January 6, 2023

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

Dear Administrator Brooks-LaSure:

We are writing as nonprofit members of the Patient, Consumer, and Public Health Coalition to express our support for your previously released Coverage with Evidence Development (CED) for Food and Drug Administration (FDA)-approved monoclonal antibodies (mAbs) directed against amyloid for the treatment of Alzheimer's disease. We applaud your National Coverage Determination that made the wise decision to limit coverage of this class of drugs solely to patients participating in clinical trials following the approval of aducanamab (Aduhelm) by the FDA.[1] We understand that CMS is under pressure from industry-backed groups and providers to reconsider this policy and instead provide coverage based on preliminary results from a clinical trial regardless of the quality of the evidence regarding safety or clinically meaningful benefits. For example, more than 100 providers who signed an Alzheimer's Association letter in support of lecanumab approval and coverage, have reported conflicts of interest. This must be considered when weighing the legitimacy of lobbying against the current CED requirements for FDA approved mAbs.

The FDA approved Biogen and Eisai's lecanemab today and will make a decision about Eli Lilly's donanemab in a few weeks. We understand the competing pressure from the many stakeholders invested in finding an effective treatment for Alzheimer's disease and urge you to hold firm to your decision to prioritize patient safety and the scientific credibility of CMS's coverage decisions.

We strongly opposed the FDA accelerated approval of Aduhelm, because of the lack of data supporting a clinically meaningful benefit, the clear safety issues, and the fact that the inclusion criteria for the studies submitted to the FDA excluded 85% of the Medicare population with Mild Cognitive Impairment. Many excluded patients were on blood thinners, which an article in the New England Journal of Medicine explained has been fatal for at least one patient taking the Alzheimer's drug.

As you know, the costs of coverage for this class of drug without demonstrated effectiveness in the Medicare population would be extremely harmful to the program and to all Medicare beneficiaries. The Institute for Clinical and Economic Review (ICER) recommended a lower price for Aduhelm because of questionable benefits and subsequently recommended that the price of lencanemab be listed even lower than Aduhelm, also because of its questionable benefits. Any change in the CMS coverage decision has the potential to overwhelm an already stressed system without benefitting patients.

The findings from a joint Congressional investigation by the House Energy and Commerce and Oversight and Reform Committees strongly criticized numerous unusual actions by FDA officials leading up to the approval of Aduhelm, including 115 meetings, calls, and email discussions related to Aduhelm, as well as an unknown number of informal meetings that were undocumented.[2] The joint briefing document from FDA and Biogen failed to incorporate differing views within the FDA, including concerns from FDA statistical reviewers over the quality of the data on safety and effectiveness. We note that the report documented that Biogen set an inappropriately high price for Aduhelm with the goal of "making history," despite the impact it would have on Medicare and patients.

It is unclear to what extent these irregular practices continued with the development of lecanemab, and it is disturbing that the FDA has not scheduled an Advisory Committee meeting to discuss the data prior to their approval decision. Our organizations believe that this lack of transparency strongly supports the key role of CMS as a gatekeeper that keeps Medicare beneficiaries safe by keeping the current CED in place.

Sincerely,

National Center for Health Research

AMSA Wisconsin

Doctors for America

Jacobs Institute of Women's Health

Mothers Against Medical Error

Medical Device Problems

MedShadow Foundation

National Women's Health Network
Patient Safety Action Network

PharmedOut

TMJ Association

USA Patient Network

WoodyMatters

[1] Zuckerman, D. (2022) Statement of Dr. Diana Zuckerman Regarding the January 11, 2022 CMS Decision about Aduhelm. *National Center for Health Research.* https://www.center4research.org/statement-of-dr-diana-zuckerman regarding-the-january-11-2022-cms-decision-about-aduhelm/

[2] U.S. House of Representatives. (2022). The High Price of Aduhelm's Approval: An Investigation into FDA's Atypical Review Process and Biogen's Aggressive Launch Plans. https://democrats energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Final%20Aduhelm%20R e port_12.29.22.pdf