February 10, 2022

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) thanks the Centers for Medicare & Medicaid Services (CMS) for its work crafting an appropriate National Coverage Determination (NCD) for monoclonal antibodies that target amyloid for the treatment of Alzheimer's disease. A proposed NCD was published on January 11 and would cover these types of Food and Drug Administration (FDA)-approved monoclonal antibodies for people with Medicare only if they are enrolled in qualifying clinical trials. Alzheimer's Disease is a devastating terminal condition afflicting more than 6 million or almost one in nine seniors. Accountable care organizations (ACOs) caring for affected beneficiaries utilize a variety of clinical and care coordination interventions to improve outcomes and patients' quality of life.

Expressing concerns that the expected costs of Aduhelm (aducanumab), which was approved by the FDA on June 7, would outweigh its clinical benefits, NAACOS submitted comments in August asking for narrow Medicare coverage determination until more scientific evaluations exist to support its efficacy. **We thank you for listening to our concerns and feel the proposed NCD is appropriate. Therefore, we urge CMS to finalize the proposed NCD this April.**

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 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.

ACOs continue to be one of the most successful value-based care models, benefitting a significant number of Medicare patients. Since 2012, ACOs have saved Medicare $13.3 billion in

gross savings and $4.7 billion in net savings. Importantly, data show these ACOs continued to provide high-quality care and yield satisfied patients. In 2022, 483 ACOs are participating in the MSSP, which is a voluntary model. Today, ACOs care for nearly 20 percent of all Medicare patients and nearly a third of traditional Medicare patients.

The evidence to use Aduhelm is scant and continues to be questioned by medical and policy experts. In 2020, an FDA advisory committee recommended against approving the drug, citing a lack of clinical benefit. When the FDA did approve the drug last 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, including the Cleveland Clinic and Mount Sinai, have publicly said they will not prescribe Aduhelm because of concerns over its efficacy and safety. The Veterans Health Administration will also not cover Aduhelm. Because of these facts, NAACOS supports CMS's proposed NCD that would limit the drug's coverage while more clinical trials are conducted.

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. Even with the initial price of Aduhelm was halved to $28,000 per person for a year of treatment, if just one in 10 of the 6 million Alzheimer's Disease patients took the drug for a year, Aduhelm would cost roughly $16 billion. By comparison, Medicare spent roughly $37 billion on Part B drugs in 2019. According to CMS data, the average per capita spending target or benchmark for MSSP ACOs in Performance Year 2020 was $11,475. The projected cost of Aduhelm is nearly two 1/2 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.

Should CMS reverse its proposed NCD and grant wide coverage, 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 NCD, 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.

NAACOS appreciates the opportunity to submit public comments in response to the proposed NCD. While we are sympathetic to the devastating effects of Alzheimer's disease, we believe the expected costs of Aduhelm would outweigh its clinical benefits and encourage you to finalize the proposed NCD.

Sincerely,

Clif Gaus, Sc.D.
President and CEO