Record Status
This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors' objectives
In April, 2011, for the first time in 27 years, diagnostic criteria for Alzheimer's disease (AD) were revised by clinical and policy experts under the leadership of the National Institutes of Health and the Alzheimer's Association. These new guidelines were the first to include consideration of the findings of multiple forms of biomarker tests and highlighted the major changes that had occurred in how experts think about AD and design studies of potential treatments. This evolution in diagnostic criteria has come 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.

Authors' conclusions
Outside of their uses in drug development and clinical research trials, the current clinical value of performing any type of formal diagnostic or biomarker testing for AD is controversial. The possible benefits of testing have been posited to include: helping identify patients, possibly even individuals with no symptoms, for initiation of treatment; helping clinicians decide whether additional diagnostic evaluation is necessary to look for disorders other than AD that impair cognitive function; reassuring patients who receive a negative test; and allowing patients with a positive test to plan their future more effectively. But at a time when available treatments for AD are unable to improve long-term outcomes, there is no consensus regarding the clinical benefits of diagnostic testing, and most imaging and biomarker tests for AD are not covered by public or private insurers. As the search for more effective treatments for AD continues, many questions remain about how to design clinical trials so that it is possible to evaluate different tests for AD in a way that will generate "adequate" evidence not only for patients and clinicians, but for insurers as well. The goal of this project is to seize the opportunity to address this policy need in a collaborative and pro-active manner. It is collaborative because this white paper is the product of a process involving input from patient advocates, clinicians, clinical researchers, manufacturers, and insurers. It is pro-active because the specific aim of the project is to define the standards by which evidence will be evaluated for coverage, both at the current time and after the potential advent of more effective treatments. This aim will be accomplished by providing specific research recommendations to help clinical researchers and manufacturers generate the level of evidence required to meet these standards.

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