



GENETIC TESTING BENEFIT COVERAGE STANDARD - DRAFT

Note: Capitalized terms within this Benefit Coverage Standard, which do not refer to the title of a benefit, program, or organization, have the meaning specified within the *Definitions* section, found on page 6.

BRIEF COVERAGE STATEMENT

The genetic testing benefit includes coverage of certain Diagnostic, Predictive, and Pharmacogenomic genetic testing services for both adults and children.

Because the field of genetic testing is rapidly expanding, there is often insufficient high quality evidence supporting the use of genetic testing. Colorado Medicaid has therefore based much of this Benefit Coverage Standard on CDC Office of Public Health Genomics criteria, which rank genetic testing by levels of evidence and are updated frequently. Included in Colorado Medicaid coverage are all Genetic Tests that meet CDC Tier 1, or “green” criteria, as described on the CDC Office of Public Health Genomics website. CDC Tier 1 criteria have a high level of evidence supporting utilization.

Colorado Medicaid also covers (as specified in the *Additional Covered Tests* section below):

- Genetic Tests that meet a subset of CDC Tier 2, or “yellow”, criteria, for which Colorado Medicaid has found that there is sufficient evidence to support coverage; and
- Tests which the CDC has not yet addressed, but for which evidence of clinical utility exists.

CDC Tier 1 criteria are located on the CDC Office of Public Health Genomics website: <http://www.cdc.gov/genomics/gtesting/tier.htm>. All other circumstances, that do not meet CDC Tier 1 criteria, under which genetic testing services may be provided, are listed in the *Covered Services* section of this Benefit Coverage Standard.

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

RELATED BENEFITS ADDRESSED IN OTHER BENEFIT COVERAGE STANDARDS

- Prenatal Genetic Testing is addressed in the Maternity Services Benefit Coverage Standard.



ELIGIBLE PROVIDERS

All genetic testing and counseling service providers must be enrolled with Colorado Medicaid. Providers may render services within the scope of their practice, certifications, and licensure.

- Providers 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 Provider 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

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

ELIGIBLE CLIENTS

All Medicaid eligible clients, who meet the criteria listed within the *Covered Services* section of this Benefit Coverage Standard, may receive genetic testing services.

SPECIAL PROVISION: EXCEPTION TO POLICY LIMITATIONS FOR CLIENTS AGED 20 AND YOUNGER

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid program that requires the state Medicaid agency to cover services, products, or procedures for Medicaid clients ages 20 and younger if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition (health problem) identified through a screening examination (includes any evaluation by a physician or other licensed clinician). EPSDT covers most of the medical or remedial care a child needs to improve or



maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure that is:

- Unsafe, ineffective, or experimental/investigational.
- Not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

COVERED SERVICES

Covered Genetic Tests are those that:

- Meet CDC Tier 1 criteria; or
- Meet a specific subset of criteria, as specified in the *Covered Services* section of this Benefit Coverage Standard (see *Additional Covered Tests* section below) including:
 - Certain tests that meet CDC Tier 2 criteria;
 - Certain tests which the CDC has not yet addressed, but for which sufficient evidence of clinical utility exists.

COVERED CDC TIER 1 TESTS

All tests indicated on CDC Tier 1 are covered when a client meets the Disorder/Indication-Use Criteria listed therein.

- Refer to the CDC Office of Public Health Genomics website for a complete list of Tier 1 criteria. This list is updated regularly. <http://www.cdc.gov/genomics/gtesting/tier.htm>

Note: A test may appear on all three CDC tiers but will only be covered (unless specified otherwise in the *Additional Covered Tests* section below) when used for the purpose(s) detailed in CDC Tier 1. For example:

- Testing for the BRCA mutation is described on CDC Tier 1 and Tier 3.
- BRCA mutation testing is covered for individuals with a known Family History of BRCA related cancers, as specified on Tier 1.



- BRCA mutation testing for general population individuals without a Family History of related cancers, as specified on Tier 3, is not a covered benefit.

Note: Prenatal Genetic Tests that appear on CDC Tier 1 are not included in this Benefit Coverage Standard. Refer to the Maternity Services Benefit Coverage Standard for details regarding coverage of prenatal genetic testing.

ADDITIONAL COVERED TESTS

In addition to all tests that meet CDC Tier 1 criteria, Colorado Medicaid covers the following testing when the following Disorders/Indications are present, and for the following use(s):

ER-alpha and PgR status/ER-alpha (ESR1) modulating agents

Disorder/Indication: Invasive breast cancer

Use: PGx-recurrence: risk prediction; prognostic

Testing for Lynch syndrome

Disorder/Indication:

- Patients meeting revised Bethesda guidelines or Amsterdam criteria
- Colorectal cancer diagnosed under 70 years of age , and those 70 years and older who meet Bethesda guidelines
- Colorectal cancer in patients younger than 50 years
- MSI-H histology in colorectal cancer in patients younger than 60 years
- Colorectal cancer in patient with relative (one or more first-degree) with Lynch syndrome related cancer that was diagnosed under age 50 years
- Colorectal cancer in patient with relatives (two or more first- or second-degree) with Lynch syndrome related cancer at any age

Use: Diagnostic, screening

Consideration of testing for Lynch syndrome

Disorder/Indication: People with 5% or higher risk of Lynch syndrome based on any prediction model

Use: Diagnostic, screening

FLT3-ITD

Disorder/Indication: Acute myeloid leukemia

Use: Predictive; prognostic



CEBPA mutation

Disorder/Indication: Acute myeloid leukemia

Use: Predictive; prognostic

NPM1 mutation

Disorder/Indication: Acute myeloid leukemia

Use: Predictive; prognostic

KIT mutation

Disorder/Indication: Acute myeloid leukemia

Use: Predictive; prognostic

Companion Testing for BRCA 1/2

Disorder/Indication: Ovarian cancer diagnosis

Use: Companion Diagnostic for PARP Inhibitor treatment

CYP2D6 extensive, intermediate, or poor metabolizer

Disorder/Indication: Bile acid synthesis disorders.

- Member must be greater than 3 weeks old in age: and
- Member must have a diagnosis for bile acid synthesis disorder due to single enzyme defect.

Use: PGx

G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R, R117H mutations

Disorder/Indication: Cystic fibrosis, Kalydeco appropriateness

Use: PGx

F508del homozygous mutation

Disorder/Indication: Cystic fibrosis, Orkambi appropriateness

Use: PGx

LDLR DNA Sequence Analysis

Disorder/Indication: Homozygous familial hypercholesterolemia, Kynamro appropriateness.

Use: PGx

LDLR Deletion/Duplication Analysis for large gene rearrangement testing

Disorder/Indication: Homozygous familial hypercholesterolemia, Kynamro appropriateness.



- LDLR Deletion/Duplication Analysis is covered only when Sequence Analysis is negative

Use: PGx

APOB and dPCSK9

Disorder/Indication: Homozygous familial hypercholesterolemia, Kynamro appropriateness.

- If both LDLR analyses mentioned above is negative but a strong clinical picture exists.

Use: PGx

Common Variable Immunodeficiency (CVID)

Disorder/Indication: Intravenous Immunoglobulin (IVIG) Administration Treatment

Use: PGx

Severe Combined Immunodeficiency (SCID)

Disorder/Indication: Intravenous Immunoglobulin (IVIG) Administration Treatment

Use: PGx

X-Linked Agammaglobulinemia

Disorder/Indication: Intravenous Immunoglobulin (IVIG) Administration Treatment

Use: PGx

X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency

Disorder/Indication: Intravenous Immunoglobulin (IVIG) Administration Treatment

Use: PGx

Wiskott-Aldrich Syndrome

Disorder/Indication: Intravenous Immunoglobulin (IVIG) Administration Treatment

Use: PGx

Testing for urea cycle disorder (UCD)

Disorder/Indication: Ravicti Appropriateness

Use: PGx

Note: Refer to the *Definitions* section of this Benefit Coverage Standard for further explanation of how to interpret the Disorder/Indication-Use Criteria above.



GENERAL LIMITATIONS

- Genetic Testing is only covered when:
 - Test meets criteria established on CDC Tier 1; or
 - Test meets criteria present in *Additional Covered Tests* section above.
- Units allowed for any particular test will be once in a lifetime.

NON-COVERED SERVICES

- All tests that meet CDC Tier 2 (or “yellow”) criteria that are not explicitly listed in the *Additional Covered Tests* section above.
- All tests that meet CDC Tier 3 (or “red”) criteria that are not explicitly listed in the *Additional Covered Tests* section above.
- Tests that are not currently addressed by CDC tier system and which do not meet the criteria specified in the *Additional Covered Tests* section above.

PRIOR AUTHORIZATION REQUIREMENTS

All orders for genetic testing must be reviewed by Colorado Medicaid for prior authorization before rendered.



DEFINITIONS

TERM	DEFINITION
CDC OFFICE OF PUBLIC HEALTH GENOMICS	<p>The CDC Office of Public Health Genomics is a federal entity which “provides timely and credible information for the effective and responsible translation of genomics research into population health benefits.”</p> <p>Definition from the CDC website, available here: http://www.cdc.gov/genomics/</p>
DESIGNATED REVIEW ENTITY	<p>The Designated Review Entity is an entity that has been contracted by Colorado Medicaid to review prior authorization requests for medical necessity and appropriateness.</p>
DIAGNOSTIC GENETIC TEST	<p>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.</p>
DISORDER/INDICATION-USE CRITERIA	<p>Disorder/Indication – Use criteria are used to determine whether a specific test is appropriate for a specific client. A client must fit the criteria listed in the Disorder/Indication field.</p> <p>When a client meets the Disorder/Indication criteria, a test is appropriate for the uses listed in the Use field.</p>
FAMILY HISTORY	<p>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.</p>



TERM	DEFINITION
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).
PREDICTIVE GENETIC TEST	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.
PRENATAL GENETIC TEST	Genetic Testing performed on a fetus during gestation.

Medicaid Director Signature

Date