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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Alzheimer's disease Biomarkers **Policy**

Indication/Usage:

Alzheimer disease (AD) is the most common form of dementia, characterized by loss of mental ability severe enough to interfere with normal ADL's, lasting at least six months and not present from birth. AD usually occurs in adulthood and is marked by a decline in cognitive functions such as remembering, reasoning and planning. Progression of AD is associated with certain indicators, or biomarkers, which are believed to assist with diagnosis and disease monitoring.

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Medical Indications for Authorization Commercial and Medicare Members

SummaCare considers CSF biomarker testing of amyloid beta peptides and tau protein for the evaluation for the initiation of amyloid beta targeting therapy in individuals with mild cognitive impairment or mild dementia due to Alzheimer disease is considered medically necessary.

CPT code covered if criteria above is met

0445U: β-hyphenamyloid (Abeta42) and phospho tau (181P) (pTau181), electrochemiluminescent immunoassay (ECLIA) cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology

0459U: B-hyphenamyloid (Abeta42) and total tau (tTau), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology

The following CSF or plasma biomarkers for Alzheimer disease are considered experimental, investigational, or unproven for the diagnosis and management of members with AD and related dementia due insufficient evidence of improved health or medical management.

CPT code not covered

0568U: Neurology (dementia), beta amyloid, tau protein phosphorylated at residue (eg, pTau217), neurofilament light chain (NfL), and glial fibrillary acidic protein (GFAP), by ultra high sensitivity molecule array detection, plasma, algorithm reported as positive, intermediate, or negative for Alzheimer pathology. LucentADTM Complete, Quanterix Corporation.

0570U: Neurology (traumatic brain injury), analysis of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl terminal hydrolase L1 (UCHL1), immunoassay, whole blood or plasma, individual components reported with the overall result of elevated or non elevated based on threshold comparison i-STAT TBI, Abbott Point of Care

82233: Beta-amyloid; 1-40 (Abeta 40)
82234: Beta-amyloid; 1-42 (Abeta 42)
84393: Tau, phosphorylated
84394: Tau, total (tTau)

There are currently no NCD or LCD for per CMS

Limitations

Biomarkers can be measured in fluids such as blood, urine, saliva, serum and plasma.
Measurement of the biomarkers 82233, 82234, 84393, 84394 are considered investigational for the diagnosis and management of Alzheimer disease due to inadequate medical evidence showing they are clinically useful.

Coverage Decisions

Coverage decisions made per CMS, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

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CMS MCD Search

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