VIA EMAIL (FOIA_Requests@cms.hhs.gov)

April 14, 2022

Mr. Hugh Gilmore
Director, Division of Freedom of Information
Centers for Medicare & Medicaid Services
Mailstop N2-20-16
7500 Security Boulevard
Baltimore, MD 21244

RE: Freedom of Information Request Related to National Coverage Determination Regarding Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N)

Dear Mr. Gilmore:

On behalf of UsAgainstAlzheimer's ("UsA2"), this is a request for records under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552.

UsA2 is a nonprofit, tax-exempt organization with a mission of ending Alzheimer's disease while supporting people living with Alzheimer's and their caregivers. This includes promoting efforts to treat the disease until such time it is cured. We are submitting this FOIA request to assist the public in better understanding the rationale and reasoning of the Centers for Medicare and Medicaid Services ("CMS") in issuing its April 7, 2022 National Coverage Determination regarding Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease, CAG-00460N ("NCD"), as well as the process by which CMS developed the NCD.

This FOIA request relates to a matter of exceptional public interest and the public has every right to understand precisely why and how CMS arrived at its decision. Among other things, this FOIA request seeks documents that would indicate whether and how CMS took cost considerations into account when issuing the NCD. The FOIA request also seeks information regarding whether CMS has ever before professed concern regarding FDA's accelerated approval pathway when making a Medicare coverage decision and how and why this NCD differs from Medicare coverage determinations for other drugs approved under the FDA accelerated approval pathway.

The Food and Drug Administration ("FDA") has been transparent in sharing with the public documents regarding its June 2021 decision to approve the drug Aduhelm for the treatment of Alzheimer's disease. ***UsA2 asks that CMS be at least as transparent as FDA.*** Millions of Americans and their families, as well as the broader public, are entitled to understand why the government has made the decision that for them means access to a potential disease modifying therapy will be out of reach in time to make a difference in their lives. As noted in public

comments, 1,000 people each day convert from mild to moderate Alzheimer's, moving them outside of the label indication for Aduhelm and presumably for other drugs soon to be considered for accelerated approval or traditional approval by the FDA and covered by this NCD. Just as the FDA has shared with the public complete information regarding the decision to approve Aduhelm, CMS should share with the public comparable information about this NCD.

Accordingly, we request in advance that CMS not interpose legalistic objections and assertions of privilege. ***It is well-established that government agencies may produce documents covered by FOIA Exemption 5 (deliberative process privilege), and UsA2 specifically requests that CMS does so here given the urgency and extraordinary nature of the public interests at stake.*** The public interest will be best served here by transparency – not by legalistic assertions of supposedly applicable FOIA exemptions.

Background

Alzheimer's is a cruel and devastating illness for the six million Americans who have it, as well as their families. Additionally, there is no cure. In fact, it is the sixth leading cause of death in the United States.

Because of prevalence and lethality of Alzheimer's, and the fact that 85 percent of people diagnosed with it are on Medicare, this FOIA request concerns a matter of exceptional public interest. An estimated 1,000 people per day progress from a diagnosis of mild to a diagnosis of moderate Alzheimer's disease. The class of medications included in the NCD are most effective for patients in the early stages of the disease and in all likelihood each drug within this class will carry a consistent label indication for this group of patients

As noted above, in June 2021 the FDA approved the drug Aduhelm (aducanumab) for the treatment of Alzheimer's. Aduhelm is a monoclonal antibody ("mAb") directed against amyloid beta to reduce amyloid accumulations. In Alzheimer's disease, brain cell functioning is disrupted resulting in the failure of brain cells to communicate with one another, leading eventually to cell death. Aggregates of beta amyloid are thought to play an important role in the onset and progression of Alzheimer's disease. Aduhelm is the first treatment the FDA has approved for Alzheimer's since 2003 and is the first therapy that targets the fundamental pathophysiology of the disease. Additional medications targeting amyloid accumulations which will be impacted by this NCD are currently undergoing clinical trials.

On April 7, 2022, CMS issued its NCD allowing for Medicare coverage of FDA-approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease subject to requirements for further CMS-approved studies and data collection. When a drug receives accelerated approval, CMS will cover the drug only for those individuals enrolled in an FDA-approved or NIH-conducted clinical trial. For mAbs receiving traditional approval, CMS will cover the drug through CMS-approved prospective comparative studies, allowing such study data to be collected through a registry.

While many details of this NCD remain unclear, what is clear is that CMS's decision will deprive millions of Americans access to a medication approved by the FDA to treat Alzheimer's

disease. Millions of Americans will be consigned to inevitable decline and death without the opportunity to take a medication that can halt the progression of their devastating disease. Many – including UsA2 – are concerned that in adopting the NCD, CMS may have taken cost or other factors into consideration that, by law, were impermissible bases for its decision. References to the "immense burden" on Medicare[1] posed by the Alzheimer's population often appear to be a euphemistic code for costs.

Because of the tremendous importance of this issue, UsA2 respectfully requests that CMS expedite its consideration and production of documents responsive to this FOIA request and not delay based on any assertion of a FOIA exemption.

Request for Records

Please produce copies of the documents set forth below.

1. All documents pertaining in any way to the price of any or all monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.
2. All documents pertaining in any way to the potential cost to Medicare or other federal health programs or any other financial implications or regulatory burden that would result from Medicare coverage for any or all monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.
3. All communications and contacts between CMS and the Institute for Clinical and Economic Review ("ICER") or any other external, non-government agency advisor or contractor regarding any or all monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.
4. Documents sufficient to identify the number of neurologists employed by CMS who participated in or contributed to the drafting of the NCD.
5. All documents discussing or referring to FDA's decision to approve Aduhelm, including all documents reflecting or pertaining to any occasion in which CMS discussed with FDA, or requested information from FDA, on the agency's accelerated approval of Aduhelm, including but not limited to discussions of evidence relied upon to support such approval.
6. All documents made available to the Administrator of CMS and/or to the Secretary of Health and Human Services regarding Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.
7. All documents mentioning in any way the possible or anticipated impact on patients by a determination that CMS might adopt regarding Medicare coverage for any or all monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.

[1] Tamara Syrek Jensen, JD Director, Coverage & Analysis Group. CMS National Stakeholder Call on Final National Coverage Decision for Treatment of Alzheimer's Disease with Monoclonal Antibodies Directed Against Amyloid. Recording not posted on CMS website at this time.

8. All analyses regarding Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease, including all drafts of the NCD, or portions of the NCD, or analyses or commentaries on all or part of the NCD.

9. Documents reflecting all occasions in which CMS determined that Medicare coverage for a drug should be narrower than the indications approved by FDA. This response should include, but not be limited to, instances where CMS's decision was, in whole or in part, due to the fact that FDA approval decision was based on clinical studies that measured the drug's satisfaction of a surrogate endpoint to predict a clinical outcome (accelerated approval pathway). ***If there are no such prior occasions, as UsA2 believes, please state "none."***

To the extent not included in the above:

10. All internal CMS communications regarding:

    a. The NCD;

    b. The FDA review of Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease; and

    c. Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.

11. All communications between CMS and:

    d. FDA regarding Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease;

    e. The Agency for Healthcare Quality and Research regarding Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease;

    f. The National Institutes of Health regarding Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease; and

    g. The Office of the Secretary or Deputy Secretary or General Counsel of the U.S. Department of Health and Human Services regarding Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.

12. To the extent not covered in Request 11 above, all communications between CMS and:

    h. A component of the U.S. Department of Health and Human Services regarding Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease;

    i. The Executive Office of the President regarding Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease;

    j. The Office of Management and Budget regarding Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease;

    k. The Government Accountability Office regarding Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease; and

l. A Congressional or Senate office, a Member of the U.S. House of Representatives, or a U.S. Senator regarding Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.

13. To the extent not covered in Request 12 above, all communications between CMS and any component of the federal government regarding Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.
14. All communications between CMS and any member of the public, including both individuals and entities, that is not posted on CMS's website and pertains to Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease or the NCD.
15. All communications between CMS and a non-United States individual, entity or government agency regarding Aduhelm and/or monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.

Please provide documents in the format that is most convenient to CMS. We would prefer to receive the documents in electronic format.

Fees

UsA2 respectfully submits that CMS should furnish the requested records at no charge. Under the FOIA, documents shall be furnished without charge or at a reduced charge "if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii). This request plainly fits within this statutory provision; the records are likely to contribute significantly to public understanding of the operations or activities of the government. UsA2 intends to disclose records that it receives with the broader public via its website and otherwise. In addition, the disclosure of the records is not in the commercial interest of UsA2, a nonprofit patient advocacy organization.

If CMS intends to charge for these records an amount that exceeds $250, please contact me to discuss the proposed charges.

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Thank you for your attention to this request. If you have any questions, please do not hesitate to contact me at vradenbug@aol.com.

Sincerely,

George Vradenburg
Founder and Board Chair, UsAgainstAlzheimer's