Clinical Policy: Genetic and Pharmacogenetic Testing

Reference Number: PA.CP.MP.89
Effective Date: 01/18
Last Review Date: 2/26/2021 Revision Log

Description

This policy includes criteria for making medical necessity determinations for genetic tests when specific criteria are not available for the requested genetic test. PA Health & Wellness (PHW) utilizes the InterQual Molecular Diagnostic Testing criteria to assess medical necessity for testing and applies this policy for testing not addressed in the InterQual criteria. (See PHW policy PA.CP.MP 68 Medical Necessity Guidelines, Attachment I for current InterQual Level of Care and Care Planning products.) Genetic testing is the analysis of human DNA, RNA, or chromosomes in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes. Such purposes include predicting risk of disease, identifying carriers, and establishing prenatal and clinical diagnosis or prognosis. There are currently more than 1000 genetic disorders for which genetic testing is available on a clinical or research basis

Policy/Criteria

I. It is the policy of PA Health & Wellness® (PHW) that genetic testing is **medically necessary** when *all* the following criteria are met:

A. The requesting physician identifies that the member displays clinical features, or is at direct risk of inheriting the mutation in question, *and*
B. The test results will be used to develop a clinically useful approach or course of treatment or to cease unnecessary monitoring or treatments for the individual being tested. Clinically useful test results allow providers to do at least one of the following:
    1. Inform interventions that could prevent or delay disease onset,
    2. Detect disease at an earlier stage when treatment is more effective,
    3. Manage the treatable progression of an established disease,
    4. Treat current symptoms significantly affecting a member's health,
    5. Guide decision making for the member's current or planned pregnancy; *and*
C. The genetic disorder could not be diagnosed through completion of conventional diagnostic studies, pedigree analysis and genetic counseling consistent with the community standards.
D. The member has not previously undergone genetic testing for the disorder, unless significant changes in testing technology or treatments indicate that test results or outcomes may change due to repeat testing.
E. Technical and clinical performance of the genetic test is supported by published peer-reviewed medical literature.

II. It is the policy of PHW that *pharmacogenetic testing* is **medically necessary** when all the following criteria are met:

A. Targeted drug therapy is reasonable and necessary for the treatment of the diagnosis;
B. Targeted drug therapy is associated with a specific gene biomarker or mutation;
C. The test results will be used to guide drug therapy decisions (e.g., drug choice, dose, evaluate adverse effects or non-responsiveness);

D. Previous pharmacogenetic testing has not been done for the gene biomarker or mutation, unless significant changes in testing technology or treatments indicate that test results or outcomes may change due to repeat testing;
E. Technical and clinical performance of the genetic test is supported by published peer-reviewed medical literature.

Note: *All requests for genetic or pharmacogenetic testing reviewed under this policy require medical director review.*

Note: *When using testing panels, including but not limited to, multiple genes or multiple conditions, and in cases where a tiered approach/method is clinically available, testing would be covered ONLY for the number of genes or tests deemed medically necessary to establish a diagnosis.*

III. It is the policy of PHW that all other requests for genetic or pharmacogenetic testing not meeting the above stated criteria, including direct-to-consumer testing and genetic banking/DNA storage, are considered not medically necessary.

Authorization Protocol
Requests for prior authorization will be accepted up to 10 business days following specimen collection and will be reviewed for medical necessity based on the above stated criteria.

Testing in Children
Testing in children should take into account the availability of evidenced based risk reduction strategies and the probability of developing a serious medical condition during childhood. Unless there is a clinical intervention appropriate in childhood, parents should be encouraged to defer genetic testing for adult-onset conditions until adulthood. Advocating for the best interests of the child is necessary until he/she is able to make the personal choice to have genetic testing. [5]

Background
Genetic testing identifies changes in chromosomes, genes or proteins. Genetic testing results can confirm or rule out a suspected genetic condition or can help determine a person's chance of developing or passing on a genetic disorder. Test results can direct a person towards appropriate prevention, monitoring and treatment options. There are three methods used for genetic tests: gene tests, chromosomal tests and biochemical tests. Gene tests look at DNA or RNA taken from blood or body fluids such as saliva or other tissue. These tests can look for large changes, such as missing or added sections of a gene, or small changes, such as a missing, added, or altered chemical base within a DNA strand. They can also detect genes with too many copies, those that are too active, turned off, or lost entirely. Genes can be tested using DNA probes or rely on DNA or RNA sequencing.

Chromosomal tests look at features of chromosomes for changes such as pieces being deleted, expanded, or switched to a different chromosomal location. There are two types of chromosomal tests, karyotype and FISH (florescent *in situ* hybridization) analysis. A karyotype test gives a picture of all of a person's chromosomes and can identify changes in chromosome number and large changes in DNA structure. FISH analysis can identify irregularities in certain regions of

chromosomes using fluorescent DNA probes. Additionally, FISH analysis can identify small changes that can be missed by overall karyotype testing.

Biochemical tests measure the amount or activity of proteins or particular enzymes. Genes contain the DNA code for making proteins. An abnormal amount or activity of proteins can indicate that genes are not working normally. These tests are most commonly used for newborn screening to detect conditions such as phenylketonuria (PKU).

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed	11/17	01/01/18
References reviewed and updated. Added I.D: member has not previously undergone genetic testing for the disorder. Added statement that direct-to-consumer genetic testing is not medically necessary.	05/18	09/18/18
Changed period in which authorizations can be requested from 5 days post-service to 10 days. Added note that all genetic testing requests require medical director review.	10/19	12/20/2019
Added that technical and clinical performance of the genetic test is supported by published peer-reviewed medical literature. Added general criteria for pharmacogenetic testing. Updated background on pharmacogenetic testing. Added/Inserted Section II that indicates that *pharmacogenetic testing* is **medically necessary** when specified criteria is met. Changed title to reflect pharmacogenetic criteria. References reviewed and updated. Annual Review performed.	2/26/2021	

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