Appropriate Use Criteria For Imaging Brain Beta-Amyloid

Kevin Donohoe
Beth Israel Deaconess Medical Center
Boston, MA
Conflicts of Interest

- I have been a consultant for Avid (florbetapir)
Important Topics

- Alzheimer disease
- The Need For Appropriate Use Criteria (AUC)
- Development of AUC Document
- CMS Consideration of AUC Document
Alzheimer Disease

- Described in 1906 by Alois Alzheimer
  - 51 year old patient with pre-senile dementia
  - Post-mortem showed amyloid plaques using new silver stain
- Most common form of dementia
  - Most commonly diagnosed over age 65
  - Predicted to affect more than 1% of the population by 2050
Alzheimer Disease - Cause

- Unknown
  - Some with genetic component – Early onset familial Alzheimer Disease
  - Amyloid hypothesis

- How does amyloid beta cause dementia?
Alzheimer Disease Symptoms

- Variable, which is a problem for diagnosis
- Mild Cognitive Impairment (MCI)
  - Short-term memory loss
  - Inability to acquire new information
  - Difficulty with executive functions – attentiveness, planning, abstract thinking.
  - Apathy
  - Reduced awareness of memory difficulties
- Word-finding difficulties
- Difficulties with common activities of daily living
- Motor difficulties
- Irritability ➔ apathy
- Eventually death due to secondary factors
Alzheimer Disease – Diagnosis

- Often difficult, particularly in early stages.
  - 20% of people diagnosed with AD do not have it.
- Definitive diagnosis only made at autopsy
  - Extracellular amyloid plaques
- Amyloid scanning
  - PiB – First scan 2002, results published in 2004
    - Bill Klunk, University of Pittsburgh
    - Needed a compound to diagnose disease in-vivo
    - Needed a way to monitor response to amyloid beta clearing agents.
Appropriate Use Criteria

- AUC documents distill the current literature and expert opinion to provide medical practitioners with guidance about the proper use of a given test or procedure.
Appropriate use criteria for amyloid PET: A report of the Amyloid Imaging Task Force, the Society of Nuclear Medicine and Molecular Imaging, and the Alzheimer’s Association

Keith A. Johnson\textsuperscript{a}, Satoshi Minoshima\textsuperscript{b}, Nicolaas I. Bohnen\textsuperscript{c}, Kevin J. Donohoe\textsuperscript{d}, Norman L. Foster\textsuperscript{e}, Peter Herscovitch\textsuperscript{f}, Jason H. Karlawish\textsuperscript{g}, Christopher C. Rowe\textsuperscript{h}, Maria C. Carrillo\textsuperscript{i,*}, Dean M. Hartley\textsuperscript{j}, Saima Hedrick\textsuperscript{k}, Virginia Pappas\textsuperscript{l}, William H. Thies\textsuperscript{i}

\textsuperscript{a}Departments of Radiology and Neurology, Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA
\textsuperscript{b}Department of Radiology, University of Washington, Seattle, WA, USA
\textsuperscript{c}Departments of Radiology and Neurology, University of Michigan, and VA Ann Arbor Healthcare System, Ann Arbor, MI, USA
\textsuperscript{d}Beth Israel Deaconess Medical Center, Boston, MA, USA
\textsuperscript{e}Department of Neurology, University of Utah, Salt Lake City, UT, USA
\textsuperscript{f}PET Department, NIH Clinical Center, National Institutes of Health, Bethesda, MD, USA
\textsuperscript{g}Department of Medicine, University of Pennsylvania, Philadelphia, PA, USA
\textsuperscript{h}Department of Nuclear Medicine and Centre for PET, Austin Health, Victoria, Australia
\textsuperscript{i}Division of Medical and Scientific Relations, Alzheimer’s Association, Chicago, IL, USA
\textsuperscript{j}Society of Nuclear Medicine and Molecular Imaging, Reston, VA, USA
Center for Medicare and Medicaid Services (CMS)

- Advised by Medicare Evidence Development & Coverage Advisory Committee
  - Met January 30, 2013 to consider brain amyloid imaging
- CMS Proposed Decision
  - July 3, 2013
- Public Comment Period
  - 7/3/13 – 8/02/13
- CMS Final Decision
  - 9/27/13