ALZHEIMER’S DISEASE, BIOCHEMICAL MARKERS

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.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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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ALZHEIMER’S DISEASE, BIOCHEMICAL MARKERS (cont.)

**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 AlzheimAlert™.

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.

**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
ALZHEIMER’S DISEASE, BIOCHEMICAL MARKERS (cont.)

Resources:

Literature reviewed 09/15/15. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.


