November 8, 2012

Brijet Burton, MPP, MS, PA-C
Stuart Caplan, RN, MAS
Joseph Hutter, MD, MA
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear CMS Officials:

The American Society of Neuroradiology (ASNR) represents 5,000 physicians specializing in the field of neuroradiology. As the preeminent society concerned with the diagnostic imaging and image-guided intervention of diseases of the brain, spine, and head and neck, we appreciate the opportunity to comment on coverage of brain PET amyloid imaging. Advanced imaging methods such as computed tomography (CT), magnetic resonance imaging (MRI) and positron emission tomography (PET) constitute the majority of the diagnostic imaging medical practice of ASNR members. ASNR supports CMS coverage of brain PET as it relates to beta-amyloid imaging in the context of the diagnosis of neurocognitive deficits. The American Society of Functional Neuroradiology (ASFNR), a 265 member specialty society of physicians with specialized interests in advanced neuroimaging techniques, including PET, joins the ASNR in supporting coverage.

Alzheimer’s disease (AD) is a neurodegenerative process characterized by abnormal accumulation of amyloid beta (amyloid) in the brain (Selkoe, 1991; Jack et al., 2010). It is by far the leading cause of acquired neurocognitive deficits, accounting for up to 80 percent of all dementia in the United States (Alzheimer's Association, 2012). AD is an inexorably progressive, terminal illness with substantial burdens inflicted upon patients and their caregivers, often family members. Further, the financial impact of AD is large and increasing and represents a challenge to patients, their families and the healthcare system (Alzheimer’s Association, 2012).

Given the progressive and terminal nature of AD, accurate diagnosis is essential to target appropriate interventions, including symptom management, life planning, and access to clinical trials of potential disease-modifying medications. A delayed or missed diagnosis of AD can be harmful in several regards. A definitive diagnosis can
significantly reduce levels of anxiety in patients and caregivers by reducing the uncertainty of “not knowing” (Carpenter et al., 2008). Access to special support services, not otherwise available to those without a diagnosis, may be missed. Important life planning opportunities may be missed or delayed to a time in which the patient is less capable of making critical and sensitive decisions. Family members, friends and other caregivers may be deprived of the opportunity to act in a timely manner. Inappropriate therapies may be instituted, and the window of opportunity for appropriate therapies may be missed. Similarly, a mistaken diagnosis of AD in the absence of disease may have similarly significant consequences and also lead to inappropriate interventions.

Consistent with the goals of the National Alzheimer’s Project Act (U.S. Department of Health and Human Services, 2012), the ASNR supports the use of new, innovative and effective approaches to the diagnosis and treatment of AD. Brain amyloid PET imaging is an important new non-invasive diagnostic modality (Klunk et al., 2004; Rowe et al., 2007). Extensive experience with amyloid imaging, including results with florbetapir, demonstrate the utility of amyloid imaging in the evaluation of neurodegenerative disease (Klunk, 2011; Quigley et al., 2011), and these results form the basis for the FDA approval of florbetapir.

The evaluation of neurocognitive deficits may be a complex undertaking, and should be performed within the context of a comprehensive health care program. ASNR recognizes that imaging, including structural imaging as performed by CT or MRI, and PET imaging, including amyloid as well as fluorodeoxyglucose PET, should be performed only as necessary and appropriate. ASNR recognizes the work and recommendations of the National Institute on Aging and the Alzheimer’s Association (Albert et al., 2011; Jack et al., 2011; McKhann et al., 2011; Sperling et al., 2011), and the recommendations of the European Federation of the Neurological Societies (Filippi et al., 2012), among others.

Additionally, the ASNR supports the current collaboration of the Society of Nuclear Medicine and the Alzheimer’s Association to develop guidelines for appropriate utilization of brain amyloid PET imaging. Similarly, we recognize and support the efforts of the International Working Group for New Research Criteria for Alzheimer’s disease to develop similar guidelines for application to research protocols.

Alzheimer’s disease is a fearsome and dreaded diagnosis. This can be a powerful motivation to a potentially vulnerable population that may be in pursuit of any chance of diagnosis and treatment. Consequently, there is substantial risk of inappropriate application of brain amyloid PET imaging that could result in mis-diagnosis and subsequent inappropriate treatment or over-treatment. It must be clearly communicated to patients and medical practitioners that brain amyloid PET imaging is not an “Alzheimer’s scan”, and that amyloid imaging is not an appropriate screening test for asymptomatic individuals. ASNR advocates for clear utilization
criteria, including guidelines on physician self-referral (U S Government Accountability Office, 2012), to protect patients and optimize resource utilization.

ASNR advocates for the following positions with respect to amyloid PET imaging:

1) Standards should be instituted for the high quality performance and interpretation of brain amyloid PET imaging, commensurate with the FDA approval and guidelines for florbetapir.

2) Patients should be appropriately selected for amyloid PET imaging, and criteria should be established for appropriate indications. In particular, patients should have or be suspected to have acquired neurocognitive deficits concerning for AD.

3) Brain amyloid PET imaging should not be performed as a screening test in asymptomatic individuals outside of IRB-approved research programs.

4) With respect to the potential for mis-application of brain amyloid PET imaging, clear utilization guidelines should be established, including explicit criteria regarding physician self-referral and patient protection.

The appropriate performance of amyloid PET imaging and interpretation of these results by qualified, well-trained medical professionals is essential to compiling the body of data that will be used for evaluation of interventions in AD. This data will be critical for the development of disease modifying therapies for AD, including several drugs and lifestyle interventions currently under investigation. The ASNR advocates strongly for appropriate standards for amyloid PET imaging and interpretation, and we will work with CMS and other professional societies to develop and maintain these standards. In particular, the ASNR supports the development of open standards for quantitative evaluation of amyloid imaging results.

In advocating for Medicare coverage for brain amyloid PET imaging, ASNR seeks to reduce barriers to access for appropriate services. Similarly, ASNR advocates for guidelines and regulation to diminish the incentive for inappropriate, non-evidence based practice. We expect that amyloid imaging will have great benefit for clinical care of patients, and will play a major role in the development of disease modifying therapy in amyloid-related neurodegenerative processes.

In summary, the ASNR requests that CMS update section 220.6 of the Medicare National Coverage Determination Manual to authorize Medicare coverage for PET amyloid imaging in the evaluation of acquired neurocognitive deficits in adults. Further, the ASNR pledges its support in the evaluation of the clinical application of
amyloid PET imaging, with the goal of determining appropriate imaging indications and to provide optimum patient care and appropriate resource utilization.

ASNR and its members are looking forward to the advancement in clinical practice that PET amyloid imaging represents. The Society will continue to serve our members as a resource for the development and exchange of data in this emerging field, and we will work collaboratively with CMS and other professional societies to achieve the best evidence-based practices for optimal, appropriate and responsible patient care.

Sincerely,

Pamela W. Schaefer, MD
ASNR President
Associate Professor of Radiology, Harvard Medical School
Clinical Director of MRI and Associate Director of Neuroradiology, MGH

Daniel P. Barboriak, MD
ASFNJ President
Professor in Radiology, Duke University School of Medicine

Robert M. Barr, MD
Chair, ASNR Clinical Practice Committee
President, Mecklenburg Radiology Associates
Presbyterian Hospital, Department of Radiology
Charlotte, North Carolina

Mykcol Larvie, MD, PhD
Director, Clinical Molecular Neuroimaging, Divisions of Neuroradiology and Nuclear Medicine and Molecular Imaging, MGH;
Instructor in Radiology, Harvard Medical School
References


