MetroPlus Health

Policy and Procedure

Title: UM-PT118 Leqembi (lecanemab-irmb)	**Division: Medical Management** **Department: Pharmacy**
Approval Date: 12/16/2025	**LOB: Medicaid, SNP, HARP, CHP, QHP, EP, Gold, Goldcare**
Effective Date: 12/16/2025	**Policy Number: UM-PT118**
Review Date: 12/16/2025	**Cross Reference Number:**
Retired Date:	**Page 1 of 6**

I. POLICY DESCRIPTION:

Central Nervous System Agent – Leqembi (lecanemab-irmb)

II. RESPONSIBLE PARTIES:

Medical Management Administration, Pharmacy Department, Utilization Management, Integrated Care Management, Claims Department

III. DEFINITIONS:

Leqembi (lecanemab-irmb) is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody that is directed against aggregated soluble and insoluble forms of amyloid beta, which is a clinical characteristic seen in Alzheimer's disease (AD). This reduces the accumulation of amyloid beta plaques and slows the progression of the disease.

IV. POLICY:

Leqembi will be considered medically necessary once the following coverage criteria is met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

INITIAL REQUEST:

1. **Alzheimer's Disease (AD)**
   - **A.** Member is 50 to 90 years of age;

   AND
   - **B.** Prescribed by or in consultation with board certified gerontologist, neurologist, geriatric psychiatrist, or neuropsychiatrist;

   AND
   - **C.** Member has a confirmed diagnosis of mild cognitive impairment (MCI) caused by Alzheimer's Disease (AD) or Mild Dementia due to AD;

   AND
   - **D.** Member has ONE of the following baseline scores;
     - **a.** Clinical Dementia Rating (CDR)-Global Score of 0.5 to 0.1;

     OR
     - **b.** Mini-Mental Examination Status (MMSE) score of ≥22 to ≤ 30;

     OR
     - **c.** Montreal Cognitive Assessment (MoCA) score of ≥ 16;

   AND
   - **E.** Member has confirmed presence of β-amyloid peptide (Aβ) deposits by ONE of the following:
     - **a.** Positron emission tomography (PET) brain scan

     OR

b. Lumbar puncture showing positive CSF (i.e., Aβ42, Aβ42/Aβ40 ratio, tau/Aβ42 ratio) assay showing presence of amyloid deposition;

OR

c. Brain biopsy confirming presence of β-amyloid peptide (Aβ) deposits

AND

F. Member does not have symptoms related to another neurological or psychiatric condition (e.g. Lewy body dementia, cerebrovascular disease, Parkinson's disease, vitamin B12 deficiency);

AND

G. ALL of the following:

a. Member has received a Magnetic resonance imaging (MRI) within the past year

AND

b. Provider attests that member will receive a MRI prior to 5th, 7th and 14th infusion for monitoring of amyloid-related imaging abnormalities (ARIA);

AND

H. Member has genetic testing assessing presence of apolipoprotein E ε4 (ApoE ε4) and member is not homozygous for the ApoE e4 genes;

AND

I. Member does not have ANY of the following:

a. Significant pathological findings on pre-treatment MRI (within 1 year of treatment initiation) including but not limited to ANY of the following

i. More than four microhemorrhages (defined as ≤10 mm at the greatest diameter); a single macrohemorrhage >10 mm at greatest diameter;

OR

ii. An area of superficial siderosis;

OR

iii. Evidence of vasogenic edema;

OR

iv. Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions;

OR

v. Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease;

OR

vi. Space occupying lesions;

OR

vii. Brain tumors (however, lesions diagnosed as meningiomas or arachnoid cysts and <10 mm at their greatest diameter need not be exclusionary);

OR

b. History of cerebrovascular abnormalities or bleeding disorder that would present a risk for ARIA-related bleeding;

OR

c. History of transient ischemic attacks (TIA), stroke, or seizures within 12 months of screening;

AND

J. Member has tried at least one cholinesterase inhibitor (e.g. donepezil, galantamine, rivastigmine) for at least 3 months or has had a contraindication;

AND

K. If member is on anticoagulant or antiplatelet therapy then, member must be on stable doses for at least 1 month prior to the initiation of Leqembi;

AND

L. Leqembi will not be used concomitantly with any other amyloid beta-directed antibodies (e.g. Kisunla (donanemab));

AND

M. Member is not enrolled in a clinical trial;

AND

N. Authorization is for no more than 3 months

RENEWAL REQUEST:

1. Alzheimer's Disease (AD)

A. Initial conditions of coverage have been met;

AND

B. Member has adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history;

AND

C. Member has shown positive clinical response to therapy as evidenced by displaying delayed progression of Alzheimer's disease;

AND

D. Member does not have any unacceptable toxicities from Leqembi (i.e., amyloid related imaging abnormalities-edema (ARIA-E) and -hemosiderin deposition (ARIA-H), intracerebral hemorrhage, severe hypersensitivity reactions);

AND

E. Member does not have a significant pathology finding from MRI imaging results

AND

F. Prescribers submited chart notes documenting adherence to MRI monitoring;

AND

G. Prescriber attests that member is not receiving any new medications that would increase risk for ARIA (e.g. Tissue plasminogen activator (Tpa) use within time since last authorization, antiplatelets, anticoagulants);

AND

H. Authorization is for no more than 6 months

V. LIMITATIONS/ EXCLUSIONS:

Leqembi is considered to be experimental and investigational if prescribed for indications that have not been approved by the FDA and will not be covered under this policy.

Leqembi is to be administered at a Leqembi infusion center.

VI. APPLICABLE PROCEDURE CODES:

CPT	Description
J0174	Injection, lecanemab-irmb, 1 mg

VII. APPLICABLE DIAGNOSIS CODES:

CODE	Description
G30.0	Alzheimer's disease with early onset
G30.1	Alzheimer's disease with late onset
G30.8	Other Alzheimer's disease
G30.9	Alzheimer's disease, unspecified

VIII. REFERENCES:

1. Leqembi (lecanemab-irmb) [prescribing information]. Nutley, NJ: Eisai Inc; January 2025.
2. Eisai Inc., Biogen. A Placebo-Controlled, Double-Blind, Parallel-Group, Bayesian Adaptive Randomization Design and Dose Regimen-finding Study With an Open-Label Extension Phase to Evaluate Safety, Tolerability and Efficacy of BAN2401 in Subjects With Early Alzheimer's Disease. clinicaltrials.gov. https://clinicaltrials.gov/ct2/show/NCT01767311
3. Eisai Inc., Biogen. A Study to Confirm Safety and Efficacy of Lecanemab in Participants With Early Alzheimer's Disease (Clarity AD). clinicaltrials.gov. https://clinicaltrials.gov/study/NCT03887455
4. Rabins PV, Rovner BW, Rummans T, Schneider LS, Tariot PN. Guideline Watch (October 2014): Practice Guideline for the Treatment of Patients With Alzheimer's Disease and Other Dementias. Focus. 2017;15(1):110-128. doi:10.1176/appi.focus.15106.
5. Berg-Weger M, Stewart DB. Non-Pharmacologic Interventions for Persons with Dementia. Mo Med. 2017 Mar-Apr;114(2):116-119. PMID: 30228557; PMCID: PMC6140014.

REVISION LOG:

REVISIONS	INITIAL	DATE
Creation date	XZ	12/16/2025

Approved: **Date:**	**Approved:** **Date:**
Suzana Patel 2/18/2026	02.18.2026
Suzana Patel, PharmD **Senior Director of Pharmacy**	**Sanjiv Shah, MD** **Chief Medical Officer**

Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and website links are accurate at time of publication.

MetroPlus HealthPlan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.