United States Senate
WASHINGTON, DC 20510

February 18, 2022

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

Dear Administrator Brooks-LaSure:

The Centers for Medicare and Medicaid Services (CMS) recently released a draft National Coverage Determination (NCD) proposing that "monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease" be covered for Medicare beneficiaries only under the Coverage with Evidence Development pathway – meaning that Medicare proposes to cover this class of drugs only for people enrolled in qualifying clinical trials. We write to urge you to carefully consider stakeholder feedback as you work to finalize coverage for this product class, to ensure that CMS action does not inappropriately threaten patient access to treatment, including for those living in rural areas, or thwart advances in research and development in Alzheimer's disease treatments.

Approval of a new treatment – the first in nearly 20 years – was a landmark moment in the fight against Alzheimer's that brought significant hope to the more than six million Americans with Alzheimer's disease and their families. The Food and Drug Administration (FDA) determined that Aduhelm demonstrated a meaningful effect on the reduction of beta amyloid plaque, which is expected, although not established, to predict a clinical benefit. FDA thus granted the drug accelerated approval, a regulatory pathway that allows drugs for serious or life-threatening illnesses that provide a meaningful therapeutic advantage over existing treatments to be marketed while the predicted clinical benefit – which can often take years to manifest – is confirmed. For patients with Alzheimer's and their families, it might mean more time with improved cognition to spend together while research continues on this and other therapies. CMS's decisions regarding payment will have major implications not just for Medicare beneficiaries, but for the entire market, because private insurers generally follow Medicare's lead.

Though the NCD process is rarely used for drugs, it provides a way for CMS to evaluate evidence and determine if novel products or services meet statutory requirements that Medicare cover only those products and services that are considered "reasonable and necessary" for diagnosis or treatment of an illness or injury. There are a wide range of coverage decisions CMS might propose through an NCD process, but in this case, CMS proposed a particularly burdensome and restrictive approach that could sharply curtail access not just to one approved product, but to an entire class of potential future products still in the development pipeline.

Specifically, CMS proposed that Medicare coverage would occur only in "CMS approved randomized controlled trials that satisfy the coverage criteria specified [in the NCD] and in trials supported by the National Institutes of Health." CMS further proposed that trials answer questions about a drug's safety and efficacy, including whether use "result[s] in a statistically significant and clinically meaningful difference in decline in cognition and function."

We appreciate the significant policy challenges that CMS has grappled with in considering how to cover Aduhelm, the drug that motivated this class-wide proposal. It is highly unusual, however, if not precedent setting, for CMS to attempt to evaluate a drug's clinical benefit. Congress has reserved this task for the FDA, which said that Aduhelm's effect on cognition was enough to merit accelerated approval pending confirmation of the clinical benefit.

Driven by the National Alzheimer's Project Act, which set a goal of effectively treating, curing, or preventing Alzheimer's disease by 2025, Congress has repeatedly enacted historic levels of funding for Alzheimer's disease research. Energetic researchers and medical professionals are working hard on effective treatments and cures, but neurological disease is a tremendously high-risk research area and a string of failures gave researchers reason for trepidation. Finalizing a class-wide NCD could compound these challenges, especially as there is no reason to prejudge FDA's assessment of pipeline therapies.

CMS's proposal would also dramatically restrict access to this class of therapies to only those patients who are able to participate in a CMS-approved clinical trial or those who can afford to pay out-of-pocket. CMS has provided limited information on clinical trial criteria, but the high level preview suggests inclusion criteria will be narrow and difficult to satisfy, exacerbating the challenges that patients have already experienced finding providers that administer Aduhelm. In particular, a proposed requirement that patients obtain drugs only through hospital outpatient settings will push patients towards one of the most expensive sites of infusion care and removes a significant number of access points from consideration. Trials are also likely to occur only in well-resourced major medical centers, which could complicate, if not revoke, access for rural seniors.

In addition, while CMS's interest in promoting diversity in clinical trials is commendable, the agency has not made clear what its new diversity requirements will mean for drug developers with ongoing trials. Many of those trials have made important advances in expanding access to diverse populations, but if they need to be amended to meet new CMS criteria, this could adversely affect enrollees and delay results. Moreover, there is potential that restricting coverage to NIH clinical trials could inadvertently restrict minority access, as minorities are regrettably often under-represented in NIH clinical trials.

As CMS evaluates public comment, we urge you to take these considerations into account and to ensure that agency decision-making does not impede research and development in this field or restrict patient access in a manner that is inappropriate or avoidable and thus

deprives some Medicare beneficiaries with Alzheimer's of access to an FDA-approved medication.

Sincerely,

Susan M. Collins
United States Senator

Shelley Moore Capito
United States Senator