



August 11, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Administrator Brooks-LaSure:

The National Association of ACOs (NAACOS) appreciates the opportunity to submit public comments in response to the National Coverage Determination for Aduhelm (aducanumab), which was opened by the Centers for Medicare & Medicaid Services (CMS) on July 12. Alzheimer's Disease is a devastating terminal condition afflicting [more than 6 million](#) or almost one in nine seniors, and ACOs caring for affected beneficiaries utilize a variety of clinical and care coordination interventions to improve outcomes and patients' quality of life. While that important work continues, NAACOS writes to share serious concerns about the expected costs of Aduhelm far outweighing its clinical benefits, which continue to be questioned by the medical research and treatment community. As we further outline below, **we urge you to implement a narrow national Medicare coverage determination of Aduhelm until more scientific evaluations exist to support its efficacy.**

NAACOS represents more than 370 ACOs participating in a variety of value-based payment and delivery models in Medicare, Medicaid, and commercial insurers. Serving more than 12 million beneficiaries, our ACOs participate in models such as the Medicare Shared Savings Program (MSSP), the Next Generation ACO Model, the Direct Contracting Model, and other alternative payment models (APMs). NAACOS is a member-led and member-owned nonprofit organization that works to improve quality of care, health outcomes, and healthcare cost efficiency.

ACO models continue to be one of the most successful value-based care models, benefitting a significant number of Medicare patients. The MSSP, the largest Medicare value-base care model serving 11.2 million beneficiaries, continues to produce greater savings each year. In 2019, the most recent year for which data are available, the MSSP [saved](#) Medicare \$2.6 billion total and \$1.2 billion after accounting for shared savings and losses. Importantly, this model accounts for the largest number of participants in Medicare's Quality Payment Program (QPP).

ACOs and other total-cost-of-care models are accountable for beneficiaries' Medicare Parts A and B fee-for-service expenditures across an entire year. CMS establishes a benchmark, which is based on ACO providers' historic, risk-adjusted spending and adjusted for regional and national spending trends. Those historic benchmarks would not account for Aduhelm's unprecedented costs. **At the initial list price of**

[\\$56,000 per person](#) for a year of treatment if just one in 10 Alzheimer's Disease patients took the drug for a year, Aduhelm would cost more than all other Medicare Part B drugs combined, which totaled roughly \$37 billion in 2019. According to CMS data, the mean per capita spending target or benchmark for MSSP ACOs in Performance Year 2018 was \$10,986 and the median was similar at \$10,880. The projected cost of Aduhelm is five times the average ACO's benchmark. Therefore, utilization of Aduhelm has the potential to totally disrupt ACOs' ability to effectively manage costs compared to a historic benchmark and would make it virtually impossible for ACOs treating beneficiaries on Aduhelm to generate or earn savings. Unfortunately, the cost disruptions from this drug could alter the course of Medicare's transition to more APMs.

The evidence to use Aduhelm is scant and [continues to be questioned](#) by medical and policy experts. Last year, the Food and Drug Administration's (FDA) advisory committee [recommended against](#) approving the drug, citing a lack of clinical benefit. When the FDA did approve the drug in June, three members of the panel quit, [calling](#) it "probably the worst drug approval decision in recent U.S. history." In 2018, [the FDA said](#) there was "no sufficiently reliable evidence" that Aduhelm's surrogate endpoint of reducing amyloid beta plaques would be "reasonably likely" to predict clinical benefit. In 2013, CMS [declined to cover](#) the specific PET scans used in trials to help determine whether a patient has the amyloid buildups that indicate Alzheimer's. In 2019, Biogen [announced it was halting a clinical trial](#) after an interim analysis of the data suggested the drug provided no benefit to patients. According to a [recent Medscape poll](#), 79 percent U.S.-based physicians and 68 percent of neurologists said they do not plan to prescribe Aduhelm to their Alzheimer's patients. Major hospital systems Cleveland Clinic and Mount Sinai have [publicly said](#) they will not prescribe Aduhelm because of concerns over its efficacy and safety. **Because of these facts, NAACOS supports narrow coverage of the drug with more scientific evaluations needed to support the efficacy.**

Should CMS grant any sort of coverage of Aduhelm, we ask that you take steps to mitigate the potential impact on APMs that make providers responsible for patients' total-cost-of-care. **While not necessarily part of CMS's work on a National Coverage Determination by the agency's Coverage and Analysis Group, NAACOS specifically urges CMS to adjust ACO benchmarks to mitigate for Aduhelm's cost.** CMS policy as defined in §425.601(a)(4) truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for performance years to minimize variation from catastrophically large claims. However, Aduhelm's steep list price combined with the prevalence of Alzheimer's Disease would create situations where ACOs would be responsible for numerous beneficiaries on the drug whose claims would not be truncated. CMS should create a policy to mitigate for Aduhelm's cost so as not to disrupt value-based care programs predicated on patient's cost of care.

We appreciate the opportunity to provide comments on this important issue. We urge you to listen to the data and feedback provided by medical experts in this field, who question Aduhelm's clinical benefit. Thank you for your consideration of our comments.

Sincerely,



Clif Gaus, Sc.D.
President and CEO