

4 Case Studies Using Amyvid in Clinical Practice:  
The “Value of Knowing”

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Neurodegenerative Disease”  
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# Disclosure Statement

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- I am speaking today in my capacity as a geriatrician in private practice in New York for over 30 years, primarily caring for people with Alzheimer's disease. I am presenting 4 clinical cases from my private medical practice.
- I am also the founding Executive Director and Chief Science Officer for the Alzheimer's Drug Discovery Foundation (ADDF) and its private foundation affiliate the Institute for the Study of Aging (ISOA). The ISOA provided seed funding for the Amyvid program at the University of Pennsylvania from 2000-2004. As a result, the foundation receives a pro rata share of royalty payments from the University of Pennsylvania on royalties from their license with Avid. I do not receive any personal compensation from these royalties.
- I have been a consultant or served on the advisory boards of numerous pharmaceutical and biotechnology companies over the years. Of relevance to this meeting, I currently serve as a consultant to Eli Lilly with regard to health economic studies of data from recent clinical trials with an anti-amyloid therapy. These studies are unrelated to Amyvid. I have also served during the past year on 2 Advisory Boards for Eli Lilly, unrelated to the use of Amyvid in clinical practice. My total compensation for these activities was  $\leq$ \$10,000.
- I have no other intellectual conflicts of interest (e.g. involvement in a federal or nonfederal advisory committee that has discussed the issue) that may pertain in any way to the subject of this meeting.

# 4 Case Studies on the Value of Amyvid™ in Clinical Practice

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- Case 1: 80 year old successful and very active businessman whose wife reported husband's "memory problems." Patient diagnosed with amnestic MCI due to Alzheimer's disease. Lifestyle modifications were recommended, including reduced alcohol intake, exercise, and a significant reduction in his stressful business life including the plan to ultimately withdraw from the business he devoted his life to. As a result the patient improved to "normal," creating uncertainty regarding diagnosis. The family sought certainty for care planning and life management. Amyvid scan was negative, suggesting the absence of a neurodegenerative process due to Alzheimer's disease. The patient remains active in his business with no current plan to retire, while continuing his lifestyle modifications.
- This case illustrates the value of Amyvid in diagnosis, prognosis and care planning. The negative scan significantly changed (improved) prognosis, enabled the patient to remain active in life and in his business, and significantly reduced caregiver stress and burden.

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- Case 2: 75 year old with unusual history of slowly progressive dementia over 12 years. Past history of falls from a horse and head trauma with concussions. MRI of the brain showed communicating hydrocephalus. Patient did not have a gait disorder or incontinence, so the diagnosis of normal pressure hydrocephalus deemed unlikely, and the patient was given a diagnosis of Alzheimer's disease. He did not receive a shunt because of uncertainty in the diagnosis of hydrocephalus as the cause of his cognitive impairment. Family sought certainty on diagnosis to explain unusual and prolonged course. Amyvid scan was negative, changing diagnosis, prognosis and care planning.
- This case illustrates the value of Amyvid in diagnosis, prognosis and care planning. The case also illustrates that, if the scan had been available earlier in the course of the patients illness, surgeons might have felt more confident in placing a shunt, and he might have had improvement in the course of his illness.

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- Case 3: 75 year old man with a typical course of Alzheimer's disease first seen in the amnestic MCI stage. Family valued "doing everything they can," and placed a high "value on knowing." Patient was found to be apoE4 positive indicating an inheritable risk. Spouse and patient were considering entering a clinical trial for anti-amyloid therapy, but were very concerned about possible risks and benefits, time and effort, and sought certainty regarding diagnosis. An Amyvid scan was positive. As a result, patient was entered into a clinical trial for anti-amyloid therapy.
- This case illustrates the how the "value of knowing" the specific diagnosis of Alzheimer's disease using Amyvid created certainty, and illustrates how certainty in the diagnosis can encourage patients to enroll in clinical trials.

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- Case 4: 59 year old woman with depression, subjective memory complaints, some episodes of confusion and disorientation for 3 years. Neuropsychological testing revealed mild deficits in executive function and working memory. Treatment with anti-depressants relieved her mood, but there was no change in cognitive function. She was thought to be a malingerer by her employer, prior physicians were unable to provide a diagnosis, and family thought she was “crazy.” MRI of the brain was negative. Impression was either non-amnesic MCI due to Alzheimer’s disease, or fronto-temporal dementia, but a more definitive diagnosis was needed. An Amyvid scan was recommended, but the patient could not afford it. Instead, an FDG-PET scan was done which indicated mild decrease in metabolism in bilateral temporal lobes. While Alzheimer’s disease seems likely, her presentation at an early age and early stage of illness, and slow course, create uncertainty in the diagnosis and prognosis. Patient is awaiting the “test of time” for a more definitive diagnosis, but in the meantime has lost her job while having difficulty obtaining disability, and is unable to do appropriate advanced care planning with any certainty.
- This case illustrates how Amyvid scan might have created certainty in diagnosis and prognosis for this patient with a high “value on knowing,” and how that certainty might change her care planning and life course. However, the lack of ability to pay for Amyvid prevented her from getting the test.