FEHB Program Carrier Letter
All FEHB Carriers

U.S. Office of Personnel Management
Healthcare and Insurance

Letter Number 2022-11

Date: May 24, 2022

Fee-for-service [9] Experience-rated HMO [9] Community-rated HMO [10]

Subject: Coverage of Monoclonal Antibodies Directed Against Amyloid in the FEHB Program

This Carrier Letter provides guidance on coverage for monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease (AD).

Background

On June 7, 2021, the U.S. Food and Drug Administration (FDA) approved aducanumab (brand name Aduhelm) with an indication for use in the treatment of Alzheimer's disease. On July 7, 2021, the indication for use was updated to clarify that treatment with Aduhelm should be initiated in patients with mild cognitive impairment or the mild dementia stage of Alzheimer's disease, the population in which treatment was initiated in clinical trials.[1]

On January 11, 2022, The Centers for Medicare & Medicaid Services (CMS) released a proposed National Coverage Determination (NCD) decision memorandum and on April 7, 2022, CMS adopted the proposed NCD without significant changes.[2] The NCD covers FDA-approved monoclonal antibodies directed against amyloid for the treatment of AD under

[1] Aduhelm – supplement approval: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/761178Orig1s003ltr.pdf

[2] CMS Final Decision Memo - National Coverage Determination for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=305

Coverage with Evidence Development (CED)[3] in CMS approved randomized controlled trials and in trials supported by the National Institutes of Health (NIH). All trials must be conducted in a hospital-based outpatient setting.

OPM's determination is that FEHB Carriers are encouraged to cover monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease in CMS-approved randomized controlled trials and in clinical trials approved by NIH using CMS CED criteria. This is consistent with HHS' policy of encouraging coverage in limited circumstances. Please refer to Carrier letter 2018-10 for guidance on the coverage of FDA-approved drugs, devices and biological products and Carrier letter 2012-09, for guidance on the requirements for FEHB Carriers to provide coverage for approval clinical trials consistent with the Clinical Trial Coverage Requirement Section 2709 of the Public Health Service Act, as amended by the Affordable Care Act.

For questions about this Carrier Letter or other aspects of pharmaceutical coverage for the FEHB Program, please write to OPMPharmacy@opm.gov and copy your Health Insurance Specialist.

Sincerely,

Laurie Bodenheimer
Associate Director
Healthcare and Insurance

[3] CMS: Guidance for the Public, Industry, and CMS Staff Coverage with Evidence Development: https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?MCDId=27