Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP350

Section: Medical Benefit Policy

Subject: Genetic and Biochemical Testing for Alzheimer's Disease and Dementia

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I. Policy: Genetic and Biochemical Testing for Alzheimer's Disease and Dementia

II. Purpose/Objective:

To provide a policy of coverage regarding Genetic and Biochemical Testing for Alzheimer's Disease and Dementia

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional

capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION: Alzheimer disease is the most common cause of dementia. Alzheimer disease is a progressive, irreversible neurodegenerative disease. Individuals are typically classified into early-onset and late-onset disease using the age of 65 years as a cutoff. Genetic testing and biomarker testing has been proposed as a means to identifying a definitive diagnosis, improving understanding for the family, and allowing at-risk relatives to have predictive testing.

EXCLUSIONS:
The Plan considers testing of genetic markers for the diagnosis of Alzheimer's disease to be **experimental, investigational or unproven** and therefore **NOT COVERED** as a diagnostic technique for individuals with symptoms suggestive of Alzheimer's disease. There is insufficient evidence in the peer-reviewed medical literature to support testing for Alzheimer disease-related biomarkers improves health outcomes for people diagnosed with Alzheimer's disease, dementia, or mild cognitive impairment.

The Plan considers measurements of serum, urinary, CSF or skin fibroblast biochemical markers (including but not limited to tau protein, AB-42, neural thread protein) to be **experimental, investigational or unproven** and therefore **NOT COVERED** as a diagnostic technique for individuals with symptoms suggestive of Alzheimer's disease. There is insufficient evidence in the peer-reviewed medical literature to support testing for Alzheimer disease-related biomarkers improves health outcomes for people diagnosed with Alzheimer's disease, dementia, or mild cognitive impairment.

The Plan considers genetic testing or measurements of biochemical markers as a screening technique in asymptomatic individuals with or without a family history of Alzheimer's disease to be **experimental, investigational or unproven** and therefore **NOT COVERED.** There is insufficient evidence in the peer-reviewed medical literature to support testing for Alzheimer disease-related biomarkers improves health outcomes for people diagnosed with Alzheimer's disease, dementia, or mild cognitive impairment.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Genetic and Biochemical Testing for Alzheimer's Disease and Dementia
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

81401 Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat) [when specified as the following]:

- APOE (apolipoprotein E) (eg, hyperlipoproteinemia type III, cardiovascular disease, Alzheimer disease), common variants (eg, *2, *3, *4)

81405 Molecular pathology procedure, Level 6 (eg, analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons, regionally targeted cytogenomic array analysis) [when specified as the following]:

- PSEN1 (presenilin 1) (eg, Alzheimer disease), full gene sequence

81406 Molecular pathology procedure, Level 7 (eg, analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia) [when specified as the following]:

- APP (amyloid beta [A4] precursor protein) (eg, Alzheimer disease), full gene sequence
- PSEN2 (presenilin 2 [Alzheimer disease 4]) (eg, Alzheimer disease), full gene sequence

83520 Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified [when specified as tau protein, amyloid beta peptide testing]

84999 Unlisted chemistry procedure [when specified as tau protein, amyloid beta peptide or neural thread protein biochemical testing]

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 *{DISCERN™, NeuroDiagnostics, NeuroDiagnostics}*

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 *{DISCERN™, NeuroDiagnostics, NeuroDiagnostics}*

0289U Neurology (Alzheimer disease), mRNA, gene expression profiling by RNA sequencing of 24 genes, whole blood, algorithm reported as predictive risk score { *MindX Blood Test*™ }

S3852 DNA analysis for APOE epsilon 4 allele for susceptibility to Alzheimer's disease

ICD-10 Diagnosis

- F03.90-F03.91 Unspecified dementia
- G30.0-G30.9 Alzheimer's disease
- G31.1 Senile degeneration of brain, not elsewhere classified
- R41.0 Disorientation, unspecified
- R41.3 Other amnesia (memory loss NOS)
- R41.81 Age-related cognitive decline

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 11/21

Revised:

Reviewed: