



Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease

January 30, 2012

Purpose of the Meeting

CMS convened this MEDCAC panel to review the available evidence on the use of beta amyloid PET imaging for the management of dementia and neurodegenerative disease.

Purpose of the Meeting

CMS is most interested in the ability of this technology to inform the clinical diagnosis and management of dementia by improvement in health outcomes, particularly patient function and quality of life. We also seek the panel's input on whether the published evidence identifies patient characteristics that predict improved health outcomes of patients who undergo PET imaging for beta amyloid.

Alzheimer's Disease (AD)

- AD is the #1 cause of dementia in older Americans (age 65 and over)
- Fatal typically in 2 – 20 years; can require round-the-clock supervision and care
- In 2005, was 5th leading cause of death in older Americans (7th overall)
- Currently, > 5 million (12.5%) of older Americans have AD
 - By 2030, this will rise to 8.7 million

AD: The National Plan

- The Secretary of HHS has created the National Plan to Address Alzheimer's Disease.
- Includes the goal of preventing and effectively treating Alzheimer's Disease by 2025

Role for Amyloid Imaging?

- While there is no definitive diagnosis (other than postmortem) or any effective treatment, for AD, some argue that the value of beta amyloid PET imaging is:
 - if negative, it could:
 - (1) effectively exclude AD, and therefore preclude potentially harmful and burdensome treatments in patients mistakenly diagnosed with AD;
 - (2) hasten work up for a correct diagnosis that perhaps could be treated;
 - (3) expedite and improve the quality of research to develop effective treatments for AD

CMS Authority

42 CFR 410.32

(a) Ordering diagnostic tests. All diagnostic . . . tests must be ordered by the physician who . . . treats a beneficiary for a specific medical problem and **who uses the results in the management of the beneficiary's specific medical problem.**

Current Coverage Status

- Found in NCD manual 220.6
- National noncoverage for all PET uses that are not specifically covered; thus amyloid PET imaging is currently noncovered.
- No local coverage for amyloid PET imaging.

Voting Scale

For the voting questions, use the following scale identifying level of confidence - with 1 representing the lowest or no confidence, 3 representing intermediate confidence and 5 representing a high level of confidence.

1 Low Confidence	2	3 Intermediate Confidence	4	5 High Confidence
---------------------	---	---------------------------------	---	-------------------------

Voting Question #1A

- How confident are you that there is adequate evidence to determine whether or not PET imaging of brain beta amyloid changes health outcomes (improved, equivalent or worsened) in patients who display early symptoms or signs of cognitive dysfunction?

Voting Question #1B

- If there is at least intermediate confidence (mean score ≥ 2.5 in question 1a), how confident are you that PET imaging of brain beta amyloid improves health outcomes in patients who display early symptoms or signs of cognitive dysfunction?

Panel Discussion following Questions #1A and #1B

- Please discuss the factors that led to your vote.
- If there is at least intermediate confidence that PET imaging of brain beta amyloid improves health outcomes in patients who display early symptoms or signs of cognitive dysfunction (mean score ≥ 2.5 in Question 1b), please proceed to Question 2a. If not, please proceed to Question 3.

Voting Question #2A

- How confident are you that there is adequate evidence to identify patient characteristics that predict improved health outcomes of patients who undergo PET imaging for beta amyloid?

Discussion Question #2B

- If there is at least intermediate confidence there is adequate evidence to identify patient characteristics that predict improved health outcomes of patients who undergo PET imaging for beta amyloid (mean score ≥ 2.5 in question 2a), please identify and discuss the relative weight of those characteristics.

Voting Question #3

- How confident are you that these conclusions are generalizable to the Medicare beneficiary population?

Discussion Question #4

- Please discuss any evidence gaps and the types of clinical studies that would be needed to confidently close those gaps.

Next....

Our 5 experts will discuss the current clinical work up and management of patients with cognitive impairment and possible Alzheimer's Disease, the state of research, and the potential impact of beta amyloid PET imaging.