



February 9, 2022

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

Dear Administrator Brooks-LaSure,

On behalf of the nation's Medicaid Directors, NAMD is writing in response to CMS's proposed National Coverage Determination (NCD) of Coverage with Evidence Development (CED) for monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease. While we recognize the sound clinical reasoning behind this coverage decision, limited Medicare coverage will shift primary coverage responsibility onto state Medicaid programs for individuals dually eligible for both Medicare and Medicaid who are prescribed these therapies.

It is therefore imperative that CMS allow states to employ the full array of medical necessity and prior authorization criteria to ensure appropriate utilization of these therapies while the evidence base continues to develop. Fundamentally, Medicaid programs should not be expected to provide widespread coverage for therapies that do not meet evidentiary standards for similarly widespread Medicare coverage.

NAMD is a bipartisan, nonprofit association representing the Medicaid Directors leading programs across the 50 states, the District of Columbia, and the five U.S. territories. The Medicaid program is a critical component of the health care system, providing access to services and supports for millions of Americans, many of whom are the most vulnerable populations in the country. These include pregnant women and children, individuals living with physical, intellectual, or developmental disabilities, and individuals in need of substance use disorder treatment.

CED Risks Medicare Shifting Costs to Medicaid

NAMD recognizes and agrees with the clinical rationale CMS provides in proposing to limit coverage for these therapies to a CED. As explained in its decision memorandum, the clinical evidence for the effectiveness of these therapies is mixed and the risk of serious side effects is significant. [In our August 2021 response to the initial NCD comment period](#), NAMD called for consideration of CED for precisely these reasons. Further, the post-market confirmatory trials that accompany the Food and Drug Administration's (FDA) accelerated approval pathway, which was utilized to approve the first monoclonal antibody therapy, naturally lend themselves to this coverage approach.

However, as we also noted in our comments, Medicare's coverage decision for these therapies has significant ramifications for state Medicaid programs. Specifically, a

decision to restrict Medicare coverage or deny coverage entirely would shift first-dollar coverage responsibility to state Medicaid programs in instances where these therapies are prescribed to dually eligible Medicare-Medicaid members. NAMD's preliminary analysis of cost projections from 19 states at that time suggested total state and federal Medicaid spending on these therapies would increase by roughly 250 percent in a Medicare non-coverage scenario.

This estimate was based on the initial \$56,000 per year list price of the only approved therapy in this category, Aduhelm. While this price has since been cut in half by the manufacturer over widespread concerns with its unjustifiably high cost, the fundamental issue of cost-shifting from the federal government to the states remains.

States Must Retain Ability to Set Appropriate Medicaid Utilization Controls

Ensuring that the costs of Medicare's limited Aduhelm coverage do not overwhelm state Medicaid pharmacy budgets is critical – especially given the state of the current evidence for the safety and efficacy of this therapy. Just as CMS utilized its clinical judgement to set narrow coverage parameters for Aduhelm, so too should states have the ability to employ sound clinical decision making in creating medical necessity and prior authorization criteria.

CMS has historically shown deference to states in medical necessity decisions in Medicaid. Aduhelm and other monoclonal antibody therapies in the clinical trial pipeline should be no exception. Each state has unique budgetary considerations, provider and beneficiary demographics, and delivery system characteristics that must be taken into consideration in crafting utilization controls. This is particularly important for a therapy such as this one, where evidence remains mixed and there is a clear need to better understand its application in broader populations. So long as there are ongoing clinical trials to answer these questions, a cautious approach to utilization that prioritizes patient safety is appropriate across payers.

Congressional Action Is Necessary to Resolve Cost and Coverage Questions for Specialty Therapies

The decisions that CMS and states must make around these therapies is indicative of a broad and persistent challenge in the prescription drug space. The FDA's accelerated approval pathway, with its reliance on surrogate clinical endpoints for initial approval and post-market confirmatory trials that can take years to complete, makes setting appropriate utilization parameters difficult. As we noted in our previous comments, this challenge is particularly acute in Medicaid due to coverage requirements that attach to the Medicaid Drug Rebate Program (MDRP).

Where commercial payers, Medicare, and other payers have the option to choose to limit coverage for accelerated approval drugs until evidence of their efficacy improves, states must provide coverage under the parameters of the MDRP. Because confirmatory trials can take extended time to complete and, in some cases, can result in

the FDA removing its initial approval, Medicaid programs are left covering products that may prove inefficacious. These products are often entering the market with extremely high list prices, creating strain for Medicaid budgets and forcing difficult trade-offs in other programmatic areas to meet pharmacy coverage obligations.

These dynamics are ultimately consequences of statutory frameworks around both FDA approval processes for new therapies and Medicaid coverage requirements for pharmaceutical therapies. NAMD recognizes and agrees with the prioritization for new and more effective therapies to address complex or currently untreatable conditions. However, this emphasis on innovation in therapeutic options must be paired with more innovative approaches to coverage and payment within the Medicaid program.

The MDRP has been and continues to be effective for the majority of drugs covered by Medicaid. However, the increasing rate of specialty drugs entering the market at high price points and potentially broad patient populations is creating constant pressure on Medicaid pharmacy budgets. States will need new tools for coverage and payment of these types of therapies. We encourage Congress to explore pathways to promote payment innovations that mirror the clinical innovations encouraged through the 21st Century Cures Act and other legislation.

NAMD appreciates CMS's consideration of this critical issue and continues to encourage careful examination of the implications of Medicare coverage decisions on the Medicaid program.

Sincerely,



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Director
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System



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