



Charles N. Kahn III
President and CEO

February 10, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Proposed National Coverage Determination for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N)

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, D.C and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The Federation supports CMS' recognition of the importance of providing Medicare coverage for new and potentially innovative treatment of Alzheimer's disease. With nearly 6 million Americans suffering from Alzheimer's disease, there is a well-recognized unmet need for treatment. Alzheimer's disease is the primary cause of dementia in older Americans and the disease also is prevalent in Black and Hispanic populations. CMS' proposed coverage will advance efforts to treat America's seniors suffering from Alzheimer's disease, as well as contribute to reduced health disparities, an important goal for this Administration and the Federation.

CMS proposes to cover FDA-approved monoclonal antibodies against amyloid for the treatment of Alzheimer's disease under Coverage with Evidence Development (CED) in CMS-approved randomized controlled trials and in trials supported by the National Institutes of Health. For trials covered by CMS, CMS proposes that these trials also meet the CED requirements in the Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease NCD (220.6.20). Although there is currently one monoclonal antibody against amyloid approved by the FDA, the proposed CED would cover the entire class of similar drugs if, and when, they are approved by the FDA.

The Federation supports the proposed CED but does not think that it should be inclusive of all drugs that are FDA-approved monoclonal antibodies against amyloid. The FAH believes that CMS should determine the appropriate coverage for each drug based on the specific clinical benefits and risks associated with each drug in this class. We do not believe it is appropriate to propose a broad class CED based on the evidence from Aduhelm™, the first drug approved by the FDA. We agree with CMS' conclusions that the evidence for Aduhelm does not support a clear clinical benefit and it is difficult to assess if the benefits from treatment outweigh the risks of adverse events such as ARIA. For Aduhelm, we support CMS' proposal to conduct clinical trials to evaluate whether the treatment results in a significant and clinically meaningful difference in decline in cognition and function and to quantify the adverse events associated with this treatment. We are concerned, however, that CMS is assuming that all other FDA-approved drugs in this class will have the same limitations in the evidence (provided for both clinical benefits and risks).

We appreciate that CMS generally provides broad national coverage for a medical procedure that involves a device, and coverage is not specific to each device manufactured by different companies. Although monoclonal antibodies directed against amyloid can be considered a drug class, there can be important differences in the monoclonal antibodies that can produce significant differences in clinical outcomes and associated risks. We believe CMS is premature in proposing CED coverage for this entire class. Instead, in order to facilitate treatment with innovative therapies, CMS should evaluate each drug and expand the CED only if appropriate.

The Federation also believes it is important for CMS to closely monitor the data accumulated from CEDs and make public determinations, potentially annually, as to whether or not additional data are needed for CMS to conclude that a treatment is reasonable and necessary for treatment of Medicare beneficiaries. We appreciate the Administration's actions to increase the diversity of patients enrolled in clinical trials, but the most equitable way to reduce health disparities is to provide treatment in all clinical settings and not restrict access to clinical trials. We recommend that CMS evaluate the duration of CEDs to ensure they are completed in a timely fashion.

The FAH appreciates the opportunity to provide these comments on the proposed NCD. If you have any questions or would like to discuss further, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,

A handwritten signature in black ink, appearing to read "A. M. K. Smith". The signature is fluid and cursive, with a long horizontal stroke extending to the right.