August 2, 2013

Louis B. Jacques, MD
Director, Coverage & Analysis Group
Centers for Medicare and Medicaid Services
Mail Stop S3-02-01
7500 Security Boulevard Baltimore, MD 21244-1850

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

Dr. Jacques:

We thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comment on its July 3 Proposed Decision Memorandum on National Coverage Analysis (NCA) for Beta-Amyloid Positron Emission Tomography (Aβ PET) in Dementia and Neurodegenerative Disease (CAG-00431N). We write today on behalf of more than 5 million Americans who have Alzheimer's disease and millions more who have vascular, Lewy body or frontotemporal dementia; many overcame enormous obstacles to receive their diagnosis, many others remain undiagnosed.

We reiterate the recommendation of our April 30 comment (http://www.leadcoalition.org/?wpfb_dl=103) and strongly encourage that **CMS issue a final decision to provide full nationwide coverage of Aβ PET imaging in the evaluation of progressive cognitive decline when its use is consistent with the appropriate use criteria (AUC) developed by the Alzheimer's Association and Society of Nuclear Medicine and Molecular Imaging (SNMMI) and there should not be a requirement for Coverage with Evidence Development (CED).**

Requiring CED is inconsistent with the overwhelming balance of scientific evidence provided in the FDA decision, the initial application for coverage, testimony before the MEDCAC, comments prior to the proposed decision and comments being submitted in response to the proposed decision. The proposed decision does not appear to account for the fact that, under the AUC, use would be limited to a modest number of the most difficult diagnostic cases and would provide scientifically rigorous, evidence-based, and clinically meaningful results for patients, caregivers and medical providers.

The proposed decision would dramatically and unnecessarily delay AUC availability of Aβ PET imaging to make differential diagnoses that medical professionals need to diagnose these conditions and begin the much-needed

therapies. This CED threatens to jeopardize patient safety for those otherwise misdiagnosed and erroneously subjected to the wrong treatments.

This misapplication of CED also threatens to retard the pipeline of scientific innovation in the imaging field and potentially in other fields concerned by CMS' unprecedented, unnecessary and ill-defined seismic shift in coverage criteria. The proposed decision runs counter to our national economic policy that depends on scientific innovation and to the National Plan to Address Alzheimer's Disease that calls for ensuring timely and accurate diagnosis, enhancing care quality and efficiency, and educating and supporting people with Alzheimer's disease and their families. The Advisory Council on Alzheimer's Research, Care, and Services specifically recommended that Congress and CMS redesign Medicare coverage and reimbursement to encourage appropriate diagnosis of Alzheimer's disease and provide care planning to diagnosed individuals and their caregivers.

The proposed CED conveys to patients a perplexing message that the diagnostic tool somehow is good enough for clinical trials but not good enough for patients to know whether they have Alzheimer's disease, frontotemporal degeneration, or some other dementing condition. It tells patients that coverage will be available in clinical trials but creates a potentially prohibitive environment for clinical trials by covering only one test and giving no clear indication of what trial designs would be approved. It tells patients that autopsy remains the only reliable means of diagnosis both undermining confidence in the value of participating in any such clinical trials and essentially telegraphing that CMS does not intend to approve diagnostic advances for at least another five to ten years or more.

This is not about one company's product; it is about a generation of diagnostic tools, a generation of clinical trials, and a generation of patients and families. We urge CMS to reconsider its proposed ruling and issue a final ruling which removes the CED requirement in favor of full national coverage under the AUC.

Thank you for considering our views. Please contact Ian Kremer, the LEAD Coalition's executive director, at ikremer@leadcoalition.org or (571) 383- 9916, with questions or for additional information.

Sincerely,

Academy of Radiology Research

Alzheimer's & Dementia Alliance of Wisconsin

Alzheimer's Foundation of America

Alzheimers North Carolina

Alzheimer's Tennessee

American Association for Geriatric Psychiatry

American Association for Long Term Care Nursing

Assisted Living Federation of America

Banner Alzheimer’s Institute

Beating Alzheimer's by Embracing Science

BrightFocus Alzheimer’s Disease Research

Caregiver Action Network

Center for Alzheimer Research and Treatment, Harvard Medical School

Cleveland Clinic Foundation

Coalition for Imaging and Bioengineering Research

Cognition Therapeutics

Cortica Neurosciences, Inc.

Jeffrey Cummings, MD, ScD (Cleveland Clinic Lou Ruvo Center for Brain Health*)

Cure Alzheimer’s Fund

Dr. Michael Devous Sr. (University of Texas Southwestern Medical Center*)

Rachelle S. Doody, MD, PhD (Baylor College of Medicine*)

Geoffrey Beene Foundation - Alzheimer's Initiative

Georgetown University Medical Center Memory Disorders Program

Global Coalition on Aging

Howard University, Aging and Memory Disorder Programs

Janssen Alzheimer Immunotherapy

Janssen Research & Development, LLC

Latino Alzheimer’s and Memory Disorders Alliance

Linked Senior, Inc.

Kostas Lyketsos, M.D., M.H.S. (Johns Hopkins Memory and Alzheimer's Treatment Center*)

Dave Morgan, PhD (USF Health Byrd Alzheimer's Institute*)

National Association of States United for Aging and Disabilities

National Down Syndrome Society

National Hispanic Council on Aging

National Task Group on Intellectual Disabilities and Dementia Practices

Neurotechnology Industry Organization

New York Academy of Sciences

NYU Langone Comprehensive Center on Brain Aging/NYU Langone Silberstein Alzheimer's Institute

NYU Alzheimer's Disease Center

Thomas O. Obisesan, MD, MPH (Howard University Hospital*)

OWL-The Voice of Midlife and Older Women

Piramal Imaging

Project Lifesaver International

RemeGenix, Inc.

ResearchersAgainstAlzheimer's

Stephen Salloway, M.D., M.S. (The Warren Alpert Medical School of Brown University*)

Reisa A. Sperling, MD, MMSc (Center for Alzheimer Research and Treatment, Harvard Medical School*)

R. Scott Turner, MD, PhD (Georgetown University Memory Disorders Program*)

USAgainstAlzheimer's

USF Health Byrd Alzheimer's Institute

Volunteers of America

Vradenburg Foundation

Michael W. Weiner, MD (University of California San Francisco*)

WomenAgainstAlzheimer's

Wooten Laboratory for Alzheimer's and Neurodegenerative Diseases Research

* *Affiliations of individual researchers are for identification purposes only and do not necessarily represent the endorsement of the affiliated institution.*

Leaders Engaged on Alzheimer's Disease (LEAD) is a diverse and growing coalition of 61 member organizations including patient advocacy and voluntary health non-profits, philanthropies and foundations, trade and professional associations, academic research and clinical institutions, and biotechnology and pharmaceutical companies. The LEAD Coalition works collaboratively to focus the nation's strategic attention on Alzheimer's disease and related disorders and to accelerate transformational progress in care and support, detection and diagnosis, and research leading to prevention, effective treatment and eventual cure. One or more participants may have a financial interest in the subjects addressed.