

February 10, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Proposed National Coverage Determination for Monoclonal Antibodies Directed
Against Amyloid for the Treatment of Alzheimer's Disease

Dear Administrator Brooks-LaSure:

The Medicaid Health Plans of America (MHPA) appreciates the opportunity to comment on the proposed National Coverage Determination (NCD) decision memorandum released by the Centers for Medicare & Medicaid Services (CMS) related to the coverage of Food and Drug Administration (FDA) approved monoclonal antibodies (mAbs) that target amyloid for the treatment of Alzheimer's disease through coverage with evidence development. The proposed NCD would provide Medicare coverage only for beneficiaries enrolled in qualifying clinical trials. Specifically, we are seeking clarity from CMS related to Medicaid coverage for this class of therapies, including the FDA-approved Aduhelm. Alzheimer's disease is the sixth-leading cause of death in the United States with an estimated 6.2 million Americans aged 65 and older living with Alzheimer's dementia in 2021.¹ Alzheimer's disease can also place a heavy emotional, physical, and financial toll on caregivers and family members.

MHPA is the only national trade association with a sole focus on Medicaid, representing more than 130 managed care organizations (MCOs) serving more than 43 million Medicaid beneficiaries in 40 states, the District of Columbia and Puerto Rico. MHPA's members include both for-profit and non-profit, national and regional, as well as single-state health plans that compete in the Medicaid market. Nearly three-quarters of all Medicaid beneficiaries receive health care through MCOs, and the association provides research and advocacy services that support policy solutions to enhance the delivery and coordination of comprehensive, cost-effective, and quality health care for Medicaid beneficiaries.

In the proposed NCD, CMS states that, based on its review of the totality of the evidence, "due to the lack of clear clinical benefit and the frequency of adverse events like ARIA², the evidence does not support that the benefits outweigh the harms for mAbs directed against amyloid for the treatment of AD." CMS adds that more rigorous clinical trials continue to be necessary to determine the clinical benefit. While the NCD is an important step for establishing Medicare-focused coverage for drugs such as Aduhelm, we would like to underscore that the NCD also has ramifications for coverage in Medicaid and particularly for people dually eligible for Medicare and Medicaid. Medicaid covers some services that Medicare either does not cover or only partially covers, such as nursing home care and home- and community-based care. When an individual is dually eligible for coverage under both

¹ <https://www.alz.org/media/documents/alzheimers-facts-and-figures.pdf>

² Note: ARIA references amyloid-related imaging abnormalities

the Medicare and Medicaid programs and receives health care services that could be covered by either Medicare or Medicaid, Medicare is the primary payer.

However, current policies can also position Medicaid as the primary payor in certain circumstances. For example, created by the Omnibus Budget Reconciliation Act of 1990, the Medicaid Drug Rebate Program (MDRP)³ requires that participating pharmaceutical manufacturers provide specific discounts to state Medicaid programs in exchange for coverage of the manufacturer's FDA-approved products. As a result, should a dually eligible individual be prescribed a drug that is not covered by Medicare, but that drug meets the definition of "covered outpatient drug" under the terms of the Medicaid Drug Rebate Program, then the state Medicaid Program becomes the primary source of coverage for that drug. With the combination of the proposed policy under the NCD and the established policy under the MDRP, we believe a shift of coverage of monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease, like Aduhelm, from Medicare to Medicaid is likely, raising questions about the allowance for state flexibilities to address the clinical and patient safety issues noted in the NCD and causing concern about the potential financial implications for Medicaid due to the cost-shifting construct.⁴

Given the "lack of a clear clinical benefit and the frequency of adverse events" that CMS found in its assessment of this class, in support of financial sustainability of the Medicaid program, and in furtherance of the efficiencies of a consistent application of coverage guidance across government programs, we respectfully request that CMS address and clarify in guidance the following for state Medicaid programs:

- Whether and how states are allowed to implement utilization management criteria for monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease, including Aduhelm, that mirror the Medicare NCD, in the Medicaid program.
- Specify the types of medical necessity criteria and other flexibilities that may be available to state Medicaid programs.
- Provide risk mitigation options to minimize the impact of cost-shifting from Medicare that would safeguard state Medicaid programs from significant budgetary impacts and that would allow the Medicaid program to continue as a viable and sustainable approach for meeting public health needs.

Thank you for the opportunity to provide feedback on this important coverage decision. Should you have any questions, please do not hesitate to contact me at sattanasio@mhcpa.org.

Sincerely,

/s/

Shannon Attanasio
Vice President, Government Relations and Advocacy

³ https://www.ssa.gov/OP_Home/ssact/title19/1927.htm

⁴ For 2021, the total national cost of caring for people living with Alzheimer's and other dementias was projected to reach \$355 billion, not including the estimated \$257 billion price of unpaid caregiving. Coverage under Medicare and Medicaid was estimated at \$239 billion, or 67%, of the total health care and long-term care payments for people with Alzheimer's or other dementias. See <https://www.alz.org/media/documents/alzheimers-facts-and-figures.pdf>.