ATRIO HEALTH PLANS

Alzheimer's Disease
Aduhelm (aducanumab-avwa) J0172
Leqembi (Lecanemab-irmb) J0174
Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ Aduhelm - New Start or Initial Request: (Clinical documentation required for all requests)

- ☐ Patient has a diagnosis of Alzheimer's Disease
- ☐ Patient has MILD cognitive impairment or MILD dementia stage of disease.
- ☐ Prescribed by a Neurologist or Geriatrician, Neurophsychiatrist or Psychiatrist.
- ☐ Diagnosis of Alzheimer's Disease based on one of the following:
  - ☐ Cerebral Spinal Fluid (CSF) biomarkers.
  - ☐ Amyloid positron emission tomography (PET).
- ☐ Member had a brain magnetic resonance imaging (MRI) in the previous three months.
- ☐ Enrollment in an FDA-approved randomized controlled trial or a clinical trial supported by the NIH (National Institutes of Health)

☐ Leqembi - New Start or Initial Request: (Clinical documentation required for all requests)

- ☐ Prescribed by, or in consultation with, a neurologist, geriatrician, neuropsychiatrist, or psychiatrist;
- ☐ Individual is 50 to 90 years of age;
- ☐ Individual has a diagnosis of one of the following:

- ☐ Mild cognitive impairment (MCI) due to Alzheimer's Disease (AD);
- ☐ Mild Alzheimer's Disease dementia;

☐ Documentation is provided that individual has objective impairment in episodic memory according to memory tests [i.e., Free and Cued Selective Reminding Test, the Rey Auditory Verbal Learning Test, the California Verbal Learning Test, or the Logical Memory I and II of the Wechsler Memory Scale Revised

☐ Documentation is provided that individual has a Clinical Dementia Rating (CDR)-Global score of 0.5 to 1.0

☐ Documentation is provided that individual has a CDR Memory Box score ≥ 0.5

☐ Documentation is provided that individual has a Mini Mental State Examination (MMSE) score of 22 to 30 (inclusive)

☐ Documentation is provided that individual has presence of amyloid beta based on ONE of the following diagnostic tests

- ☐ PET imaging showing presence of amyloid beta;
- ☐ Presence of long form amyloid beta (i.e., Aβ1-42, Beta-amyloid [1-42], Abeta42) in the cerebrospinal fluid;

☐ Documentation is provided that individual has had a baseline MRI (within the past year) that does not show ANY of the following

- ☐ More than 4 microhemorrhages (defined as 10 mm or less at the greatest diameter);
- ☐ A single macrohemorrhage >10 mm at the greatest diameter;
- ☐ An area of superficial siderosis;
- ☐ Evidence of vasogenic edema;
- ☐ Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions;
- ☐ Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease;
- ☐ Space occupying lesions;
- ☐ Brain tumors (except those diagnosed as meningiomas or arachnoid cysts and <1 cm at their greatest diameter);

☐ MRI will be reviewed by the prescriber prior to the 5th, 7th, and 14th infusions;

☐ MRI will be reviewed by the prescriber prior to the next dose if ARIA is suspected;

☐ The prescriber and individual (or caregiver) have discussed and acknowledged the potential safety risks of treatment, including risks of

☐ The prescriber and individual have discussed and acknowledged that individuals who are apolipoprotein E (ApoE) ε4 homozygotes (approximately 15% of individuals with AD) treated with Leqembi have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA compared to heterozygotes and non-carriers

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Patient had a brain magnetic resonance imaging (MRI) in the previous three months.

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Alzheimer's Disease Drugs PA

Drug Name(s):

ADUHELM	**ADUCANUMAB-AVWA**
LEQEMBI	**LECANEMAB-IRMB**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Patient has MILD cognitive impairment or MILD dementia stage of disease.
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.
- Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:

N/A

Prescriber Restrictions:

Neurologist, Geriatrician, Neuropsychologist or Psychiatrist

Coverage Duration:

Approval will be for 12 months

FDA Indications:

Aduhlem

- Alzheimer's Disease in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

Leqembi

- Alzheimer's disease, Mild cognitive impairment or mild dementia stage of disease

Off-Label Uses:

N/A

Age Restrictions:

The safety and effectiveness in pediatric patients have not been established

Other Clinical Consideration:

Treatment 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

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/0F0D9D/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/B0C151/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=aduhelm&UserSearchTerm=aduhelm&SearchFilter=filterNone&navitem=searchGlobal#

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