Biotechnology Industry Organization

August 1, 2013

BY ELECTRONIC DELIVERY

Louis Jacques, M.D.
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Proposed Decision Memorandum on National Coverage Analysis (NCA) for Beta-Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (CAG-00431N)

Dear Dr. Jacques:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the *Proposed Decision Memo for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (CAG-00431N)*.[1] Specifically, our comments oppose CMS' draft decision to apply coverage with evidence development (CED) to beta-amyloid Positron Emission Tomography (PET Aß) imaging. Instead, we express support for Medicare coverage of this innovative and promising technology used in the early detection and treatment of Alzheimer's disease (AD) or cognitive impairment.

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products.

As the representative of an industry that is devoted to improving health care through the discovery of new diagnostics and therapies, BIO supports the Department of Health and Human Services' (HHS') initiatives to accelerate research on detection, treatment, and prevention of AD through its National Plan to Address Alzheimer's Disease released by the Assistant Secretary for Planning and Evaluation (ASPE) on January 9, 2012.[2] The Plan's initiatives include expanding research and tools for clinicians, especially in the realm of emerging technologies and new approaches in clinical testing.[3] In comments submitted February 8, 2012,[4] BIO emphasized that any framework for improving diagnosis and care

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[1] Centers for Medicare and Medicaid Services (CMS). 2013. Proposed Decision Memo for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (CAG-00431N). Baltimore, MD: CMS, Available at: http://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=265.
[2] Department of Health and Human Services (HHS). 2013. *National Plan to Address Alzheimer's Disease: 2013 Update*. Washington, DC: HHS. Available at, http://aspe.hhs.gov/daltcp/napa/NatlPlan2013.shtml.
[3] HHS Press Office. 2012. *News release: Obama administration presents national plan to fight Alzheimer's disease*. Washington, DC: HHS, Available at: http://www.hhs.gov/news/press/2012pres/05/20120515a.html.
[4] Biotechnology Industry Organization (BIO). 2012. *Comments on the Draft Framework for the National Plan to Address Alzheimer's Disease*. Washington, DC: BIO, Available at:

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for serious, complex illnesses, such as AD, must include measures to provide access to innovative diagnostic and treatment options. As such, BIO has a particular concern with actions by the Centers for Medicare and Medicaid Services (CMS) that may continue to limit patient access to PET Aß imaging.

PET Aß imaging technology represents a significant advancement in AD care, as it aids in the early diagnosis of AD or cognitive impairment by detecting amyloid-β deposition in the brain—one of the two defining pathologic lesions of AD. The status quo for differentiating definitive causes of AD and other cognitive decline has historically been post-mortem exams; thus, PET Aß imaging allows for greater opportunity to manage clinical treatment earlier, potentially improving quality of life and health outcomes in patients living with the disease. Furthermore, the technology can help target therapeutic interventions in early stages of the illness, as well as avert unnecessary treatments. In addition to guiding existing treatment options, early diagnosis of AD allows patients to explore candidacy for clinical trials and helps patients and their caregivers seek out planning and support services.

As we have expressed in previous comment letters, BIO supports the use of CED when it is used to help patients gain access to otherwise unavailable drugs, biologicals and other therapies. Our members invest billions of dollars each year in clinical research to develop and disseminate evidence to help guide the effective use of their therapeutics and diagnostics. However, BIO does not believe CED is appropriately used when it narrows the uses of FDA-approved drugs and biologicals.

Despite receiving approval by the Food and Drug Administration (FDA) last year, CMS proposed CED for PET Aß imaging. Specifically, CMS proposes to cover one PET Aß scan per patient only for those patients enrolled in a clinical trial whose objective meets one of two predefined aims: to develop better treatments or prevention strategies for AD, or as a strategy to identify subpopulations at risk for developing AD; or, to resolve clinically difficult differential diagnoses where the use of PET Aß imaging appears to improve health outcomes. A trial must be preapproved by CMS and is subject to many other criteria including that it must: involve subjects from appropriate populations; be comparative, prospective, and longitudinal; and use randomization and postmortem diagnosis as the endpoint. If finalized, this decision will continue to exclude this technology from Medicare coverage, and therefore, it will remain inaccessible to most Medicare beneficiaries. Instead, BIO urges CMS to provide immediate Medicare coverage for the use of PET Aß imaging in the evaluation of progressive cognitive decline. BIO specifically supports Medicare coverage for PET Aß imaging when its use adheres to the criteria developed by the Alzheimer's Association and Society of Nuclear Medicine and Molecular Imaging's Amyloid Imaging Taskforce (AIT). These guidelines ensure appropriate use of this technology for intended populations only, as indicated by its appropriate use criteria (AUC) released earlier this year.[5] Thus, CED is inappropriate for the "medically accepted" AUC population.

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http://www.bio.org/advocacy/letters/alzheimer%E2%80%99s-disease-bios-comments-draft-framework-national-plan-address-alzheimer%E2%80%99s.

[5] Johnson, K. A., S. Minoshima, N. I. Bohnen, K. J. Donohoe, N. L. Foster, P. Herscovitch, J. H. Karlawish, et. al. 2013. 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. *Alzheimer's & Dementia 5*(1):1-15, Available at: http://www.alz.org/research/downloads/appropriate_use_criteria_for_amyloid_pet_alz_and_dem_january_2013.pdf.

BIO appreciates the opportunity to submit these comments. CMS should endeavor to develop coverage policies that are flexible and that allow for innovative diagnostics and therapies to get to the right patients, at the right time. We urge CMS to provide coverage for PET Aß imaging immediately, in concurrence with guidelines supported by the Alzheimer's Association and the Society of Nuclear Medicine and Molecular Imaging. It is critical that the appropriate Medicare beneficiaries gain access to this and other innovative technologies that detect and treat this debilitating disease earlier in its progression. Please contact me if you have any questions about these comments. Thank you for your attention to this very important matter.

Sincerely,

/s/

Laurel L. Todd,
Managing Director,
Reimbursement and Health Policy