within 1 month preceding initiation.
9. Patient will receive brain MRI throughout therapy (Aduhelm®: prior to the 5th, 7th, 9th, and 12th dose or Leqembi™: prior to the 5th, 7th, and 14th dose or Kisunla™: prior to the 2nd, 3rd, 4th, and 7th dose); **AND**
10. Dosing and titration follow product labeling; **AND**
11. Patient does not have any of the following within 1 year of treatment initiation:
    a. Pre-treatment localized superficial siderosis
    b. ≥ 10 brain microhemorrhages
    c. Brain hemorrhage > 1 cm; **AND**
12. Prescriber has assessed and documented baseline disease severity utilizing an objective measure/tool (e.g., MMSE, Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB]); **AND**
13. Prescriber has informed the patient of the known or potential risks and minimal established clinical benefit based on clinical trials to date with Aduhelm®, Leqembi™, Kisunla™ treatment.

Criteria for Renewal

1. Patient continues to meet the above criteria; **AND**
2. Patient has not had unacceptable toxicity from the drug (e.g., amyloid related imaging abnormalities [ARIA]-edema [ARIA-E], severe hypersensitivity reactions); **AND**
3. Patient has responded to therapy compared to pre-treatment baseline as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment in ≥ 1 of the following (not all-inclusive) objective measures assessed and documented at baseline:
    a. ADAS-Cog 13
    b. ADCS-ADL-MCI
    c. MMSE

d. CDR-SB; **AND**

4. Patient has not progressed to moderate or severe AD; **AND**
5. Patient must continue maintenance therapy at the recommended dosage of 10 mg/kg (Aduhelm® every 4 weeks or Leqembi™ every 2 weeks) or Kisunla™ 1400 mg every 4 weeks; **AND**
6. Patient has received recommended MRIs (Aduhelm®: prior to the 5th, 7th, 9th, and 12th dose **or** Leqembi™: prior to the 5th, 7th, and 14th dose **or** Kisunla™: prior to the 2nd, 3rd, 4th, and 7th dose) for monitoring of ARIA-hemosiderin (ARIA-H) microhemorrhages; **AND**
   a. Patient has < 10 new incident microhemorrhages or ≤ 2 focal areas of superficial siderosis (radiographic mild to moderate ARIA-H) observed; **OR**
   b. Patient has ≥ 10 new incident microhemorrhages or > 2 focal areas of superficial siderosis (radiographic severe ARIA-H†) are observed **and** patient meets the following criteria:
      i. Treatment is continued with caution only after a clinical evaluation; **AND**
      ii. Subsequent follow-up MRI demonstrates radiographic stabilization (e.g., no increase in size or number of ARIA-H).

Length of Authorization: 6 months

ARIA Classification and Radiographic Severity			
Severity	**ARIA-E (based on FLAIR hyperintensity)**	**ARIA-H microhemorrhage (quantity of new incident microhemorrhages)**	**ARIA-H superficial siderosis (quantity of superficial siderosis focal areas)**
Mild	Confined to sulcus and/or cortex/subcortical white matter in 1 location < 5 cm	≤ 4	1
Moderate	5 to 10 cm, or > 1 site of involvement, each measuring < 10 cm	5 to 9	2
Severe	> 10 cm, often with significant subcortical white matter and/or sulcal involvement; ≥ 1 separate site of involvement may be noted	≥ 10	> 2

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	06/02/2022
Commissioner Designee	Approval	07/12/2022
DUR Board	Update	06/19/2023
Commissioner Designee	Approval	06/29/2023
DUR Board	Update	10/15/2024
Commissioner Designee	Approval	11/21/2024