United States Senate
WASHINGTON, DC 20510

March 21, 2022

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

Dear Administrator Brooks-LaSure:

We're writing to share concerns about the recently proposed National Coverage Determination (NCD) decision memo for Aduhelm and similar drugs, released by the Centers for Medicare & Medicaid Services (CMS) on January 11, 2022. Although more data is needed on Aduhelm's impact on Alzheimer's disease, we urge you not to include in the NCD the whole class of similar drugs that have not yet been considered by the Food and Drug Administration. Further, we ask that CMS work to ensure that in any studies required by CMS, robust and representative participation by communities of color are prioritized.

As CMS notes in its decision memo, more than 6 million people in America have Alzheimer's disease and this is expected to rise to 14 million by 2060. Monoclonal antibody treatments that target amyloid plaques in the brain are the therapies furthest along in their potential for treating certain individuals with Alzheimer's disease. We are concerned that by including the entire class of drugs in this coverage decision—before final data on safety and efficacy are even released on other therapies in the pipeline—CMS may limit future access to treatments.

As you know, there is a large unmet need for treatments for those with Alzheimer's, a devastating and fatal disease. In Aduhelm's class of drugs, three drugs are working their way through the FDA approval process. Although all in the same class, no two drugs work exactly the same for all individuals. Further, the evidence gathered from Aduhelm's FDA confirmatory trial as well as additional evidence gathered by CMS may inform coverage decisions of potential future drugs. Each new medicine, in our view, should be reviewed on its own merits and not as a class.

Additionally, CMS should ensure that its final NCD does not make it more difficult for Medicare beneficiaries of color to both obtain these treatments if trials are required by CMS and also for us to obtain needed data on Alzheimer's treatments in such trials, as Black and Latino populations have higher incidences of Alzheimer's than non-Hispanic whites.[1] The draft NCD proposes to limit coverage only to drugs administered in hospital outpatient settings. This will make it significantly more difficult, if trials are required, to enroll beneficiaries of color, as aggressive outreach and the use of disparate sites is often needed to meet diversity targets. The draft NCD's requirement for randomized controlled trials could also limit inclusion of people of color, as these populations are often underrepresented in such trials.[2]

Alzheimer's patients and their families have been waiting 20 years since the last therapy was approved, and this class of therapies holds the promise that those living with the disease may soon have multiple disease-modifying therapies from which to choose. Time is not on the side of those with Alzheimer's, and we urge you to issue a final NCD that puts patients and their loved ones first by examining each potential new treatment on its own.

Thank you for your commitment to ending Alzheimer's disease, and we look forward to continuing our work with you in this crucial area.

Sincerely,

Mark R. Warner
United States Senator

Edward J. Markey
United States Senator

Chris Van Hollen
United States Senator

Debbie Stabenow
United States Senator

[1] CDC Newsroom, U.S. burden of Alzheimer's disease, related dementias to double by 2060, https://www.cdc.gov/media/releases/2018/p0920-alzheimers-burden-double-2060.html

[2] Manuel Ma et al, Minority Representation in Clinical Trials in the United States: Trends Over the Past 25 Years, Mayo Clinical Proceedings, (Jan. 1, 2021), https://www.mayoclinicproceedings.org/article/S0025-6196(20)31259-3/fulltext.