



MEDICAL COVERAGE GUIDELINES  
SECTION: LABORATORY

ORIGINAL EFFECTIVE DATE: 08/19/10  
LAST REVIEW DATE: 09/16/14  
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## ALZHEIMER'S DISEASE, BIOCHEMICAL MARKERS

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Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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### Description:

Historically, Alzheimer's disease (AD) has been diagnosed by ruling out other possible causes of senile dementia. Diagnosis is verified by the presence of senile plaques, neurofibrillary tangles (NFTs), neuronal loss and the accumulation of amyloid beta protein (AB-42) upon postmortem examination of brain tissue. Tests include ADmark® CSF Analysis and AlzheimerAlert™.

The following biochemical markers have been investigated as a diagnostic tool of AD:

#### Amyloid Beta Protein (AB-42):

AB-42 is found in senile plaque. Low levels have been found in cerebrospinal fluid (CSF) of individuals with AD.

#### Neural Thread Protein (NTP):

NTP is found in neurofibrillary tangles. High levels have been found in CSF and/or urine of individuals with AD.

#### Tau Protein:

Tau protein is found in neurofibrillary tangles. High levels have been found in CSF of individuals with AD.

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## **ALZHEIMER'S DISEASE, BIOCHEMICAL MARKERS (cont.)**

### **Criteria:**

- Measurement of the following biochemical markers of Alzheimer's disease in cerebrospinal fluid or urine is considered **experimental or investigational** based upon:
1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

These markers include, *but are not limited to:*

- Amyloid beta protein
- Neural thread protein
- Tau protein

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### **Resources:**

1. 2.04.14 BCBS Association Medical Policy Reference Manual. Biochemical Markers Of Alzheimer's Disease. Re-issue date 08/14/2014, issue date 07/16/1999.
2. Czarna JM, Waldemar G, Heegaard NH. [Biochemical markers for Alzheimer disease]. *Ugeskr Laeger*. 2006;168(10):1010-1014.
3. Modrego PJ. Predictors of conversion to dementia of probable Alzheimer type in patients with mild cognitive impairment. *Curr Alzheimer Res*. 2006;3(2):161-170.
4. Proto C, Romualdi D, Cento RM, et al. Plasma levels of neuropeptides in Alzheimer's disease. *Gynecol Endocrinol*. 2006;22(4):213-218.