Prospective Coverage Policy:  
Defining Evidence Standards for Insurance Coverage of  
Diagnostic Tests for Alzheimer’s Disease

Scoping Teleconference Materials

Introduction
In April, 2011, for the first time in 27 years, clinical diagnostic criteria for Alzheimer’s disease (AD) were revised by a group of clinical and policy experts under the leadership of the National Institutes of Health and the Alzheimer’s Association. These new guidelines were heralded as marking a major change in how experts think about and study AD. Accompanied by a series of articles in the New York Times, the evolution in diagnostic criteria comes at a time when research on different diagnostic techniques is expanding rapidly, many new treatments intended to delay the progression of AD are undergoing evaluation, and public interest in obtaining access to promising tests and treatments is growing.

But there are as of yet no treatments with substantial benefits, and so questions regarding insurance coverage for diagnostic tests for AD have remained muted. As the science continues to accumulate, this phase may be rapidly drawing to a close. How can studies of diagnostic tests for AD be designed to provide “adequate” evidence for coverage and reimbursement decisions? What type and strength of evidence on diagnostic accuracy, impact on clinical impressions, treatment choices, and possibly broader patient, family, and societal outcomes will be needed to guide payer decisions?

The goal of this project is to seize the opportunity to address these questions in a prospective and collaborative manner. The clinical and research communities, life sciences industry, and payers may have different views of the evidence development needs for diagnostic tests for AD. This project will bring leading representatives of these stakeholders together to share their perspectives, seek common understanding, and build a platform from which to generate better evidence to guide the coverage decisions of the future.

Teleconference Agenda

1. Introduction of ICER and Policy Development Group (PDG) members

2. Discussion of PDG role, project processes, and products
   a. Systematic review of medical literature
   b. Decision analytic model to highlight evidence needs
   c. Evidence standards white paper
   d. Academic papers

3. Review of key questions
Key Questions

Patients

1. How would it be most useful to categorize the types of patients for whom AD diagnostic testing would be considered?

   - Proposed option 1:
     a. Asymptomatic
     b. Clinical evaluation leading to designation as: 1) Mild cognitive impairment (MCI) due to probable AD; 2) Dementia due to probable AD; 3) No evidence of MCI or dementia

   - Option 2: other ways to categorize based on other features that create distinct prior probabilities of AD?

Systematic Review

2. Have recent advances in PET imaging, CSF diagnostics, etc. rendered earlier data on test accuracy irrelevant? At what date should we consider published evidence “obsolete”?

   - Proposed option 1: Include articles published 2005-current

   - Option 2: other timeframe?

3. Are there any published studies of diagnostic accuracy whose results should be discounted due to serious limitations that might not be obvious upon review (e.g., patient selection, measurement standards, blinding, etc.)?

Diagnostic Pathways

4. Does the figure on the following page represent a useful way to conceptualize diagnostic pathways in such a way as to highlight potential areas where evidence will be needed for decisions related to coverage and reimbursement?
Figure. Possible pathways for diagnostic testing in Alzheimer’s disease.

Prior Probability of AD Dementia

Clinical Evaluation

Likely AD Dementia

Likely MCI due to AD

No Evidence of MCI or Dementia

No Further Testing

Additional Testing

No Treatment

Treat All

Treat

No Treatment

Uncertain results

Possible Outcomes

- Cognitive and behavioral function
- Biomarker progression
- Additional dementia workup
- Patient-reported anxiety, reassurance
- Planning performed in response to test findings

Additional Testing?

No Further Testing

Treat All

Treat

No Treatment

Uncertain results
Included Background Material

   - An introductory article to new NIA-AA guidelines on the inclusion of biomarker and imaging testing in the diagnosis of preclinical AD, mild cognitive impairment, and AD dementia

   - A summary article that describes a common framework for evidence in understanding the potential benefits and harms of new diagnostic tests, using imaging as a focus.

   - A brief article that introduces a framework for considerations of the place of a new diagnostic test in relation to current diagnostic pathways as well as the types of evidence that should be generated for the new test.

   - A blog entry that describes, in lay terms, the major findings from the study in #5 below:

   - A study of the relative predictive power of imaging, biomarker testing, genetic testing, and cognitive assessments in identifying patients with mild cognitive impairment at risk of conversion to AD dementia.

   - A press release describing a study commissioned by a patient advocacy organization (Alzheimer’s Disease International) to document the benefits of early AD diagnosis.