July 10, 2013

BY ELECTRONIC MAIL

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Comment Period Extension on Proposed Decision Memo for National Coverage Analysis for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (CAG-00431N)

Dear Administrator Tavenner:

On behalf of the Alzheimer's Association (AA), the American College of Radiology (ACR), the Council on Radionuclides and Radiopharmaceuticals (CORAR), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the Medical Imaging and Technology Alliance (MITA) and the World Molecular Imaging Society (WMIS), we respectfully request an extension of the comment period on the Centers for Medicare and Medicaid Services' (CMS) proposed coverage decision memorandum for Beta Amyloid (Aβ) Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease (CAG-00431N) for an additional 30 days.

We greatly appreciate the time and effort CMS has dedicated to analyzing the clinical evidence regarding Aβ PET for dementia and neurodegenerative disease and are particularly grateful for Patrick Conway's and Louis Jacques' interest and accessibility throughout this process. That said, we are disappointed that the agency found this evidence to be insufficient and concluded in the proposed decision that PET Aβ imaging is not reasonable and necessary for any patient population under §1862(a)(1)(A) of the Social Security Act (SSA). Rather than follow the Appropriate Use Criteria, outlining the appropriate and inappropriate use of amyloid PET imaging thoughtfully developed and published by a task force of experts organized by the AA and SNMMI,[1] CMS instead proposes coverage with evidence development (CED) for two scenarios in clinical studies that meet an extensive list of criteria. CMS's proposed decision is 91 pages long, and the

[1] Keith A. Johnson, Satoshi Minoshimab, Nicolaas I. Bohnen, Kevin J. Donohoe, Norman L. Foster, Peter Herscovitch, Jason H. Karlawish, Christopher C. Rowe, Maria C. Carrillo, Dean M. Hartley, Saima Hedrick, Virginia Pappas, William H. Thies. Appropriate use criteria for amyloid PET: A report of the Amyloid Imaging Task Force, the Society of Nuclear Medicine and Molecular Imaging, and the Alzheimer's Association. First published January 28, 2013, doi: 10.2967/jnumed.113.120618 J Nucl Med March 1, 2013 jnumed.113.120618.

criteria, as well as the decision itself, are complex. It was released the day before the long July 4 holiday weekend. Ideally, to be able to comment meaningfully on the proposed decision, including the two scenarios and study criteria, we and other stakeholders will need to gather experts in dementia and neurodegenerative disease and clinical trial design for some thoughtful discussions. This will take time, particularly given the challenges of summer schedules.

To further complicate these issues, CMS released a Draft Guidance for the Public, Industry, and CMS Staff on CED in the context of coverage decisions on November 29, 2012,[2] but this guidance still has not been finalized. In the proposed decision, CMS refers to its earlier guidance on CED from July 12, 2006;[3] however, the agency's thinking on CED clearly has evolved since this time. Allowing an additional 30 days to comment on CMS's proposed decision will enable us and other stakeholders to analyze the complex issues involved in CMS's proposed decision and its suggested use of CED more comprehensively and to provide more meaningful comments to the agency. Section 1862(l) of the SSA, governing the national coverage determination (NCD) process, describes a timeframe for development of an NCD to ensure that the public has meaningful opportunity to comment while also requiring CMS to act promptly on requests for NCDs, but it does not prohibit CMS from granting an extension of the comment period.

Obtaining meaningful public comments in the national coverage analysis process always has been a key objective of CMS. This objective is even more important for this proposed decision because of the National Alzheimer's Project Act (NAPA), signed by President Obama on January 4, 2011. Among other goals, the National Alzheimer's Project seeks to improve early diagnosis and coordination of care and treatment of Alzheimer's disease and coordinate Alzheimer's disease research and services across all federal agencies.[4] The level of discourse at the January 30, 2013 Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)[5] coupled with this disappointing proposed decision demonstrate how far we have to go to see the promise of NAPA realized. It is imperative that CMS's final decision memo reflect the important goals of NAPA.

For all of these reasons, we respectively request that CMS extend the comment period on the proposed decision for an additional 30 days. The additional time would allow us and

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[2] CMS, Draft Guidance for the Public, Industry, and CMS Staff, Coverage with Evidence Development in the context of coverage decisions, Nov. 29, 2012, available at: http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=23.

[3] CMS, Guidance for the Public, Industry, and CMS Staff, National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development, July 12, 2006, available at: http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/ced.pdf.

[4] U.S. Department of Health and Human Services, National Plan to Address Alzheimer's Disease, at 3, available at: http://aspe.hhs.gov/daltcp/napa/NatlPlan.pdf.

[5] MEDCAC, Beta Amyloid PET in Dementia and Neurodegenerative Disease, Jan 30, 2013, available at: http://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=66.

other stakeholders to comment more meaningfully on CMS's proposal while also giving the agency time to fully consider and respond to those comments. Thank you for your consideration of this request.

Sincerely,

Robert J. Egge
Alzheimer's Association

Harvey L. Neiman, MD
American College of Radiology

Michael J. Guastella
Council on Radionuclides and Radiopharmaceuticals

Gail Rodriguez, Ph.D.
Medical Imaging & Technology Alliance

Gary Dillehay, MD
Society of Nuclear Medicine and Molecular Imaging

Zaver Bhujwalla, Ph.D.
World Molecular Imaging Society

cc: Patrick Conway, M.D., M.Sc.
Chief Medical Officer
Director of the Center for Clinical Standards and Quality

Louis B. Jacques, M.D.
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