

Amyloid Imaging Coverage with Evidence Development and the IDEAS Study

Peter Herscovitch, MD, SNMMI President

Before the first PET radiopharmaceutical for β -amyloid imaging was approved for marketing by the U.S. Food and Drug Administration in April 2012, the Alzheimer's Association and SNMMI assembled an Amyloid Imaging Taskforce (AIT), comprising dementia and imaging experts, to review the scientific literature and develop consensus recommendations for clinical use of this promising new technology. The AIT concluded that amyloid imaging could be helpful in the diagnosis of cognitive impairment, when considered along with other clinical information. In addition, the taskforce emphasized that the decision to order amyloid imaging should be made only after a comprehensive evaluation by a physician experienced in the assessment and diagnosis of cognitive impairment and dementia, and only if the presence or absence of brain amyloid would increase certainty in the diagnosis and alter the management plan.

This led to publication in May 2013 of the first appropriate use criteria (AUC) for β -amyloid imaging to aid in assessment of patients with cognitive impairment when the diagnosis is uncertain after a comprehensive evaluation. The primary goal of the criteria was to provide health care practitioners with the information and options needed to offer patients the best possible diagnosis and care in a cost-effective manner. It was felt that these carefully crafted AUC would also support coverage of reimbursement.

Unfortunately, in September 2013 the Centers for Medicaid & Medicare Services (CMS) released its decision that there was insufficient evidence to conclude that PET amyloid imaging is reasonable and necessary for the diagnosis or treatment of Medicare beneficiaries with dementia or neurodegenerative disease. However, CMS did state there was sufficient evidence that amyloid imaging is promising to exclude Alzheimer disease (AD) in clinically difficult differential diagnoses, such as AD versus frontotemporal dementia, and to enrich clinical trials seeking better treatments or prevention strategies for AD. Therefore, CMS did allow reimbursement of one amyloid scan per patient, through coverage with evidence development, in relevant clinical studies. These studies must be designed to demonstrate that use of the scan improves patient health outcomes, including

short-term outcomes related to changes in management or longer-term dementia outcomes.

In response to Medicare's decision, an Amyloid Imaging Coverage with Evidence Development (AICED) Workgroup was created, with representatives from the Alzheimer's Association, SNMMI, the American College of Radiology Imaging Network, and the World Molecular Imaging Society. The AICED crafted an evidence development study for

PET amyloid imaging in patients with either progressive, unexplained mild cognitive impairment or dementia of uncertain etiology. This evolved into the "Imaging Dementia—Evidence for Amyloid Scanning" (IDEAS) study. After detailed review by CMS and protocol revisions, the study was approved on March 25, 2015.

The IDEAS study is an open-label, longitudinal cohort study to assess the impact of amyloid PET on outcomes in patients meeting the AUC developed by SNMMI and the Alzheimer's Association. The primary hypothesis of the study is that, in diagnostically uncertain cases, knowledge of amyloid status as determined by amyloid PET will lead to significant changes in patient management with resulting improved health outcomes. The study also aims to assess the impact of amyloid PET on hospital admissions and emergency visits in patients enrolled in the study cohort over a 12-month period. Participants must be Medicare beneficiaries referred by qualified dementia specialists and must meet the AUC for amyloid PET, along with other criteria. A total of 18,488 Medicare beneficiaries will be enrolled over 24 months at sites throughout the United States.

SNMMI will continue its work and advocacy along with the Alzheimer's Association and other stakeholders to ensure that dementia patients have access to the best care possible. More information on brain amyloid imaging for Alzheimer disease and the appropriate use criteria can be found at: <http://www.snmmi.org/Content.aspx?ItemNumber=5971>.



Peter Herscovitch, MD