World Molecular Imaging Society

October 25, 2012

BY ELECTRONIC DELIVERY

Louis Jacques, M.D.
Coverage and Analysis Group, Director
Centers for Medicare & Medicaid Services
Department of Health and Human Services
2500 Security Boulevard
Baltimore, MD 21244

Re: **Beta-Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (CAG-0431M)**

Dear Dr. Jacques:

The World Molecular Imaging Society (WMIS) is pleased to provide this comment in support of Medicare coverage of beta amyloid imaging with positron emission tomography in Medicare beneficiaries with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline. In addition to these comments, WMIS plans to present at the at the upcoming Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting on this topic scheduled for January 30, 2013.

WMIS is an international scientific educational organization dedicated to the understanding of biology and medicine through multimodal in vivo imaging of cellular and molecular events involved in normal and pathologic processes, and the utilization of quantitative molecular imaging in patient care. At present, WMIS has over 1,000 members. WMIS was formed in 2011, as a result of the merger of two of the premier molecular imaging societies — the Academy of Molecular Imaging and the Society for Molecular-Genetic Imaging. Between 2006 and 2011, AMI was the sponsor of the original NOPR, and post-merger, WMIS has continued to sponsor the current iterations of the registry, NOPR 2009 and NOPR (NaF-PET). WMIS has been deeply involved in supporting the Centers for Medicare & Medicaid Services effort to make evidence-based coverage decisions on PET imaging.

The burdens of Alzheimer's disease are well known. The Alzheimer's Association released a report detailing that care costs for people with Alzheimer's disease and other types of

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dementias will reach $200 billion, with the majority of these costs borne by Medicare and Medicaid. An estimated 5.4 million people are living with Alzheimer's disease.

Far too many people with Alzheimer's disease are not diagnosed until their symptoms have become severe. Today Alzheimer's disease pathology only can be inferred through the recognition of a characteristic phenotype. By the time dementia is obvious, deficits often are so pervasive that the typical phenotype may be difficult to recognize.

Significant advances in the use of imaging have made it possible to detect the onset of Alzheimer's disease, track its progression, and monitor the effects of treatment in people with the disease. This ongoing work builds off the public-private Alzheimer's Disease Neuroimaging Initiative (ADNI)[1]. Empowered with the knowledge of brain pathology, clinicians will be more likely to begin and maintain appropriate treatment.[1]

On April 6, 2012 the Food and Drug Administration (FDA) announced approval of florbetapir injection (Amyvid) for PET imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline. Florbetapir is an adjunct to other diagnostic evaluations.

There is a high level of public and professional interest in amyloid imaging. Amyloid deposition in the brain is one of the most important pathological hallmarks of Alzheimer's disease. According to the FDA-approved labeling a negative scan indicates sparse to no amyloid plaques are currently present, which is inconsistent with a neuropathological diagnosis of Alzheimer's disease and reduces the likelihood that a patient's cognitive impairment is due to Alzheimer's disease. A positive scan indicates moderate to frequent amyloid plaques are present; this amount of amyloid plaque is present in patients with Alzheimer's disease, but may also be present in patients with other neurologic conditions and in older people with normal cognition

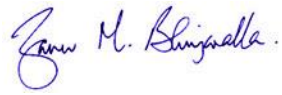
WMIS believes that CMS should make explicitly clear that beta amyloid PET scans should not be used for screening of asymptomatic patients or evaluation of those with no documentation of cognitive decline. Moreover, WMIS believes that use of beta amyloid PET scans should not be considered reasonable and necessary in patients who present with symptoms and clinical profiles that make their diagnosis clear and confident without the scan, in the judgment of the treating physician.

WMIS is committed to working with you to ensure that Medicare beneficiaries have access to this important new technology, and to work with physicians and patients to develop

guidelines for appropriate use. We are aware that new appropriate use recommendations for the use of beta amyloid imaging agents are being developed by the Alzheimer's Association in partnership with the Society of Nuclear Medicine. WMIS is collaborating with these groups and others to educate providers and patients.

WMIS looks forward to continuing to work collaboratively with CMS, and we are pleased to provide CMS with any additional information that it may find useful in reaching its decision on this reconsideration request.

Sincerely,



Zaver M. Bhujwalla, PhD
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Juri Gelovani, MD, PhD

Past-President & Executive Committee Member

[1]Weiner *et al.,* The Alzheimer's Disease Neuroimaging Initiative: A review of papers published since its inception. Alzheimer's & Dementia 8 (2012)S1-S68