



GENETIC TESTING BENEFIT COVERAGE STANDARD - DRAFT

BRIEF COVERAGE STATEMENT

The Genetic Testing benefit includes diagnostic, predictive, and pharmacogenomic genetic testing in adults and children.

Diagnostic genetic tests are used to detect or rule out a known or suspected disorder in an individual with signs or symptoms of a disease. Predictive genetic tests are offered to individuals who have a known or suspected family history of a genetic disorder, but who have no signs or symptoms of disease themselves. Finally, pharmacogenomic tests are used to monitor variation in drug metabolism and response to drug therapy.

Colorado Medicaid coverage of genetic tests is based on the Centers for Disease Control (CDC) guidelines for genetic testing. The CDC ranks genetic tests based on current scientific evidence. The Department covers all tests which are ranked as Tier 1 or “green” tests. Tier 1 tests have a high level of evidence supporting utilization. Tier 1 tests also have client requirements in the Disorder/Indicator field that must be met before the test can be considered Tier 1 for a particular client.

The CDC guidelines are located at: <http://www.cdc.gov/genomics/gtesting/tier.htm>.

Note: This Benefit Coverage Standard does not address Prenatal Genetic Testing.

SERVICES ADDRESSED IN OTHER BENEFIT COVERAGE STANDARDS

Prenatal Genetic Testing is addressed in the Maternity Services benefit coverage standard.

ELIGIBLE PROVIDERS

Genetic testing and test counseling must be provided by Colorado Medical Assistance Program (Colorado Medicaid) enrolled practitioners who can render the service within the scope of their practice, certifications, and licensure.

- Genetic testing must occur in laboratories accredited by the Clinical Laboratory Improvement Amendment (CLIA).

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- All practitioners who can order genetic testing services within their scope of practice, certifications, and licensure may order CDC Tier 1 tests.
 - Practitioners must be able to counsel clients on the particular genetic test in question, and the results of that particular test, as it applies to the client.
 - If a Practitioner is unable to counsel a client regarding genetic testing, they must refer the client to a provider capable of providing genetic counseling prior to ordering the test.
- Genetic Counselors must be certified through the American Board of Genetic Counselors and be enrolled with Colorado Medicaid.

ELIGIBLE PLACES OF SERVICES

- CLIA-Certified Laboratories
- Office
- Hospital
- Clinic
- Public Health Agency
- Federally Qualified Health Center
- Rural Health Center

ELIGIBLE CLIENTS

Any client enrolled in Colorado Medicaid, for whom screening indicates that a genetic test is warranted, is eligible.

Screening may include signs or symptoms detected via personal or family history, physical exam, and laboratory or imaging studies, as defined by the CDC guidelines.

CDC guidelines indicate screening criteria for Tier 1 tests under Disorder/Indication.

Note: Pregnant clients who wish to seek prenatal genetic testing should refer to the Maternity Services benefits coverage standard.

COVERED SERVICES

Covered genetic tests are those ranked by the CDC as being Tier 1.

- This does not include Tier 1 tests which relate to Prenatal Genetic Testing.
- For a Tier 1 test to be covered a client must also meet the Disorder/Indication listed next to a specific test.

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- A test may be both Tier 1 (covered) and Tier 2 or Tier 3 (not covered) depending on the particular client. For example, testing for the BRCA mutation is both classified as both Tier 1 and Tier 3 by the CDC. It is Tier 1 for individuals with a known family history of BRCA related cancers. BRCA Mutation testing is Tier 3 for general population individuals without a family history of related cancers, and is not a covered benefit.

GENERAL LIMITATIONS

- Genetic Testing is only covered when the test appears on the CDC Tier 1 list and the client meets the associated Disorder/Indication criteria.
- Units allowed for any particular test will be once in a lifetime.

Note: For covered prenatal services see the Maternity benefit coverage standard.

NON-COVERED SERVICES

All tests that are identified as Tier 2 (or “Yellow”) and Tier 3 (or “Red”) tests by the CDC, and when the client does not meet the higher Tier Disorder/Indication criteria. Tests that are not currently ranked in the CDC guidelines are also not covered.

PRIOR AUTHORIZATION REQUIREMENTS

All orders for genetic testing must be reviewed by the Colorado Department of Healthcare Policy and Financing, or its Designated Review Entity, and be prior authorized before being rendered.



DEFINITIONS

TERM	DEFINITION
FAMILY HISTORY	Indications in an individual's direct family that there is the potential the person has a genetic disorder. For example: If an individual's mother has had breast cancer, this would be considered a family history of breast cancer.
GENETIC DISORDER	A mutation or variance in an individual's genes that makes that individual predisposed to a disease or condition.
GENETIC TEST	A test which assesses an individual's genes for genetic disorders. These can be diagnostic, to assess a symptomatic individual, and predictive, to assess an asymptomatic individual with a family history or other risk factor.
PHARMACOGENOMIC TEST	Gene based tests that assess drug metabolism and response, in order to select therapies most appropriate for an individual's genetics (e.g. CYP2C9 variations and warfarin).



REFERENCES

Dotson, W, Douglas, M, Kolor, K, Stewart, A, Bowen, M, Gwinn, M, et al; *Prioritizing Genomic Applications of action by Level of Evidence: A Horizon Scanning Method*; 95 Clinical Pharmacology & Therapeutics, 394-402 (April, 2014).

Khoury, M, Coates, R, and Evans, J; *Evidence-based classification of recommendations on use of genomic tests in clinical practice: Dealing with insufficient evidence*; 12 Genetics in Medicine 11 (Nov. 2010).

Center for Disease Control and Prevention; *Genomic Tests and Family History by Levels of Evidence*; (Updated Sept., 2014); <http://www.cdc.gov/genomics/gtesting/tier.htm>.

Medicaid Director Signature

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