



June 28, 2013

BY ELECTRONIC DELIVERY

Patrick Conway, MD, MSc.
Chief Medical Officer for the Centers for Medicare & Medicaid Services
Director of the Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard, Baltimore, MD 21244

Re: National Coverage Analysis (NCA) for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (CAG-00431N)

Dear Dr. Conway:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on Section 220.6 of the National Coverage Determination (NCD) Manual, which addresses coverage for Positron Emission Tomography (PET) scans. Specifically, our comments express support for Medicare coverage of beta-amyloid PET imaging, an 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, 2012.¹ The Plan's initiatives include expanding research and tools for clinicians, especially in the realm of emerging technologies and new approaches in clinical testing.² In comments submitted February 8, 2012,³ BIO emphasized that any framework for improving diagnosis and care for serious, complex illnesses, such as AD, must include measures to provide access to

¹ Draft Framework for the National Plan to Address Alzheimer's Disease, Jan. 9, 2012, available at: <http://aspe.hhs.gov/daltcp/napa/natplan.shtml>.

² U.S. Department of Health & Human Services, HHS Press Office. (2012). *News release: Obama administration presents national plan to fight Alzheimer's disease*, available at: <http://www.hhs.gov/news/press/2012pres/05/20120515a.html>.

³ BIO's Comments on the Draft Framework for the National Plan to Address Alzheimer's Disease, Feb. 8, 2012, available at: <http://www.bio.org/advocacy/letters/alzheimer%E2%80%99s-disease-bios-comments-draft-framework-national-plan-address-alzheimer%E2%80%99s>.

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 amyloid PET imaging.

Amyloid PET 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 Alzheimer’s disease and other cognitive decline has historically been post-mortem exams; thus, amyloid PET 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.

Despite receiving approval by the Food and Drug Administration (FDA) last year, this technology continues to be excluded from Medicare coverage, and therefore remains inaccessible to most Medicare beneficiaries. BIO thus urges CMS to provide immediate Medicare coverage for the use of amyloid PET imaging in the evaluation of progressive cognitive decline. BIO specifically supports Medicare coverage for PET amyloid 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.⁴ Further, coverage with Evidence Development (CED) would not be appropriate for the “medically accepted” AUC population.

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 amyloid PET 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,

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

⁴ Johnson, K. 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.