Aducanumab

Included Products: Aduhelm (aducanumab-avwa)

Nonformulary for outpatient benefit. PA required on medical benefit.

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Alzheimer's disease

Initial Criteria		If yes	If no
1.	Is the therapy prescribed by or in consultation with a neurologist?	Continue to #2.	Do not approve.
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)?	Continue to #3.	Do not approve.
3.	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: a. Clinical Dementia Rating (CDR)-Global Score of 0.5; AND b. Objective evidence of cognitive impairment at screening; AND c. Mini-Mental Status Exam (MMSE) score between 24 and 30 (inclusive); AND d. Positron Emission Tomography (PET) scan positive for amyloid beta plaque or presence of amyloid confirmed in cerebrospinal fluid (CSF)?	Continue to #4.	Do not approve. There is insufficient evidence for use of this agent in treating moderate or severe AD.
4.	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?	Continue to #5.	Do not approve.

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5.	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 ScaleCognitive Subscale [ADAS-Cog-13], Alzheimer's Disease Cooperative StudyActivities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADLMCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB], or other validated AD patient monitoring tool)?	Continue to #6.	Do not approve.
6.	Has the prescriber scheduled additional brain MRIs to be obtained as outlined below 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)?	Continue to #7.	Do not approve.
7.	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)?	Continue to #8.	Do not approve.
8.	Approve for 6 months.		
Renewal Criteria		**If yes**	**If no**
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: a. Clinical Dementia Rating (CDR)- Global Score of 0.5; AND b. Objective evidence of cognitive impairment at screening; AND c. Mini-Mental Status Exam (MMSE) score between 24 and 30 (inclusive)	Continue to #2.	Do not approve.
2.	Is there documented evidence of follow-up MRIs performed and/or scheduled as recommended below for therapy safety surveillance?	Continue to #3.	Do not approve.
3.	Is there documented evidence of betaamyloid reduction compared to baseline confirmed by post-infusion brain imaging or CSF testing?	Continue to #4.	Do not approve.
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?	Do not approve.	Continue to #5.

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5.	Has the patient received at least 6 months of uninterrupted aducanumab therapy?	Continue to #6.	Approve remaining duration of the 6-month titration period.
6.	Is there documentation that, compared to baseline assessment, aducanumab therapy has resulted in: a. cognitive or functional improvement OR b. disease stabilization OR c. reduction in clinical decline compared to the natural disease progression? d. The same clinical measure used to assess AD (e.g., CDR-SB, MMSE, ADAS-Cog-13, ADCSADL-MCI, etc) is recommended to document clinical benefit.	Continue to #7.	Do not approve.
7.	Approve for up to 6 months.		

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