

Alzheimer's Disease (Monoclonal Antibodies)

Goal(s):

- To support medically appropriate and safe use of Alzheimer Dementia drugs (as designated by the FDA)
- To limit off-label use of Alzheimer's Dementia drugs

Length of Authorization:

- Up to 6 months

Requires PA:

- Pharmacy point-of-sale and provider-administered claims

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at <http://www.orpdl.org/drugs/>

Table 1. Dosing and ARIA Monitoring

Drug	MRI Timing for ARIA Monitoring	Dosing	Frequency of Administration	
Donanemab	Prior to Infusion 2 (no longer than 1 year)	See Prescribing Information for dosing recommendations and for interruptions in therapy due to ARIA.	Every 4 Weeks	
	Prior to Infusion 3			
	Prior to Infusion 4			
	Prior to Infusion 7			
	Annually			
Lecanemab	Prior to infusion 1 (no longer than 1 year)		See Prescribing Information for dosing recommendations and for interruptions in therapy due to ARIA.	Every 2 Weeks
	Prior to Infusion 5			
	Prior to Infusion 7			
	Prior to infusion 14			
	Annually			

ARIA = amyloid related imaging abnormalities; IV = intravenous; MRI = magnetic resonance imaging

Approval Criteria

1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the drug to be used for treatment of a patient diagnosed with Alzheimer's Dementia AND has the prescriber ruled out other types of dementia (e.g., vascular dementia, Lewy body, and frontotemporal)?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Is the request for continuation of therapy in a patient previously approved by FFS?	Yes: Go to Renewal Criteria	No: Go to #4
4. Is the therapy prescribed by or in consultation with a neurologist?	Yes: Go to #5	No: Pass to RPh. Deny; medical appropriateness

Approval Criteria

<p>5. Is the patient between 50 and 90 years of age?</p>	<p>Yes: Go to #6</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>6. Is there documented evidence that the patient has mild cognitive impairment due to Alzheimer’s disease or mild Alzheimer’s dementia as evidenced by the following assessments performed within the last 6 months:</p> <ul style="list-style-type: none"> • Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 or 1.0 AND • Mini-Mental Status Exam (MMSE) score between 22 and 30 (inclusive) AND • Positron Emission Tomography (PET) scan positive for elevated amyloid beta plaque or presence of elevated amyloid and/or elevated phosphorylated tau confirmed in cerebrospinal fluid (CSF)? 	<p>Yes: Go to #7</p> <p>Document test results and dates.</p> <p>_____</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p> <p>There is insufficient evidence for use of this agent in treating moderate or severe AD</p>
<p>7. Has the prescriber assessed and documented baseline disease severity within the last 6 months utilizing an objective measure/tool (e.g. Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB], MMSE, or other validated AD monitoring tool)?</p>	<p>Yes: Record baseline measurement.</p> <p>_____</p> <p>Go to #8</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>8. Has the patient received a baseline brain magnetic resonance imaging (MRI) within 1 year prior to initiating treatment with no evidence of pre-treatment localized superficial siderosis or brain hemorrhage?</p>	<p>Yes: Go to #9</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>9. Has the prescriber scheduled additional brain MRIs to be obtained as outlined in Table 1 to evaluate for the presence of asymptomatic amyloid related imaging abnormalities [ARIA-E]-edema (brain swelling) and/or [ARIA-H]-hemorrhage (brain bleeding or protein deposits on brain/spinal cord)?</p>	<p>Yes: Record scheduled appointment dates:</p> <p>_____</p> <p>Go to #10</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>

Approval Criteria

<p>10. Is the patient currently receiving anticoagulant or antiplatelet therapy (excluding aspirin 81 mg)?</p>	<p>Yes: Pass to RPh. Deny; medical appropriateness</p>	<p>No: Go to #11.</p>
<p>11. Is there documentation based on medical records that the prescriber has tested the patient for the presence of apolipoprotein E4 (ApoE4) and, if a carrier, has discussed benefits and risks associated with therapy?</p> <p>Note: Patients who are ApoE4 homozygotes have a higher risk of ARIA, including symptomatic, serious, and severe radiographic ARIA compared to heterozygotes and non-carriers.</p>	<p>Yes: Approve for up to 6 months</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>

Renewal Criteria

<p>1. Is there documented evidence that the patient has mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia as evidenced by the following assessments performed within the last 30 days:</p> <ul style="list-style-type: none"> • Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 or 1.0; AND • Objective evidence of cognitive impairment at screening; AND • Mini-Mental Status Exam (MMSE) score between 22 and 30 (inclusive) 	<p>Yes: Go to #2</p> <p>Document test results and dates:</p> <hr style="width: 20%; margin-left: 0;"/>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>2. Is there documented evidence of follow-up MRIs performed and/or scheduled as recommended in Table 1 for therapy safety surveillance?</p>	<p>Yes: Go to #3</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>3. Was there a serious adverse event (symptomatic moderate to severe ARIA-H or ARIA-E [brain microhemorrhage, superficial siderosis, or edema]) observed or reported with therapy?</p>	<p>Yes: Pass to RPh. Deny; medical appropriateness</p>	<p>No: Go to #4</p>
<p>4. Has the patient received at least 6 months of uninterrupted therapy?</p>	<p>Yes: Go to #5</p>	<p>No: Approve remaining duration of the 6-month titration period</p>

Renewal Criteria		
5. Is the request for donanemab?	Yes: Go to #6	No: Go to #8
6. Has PET imaging been performed within the last 6 months to confirm the presence of amyloid plaques?	Yes: Go to #7	No: Pass to RPh. Deny; medical appropriateness
7. Does the patient have amyloid plaque levels at <11 centiloids on a single PET scan or 11 to <25 on consecutive months	Yes: Pass to RPh. Deny; medical Appropriateness In clinical studies, dosing was stopped based on a reduction of amyloid levels below predefined thresholds on PET imaging.	No: Go to #8
8. Is there documentation that, compared to baseline assessment, therapy has resulted in: <ul style="list-style-type: none"> • cognitive or functional improvement OR • disease stabilization OR • a reduction in rate of clinical decline compared to the natural disease progression? The same clinical measure used to assess AD (e.g., CDR-GS, MMSE, ADAS-Cog, ADCS-ADL-MCI, etc) is recommended to document clinical benefit.	Yes: Approve for up to 6 months Document benefit: _____ _____	No: Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 12/24 (DE);10/23;10/21
 Implementation: 1/1/25; 11/1/23; 1/1/22