THE GERONTOLOGICAL SOCIETY OF AMERICA®

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February 10, 2022

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Center for Clinical Standards and Quality
Center for Medicare & Medicaid Services

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

Dear Ms. Syrek Jensen and CMS Colleagues:

On behalf of The Gerontological Society of America (GSA), thank you for the opportunity to provide comments to the Proposed National Coverage Determination for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N).

Our mission at GSA is to cultivate excellence in interdisciplinary aging research to advance innovations in practice and policy. GSA's 5,400 members include gerontologists, health professionals, behavioral & social scientists, biologists, demographers, economists, and many other disciplines. These experts study all facets of aging with a life-course orientation. The multidisciplinary nature of the GSA membership is a valued strength, enabling the Society to provide a 360-degree perspective on the issues facing our population as we age. GSA is advancing major initiatives related to improving adult immunization rates, earlier detection of cognitive impairment, improving oral, hearing, and vision health, framing our language to improve the public's understanding of aging, and understanding the impact of the longevity economy.

As a professional membership society with a long-standing commitment to translating research to inform evidence-based care for persons with dementia, GSA has developed The GSA KAER Toolkit (2020 Edition). This work is intended to support primary care teams in implementing a comprehensive approach to initiating conversations about brain health, detecting and diagnosing dementia, and providing individuals with community-based supports. We are currently working with the University of Washington and the Centers for Disease Controls' Alzheimer's Disease and Healthy Aging Program to pilot the Toolkit in a primary care system. Likewise, GSA members and staff actively participate in and serve as members federal councils such as the Advisory Council on Alzheimer's Research, Care, and Services.

GSA appreciates that we are all focused on improving care for persons living with dementia and their loved ones while advancing innovation and access to pharmacologic and non-pharmacologic therapies for prevention and treatment of Alzheimer's Disease and Related Dementias. GSA focuses our comments in three areas. We respectfully request that CMS consider these recommendations in the coverage determination:

- Reconsider application of the proposed NCD to the entire class of monoclonal antibodies
- Ensure coverage criteria reduces rather than exacerbates already existing issues of equity and access to clinical trials
- Provide specific commitments and define open ended terms of timely and quick approval of protocols

First, we respectfully request CMS reconsider the application of the proposed NCD based on research results published for one specific monoclonal antibody therapy. Several therapies are in clinical development. As with any class of medications, we must recognize variations in therapeutic profiles and improvements in efficacy. Imposing the NCD on the entire class of monoclonal antibodies fails to account for these variations and subjects these therapeutic entities to duplicative studies. Clinicians and patients need to have access to options to better target individualized treatment. Prospectively including all monoclonal antibodies in this NCD may stifle much needed innovation to improve treatment of Alzheimer's Disease and Related Dementias. We respectfully request that each therapeutic entity be considered individually.

Next, we applaud CMS for recognizing the importance of under-representation of members of racial and ethnic groups in research relating to Alzheimer's Disease and Related Dementias. The clinical trial requirements and restriction of the trials to only hospital outpatient settings however only further exacerbate the system of inequities as we have seen demonstrated. We respectfully request CMS consider additional options to improve access to monoclonal antibody therapies as well as promote activities to improve access to detection, diagnosis, and treatment for all with dementia. Given limited access to randomized controlled trials, we respectfully request CMS consider additional methods that could be more easily applied in communities across the country, such as registries, that could track the progress of patient groups and subgroups to generate additional real-world data to inform care.

Finally, we respectfully request that CMS further clarifies and provide more specific definitions related to timely response. With the progressive nature of dementias, open-ended timelines for response to protocols and research submitted and determinations of coverage fail to recognize the urgency that persons living with dementia need for access to therapeutic agents. CMS should explore its ability to provide specific time defined commitments to approving clinical trial protocols, consideration of interim results, and providing revised coverage decisions based on the results of these studies.

Pharmacologic treatments for Alzheimer's Disease and Related Dementias are in their beginning stages. How we approach decision points like coverage determination can have impact on future approaches for prevention, diagnosis, treatment, and ultimately cure.

Thank you for considering our recommendations and we look forward to working with you as this Medicare Coverage Decision advances. We believe by working together we can find a meaningful path forward. Please do not hesitate to contact GSA Vice President of Policy and Professional Affairs, Trish D'Antonio at pdantonio@geron.org or 202-587-5880 if we can provide further assistance.

Sincerely,

James C. Appleby, BSPharm, MPH, ScD (Hon)
Chief Executive Officer