Aducanumab

Goal(s):
- To support medically appropriate 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 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. Aducanumab Dosing and ARIA Monitoring

IV Infusion (every 4 weeks)	Dose	ARIA Monitoring
Infusion 1 and 2	1 mg/kg	MRI 90 days prior to Infusion 1
Infusion 3 and 4	3 mg/kg	MRI 28 days prior to Infusion 7
Infusion 5 and 6	6 mg/kg	
Infusion 7 to 11	10 mg/kg	MRI 28 days prior to Infusion 12
After Infusion 12	10 mg/kg	MRI annually

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

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this being 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. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require a PA. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee.	**Yes:** Inform prescriber of covered alternatives in class.	**No:** Go to #4
4. Is the request for continuation of therapy in a patient previously approved by FFS?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #5

Approval Criteria		
5. Is the therapy prescribed by or in consultation with a neurologist?	**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 (CDR)-Global Score of 0.5; **AND** • Objective evidence of cognitive impairment at screening; **AND** • Mini-Mental Status Exam (MMSE) score between 24 and 30 (inclusive); **AND** • Positron Emission Tomography (PET) scan positive for amyloid beta plaque or presence of amyloid confirmed in cerebrospinal fluid (CSF)?	**Yes:** Go to #7 Document test results.	**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 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 #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Has the prescriber assessed and documented baseline disease severity within the last 6 months utilizing an objective measure/tool (e.g., MMSE, Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13], 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], or other validated AD patient monitoring tool)?	**Yes:** Record baseline measurement. Go to #9	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
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**]-hemosiderin deposition (brain bleeding or protein deposits on brain/spinal cord)?	**Yes:** Record scheduled appointment dates: _____ Go to #10	**No:** Pass to RPh. Deny; medical appropriateness
10. Has the prescriber ruled out the presence of any vascular abnormalities which may increase bleeding risk/ARIA **AND** has the patient been screened to ensure they are not currently receiving anticoagulant or antiplatelet therapy (excluding aspirin 81 mg)?	**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 (CDR)-Global Score of 0.5; AND • Objective evidence of cognitive impairment at screening; AND • Mini-Mental Status Exam (MMSE) score between 24 and 30 (inclusive)	**Yes:** Go to #2	**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. Is there documented evidence of beta-amyloid reduction compared to baseline confirmed by post-infusion brain imaging or CSF testing?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
4. Was there an adverse event (ARIA-H or ARIA-E [brain microhemorrhage, superficial siderosis, or edema], hypersensitivity reaction, etc.) observed or reported with aducanumab therapy?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #5
5. Has the patient received at least 6 months of uninterrupted aducanumab therapy?	**Yes:** Go to #6	**No:** Approve remaining duration of the 6-month titration period
6. Is there documentation that, compared to baseline assessment, aducanumab therapy has resulted in: • cognitive or functional improvement **OR** • disease stabilization **OR** • reduction in clinical decline compared to the natural disease progression? The same clinical measure used to assess AD (e.g., CDR-SB, MMSE, ADAS-Cog-13, 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: 10/21 (DE)
Implementation: 1//1/22