Prior Authorization Guideline

Guideline Name	Aduhelm (aducanumab-avwa)
Formulary	• Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	1/14/2022

1 . Criteria

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation confirming patient is enrolled in a clinical trial

AND

2 - Diagnosis of one of the following:

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

AND

3 - Submission of medical records (e.g., chart notes, laboratory values, examination histories) documenting the basis for diagnosis, including all of the following:

3.1 Documentation of a comprehensive history and neurological examination, inclusive of a description of the nature and duration of cognitive symptoms within the previous 3 months

AND

3.2 Medical records documenting baseline (within the previous three months) cognitive function based on ONE of the following objective assessments:

- Mini-Mental State Examination (MMSE) score ≥ 24
- Montreal Cognitive Assessment (MoCA) score ≥ 15

AND

3.3 Medical records documenting confirmed evidence of clinically significant AD neuropathology based on ONE of the following:

- Cerebral Spinal Fluid (CSF) biomarkers
- Amyloid positron emission tomography (PET)

AND

4 - Patient has received recent (within the previous 3 months) baseline brain magnetic resonance imaging (MRI) prior to initiating treatment

AND

5 - Patient does not have significant cerebrovascular disease as established by brain MRI showing any of the following:

- Acute or sub-acute hemorrhage

- Prior macro-hemorrhage or prior subarachnoid hemorrhage (unless finding is not due to an underlying structural or vascular hemorrhage)
- 4 or more brain microhemorrhages
- Cortical infarct
- More than 1 lacunar infarct
- Superficial siderosis
- History of diffuse white matter disease

AND

6 - Patient does not have any of the following non-AD neurodegenerative disorders:

- Probable dementia with Lewy bodies by consensus criteria
- Suspected frontotemporal degeneration
- Dementia in down syndrome

AND

7 - Patient does not have any of the following exclusionary neurological or psychiatric conditions:

- Uncontrolled seizure disorder
- Uncontrolled mood disorder, anxiety disorder, or psychosis
- Substance use disorder active in the past 2 years

AND

8 - Patient does not have any of the following cardiovascular conditions:

- Uncontrolled hypertension
- Coronary artery disease (including unstable angina and myocardial infarction)
- Heart failure
- Arrhythmia
- Clinically significant carotid atherosclerosis and/or peripheral arterial disease

AND

mercy care

9 - Both of the following:

- Patient is not currently taking an anticoagulant or antiplatelet agent (unless aspirin 325 mg/day or less)
- Patient has no history of transient ischemic attack (TIA), stroke, or unexplained loss of consciousness within previous year prior to initiating treatment

AND

10 - Patient does not have any uncontrolled clinically significant chronic medical condition (e.g., liver disease, kidney disease, pulmonary disease, autoimmune disease requiring chronic immunosuppression, malignant neoplasm, active chronic infection [HIV, HCV], poorly controlled diabetes mellitus)

AND

11 - Prescribed dosing is in accordance with the United States Food and Drug Administration approved labeling

AND

12 - Prescribed by or in consultation with one of the following:

- Neurologist
- Geriatrics specialist

AND

13 - Prescriber attests that the patient and/or authorized representative (e.g., power of attorney, invoked health care proxy) has shared in decision-making and has been informed on the known and potential risks and lack of established clinical benefit associated with Aduhelm (aducanumab-avwa) treatment

AND

14 - Therapy should be discontinued permanently and the request should be denied if one or more of the following apply:

- If the patient has had ≥ 10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic)
- If the patient had a serious event [Serious events include concern for immediate risk of death (a life-threatening event); inpatient hospitalization or prolongation of existing hospitalization due to symptoms; new persistent or significant disability/incapacity]
- If the patient has had ≥ 3 new incident areas of superficial siderosis, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied

Notes	*NOTE: If the patient has had ≥10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied. *NOTE: If the patient had a serious event, therapy should be discontinued. † *NOTE: If the patient has had ≥3 new incident areas of superficial siderosis, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied. †Serious events include concern for immediate risk of death (a life-threatening event); inpatient hospitalization or prolongation of existing hospitalization due to symptoms; new persistent or significant disability/incapacity. ‡Requests should be evaluated case-by-case with clinical review and MD advisor.

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation confirming patient remains enrolled in a clinical trial

AND

mercy care

2 - Prescribed dosing is in accordance with the United States Food and Drug Administration approved labeling

AND

3 - Follow-up MRIs have been conducted at the following timeframes:

- Week 14 (after 4th infusion, prior to first 6 mg/kg dose)
- Week 22 (after 6th infusion, prior to first 10 mg/kg dose)
- Week 30 (after 8th infusion, prior to third 10 mg/kg dose)
- Week 42 (after 11th infusion, prior to sixth 10 mg/kg dose)
- Every 6 months thereafter

AND

4 - Patient's diagnosis continues to be mild cognitive impairment or mild dementia stage due to Alzheimer's disease as established by one of the following examination scales:

4.1 One of the following:

- Mini Mental State Exam (MMSE) score ≥ 24
- Montreal Cognitive Assessment (MoCA) score ≥ 15

OR

4.2 Both of the following:

- MMSE <24 or MoCA <15
- Rate of decline was slower than expected (<2 points/year)

AND

5 - ONE of the following (ARIA-H, microhemorrhages):

- Patient has had no new incident microhemorrhage

- Patient has had 1 to 4 new incident microhemorrhage(s) AND microhemorrhages are asymptomatic (no clinical symptoms)
- Patient has had 5 to 9 new incident microhemorrhages AND microhemorrhages are asymptomatic (no clinical symptoms) AND the microhemorrhages have been stabilized
- Patient has had 1 to 9 new incident microhemorrhages AND microhemorrhages resulted in mild, moderate or severe clinical symptoms AND the microhemorrhages have been stabilized

AND

6 - ONE of the following (ARIA-H, superficial siderosis)

- Patient has had no new incident areas of superficial siderosis
- Patient has had 1 new incident area of superficial siderosis AND superficial siderosis is asymptomatic (no clinical symptoms)
- Patient has had 2 new incident areas of superficial siderosis AND superficial siderosis is asymptomatic (no clinical symptoms) AND the superficial siderosis has been stabilized
- Patient has had 1 to 2 new incident areas of superficial siderosis AND superficial siderosis resulted in mild, moderate or severe clinical symptoms AND the superficial siderosis has been stabilized

AND

7 - ONE of the following (ARIA-E)

- Patient has had no new ARIA-E
- Patient has mild ARIA-E on MRI AND ARIA-E is asymptomatic (no clinical symptoms)
- Patient has had moderate or severe ARIA-E on MRI AND ARIA-E is asymptomatic (no clinical symptoms) AND the ARIA-E is stable
- Patient has had mild, moderate or severe ARIA-E on MRI AND ARIA-E resulted in mild, moderate or severe clinical symptoms AND the ARIA-E is stable

AND

8 - One of the following:

8.1 Patient does not meet ANY of the following:

- Initiation of anticoagulation
- Development of active immune-mediated/autoimmune conditions (e.g., Crohn's disease, SLE, aplastic anemia, myasthenia gravis, meningitis/encephalitis)
- Initiation of immunomodulatory medications (e.g., cancer immunotherapies, rituximab, azathioprine)
- Development of other neurologic conditions (e.g., intracerebral bleeds, TBI, stroke)

OR

8.2 BOTH of the following:

- Patient does meet one of the above
- Prescriber documents clinical rationale for continued use of aducanumab‡

AND

9 - Prescribed by or in consultation with one of the following:

- Neurologist
- Geriatric specialist

AND

10 - Therapy should be discontinued permanently and the request should be denied if one or more of the following apply:

- If the patient has had ≥ 10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic)
- If the patient had a serious event [Serious events include concern for immediate risk of death (a life-threatening event); inpatient hospitalization or prolongation of existing hospitalization due to symptoms; new persistent or significant disability/incapacity]
- If the patient has had ≥ 3 new incident areas of superficial siderosis, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied

Notes	*NOTE: If the patient has had ≥10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied. *NOTE

	: If the patient had a serious event, therapy should be discontinued. † *NOTE: If the patient has had ≥3 new incident areas of superficial side rosis, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denie d. †Serious events include concern for immediate risk of death (a life-t hreatening event); inpatient hospitalization or prolongation of existing hospitalization due to symptoms; new persistent or significant disabilit y/incapacity. ‡Requests should be evaluated case-by-case with clinic al review and MD advisor.

2 . Background

Clinical Practice Guidelines

Appendix

ARIA - H (Microhemorrhages)

		New Incident Microhemorrhages		
		Radiographic Severity		
		Mild (1 to 4)	Moderate (5 to 9)	Severe (≥10)
Clinical Sympto m Severity	Asymptomatic	Continue treatment; MRI q4w until stable	Suspend treatment; MRI q4w until stable; Restart once stable	Stop Permanently
	Mild	Suspend treatment; MRI q4w until stable Restart once stable and clinical symptoms resolved		Stop Permanently
	Moderate			
	Severe			
	Serious	Stop Permanently		

ARIA - H (Superficial Siderosis)

		New Incident Areas of Superficial Siderosis (Central Read)		
		Radiographic Severity		
		Mild (1)	Moderate (2)	Severe (≥3)
Clinical Sympto	Asymptomatic	Continue treatment; MRI q4w until stable	Suspend treatment; MRI q4w until stable; Restart once stable	Stop Permanently

m Severity	Mild	Suspend treatment; MRI q4w until stable Restart once stable and clinical symptoms resolved	Stop Permanently
	Moderate		
	Severe		
	Serious	Stop Permanently	

ARIA - E

		ARIA-E Severity on MRI (Central Read)		
		Radiographic Severity		
		Mild	Moderate	Severe
Clinical Symptom Severity	Asymptomatic	Continue treatment; MRI q4w until stable	Suspend treatment; MRI q4w until stable; Restart once stable	
	Mild	Suspend treatment; MRI q4w until stable Restart once stable and clinical symptoms resolved		
	Moderate			
	Severe			
	Serious	Stop Permanently		

3 . Revision History

Date	Notes
1/13/2022	Added submission of confirmation patient is enrolled in a clinical trial to both initial and reauth criteria