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ALZHEIMER’S ASSOCIATION TO CONTINUE TO ADVOCATE FOR COVERAGE OF DIAGNOSTIC TOOL FOLLOWING CMS ANNOUNCEMENT

- Alzheimer’s Association Statement -

CHICAGO, July 5, 2013 – The Alzheimer’s Association is disappointed by the Centers for Medicare & Medicaid Services (CMS) draft coverage decision on brain amyloid imaging, particularly given the clear, scientific consensus recommendations provided to CMS by the Association and the Society for Nuclear Medicine and Molecular Imaging (SNMMI) regarding appropriate, limited coverage, only in specific populations.

The Alzheimer’s Association understands that CMS’ evaluation of the impact of brain amyloid imaging on health outcomes is ongoing, however the needs of Alzheimer’s community are acute. With 5 million Americans living with Alzheimer’s and more than 15 million people providing care, the need to accelerate improved care and an early and accurate diagnosis today, when scientifically supported, is critical. Neither families directly impacted by the disease, nor our federal government, can afford to wait as much as seven years for a final decision about national coverage, as was the case with the National Oncology Patient Registry and the evaluation by CMS of FDG PET coverage. Seven years ago, this brain amyloid imaging technology did not even exist. The timeframe at which CMS has conducted CED processes is wholly unsuited and unacceptable to both the pace of scientific and technological innovation in the Alzheimer's field, and more importantly, the rapidly increasing needs posed by the escalating Alzheimer’s epidemic. If the federal government follows this example and timeline, it will hinder coverage of a badly needed, already FDA approved diagnostic tool in limited populations in which sufficient evidence indicates this technology has meaningful impact.

Understanding that this is a draft decision from CMS, and it is not yet final, the Alzheimer’s Association will continue to engage the scientific and healthcare communities, as well as advocates, to educate CMS on behalf of our constituents about the benefits of coverage for brain amyloid imaging -- in limited populations as defined by the scientifically-driven appropriate use criteria -- as CMS develops a final decision.
A report of the taskforce convened by the Alzheimer’s Association and SNMMI that describes appropriate use of brain amyloid imaging was published online as an article in press on January 28, 2013, by *Alzheimer’s & Dementia: The Journal of the Alzheimer’s Association* and *Journal of Nuclear Medicine*. According to those criteria, appropriate candidates for amyloid PET imaging are limited to:

- Those who complain of persistent or progressive *unexplained* memory problems or confusion and who demonstrate impairments using standard tests of cognition and memory. Additional clarification of these individuals was made by the Amyloid Imaging Taskforce (AIT) in July 2013, amyloid PET would be appropriate only in those [MCI] individuals who the dementia expert has concluded would benefit from greater certainty of the underlying pathology and whose clinical management would change as a result of this greater certainty. (*Alzheimer’s & Dementia, The Journal of the Alzheimer’s Disease, July 2013*).
- Individuals meeting tests for possible Alzheimer’s, but who are *unusual* in their clinical presentation.
- Individuals with progressive dementia and *atypically* early age of onset (before age 65).

As the largest scientifically-based patient advocacy group in the field of Alzheimer’s and dementia, the Alzheimer’s Association strongly supports early and accurate diagnosis of Alzheimer’s disease. An early diagnosis has been found to lead to better outcomes and higher quality of life for people living with the disease and their families by: enabling earlier access to appropriate treatments, allowing the family to build a care team and seek out education and support services, enabling enrollment in Alzheimer’s/dementia clinical trials, and providing an opportunity for the development of advance directives and financial planning.

We encourage CMS to have an open dialogue with all stakeholders in creating its final decision, so that the needs of all parties may be identified and taken into consideration.

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**About the Alzheimer’s Association:**

The Alzheimer’s Association is the world’s leading voluntary health organization in Alzheimer care, support and research. Our mission is to eliminate Alzheimer’s disease through the advancement of research; to provide and enhance care and support for all affected; and to reduce the risk of dementia through the promotion of brain health. Our vision is a world without Alzheimer’s.