



August 11, 2021

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 to urge that Medicare cover Alzheimer's disease therapies utilizing monoclonal antibodies directed against amyloid and avoid shifting costs for such therapies to state Medicaid programs. These therapies, whose overall efficacy must be further assessed through post-market clinical trials, would create immense fiscal pressure for states if Medicaid becomes the source of first-dollar coverage for dually eligible Medicare-Medicaid members. NAMD calls for CMS to mitigate this risk for states. Actions to achieve this include:

- Issuing a National Coverage Determination requiring Medicare coverage of aducanumab or a Coverage with Evidence Development (CED) program.
 - If Medicare pursues CED, CMS should allow states the flexibility to apply the same coverage in their Medicaid programs.
- Adding aducanumab to the list of drugs subject to restricted coverage under the Medicaid Drug Rebate Program via authority of the Secretary as described at 42 USC § 1396r-8(d)(3). This would give states the same flexibility available to other payers to scale back or pause coverage until more reliable evidence of efficacy emerges.

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.

Accelerated Approval Pathway Challenges Medicaid's Pharmacy Benefit

The Food and Drug Administration (FDA)'s accelerated approval pathway relies on surrogate clinical endpoints for initial approval of a drug, followed by post-market confirmatory trials to generate additional information regarding the drug's effectiveness. If the findings of these confirmatory trials do not produce evidence of clinical benefit, the FDA may revoke approval of a drug. Notably, confirmatory trials can take several years to complete, and are not necessarily required to study actual outcomes. A 2019 Journal of the American Medical Association study of cancer drugs receiving accelerated approval from as early as 1992 found that only 20% of such drugs had confirmatory trials demonstrating improvement in overall survival.¹

¹ Gyawali B, Hey SP, Kesselheim AS. [Assessment of the Clinical Benefit of Cancer Drugs Receiving Accelerated Approval](#). *JAMA Intern Med*. 2019;179(7):906–913. doi:10.1001/jamainternmed.2019.0462

This process contrasts with the standard approval process, which relies on complete clinical trials studying patient outcomes to inform safety and effectiveness determinations, while also producing clinical data that can inform payers' utilization management approaches for a drug.

In the context of the Medicaid program, accelerated approval poses unique challenges not faced by other payers. These challenges stem from the requirements of the Medicaid Drug Rebate Program, under which states must cover all FDA-approved products in exchange for mandatory rebates off list prices, inflationary rebates, and a guarantee of receiving the best price offered to other non-federal payers. Where commercial payers, Medicare, and other payers have the option to choose not to cover accelerated approval drugs until evidence of their efficacy improves, states must provide coverage.² These requirements are particularly challenging given the possibility for confirmatory trials to take up to a decade to complete, with no guarantee of improved patient outcomes – and potentially even removal of the drug from the market by the FDA.

Accelerated approval drugs are increasingly products with high list prices, which strain the ability of state Medicaid programs to meet their coverage obligations under federal law and within the context of limited state budgets that must be balanced on an annual or biannual basis. NAMD has long been concerned with the challenges high-cost specialty drugs pose for the Medicaid pharmacy benefit, particularly products approved through the accelerated approval pathway.³⁴⁵

Medicare Cost Shifting Alzheimer's Therapies to Medicaid Would Create Unsustainable State Costs

The FDA used the accelerated approval pathway to issue approval on June 7 for aducanumab (brand name Aduhelm), a monoclonal antibody directed against amyloid beta for the treatment of Alzheimer's disease. The list price for this product is \$56,000 per year, and the therapy is not curative. There is division among experts regarding the utility of therapies targeting amyloid beta to treat Alzheimer's, the safety profile of such therapies, and the appropriate price for such therapies. The Institute for Clinical and Economic Review recently determined that current evidence does not demonstrate this therapy provides a net health benefit to patients.⁶

The outcome of Medicare's coverage decision for this therapy will have enormous ramifications for the Medicaid program. This is due to Medicaid's obligation to cover Medicare's cost sharing requirements for individuals dually eligible for both programs. As a physician-administered drug under the Medicare Part B benefit, this cost sharing amount totals 20% of the cost of the drug if Medicare elects to cover it. Should Medicare not cover the drug, then Medicaid would become the primary source of coverage for duals and dramatically increase Medicaid spending.

² <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-185.pdf>

³ <https://medicaiddirectors.org/wp-content/uploads/2016/03/NAMD-Response-to-SFC-on-drug-value-03-04-16.pdf>

⁴ https://medicaiddirectors.org/wp-content/uploads/2015/08/namd_letter_to_congress_21st_century_cures.pdf

⁵ https://medicaiddirectors.org/wp-content/uploads/2015/08/namd_sovaldi_letter_to_congress_10-28-14.pdf

⁶ <https://icer.org/news-insights/press-releases/icer-publishes-final-evidence-report-and-policy-recommendations-on-aducanumab-for-alzheimers-disease/>

Based on preliminary cost projections from 19 states, NAMD estimates that Medicare declining to cover aducanumab would increase total state and federal Medicaid spending on the therapy by roughly 250% nationally, with spending increases in some states ranging as high as 500% depending on the number of duals meeting aducanumab prescribing criteria.

As previously noted, states must operate balanced budgets. Medicaid is one of the largest state funding obligations in a given budget cycle, and major cost increases in the program must be offset by spending reductions elsewhere in the Medicaid budget. This can translate to painful decisions in the form of provider rate reductions, reduced service offerings, or other policy changes to manage spending increases such as significant surge in pharmacy spend. Medicare choosing not to cover aducanumab would clearly represent such a shock to the system. States are simply not equipped to be the primary source of coverage for an Alzheimer's therapy of enormous cost and questionable benefit, particularly in light of Medicaid's existing role as the largest payer of long-term services and supports for the same population.

CMS must act to mitigate this risk to Medicaid's ability to provide high-quality, evidence-based, and sustainable services to the populations served by the program. These actions could include:

- Issuing a National Coverage Determination requiring Medicare coverage of aducanumab or a Coverage with Evidence Development (CED) program.
 - If Medicare pursues CED, CMS should allow states the flexibility to apply the same coverage in their Medicaid programs.
- Adding aducanumab to the list of drugs subject to restricted coverage under the Medicaid Drug Rebate Program via authority of the Secretary as described at 42 USC § 1396r-8(d)(3). This would give states the same flexibility available to other payers to scale back or pause coverage until more reliable evidence of efficacy emerges.

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

Sincerely,



Jami Snyder
NAMD Board President
Director, Arizona Health Care Cost Containment
System



Allison Taylor
NAMD Board President-Elect
Director of Medicaid, Indiana Family and Social
Services Administration