Genetic and Biomarker Testing for Alzheimer Disease

INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

Table of Contents

Related Medicare Advantage Medical/Pharmacy Coverage Policies

Aduhelm (aducanumab-avwa)
Genetic Testing
Genetic Testing for Diagnosis of Inherited Conditions

Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare	Applicable States/Territories

			Administrative Contractors (MACs)	
NCD	Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD)	200.3		
LCD LCA LCA LCD LCA	MolDX: Molecular Diagnostic Tests (MDT) Billing and coding: MolDX: ApoE Genotype Billing and coding: MolDX: Molecular Diagnostic Tests (MDT) MolDX: Repeat Germline Testing Billing and coding: MolDX: Repeat Germline Testing	L36807 A55141 A57772 L38429 A57100	J5, J8 - Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, NE
LCD LCA LCA LCD LCA	MolDX: Molecular Diagnostic Tests (MDT) Billing and coding: MolDX: ApoE Genotype Billing and coding: MolDX: Molecular Diagnostic Tests (MDT) MolDX: Repeat Germline Testing Billing and coding: MolDX: Repeat Germline Testing	L36021 A54244 A56973 L38288 A57141	J15 - CGS Administrators, LLC	KY, OH
LCD LCA LCA	MolDX: Molecular Diagnostic Tests (MDT) Billing and coding: MolDX: ApoE Genotype Billing and coding: MolDX: Molecular Diagnostic Tests (MDT)	L35160 A55094 A57526	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands

LCD LCA	MolDX: Repeat Germline Testing Billing and coding: MolDX: Repeat Germline Testing	L38351 A57331		
LCD LCA LCA LCD LCA	MolDX: Molecular Diagnostic Tests (MDT) Billing and coding: MolDX: ApoE Genotype Billing and coding: MolDX: Molecular Diagnostic Tests (MDT) MolDX: Repeat Germline Testing Billing and coding: MolDX: Repeat Germline Testing	L36256 A55095 A57527 L38353 A57332	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA LCA LCD LCA	MolDX: Molecular Diagnostic Tests (MDT) Billing and coding: MolDX: ApoE Genotype Billing and coding: MolDX: Molecular Diagnostic Tests (MDT) MolDX: Repeat Germline Testing Billing and coding: MolDX: Repeat Germline Testing	L35025 A53652 A56853 L38274 A58017	JJ, JM - Palmetto GBA	AL, GA, NC, SC, TN, VA, WV

Description

Alzheimer disease (AD) is the most common form of dementia. It is a neurologic condition characterized by loss of mental ability severe enough to interfere with normal activities of daily living, lasting at least 6 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.

Molecular biomarkers such as beta-amyloid (Aβ) and Tau proteins may be detected through cerebrospinal fluid (CSF). Other proposed methods for collecting biomarkers for AD diagnosis and screening include plasma and skin biopsy.

Genetic testing has also been proposed to aid in the diagnosis of a type of AD known as early-onset familial AD (EOFAD). EOFAD is a rare form of AD in which onset occurs at 30 to 60 years of age. Most cases are caused by a pathogenic variant in one of three known genes: *APP*, *PSEN1, PSEN2*.

Coverage Determination

iCare follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Genetic tests must demonstrate clinical utility, analytical and clinical validity and fulfill the CMS "reasonable and necessary" criteria. Analytic validity (test accurately identifies the gene variant), clinical validity (test identifies or predicts the clinically defined disorder) and clinical utility (test measurably improves clinical outcomes) of the genetic test is supported by generally accepted standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, specialty society recommendations, and views of physicians practicing in relevant clinical areas. The test must be ordered by a physician who is treating the beneficiary and the results will be used in the management of a beneficiary's specific medical problem.

For jurisdictions with no Medicare guidance, iCare will utilize the MolDX program and Technical Assessments for molecular assays as the standard to evaluate clinical utility, analytical and clinical validity in conjunction with adhering to Medicare's reasonable and necessary requirement.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

CSF testing for Aβ and Tau proteins will be considered medically reasonable and necessary when treatment with an US Food & Drug Administration (FDA) approved Aβ monoclonal antibody drug (eg, lecanemab [Leqembi]) is being considered.[35]

DNA analysis for *APOE* epsilon 4 allele (*APOE* ε4) for AD will be considered medically reasonable and necessary when treatment with an FDA approved Aβ monoclonal antibody drug (eg, lecanemab [Leqembi]) is being considered.[35]

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

The following test types are examples of testing services that may not be considered a benefit (statutory excluded) and denied as Medicare excluded tests:[45]

- Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law; **OR**
- Tests that confirm a diagnosis or known information; **OR**
- Tests to determine risk for developing a disease or condition; **OR**
- Tests performed to measure the quality of a process; **OR**
- Tests without diagnosis specific indications; **OR**
- Tests identified as investigational by available literature and/or the literature supplied by the developer and are not a part of a clinical trial

These treatments and services fall within the Medicare program's statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act). Other services/items fall within the Medicare program's statutory exclusion at 1862(a)(12), which prohibits payment.

Genetic tests that have not demonstrated clinical utility, analytical and clinical validity via the MolDX Program will not be considered medically reasonable and necessary. A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Biomarker testing for AD is considered not medically reasonable or necessary for any indications other than those listed above including, but may not be limited to:

- CSF testing for alpha-Synuclein (eg, SYNTap biomarker test); **OR**
- Plasma testing for any of the following:
  - Aβ and/or Tau proteins
    - Aβ peptide testing (eg, SOBA-AD assay)
    - Aβ42/40 ratio and *APOE* proteotype assay (eg, PrecivityAD [0412U])
    - Aβ42/40 ratio and p-Tau217 ratio (eg, PrecivityAD2)
    - Aβ42/40 ratio testing (eg, Quest AD-Detect [0346U])
    - P-Tau181 and *APOE* ε4 assay (eg, Elecsys Amyloid Plasma Panel)

    - p-Tau181 testing (eg, LucentAD)
  - U-p53AZ (AZ 284) biomarker testing (eg, AlzoSure Predict test); **OR**

- Skin biopsy (eg, DISCERN test [0206U and 0207U], Syn-One test)

A review of the current medical literature shows that the evidence is insufficient to determine that these tests are standard medical treatment for these indications. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

Genetic testing for AD is considered not medically reasonable or necessary for any indications other than those listed above including but may not be limited to, *APOE* genotyping.[11,12,13,14,15] A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

Summary of Evidence

Genetic Testing for AD
Effective April 7, 2022, CMS provides national coverage for FDA approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD) when furnished in accordance with Section B under coverage with evidence development (CED) for an individual who has a clinical diagnosis of mild cognitive impairment (MCI) due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD.[35]

There are several widely investigated biomarkers for the molecular and degenerative process of AD that can be supportive of a diagnosis of AD but are not yet recommended for routine diagnostic purposes. Plasma biomarkers (eg, SOBA-AD assay, Quest AD-Detect) show promise but do not currently have an established role in clinical practice; more studies are needed. Decreased APOE and APOE ε4 plasma levels (eg, Elecsys amyloid plasma panel, PrecivityAD) as well as a variety of other plasma/serum and CSF proteins (eg, AlzoSure Predict test, LucentAD, PrecivityAD2, SYNTap biomarker test) have been assessed for predictive value for AD in persons without dementia and in patients with MCI. Ongoing research is investigating the role of such biomarkers that may help distinguish AD from other forms of dementia.[47]

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments

81401	MOLECULAR PATHOLOGY PROCEDURE LEVEL 2	
81405	MOLECULAR PATHOLOGY PROCEDURE LEVEL 6	
81406	MOLECULAR PATHOLOGY PROCEDURE LEVEL 7	
82172	Apolipoprotein, each	
82542	Column chromatography, includes mass spectrometry, if performed (eg, HPLC, LC, LC/MS, LC/MS-MS, GC, GC/MS-MS, GC/MS, HPLC/MS), non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen	
83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified	
0206U	Neurology (Alzheimer disease); cell aggregation using morphometric imaging and protein kinase C-epsilon (PKCe) concentration in response to amylospheroid treatment by ELISA, cultured skin fibroblasts, each reported as positive or negative for Alzheimer disease	
0207U	Neurology (Alzheimer disease); quantitative imaging of phosphorylated ERK1 and ERK2 in response to bradykinin treatment by in situ immunofluorescence, using cultured skin fibroblasts, reported as a probability index for Alzheimer disease (List separately in addition to code for primary procedure)	
0289U	Neurology (Alzheimer disease), mRNA, gene expression profiling by RNA sequencing of 24 genes, whole blood, algorithm reported as predictive risk score	
0346U	Beta amyloid, Aβ40 and Aβ42 by liquid chromatography with tandem mass spectrometry (LC-MS/MS), ratio, plasma	
0358U	Neurology (mild cognitive impairment), analysis of β-amyloid 1-42 and 1-40, chemiluminescence enzyme immunoassay, cerebral spinal fluid, reported as positive, likely positive, or negative	
0412U	Beta amyloid, Aβ42/40 ratio, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and qualitative ApoE isoform-specific proteotyping, plasma combined with age, algorithm reported as presence or absence of brain amyloid pathology	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**

No code(s) identified

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