Medica Coverage Policy

Policy Name:	**Aduhelm (aducanumab-avwa)**
Effective Date:	**5/1/2023**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member's plan document for specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Use of Aduhelm (aducanumab-avwa) for indications including but not limited to FDA-approved indications of Alzheimer disease in patients with mild cognitive impairment or mild dementia stage of disease is considered experimental/investigative and therefore NOT COVERED.

Note: Claims received for Aduhelm (aducanumab-avwa), including for NOT COVERED indications will be denied as the financial responsibility of the servicing provider.

Description

Alzheimer disease (AD) is the most common cause of dementia and one of the leading sources of morbidity and mortality in the aging population. The neuropathological changes of AD are demonstrated by the accumulation of protein fragment beta-amyloid into clumps (called beta-amyloid plaques) outside neurons and the accumulation of an abnormal form of the protein tau (called tau tangles) inside neurons. These changes are followed by the damage and destruction of neurons, called neurodegeneration, which along with tau and beta-amyloid accumulation are key features of AD.

It is estimated that over 2 million Americans are afflicted with Alzheimer's dementia and an additional 2.4 million are living with mild cognitive impairment (MCI) due to Alzheimer's. People with MCI exhibit subtle symptoms such as problems with memory, language and thinking. MCI due to Alzheimer's disease is one of the earliest stages of the disease and people with MCI due to AD may exhibit biomarker evidences of changes in the brain such as abnormal levels of beta-amyloid. Among those with MCI, approximately 15% develop dementia after 2 years and not everyone who has MCI due to AD will go on to develop Alzheimer's dementia.

Identifying patients at risk and treating patients as early as possible suggest the best chance of slowing or stopping the progression of AD. Age is the most clearly established risk factor for AD. Other risk factors include family history, rare dominantly inherited mutations in genes, hypertension, cerebrovascular disease, type 2 diabetes, and obesity.

FDA Approval

Aducanumab-avwa (ADUHELM™; Biogen Inc.) was approved on June 7, 2021 by the Food and Drug Administration (FDA). On July 8, 2021, the FDA approved an updated label that recommends the treatment be used only by Alzheimer's Disease (AD) patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

Aduhelm-avwa was approved under FDA accelerated approval based on the reduction in amyloid beta plaques observed in clinical trials, and continued approval for this indication may be contingent upon verification of a clinical benefit in an additional confirmatory trial, the results of which are due to the FDA by 2030.

Limitations of use: Prior to the approval, the Peripheral and Central Nervous System Drugs Advisory Committee of the FDA voted against the approval of aducanumab-avwa for the treatment of AD in November 2020 due to a concern over lack of efficacy data. Safety and effectiveness of initiating treatment at earlier or later stages of Alzheimer disease have not been studied. ADUHELM™ was approved based on an observed decrease in beta-amyloid plaques, but it is unknown if that decrease is clinically significant. Currently there is no clear threshold for the amount of beta-amyloid decrease required to produce clinical benefit.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

HCPCS code:

J0172 - Injection, Aduhelm (aducanumab-avwa), 2 mg

Original Effective Date: 01/24/2023

Re-Review Date(s):