OPTIMA HEALTH PLAN

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization will be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Aduhelm™ (aducanumab) IV (J3590) (Medical)

DRUG INFORMATON: Authorization may be delayed if incomplete.

Drug Name/Form/Strength/Quantity: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code**: _____

Recommended Dosage:

- **Maximum Dose – 10mg/kg every 21 days** (single-dose vial for injection): 170mg/1.7ml, 300mg/3ml
- **Dosing Schedule:**

IV Infusion (every 4 weeks)	**Aduhelm Dosage** (administered over approximately one hour)
Infusion 1 and	1 mg/kg
Infusion 3 and 4	3 mg/kg
Infusion 5 and 6	6 mg/kg
Infusion 7 and beyond	10 mg/kg

- Aduhelm™ is administered as an intravenous (IV) infusion via a 0.2 or 0.22 micron in-line filter over approximately one hour every four weeks and at least 21 days apart.

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ Prescribed by or in consultation with a neurologist

AND

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- ❑ Member must be 50 years of age or older

AND

- ❑ Member has a confirmed diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia (there is insufficient evidence in moderate or severe Alzheimer's disease) based on **ONE** of the following dementia rating scales **(must submit baseline documentation)**:
  - ❑ Clinical Dementia Rating-Global score (CDR-GS) of 0.5
  - ❑ Mini-Mental State Exam (MMSE) score of 24-30
  - ❑ Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index score of 85 or below
  - ❑ Montreal Cognitive Assessment (MoCA) score of 19.0-25

AND

- ❑ Member has/is experiencing signs and symptoms of mild cognitive impairment characterized by skills that affect memory (i.e. inability to make sound decisions, judge time, sequence, steps needed to complete a complex task etc.) **(must submit chart note documentation)**

AND

- ❑ Provider must submit chart notes supporting that other differential diagnoses have been ruled out (e.g., dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), vascular dementia, pseudodementia due to mood disorder, vitamin B12 deficiency, encephalopathy, etc.)

AND

- ❑ Provider must submit documentation of beta-amyloid protein deposition, as evidenced by a positive amyloid positron emission tomography (PET) scan

AND

- ❑ Member must have undergone a recent (within the last year) brain magnetic resonance imaging (MRI) demonstrating **ALL** of the following **(must submit MRI results)**:
  - ❑ No brain hemorrhage > 1 cm within the past year
  - ❑ Less than 10 brain microhemorrhages
  - ❑ No localized superficial siderosis

AND

- ❑ Member 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 CHF, or clinically significant conduction abnormalities)

AND

- ❑ Member has not had a stroke, transient ischemic attack (TIA) or unexplained loss of consciousness in the past 12 months

AND

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- ❑ Member is not currently receiving anti-platelet agents (with the exception of prophylactic aspirin), anticoagulants (e.g., Factor Xa inhibitors), or anti-thrombins (e.g., heparin)

AND

- ❑ Member does not have impaired renal or liver function

AND

- ❑ Provider attests that counseling has been provided on the risk of amyloid-related imaging abnormalities (ARIA-E and ARIA-H) and member and/or caregiver are aware to monitor for headache, dizziness, visual disturbances, nausea and vomiting

AND

- ❑ Member has not had a clinically significant and unstable psychiatric illness in the past six months.

Continuation of Therapy – Approval Duration:

- ❑ Members with < 7 total infusions: up to the 6th total infusion (6 months)
- ❑ Members with < 12 total infusions but > 7 total infusions: up to the 11th total infusion (4 months)
- ❑ Members with > 12 total infusions: 6 infusions per PA approval (6 months)
- ❑ If infusion is missed, recommended to resume at the same dose as soon as possible. Infusions are administered every 4 weeks at least 21 days.

Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet the initial criteria

AND

- ❑ Member has responded to therapy compared to pretreatment baseline confirmed by improvement, stability, slowing cognitive and /or functional impairment or there has not been a clinically meaningful cognitive deterioration by **ONE** of the following assessments **(must submit documentation):**
  - ❑ Clinical Dementia Rating-Global score (CDR-GS) of 0.5 or Clinical Dementia Rating-Sum of Boxes (CDR-SB) score between 0.5-9
  - ❑ Mini-Mental State Exam (MMSE) score of 24-30
  - ❑ Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index score of 85 or below
  - ❑ Montreal Cognitive Assessment (MoCA) score of 19.0-25

AND

- ❑ Member has not progressed to moderate or severe dementia

AND

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- ❑ Provider continues to monitor member for the occurrence of any medical or neurological conditions (other than Alzheimer's disease) that may be a contributing cause to the member's cognitive impairment

AND

- ❑ Member has received a pre-7th AND 12th infusion MRI for monitoring of Amyloid Related Imaging Abnormalities-hemosiderin (ARIA-H) microhemorrhages. Results from MRI must meet one of the following:
  - ❑ Member has <10 new incident microhemorrhages or ≤2 focal areas of superficial siderosis (radiographic mild to moderate ARIA-H) are observed

    OR
  - ❑ Member has ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis (radiographic severe ARIA-H*) are observed **AND** treatment is continued with caution only after a clinical evaluation and subsequent follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H*)

Appendix/General Information

ARIA MRI Classification Criteria

ARIA Type	Radiographic Severity		
	Mild	**Moderate**	**Severe**
ARIA-E	FLAIR hyperintensity confined to sulcus and/or cortex/subcortical white matter in one location < 5cm	FLAIR hyperintensity 5 to 10 cm, or more than 1 site of involvement, each measuring <10 cm	FLAIR hyperintensity measuring > 10cm, often with significant subcortical white matter and/or sulcal involvement. One or more separate sites of involvement may be noted
ARIA-H microhemorrhage	≤ 4 new incident microhemorrhages	5 to 9 new incident microhemorrhages	10 or more new incident microhemorrhages
ARIA-H superficial siderosis	1 focal area of superficial siderosis	2 focal areas of superficial siderosis	>2 focal areas of superficial siderosis

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Appropriate use recommendations for the management of ARIA

If ARIA (ARIA-E or ARIA-H) is symptomatic, treatment should be suspended, and a comprehensive clinical assessment performed. MRI should then be repeated monthly; if symptoms resolve and the ARIA-E resolves or the ARIA-H stabilizes, treatment can be resumed. Patients who have severe symptoms (eg, seizure, stroke- like syndromes) should permanently discontinue aducanumab treatment.

If ARIA (ARIA-E or ARIA-H) is asymptomatic, the MRI is reviewed to determine if the ARIA is mild, moderate, or severe (applying definitions in the Prescribing Instructions and the Appropriate Use recommendations). Severe and moderate ARIA are managed using the same strategies described for symptomatic ARIA; treatment is paused and is re-initiated only if ARIA-E resolves or ARIA-H stabilizes. Dosing can be continued in mild ARIA that is asymptomatic but should be monitored with monthly MRIs.

Dementia Rating Scales

Type of dementia rating scale	Description	Rate
Clinical Dementia Rating-Global score (CDR-GS)	Useful for characterizing and tracking a patient's level of impairment/dementia	• 0 = normal • 0.5 = very mild dementia • 1 = mild dementia • 2 = moderate dementia • 3 = severe dementia
Mini-Mental State Exam (MMSE)	Series of questions asked by a health professional designed to test a range of everyday mental skills.	• 25 to 30 suggest normal cognition, • 20 to 24 suggests mild dementia, • 13 to 20 suggests moderate dementia, and • less than 12 indicates severe dementia.
Repeatable Battery for Assessment of Neuropsychological Status (RBANS)	Series of questions scaled for five cognitive domains such as immediate memory, delayed memory, attention, language, visuospatial	• Scale can range from 40 to 160. Mean score of 100 with a standard deviation of 15.
Montreal Cognitive Assessment MoCA	Series of questions to test cognitive domain relating to orientation, memory, visuospatial language, executive function	• 26-30=normal • 19.0-25=mild cognitive impairment • 21.0-11.4-alzheimers disease

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References

1. Lin GA, Whittington MD, Synnott PG, McKenna A, Campbell J, Pearson SD, Rind DM. Aducanumab for Alzheimer's Disease: Effectiveness and Value; Draft Evidence Report. Institute for Clinical and Economic Review, June 30, 2021. https://icer.org/assessment/alzheimers-disease-202
2. Aduhelm [package insert]. Cambridge, MA; Biogen Inc; July 2021
3. Langa, LM, Levine DA. The Diagnosis and Management of Mild Cognitive Impairment: A clinical Review
4. Alzheimer's Home Page: National Institute on Aging. Alzheimers.gov. https://www.alzheimers.gov/. Accessed on August 1, 2021.
5. Arvanitakis Z, Shah RC, Bennett DA. Diagnosis and management of dementia: a review. *JAMA*. 2019;322(16):1589-1599.
6. Biogen. 221AD302 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's Disease (**EMERGE**). Available from: https://clinicaltrials.gov/ct2/show/NCT02484547?term=NCT02484547&draw=2&rank=1. Accessed July 3, 2021
7. Biogen. 221AD301 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's Disease (**ENGAGE**). Available from: https://clinicaltrials.gov/ct2/show/NCT02477800?term=NCT02477800&draw=2&rank=1. Accessed June 3, 2021.
8. Cummings J. Aducanumab: Appropriate use recommendations. Alzheimer's Dementia.2021;1-3.

Medication being provided by (check box below that applies):

- ❑ Location/site of drug administration: _____

  NPI or DEA # of administering location: _____

OR

- ❑ Specialty Pharmacy - PropriumRx

For urgent reviews: Practitioner should call Optima Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Optima's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

Member Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee**: 9/16/2021
REVISED/UPDATED: 10/29/2021, **11/1/2021**