Congress of the United States
Washington, DC 20515

November 16, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
200 Independence Avenue S.W.
Washington, D.C., 20201

Dear Administrator Brooks-LaSure:

I am writing regarding CMS's decision to issue a National Coverage Determination (NCD) for Food and Drug Administration (FDA) approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease. UsAgainstAlzheimer's shared with us their concerns about the NCD for this class of drugs, and it is my hope in writing that you will listen to their concern.

As you know, Biogen's Aduhelm (aducanumab) is not the only product in development looking at using monoclonal antibodies directed against amyloid. For example, Biogen also has Lecanemab, and it is under FDA accelerated approval consideration at the time of writing. UsAgainstAlzheimer's worry is that Aduhelm set the National Coverage Decision for the entire class.

I understand the agency's hesitancy in covering the class of drugs broadly with the lack of data on clinical efficacy presented by Biogen's Aduhelm, in addition to the worrying potential side effects, like brain swelling and bleeding that elicit questions about its safety. I can understand the appropriateness for a coverage with evidence development pathway for Aduhelm. But the same may not be said of other incoming drugs, and the Alzheimer's community is concerned about the timing delays that the current NCD could impose on upcoming Alzheimer's drugs that might not have the same concerns as Aduhelm.

I ask that you keep an open mind to their concern and consider revisiting the NCD as new drugs in the class are approved by the FDA.

Sincerely,

Donald S. Beyer Jr.