ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

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# 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

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## 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?

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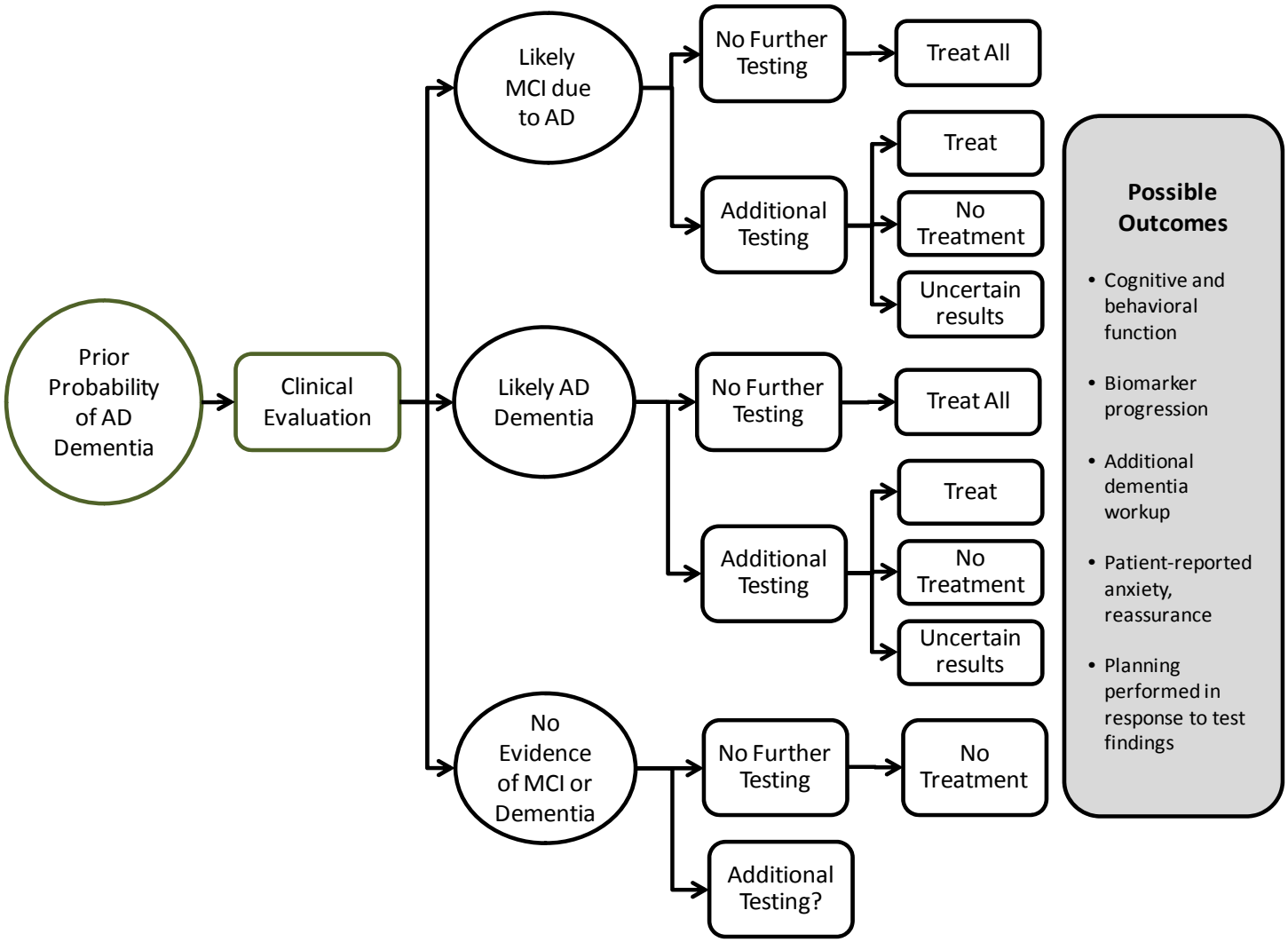
**Figure. Possible pathways for diagnostic testing in Alzheimer's disease.**



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**Included Background Material**

1. Jack CR, Albert MS, Knopman DS, et al. Introduction to the recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. *Alzheimers Dement*. 2011;7(3):257-62.
    - *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*

2. Sunshine JH, Applegate KE. Technology assessment for radiologists. *Radiology*. 230(2):309-14.
    - *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.*

3. Bossuyt PM, Irwig L, Craig J, Glasziou P. Comparative accuracy: Assessing new tests against existing diagnostic pathways. *BMJ*. 2006;332(7549):1089-92.
    - *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.*

4. "Memory quizzes still best for Alzheimer's diagnosis." http://www.npr.org/blogs/health/2011/09/06/140216789/memory-quizzes-still-best-for-alzheimers-diagnosis?ps=sh_sthdl
    - *A blog entry that describes, in lay terms, the major findings from the study in #5 below:*

5. Gomar JJ, Bobes-Bascaran MT, Conejero-Goldberg C, et al. Utility of combinations of biomarkers, cognitive markers, and risk factors to predict conversion from mild cognitive impairment to Alzheimer disease in patients in the Alzheimer's Disease Neuroimaging Initiative. *Arch Gen Psych*. 2011;68(9):961-9.
    - *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.*

6. "World Alzheimer Report 2011 shows early diagnosis of Alzheimer's disease has health, financial and social benefits." http://www.prnewswire.com/news-releases/world-alzheimer-report-2011-shows-early-diagnosis-of-alzheimers-disease-has-health-financial-and-social-benefits-129701768.html
    - *A press release describing a study commissioned by a patient advocacy organization (Alzheimer's Disease International) to document the benefits of early AD diagnosis.*