NON-PRENATAL GENETIC TESTING

Brief Coverage Statement

Non-prenatal genetic testing includes diagnostic, predictive, and pharmacogenomic testing in non-pregnant 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 study variation in drug metabolism and response to drug therapy.

Services Addressed in Other Benefit Coverage Standards

Prenatal Genetic Testing

Eligible Providers

- Genetic test counseling and provision must be provided by Colorado Medical Assistance Program (Colorado Medicaid) enrolled genetic counseling providers. Allowed providers include appropriately credentialed genetic counselors, medical or clinical geneticists, or genetic nurses. These providers must be certified by their respective boards and/or other appropriate accrediting organizations.
    - Medical Geneticist (M.D.) - American Board of Medical Genetics
    - Clinical Geneticist (Ph.D.) - American Board of Medical Genetics
    - Genetic Counselor - American Board of Genetic Counseling, or American Board of Medical Genetics
    - Advance Practice Nurse in Genetics - Genetic Nursing Credentialing Commission

- Non-prenatal genetic testing that occurs in laboratories accredited by the Clinical Laboratory Improvement Amendment (CLIA) are eligible.

Eligible Places of Services

- CLIA-certified laboratories
- Facilities licensed by the Colorado Department of Public Health and Environment

Eligible Clients

Any non-pregnant client enrolled in Colorado Medicaid for whom screening indicates that a genetic test may be warranted. Screening may include signs or symptoms detected via personal or family history, physical exam, and laboratory or imaging studies.

Covered Services and Limitations

Coverage of non-prenatal genetic testing services shall be determined according to the following algorithm unless otherwise specified below:

- For individuals with newly diagnosed colorectal cancer, genetic counseling and subsequent testing for Lynch syndrome is provided(EGAPP, 2009)
- For women whose family history is associated with an increased risk for deleterious mutations in BRCA1 or BRCA2, genetic counseling and genetic testing is provided (USPSTF, 2005)

  The USPSTF 2005 recommendation defines increased risk in the following manner:

  "A family history suggestive of a deleterious mutation in BRCA 1 or BRCA 2 for a non-Ashkenazi Jewish woman includes:

    - Two first-degree relatives with breast cancer, one of whom received the diagnosis at age 50 years or younger;
    - A combination of three or more first- or second-degree relatives with breast cancer regardless of age at diagnosis;
    - A combination of both breast and ovarian cancer among first- and second-degree relatives;
    - A first-degree relative with bilateral breast cancer;
    - A combination of two or more first- or second-degree relatives with ovarian cancer regardless of age at diagnosis;
    - A first- or second-degree relative with both breast and ovarian cancer at any age; and
    - A history of breast cancer in a male relative

For women of Ashkenazi Jewish heritage, an increased-risk family history includes any first-degree relative (or two second-degree relatives on the same side of the family) with breast or ovarian cancer" (USPSTF 2005).

GENETIC TESTING ALGORITHM FOR DIAGNOSTIC, PREDICTIVE, AND PHARMACOGENOMIC TESTING

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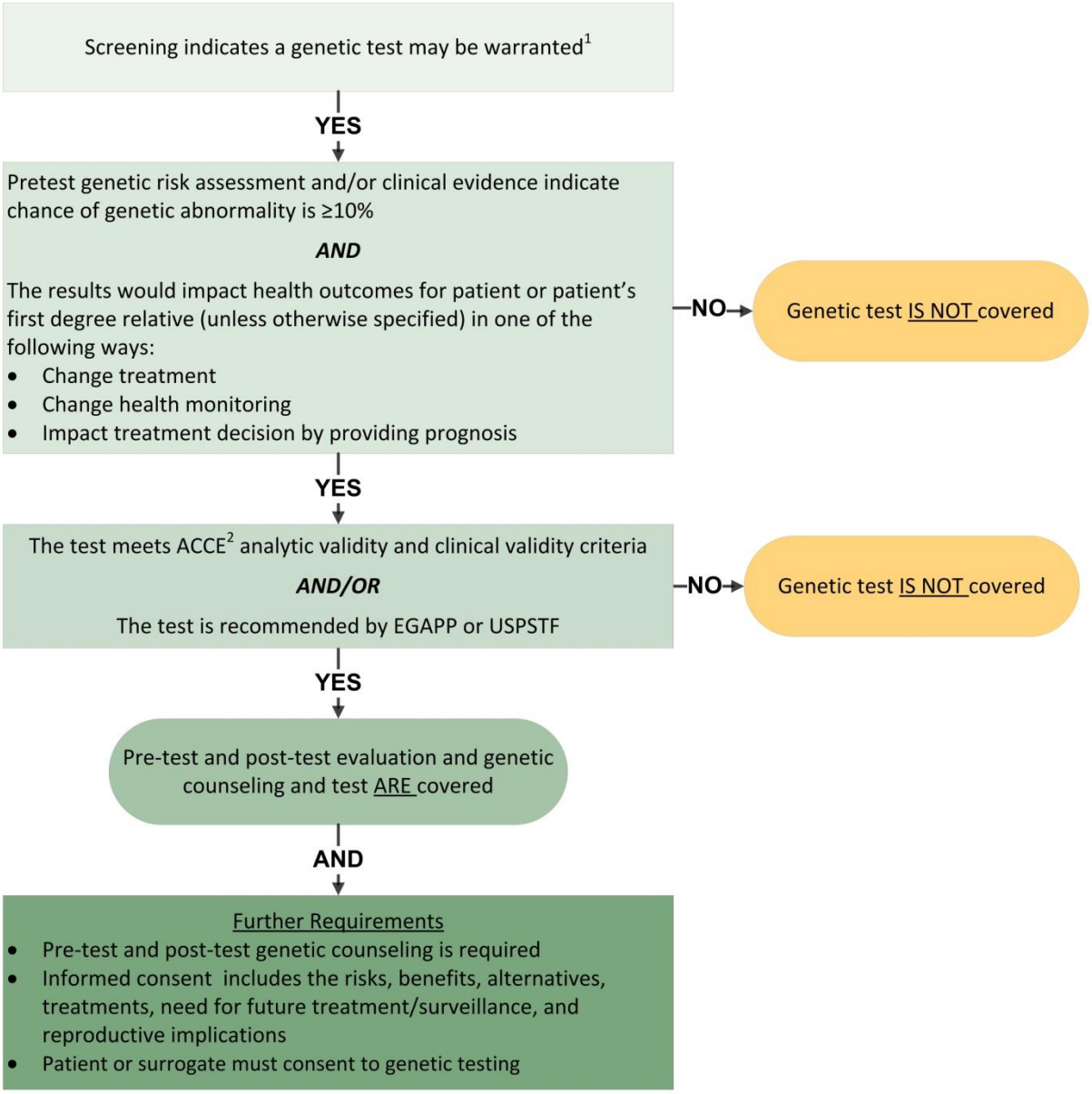

NOTES
1. Screening may include medical and family history, physical exam, laboratory or imaging studies
2. Refer to Appendix D for ACCE model questions in consideration of genetic testing

ABBREVIATIONS

EGAPP - Evaluation of Genomic Applications in Practice and Prevention Framework
USPSTF - U.S. Preventive Services Task Force
ACCE - Analytic validity; Clinical validity; Clinical utility; and Ethical, legal, and social implications Model

Special Provision: Exception to Policy Limitation 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.

Non-Covered Services and General Limitations

Genetic tests that do not meet the criteria for coverage according to the specified covered services or algorithm are not covered. In addition, the following specific tests are not covered:

- Genetic testing for Factor V Leiden and prothrombin variants for idiopathic venous thromboembolism (EGAPP, 2011)
- UGT1A1 genotyping in patients with metastatic colon cancer who are candidates for treatment with irinotecan (EGAPP, 2009)
- CYP450 testing for adults beginning SSRI therapy for non-psychotic depression (EGAPP, 2007)
- Genomic profiling to assess cardiovascular risk (EGAPP, 2010)
- Routine genetic testing for the diagnosis of autism; genetic tests can be considered, as recommended by a regional genetic counselor, if there are specific dysmorphic features, congenital anomalies and/or evidence of intellectual disability (NCCWCH & NICE 2011)

Prior Authorization Requirements

All non-prenatal genetic tests must be prior authorized before being rendered.

Definitions

Term	Definition
Non-prenatal genetic test	A genetic test for children or adults that is for the purpose of diagnosing a known or suspected disease, predicting a disease in asymptomatic individuals with a family history of a disorder, or testing for mutations that may impact drug metabolism and response.
Diagnostic genetic test	A test that is used to confirm or rule out a known or suspected genetic disorder in an individual with signs or symptoms. An example is testing for familial hypercholesterolemia in an individual with abnormally high lipids.
Predictive genetic test	A test that is offered to individuals with a family history or suspected family history of a genetic disorder without personal signs or symptoms. Tests can be presymptomatic when the eventual development of the disorder is known (i.e. Huntington disease) or predispositional in which the development of the disorder is possible (i.e. BRCA mutation).
Pharmacogenomic testing	Tests that study drug metabolism and response and are used by health care providers to select therapies most appropriate according to one's genetics (i.e. CYP2C9 variations and warfarin).
Clinical Laboratory Improvement Amendment (CLIA)	An amendment passed by Congress in 1988 specifying laboratory standards
ACCE model	A model for evaluation genetic testing that was developed by the Center for Disease Control (CDC) that assesses the analytic validity, clinical validity, clinical utility, and ethical, legal, and social implications of a genetic test
Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group	A multidisciplinary panel created by the CDC in 2004 that systematically reviews evidence and makes recommendations related to genetic testing

US Preventive Services Task Force (USPSTF)	An independent group of national experts in prevention and evidence based medicine that makes recommendations about clinical preventive services. The body was created in 1984, is authorized by Congress and supported by the Department of Health and Human Services. The panel is made of 16 volunteer members from the fields of preventive medicine and primary care.

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Medicaid Director Signature _____ Date _____