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 physician-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 www.orpdl.org/drugs/

Table 1. Dosing and ARIA Monitoring

Drug	MRI Timing for ARIA Monitoring	Dosing	Frequency of Administration
Aducanumab	90 days prior to Infusion 1	See Prescribing Information for dosing recommendations and for interruptions in therapy due to ARIA.	Every 4 Weeks
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	28 days prior to Infusion 7		
	28 days prior to Infusion 12		
	Annually		
Lecanemab	At least 28 days prior to infusion 1 (no longer than 1 year)		Every 2 Weeks
	28 days prior to Infusion 5		
	28 days prior to Infusion 7		
	28 days prior to infusion 14		

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		
5. Is the patient between 50 and 90 years of age?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
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: • 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)?	**Yes:** Go to #7 Document test results and dates. _____	**No:** Pass to RPh. Deny; medical appropriateness There is insufficient evidence for use of this agent in treating moderate or severe AD
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)?	**Yes:** Record baseline measurement. _____ Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Has the patient received a baseline brain magnetic resonance imaging (MRI) within 90 days prior to initiating treatment with no evidence of pre-treatment localized superficial siderosis or brain hemorrhage?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
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)?	**Yes:** Record scheduled appointment dates: _____ Go to #10	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
10. Has the patient been screened to ensure they are not currently receiving anticoagulant or antiplatelet therapy (excluding aspirin 81 mg)?	**Yes:** Go to #11.	**No:** Pass to RPh. Deny; medical appropriateness
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? Patient who are ApoE4 homozygotes have a higher risk of ARIA, including symptomatic, serious, and severe radiographic ARIA compared to heterozygotes and non-carriers.	**Yes:** Approve for up to 6 months	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
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: • 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)	**Yes:** Go to #2 Document test results and dates: _____	**No:** Pass to RPh. Deny; medical appropriateness
2. Is there documented evidence of follow-up MRIs performed and/or scheduled as recommended in Table 1 for therapy safety surveillance?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
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?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #4

Renewal Criteria		
4. Has the patient received at least 6 months of uninterrupted therapy?	**Yes:** Go to #5	**No:** Approve remaining duration of the 6-month titration period
5. Is there documentation that, compared to baseline assessment, therapy has resulted in: • cognitive or functional improvement **OR** • disease stabilization **OR** • a reduction in 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

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