

Appendix C: Matrix of 12 state drug formularies' prescribing criteria

State Criteria - Age of Patient											
ALASKA	CALIFORNIA	FLORIDA	KENTUCKY	LOUISIANA	MARYLAND	MINNESOTA	MONTANA	NEW YORK	NORTH CAROLINA	PENNSYLVANIA	TEXAS
Patient is 50 years of age or older	Patient must be 50 to 85 years old. Or patient is 50 years old or younger and has early onset Alzheimer's disease (AD) and meets eligibility criteria.	Patient must be ≥ 18 years of age	[Not mentioned]	The recipient is 50 years of age or older on the date of the request	Adults ≥ 50 years	Patient is at least 50 years of age	Member must be 50 years of age or older	[Not mentioned]	Beneficiary is age 50 or older	[Not mentioned]	[Not mentioned]

State Criteria - Prescriber											
ALASKA	CALIFORNIA	FLORIDA	KENTUCKY	LOUISIANA	MARYLAND	MINNESOTA	MONTANA	NEW YORK	NORTH CAROLINA	PENNSYLVANIA	TEXAS
Prescribed by or in consultation with a neurologist	Must be prescribed by or in consultation with a neurologist, geriatrician, or psychiatrist.	Drug must be prescribed by, or in consultation with, a specialist in neurology or gerontology; AND	Prescribed by or in consultation with a Neurologist, Geriatrician, Geropsychiatric	The medication is prescribed by a neurologist	Neurologist, geriatric provider	Aduhelm must be prescribed by a neurologist	Must be prescribed by a neurology specialist	Not defined	Not defined	Is prescribed Aduhelm (aducanumab) by a dementia specialist (e.g., neurologist, psychiatrist, or geriatrician) who will monitor and assess the beneficiary at least once every 3 months	Not defined

State Criteria - Validated MCI/ mild AD diagnosis assessment scales

ALASKA	CALIFORNIA	FLORIDA	KENTUCKY	LOUISIANA	MARYLAND	MINNESOTA	MONTANA	NEW YORK	NORTH CAROLINA	PENNSYLVANIA	TEXAS
Patient has the diagnosis of Alzheimer's disease	Patient must have a diagnosis of mild cognitive impairment (MCI) due to AD or mild AD disease and must have: • A global Clinical Dementia Rating (CDR) score of 0.5 • A Mini-Mental State Examination (MMSE) score of 24 to 30	Patient has mild cognitive impairment (MCI) due to Alzheimer's disease or mild dementia (there is insufficient evidence in moderate or severe AD) as evidenced by all the following: • Clinical Dementia Rating (CDR)-Global Score of 0.5; AND • Mini-Mental Status Exam (MMSE) score between 24 and 30 (inclusive)	Provider attestation that the member has a diagnosis of mild cognitive impairment (MCI) due to AD or mild dementia associated with AD disease dementia.	The prescriber has documented objective evidence of mild cognitive impairment or mild dementia due to Alzheimer's disease using BOTH of the following tests: • The recipient has a Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 (score must be stated on the request); AND • The recipient has a Mini-Mental State Exam (MMSE) score of ≥ 24 (score must be stated on the request)	Submit baseline evaluation and monitoring (all objective data must be submitted with PA request). Include documentation of: • Recent (within one year) brain MRI prior to initiating treatment • Baseline cognitive testing (establishing mild cognitive impairment or mild dementia); CDR-SB, MMSE, ADAS-Cog 13 and ADCS-ADL-MCI • Assessment of CNS bleed risk including no history of stroke/TIA within the past year	Patient has a diagnosis of Alzheimer's disease with mild cognitive impairment or mild dementia as demonstrated by 3 validated scales, one of which must be the MMSE (Mini Mental State Exam)	Member has mild cognitive impairment due to Alzheimer's disease or has mild Alzheimer's dementia stage of disease as evidenced by all of the following: • Clinical Dementia Rating (CDR)-Global Score of 0.5 • Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index score ≤ 85 • Mini-Mental Status Exam (MMSE) score between 24 and 30	Prescribers must attest that the patient has been diagnosed with mild cognitive impairment due to Alzheimer's Disease or mild Alzheimer's dementia by meeting one of the following: • Clinical Dementia Rating (CDR)-Global Score of 0.5 to 1 • Mini-Mental Status Exam (MMSE) score between 24 and 30 • Montreal Cognitive Assessment (MoCA) score of at least 18	Beneficiary has mild cognitive impairment (MCI) due to Alzheimer's disease or has mild Alzheimer's dementia as evidenced by all of the following: 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) OR equivalent tool indicating MCI or mild dementia (NOTE: range of scores may be adjusted based on educational status of patient)	Has at least two of the following: a. Mini-Mental State Examination (MMSE) score of at least 24, b. Montreal Cognitive Assessment (MoCA) score of at least 18, c. Global Clinical Dementia Rating Scale (CDR) score of 0.5;	The client has a confirmed diagnosis of Alzheimer's disease (diagnosis code G300, G301, G308, or G309).

State Criteria - Biomarkers for amyloid positivity

ALASKA	CALIFORNIA	FLORIDA	KENTUCKY	LOUISIANA	MARYLAND	MINNESOTA	MONTANA	NEW YORK	NORTH CAROLINA	PENNSYLVANIA	TEXAS
<p>Patient has the presence of beta-amyloid plaques verified by either a positron emission tomography (PET) scan or cerebrospinal fluid (CSF) testing</p>	<p>A positive amyloid Positron Emission Tomography (PET) scan or cerebrospinal fluid (CSF) testing for tau proteins.</p>	<p>Positron Emission Tomography (PET) scan is positive for amyloid beta plaque;</p>	<p>Confirmation of beta-amyloid plaques verified by one of the following: <ul style="list-style-type: none"> • Positron emission tomography (PET) scan OR • Lumbar puncture for cerebrospinal fluid (CSF) testing </p>	<p>Presence of beta-amyloid plaques is verified by one of the following (must be stated on the request): <ul style="list-style-type: none"> • Positron emission tomography (PET) scan; OR • Cerebrospinal fluid (CSF) testing; </p>	<p>[Not mentioned]</p>	<p>Patient's Alzheimer's disease is of confirmed beta amyloid pathology as evidenced by ONE of the following: <ul style="list-style-type: none"> • A positive amyloid PET scan interpreted by a radiologist or nuclear medicine specialist OR • Amyloid is detected in CSF from a lumbar puncture </p>	<p>Member must have had a positive amyloid Positron Emission Tomography (PET) scan</p>	<p>Prescribers must attest that the patient has undergone the following pre-treatment testing: <ul style="list-style-type: none"> • Genetic testing to assess apolipoprotein Eε4 carrier status AND • Positron emission tomography (PET) scan or cerebrospinal fluid (CSF) analysis to confirm the presence of amyloid beta deposits </p>	<p>[Not mentioned]</p>	<p>Has baseline magnetic resonance imaging (MRI) results as recommended in the FDA-approved package labeling; AND Has a positron emission tomography (PET) scan positive for beta-amyloid plaques</p>	<p>The prescriber confirms that amyloid-beta plaques are present.</p>

State criteria - Test evidence of cognitive impairment

ALASKA	CALIFORNIA	FLORIDA	KENTUCKY	LOUISIANA	MARYLAND	MINNESOTA	MONTANA	NEW YORK	NORTH CAROLINA	PENNSYLVANIA	TEXAS
<p>Must have objective evidence of cognitive impairment at screening AND;</p> <ul style="list-style-type: none"> • Patient has a Clinical Dementia Rating (CDR) global score of 0.5 AND; • Patient has a Mini-Mental State Exam (MMSE) of greater than or equal to 24 	<p>An objective evidence of cognitive impairment at screening</p>	<p>Objective evidence of cognitive impairment at screening</p>	<p>Prescriber has assessed and documented baseline disease severity utilizing one of the following scores (within the past 6 months):</p> <ul style="list-style-type: none"> • Mini-Mental Status Exam (MMSE) score \geq 24 • Montreal Cognitive Assessment (MoCA) \geq 15 	<p>The prescriber has assessed and documented baseline disease severity utilizing a validated tool including, but not limited to, the following:</p> <ul style="list-style-type: none"> • Alzheimer's Disease Assessment Scale – Cognitive Subscale (ADAS-Cog-13); OR • Repeatable Battery for the Assessment of Neuropsychological Status (RBANS); OR • Clinical Dementia Rating – Sum of Boxes (CDR-SB); OR • Montreal Cognitive Assessment (MoCA). <p>[name of tool and date of test must be stated on the request]</p>	<p>Baseline cognitive testing (establishing mild cognitive impairment or mild dementia): CDR-SB, MMSE, ADAS-Cog 13 and ADCS-ADL-MCI</p>	<p>[Not mentioned]</p>	<p>Objective evidence of cognitive impairment at screening</p>	<p>[Not included]</p>	<p>Prescriber has assessed and documented baseline disease severity 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]).</p>	<p>Has repeat testing and documented results of at least two of the following:</p> <ol style="list-style-type: none"> MMSE MoCA CDR 	<p>Clinical testing must confirm that the client has mild cognitive impairment caused by Alzheimer's disease or a mild stage of Alzheimer's disease.</p>

State criteria - MRI at baseline

ALASKA	CALIFORNIA	FLORIDA	KENTUCKY	LOUISIANA	MARYLAND	MINNESOTA	MONTANA	NEW YORK	NORTH CAROLINA	PENNSYLVANIA	TEXAS
<p>Patient must have a documented brain magnetic resonance imaging (MRI) within the last year showing no localized superficial siderosis, has less than 10 brain microhemorrhages, and no brain hemorrhages that are greater than 1 cm in the past year</p>	<p>Patient must have an MRI at baseline and at 7 and 12 months to monitor for amyloid-related imaging abnormalities (ARIA).</p>	<p>Patient has received a baseline brain magnetic resonance imaging (MRI) prior to initiating treatment (within 1 year prior);</p>	<p>[Not included]</p>	<p>The recipient has no contra indications to magnetic resonance imaging (MRI) and has had a brain MRI within the past 12 months (date must be specified) demonstrating all of the following (must be stated on the request):</p> <ul style="list-style-type: none"> • No localized superficial siderosis; AND • Less than 10 brain microhemorrhages; AND • No brain hemorrhage > 1 cm within the past year. <p>The recipient does not have a history of unstable angina, myocardial infarction, advanced chronic heart failure, clinically significant conduction abnormalities or unexplained loss of consciousness within 1 year of treatment initiation; AND</p> <ul style="list-style-type: none"> • The recipient has not had a seizure in the past 3 years 	<p>Recent (within one year) brain MRI prior to initiating treatment</p>	<p>Patient has had a brain MRI within the past 12 months that does NOT show ANY of the following:</p> <ul style="list-style-type: none"> • Pre-treatment localized superficial siderosis OR • 10 or more brain microhemorrhages <p>OR</p> <ul style="list-style-type: none"> • A brain hemorrhage greater than 1 cm 	<ul style="list-style-type: none"> • Adult must have recent brain MRI (within one year) prior to initiating treatment. • Adult must not have had a stroke or TIA within past year. • Member must not be currently taking any medication with platelet anti-aggregate or anti-coagulant properties (unless aspirin ≤ 325mg daily). 	<p>[Not included]</p>	<p>Beneficiary has had a recent (within one year) brain magnetic resonance imaging (MRI) prior to initiating treatment.</p>	<p>Patient does not have a brain MRI showing evidence of acute or sub-acute micro- or macro-hemorrhage, greater than 4 microhemorrhages, cortical infarct or greater than 1 lacunar infarct.</p>	<p>Documentation shows that the client has received a baseline magnetic resonance imaging (MRI) scan of the brain within the year prior to initiating treatment.</p> <p>The client must not be currently taking any anti-coagulant (except for aspirin at a prophylactic dose or less) or have a history of a clotting disorder.</p>

State criteria - Exclusion of other causes of cognitive impairment											
ALASKA	CALIFORNIA	FLORIDA	KENTUCKY	LOUISIANA	MARYLAND	MINNESOTA	MONTANA	NEW YORK	NORTH CAROLINA	PENNSYLVANIA	TEXAS
Other known causes of dementia have been ruled out (i.e., vascular dementia, Parkinson's disease, dementia, etc.)	All other causes of cognitive impairment have been excluded such as the following: • Vascular dementia (for example, stroke, transient ischemic attack) • Lewy body dementia • Frontotemporal dementia	Other conditions mimicking, but of non-Alzheimer's dementia etiology, have been ruled out (e.g., vascular dementia, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD], normal pressure hydrocephalus)	Adult does NOT have any medical or neurological condition (other than Alzheimer's Disease) that might be a contributing cause of the subject's cognitive impairment, specifically ruling out ALL of the following: vascular dementia; and lewy body dementia; and frontotemporal dementia; and dementia in Down's syndrome; and Parkinson's disease dementia	Prescriber states on the request that other causes of cognitive impairment have been ruled out (including, but not limited to, alcohol/substance abuse, frontotemporal dementia (FTD), Lewy body dementia (LBD), Parkinson's disease dementia, unstable psychiatric illness, and vascular dementia)	[Not mentioned]	Patient has undergone a complete physical and neurological exam to comprehensively rule out all other possible causes of neurocognitive decline including but not limited to: • Any medication potentially causing cognitive impairment must have been stopped for at least 4 weeks with continued cognitive symptoms • Currently uncontrolled psychiatric condition (including alcohol or substance abuse) • Parkinson's disease • Lewy body dementia • Vascular dementia (such as from a stroke)	Provider has ruled out any other medical or neurological conditions (other than Alzheimer's Disease) that may be contributing to member's cognitive impairment, including any medications that can substantially contribute to cognitive impairment (see Beer's List).	Prescribers must attest that the patient does not have evidence of any medical or neurological condition other than Alzheimer's Disease that could be contributing to the patient's cognitive impairment	Beneficiary has undergone testing to rule out reversible causes of dementia (ex. CBC, CMP, TSH, B12, urine drug screen, RPR/VDRL, folate (if alcohol abuse is present), HIV (if risk present) and has had an assessment including a review of current medications as a cause of intellectual decline.	Does not have any of the following: a. A medical or neurological condition (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment b. A history of stroke or transient ischemic attack (TIA) or unexplained loss of consciousness in the past year.	The prescriber attests that other forms of dementia except Alzheimer's disease have been ruled out by appropriate lab or other diagnostic testing.