Alzheimer's Agents:
Adlarity (donepezil patch)
Aduhelm (adacanumab-avwa)
Effective 03/01/2023

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	N/A		

Contact Information			
	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882

Exceptions	Aduhelm (adacanumab-avwa) is only available through medical benefit.

Overview

Adlarity® (donepezil patch) is indicated for the treatment of mild, moderate, and severe dementia of the Alzheimer's type.

Aduhelm® (aducanumab-avwa) is the first disease modifying therapy approved for the treatment of Alzheimer's disease. Of note, aducanumab received FDA approval based on a surrogate endpoint (reduction in amyloid-β plaques) and has not yet been shown to provide a clinical benefit. Aducanumab is a human immunoglobulin (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid-β, a defining pathophysiological feature of Alzheimer's disease.

Reference Table: †

No PA	**Drugs that require PA**
Cholinesterase Inhibitors	
	Adlarity® (donepezil patch)
Disease Modifying Agents	
	Aduhelm® (aducanumab-avwa)

†Use of donepezil-containing products in members less than 18 years of age is discussed in the MassHealth Pediatric Behavioral Health Medication Initiative guideline

The **Pediatric Behavioral Health Medication Initiative** may apply to MassHealth members <18 years of age due to polypharmacy, age, and/or drug restrictions. As indicated within this guideline, please refer to the **Pediatric Behavioral Health Initiative** guideline to assess appropriateness of therapy.

Coverage Guideline

Authorization may be granted for new members to the plan who are currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs, when continuation of therapy criteria is met.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Adlarity® (donepezil patch)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of Alzheimer's disease or dementia
2. Requested quantity is ≤ 4 units/28 days
3. Medical necessity for use instead of donepezil tablets or ODT *(forgetfulness/compliance as medical necessity for once-weekly patch is acceptable unless there are claims for daily scheduled medications)*

Aduhelm® (aducanumab-avwa)

Prescriber provided documentation of **ALL** of the following:

1. Diagnosis of mild cognitive impairment (MCI) or mild dementia associated with Alzheimer's Disease
2. Prescriber is a neurologist or geriatrics specialist or consult notes from a neurologist or geriatrics specialist are provided
3. Medical records documenting baseline (within the past three months) cognitive function based on **ONE** of the following objective assessments:
    a. Mini Mental State Exam (MMSE) score ≥ 24
    b. Montreal Cognitive Assessment (MoCA) score ≥ 15
4. Medical records documenting confirmed evidence of clinically significant AD neuropathology based on **ONE** of the following:
    a. Cerebral Spinal Fluid (CSF) biomarkers
    b. Amyloid positron emission tomography (PET)
5. Member has had a brain magnetic resonance imaging (MRI) in the previous three months
6. Appropriate dose
7. The member and/or authorized representative (e.g., power of attorney, invoked health care proxy) has been informed of the known and potential risks and lack of established clinical benefit associated with Aduhelm treatment
8. Member does **NOT** have ANY of the following non-AD neurodegenerative disorders:
    a. Probable dementia with Lewy bodies by consensus criteria
    b. Suspected frontotemporal degeneration
    c. Dementia in down syndrome
9. Member has **NOT** had ANY of the following in the past year:
    a. Stroke or transient ischemic attack
    b. Any unexplained loss of consciousness
10. Member does **NOT** have coagulopathy or requirement for therapeutic anticoagulation and/or dual antiplatelet therapy (only aspirin ≤325 mg/day monotherapy is allowed)
11. Member does **NOT** have ANY of the following neurological or psychiatric conditions:
    a. Uncontrolled seizure disorder
    b. Uncontrolled mood disorder, anxiety disorder or psychosis

12. Member does **NOT** have significant cerebrovascular disease as established by brain MRI showing ANY of the following:
    a. Acute or sub-acute hemorrhage
    b. Prior macro-hemorrhage or prior subarachnoid hemorrhage (unless finding is not due to an underlying structural or vascular hemorrhage)
    c. ≥4 microhemorrhages
    d. Cortical infarct
    e. >1 lacunar infarct
    f. Superficial siderosis
    g. History of diffuse white matter disease
13. Member does **NOT** have ANY of the following cardiovascular conditions:
    a. Uncontrolled hypertension
    b. Coronary artery disease (including unstable angina and myocardial infarction)
    c. Heart failure
    d. Arrhythmia
    e. Clinically significant carotid atherosclerosis and/or peripheral arterial disease
14. Member 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)

Continuation of Therapy

For **Adlarity**, reauthorization by prescriber will infer a positive response to therapy.

For **Aduhelm**, prescriber provides documentation of **ALL** of the following (see above for approval duration):

1. Appropriate dose
2. Follow-up MRIs have been conducted at the following timeframes:
    a. Week 14 (after 4th infusion, prior to first 6 mg/kg dose)
    b. Week 22 (after 6th infusion, prior to first 10 mg/kg dose)
    c. Week 30 (after 8th infusion, prior to third 10 mg/kg dose)
    d. Week 42 (after 11th infusion, prior to sixth 10 mg/kg dose)
    e. Every 6 months thereafter
3. A copy of MMSE or MoCA (within three months) documenting member has **NOT** had disease progression as established by **ONE** of the following:
    a. **ONE** of the following:
        i. MMSE ≥24
        ii. MoCA ≥15
    b. **BOTH** of the following:
        i. MMSE <24 or MoCA <15
        ii. Rate of decline was slower than expected (<2 points/year).
4. **ONE** of the following (Amyloid-related imaging abnormalities-hemosiderin [ARIA-H], microhemorrhages):[*‡]
    a. Member has had no new incident microhemorrhage
    b. Member has had 1 to 4 new incident microhemorrhage(s) **AND** microhemorrhages are asymptomatic (no clinical symptoms)
    c. Member has had 5 to 9 new incident microhemorrhages **AND** microhemorrhages are asymptomatic (no clinical symptoms) **AND** the microhemorrhages have been stabilized

   d. Member has had 1 to 9 new incident microhemorrhages **AND** microhemorrhages resulted in mild, moderate or severe clinical symptoms **AND** the microhemorrhages have been stabilized
5. **ONE** of the following (ARIA-H, superficial siderosis): † ‡
   a. Member has had no new incident areas of superficial siderosis
   b. Member has had 1 new incident area of superficial siderosis **AND** superficial siderosis is asymptomatic (no clinical symptoms)
   c. Member has had 2 new incident areas of superficial siderosis **AND** superficial siderosis is asymptomatic (no clinical symptoms) **AND** the superficial siderosis has been stabilized
   d. Member 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
6. **ONE** of the following (Amyloid-related imaging abnormalities-edema [ARIA-E]):
   a. Member has had no new ARIA-E
   b. Member has mild ARIA-E on MRI AND ARIA-E is asymptomatic (no clinical symptoms)
   c. Member has had moderate or severe ARIA-E on MRI AND ARIA-E is asymptomatic (no clinical symptoms) AND the ARIA-E is stable
   d. Member 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
7. **ONE** of the following:
   a. Member does **NOT** have ANY of the following:
      i. Initiation of anticoagulation
      ii. Development of active immune-mediated/autoimmune conditions (e.g., Crohn's disease, systemic lupus erythematosus, aplastic anemia, myasthenia gravis, meningitis/encephalitis)
      iii. Initiation of immunomodulatory medications (e.g., cancer immunotherapies, rituximab, azathioprine)
      iv. Development of other neurologic conditions (e.g., intracerebral bleeds, traumatic brain injury, stroke)
   b. Clinical rationale for continued use of Aduhelm§ in a member with at least one of the above noted conditions

Notes:

- **If the member has had ≥10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied.*
- *†If the member 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.*
- *‡If the member had a serious event, therapy should be discontinued. 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.*

Limitations

1. Initial approvals will be granted for:
   a. Aduhelm: 6 months
   b. All other agents: 12 months

2. Reauthorizations will be granted:
    a. Aduhelm: 6 months
    b. All other agents: 12 months
3. The following quantity limits apply:

Adlarity	4 units per 28 days

4. Dosing

Drug	Dosing
Aduhelm® (aducanumab-avwa) **Vial:** 170 mg/1.7 mL 300 mg/3 mL	1 mg/kg IV every four weeks x2 doses, followed by 3 mg/kg IV every four weeks x2 doses, followed by 6 mg/kg IV every four weeks x2 doses, followed by 10 mg/kg IV every four weeks.

Appendix A - Anticoagulant and Antiplatelet Agents

Members who are utilizing anticoagulant or dual antiplatelet therapy are excluded from utilizing Aduhelm®. Only use of aspirin (≤325 mg/day is allowed). Members utilizing any of the following medications should be denied.

Class	Agents
Direct Thrombin Inhibitors	Dabigatran etexilate mesylate (Pradaxa®)
Factor Xa Inhibitors	Apixaban (Eliquis®) Edoxaban (Savaysa®) Fondaparinux (Arixtra®) Rivaroxaban (Xarelto®)
Low Molecular Weight Heparins	Dalteparin (Fragmin®) Enoxaparin (Lovenox®)
Vitamin K Antagonists	Warfarin
Antiplatelet Agents	Anagrelide (Agrylin®) Cilostazol Clopidogrel (Plavix®) Dipyridamole (±aspirin) Prasugrel (Effient®) Ticagrelor (Brilinta®) Vorapaxar (Zontivity®)

Appendix B - Side-Effect Protocol

ARIA - H (Microhemorrhages)

<table>
<tr><th colspan="2" rowspan="3"></th><th colspan="3">New Incident Microhemorrhages</th></tr>
<tr><th colspan="3">Radiographic Severity</th></tr>
<tr><th>Mild (1 to 4)</th><th>Moderate (5 to 9)</th><th>Severe (≥10)</th></tr>
<tr><td rowspan="5">Clinical Symptom Severity</td><td>Asymptomatic</td><td>Continue treatment;
MRI q4w until stable</td><td>Suspend treatment;
MRI q4w until stable;
Restart once stable</td><td>Stop Permanently</td></tr>
<tr><td>Mild</td><td colspan="2" rowspan="3">Suspend treatment;
MRI q4w until stable
Restart once stable and clinical symptoms resolved</td><td rowspan="3">Stop Permanently</td></tr>
<tr><td>Moderate</td></tr>
<tr><td>Severe</td></tr>
<tr><td>Serious*</td><td colspan="3">Stop Permanently</td></tr>
</table>

ARIA - H (Superficial Siderosis)

		New Incident Areas of Superficial Siderosis (Central Read)		
		Radiographic Severity		
		Mild (1)	Moderate (2)	Severe (≥3)
Clinical Symptom 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 - 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		

*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.

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Review History

03/16/2022 – Reviewed and Created for March P&T; Match MH criteria Effective 05/01/2022.
01/11/2023 - Reviewed and updated for Jan P&T. Matched MH UPPL criteria. Adlarity was added to pharmacy benefit with PA and QL. Updated approval durations. Effective 3/1/23.

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.