
Medical Policy



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***Current Policy Effective Date: 5/1/24**
(See policy history boxes for previous effective dates)

Title: Genetic Testing and Counseling

This policy applies only if there is not a separate joint medical policy that outlines criteria for genetic testing for a specific condition. If a separate joint policy exists, then the inclusionary/exclusionary guidelines in that policy supersede the guidelines in this policy.

Description/Background

The purpose of this conceptual framework is to assist evaluation of the utility of genetic tests. In providing a framework for evaluating genetic tests, this review will not determine the clinical utility of genetic testing for specific disorders. Rather, it provides guidelines that can be applied to a wide range of tests.

This conceptual framework applies only if there is not a separate evidence review that outlines specific criteria for testing. If a separate review exists, then the criteria for medical necessity in that evidence review supersede the guidelines herein.

This conceptual framework does not include cytogenetic testing (karyotyping), biochemical testing, or molecular testing for infectious disease.

This conceptual framework also does not address reproductive genetic testing. There are separate medical policies for genetic testing in the reproductive setting, addressing, e.g., carrier testing for genetic diseases, invasive prenatal (fetal) diagnostic testing, and preimplantation genetic testing.

The following categories of genetic testing are addressed herein:

1. Testing of an affected (symptomatic) individual's germline to benefit the individual
 - a. Diagnostic
 - b. Prognostic
 - c. Therapeutic

2. Testing cancer cells of an affected individual to benefit the individual
 - a. Diagnostic

- b. Prognostic
 - c. Therapeutic
3. Testing an asymptomatic individual to determine future risk of disease
 4. Testing of an affected individual's germline to benefit family members.

DEFINITIONS

Genetic Testing

Genetic testing involves the analysis of chromosomes, DNA, RNA, genes, or gene products to detect inherited (germline) or noninherited (somatic) genetic variants related to disease or health.

Carrier Testing

A carrier of a genetic disorder has 1 abnormal allele for a disorder. When associated with an autosomal recessive or X-linked disorder, carriers of the causative variant are typically unaffected. When associated with an autosomal dominant disorder, the person has 1 normal copy of the gene and 1 mutated copy of the gene; such a person may be affected with the disorder, may be unaffected but at high risk of developing the disease later in life, or may remain unaffected because of the sex-limited nature of the disease. Carrier testing may be offered to people: (a) who have family members with a genetic condition; (b) who have family members who are identified carriers; and (c) who are members of ethnic or racial groups known to have a higher carrier rate for a particular condition.

Germline Variants

Germline variants are present in the DNA of every cell of the body, from the moment of conception. They include cells in the gonads (testes or ova) and could, therefore, be passed on to offspring.

Somatic Variants

Somatic variations occur with the passage of time and are restricted to a specific cell or cells derived from it. If these variants are limited to cells that are not in the gonads, they will not be passed on to offspring.

Pharmacogenomics

Pharmacogenomics studies how a person's genetic makeup affects his or her body's response to drugs.

Regulatory Status:

Several agencies are involved in oversight of genetic testing. The Centers for Medicare and Medicaid Services (CMS) regulates clinical laboratory testing to ensure laboratory compliance with the Clinical Laboratory Improvement Amendment of 1988, showing accuracy and reliability in conducting assays. The Federal Trade Commission (FTC) oversees advertising of tests and products. The Food and Drug Administration (FDA) regulates tests sold as "diagnostic devices," that is, tests manufactured by one company and then sold as a kit to a laboratory for genetic testing. However, the FDA does not regulate "home brew" tests, that is, tests that are both manufactured and performed by the same laboratory. Many common genetic tests (including the BRCA breast cancer gene tests) fall into this category. Because of this regulatory exception, genetic testing services using home brew tests can be marketed directly to the medical community - and the public - without FDA regulation or oversight.

Medical Policy Statement

The safety and effectiveness of genetic testing and counseling services have been established. They may be considered useful diagnostic options only if the testing results are expected to establish or verify a diagnosis, initiate a treatment plan and/or alter the patient's health care management.

Inclusionary and Exclusionary Guidelines

Genetic testing classified in one of the categories below is established when all criteria are met for each category:

1. Testing of an affected (symptomatic) individual's germline DNA to benefit the individual (excluding reproductive testing)
 - a. Diagnostic
 - b. Prognostic
 - c. Therapeutic
2. Testing cancer cells of an affected individual to benefit the individual
 - a. Diagnostic
 - b. Prognostic
 - c. Therapeutic
3. Testing an asymptomatic individual to determine future risk of disease

Genetic testing that does not meet the criteria for a specific category is considered experimental/investigational.

For the following category of testing, the benefit of testing is for a family member rather than the individual being tested. In this category, the criteria developed are for clinical utility.

- Testing of an affected individual's germline to benefit family member(s).

Genetic testing is considered experimental/investigational when:

- testing is not considered standard of care, such as when the clinical diagnosis can be made without the use of a genetic test;
- testing is not clinically appropriate for the patient's condition (e.g., when it would not change diagnosis and/or management). Other situations where testing is not clinically appropriate include, but are not limited to:
 - testing performed entirely for nonmedical (e.g., social) reasons;
 - testing not expected to provide a definitive diagnosis that would obviate the need for further testing.
- testing is performed primarily for the convenience of the patient, physician, or other health care provider;
- testing would result in outcomes that are equivalent to outcomes using an alternative strategy, and the genetic test is more costly.

Other Exclusions:

- Next-generation sequencing panels for conditions other than those listed under the Genetic Testing-NGS Testing of Multiple Genes (Panel) to Identify Targeted Cancer Therapy policy.
 - Whole genome or whole exome sequencing for conditions other than those listed under the Genetic Testing-Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders policy
 - Forensic testing for legal purposes
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CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. This is a general listing of all genetic testing codes currently in use. Please refer to the appropriate medical policy for the code in question, if available.)*

Genetic Test Code Ranges

G0452, G9143, S3620, S3800-S3870, 81161-81170, 81200-88291, 0002M-0010M,

Genetic Counseling

S0265

*Note: these code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage. **Reference specific policy for genetic test in question, if available.** For conditions that do not have a separate policy, the patient must meet the inclusionary guidelines in this policy.*

Rationale

GENERAL PRINCIPLES OF GENETIC TESTS

A test should be cleared or approved by the U.S. Food and Drug Administration or performed in a Clinical Laboratory Improvement Amendments–certified laboratory.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The following rubric outlines the steps in assessing a medical test. The first step is to formulate the clinical context and purpose of the test. Then the evidence is reviewed to determine whether the test is technically reliable, clinically valid, and clinically useful. However, as noted below, technical reliability is outside the scope of evidence reviews.^{1,2}

TYPES OF GENETIC TESTS ADDRESSED IN THIS CONCEPTUAL FRAMEWORK

1. Testing of an affected (symptomatic) individual's germline to benefit the individual (excluding reproductive testing)
 - a. Diagnostic: To confirm or exclude genetic or heritable variants in a symptomatic person. This refers to a molecular diagnosis supported by the presence of a known pathogenic variant. For genetic testing, a symptomatic

person is defined as an individual with a clinical phenotype correlated with a known pathogenic variant.

- b. Prognostic: To determine or refine estimates of disease natural history or recurrence in patients already diagnosed with disease in order to predict natural disease course (e.g., aggressiveness, recurrence, risk of death). This type of testing may use gene expression of affected tissue to predict the course of disease (e.g., testing breast cancer tissue with Oncotype DX).
 - c. Therapeutic: To determine that a particular therapeutic intervention is effective (or ineffective) for an individual. To determine the probability of favorable or adverse response to medications. To detect genetic variants that alter risk of treatment response, adverse events, drug metabolism, drug effectiveness, etc. (e.g., cytochrome P450 testing). To detect genetic variants that adversely affect response to exposures in the environment that are ordinarily tolerated (e.g., *G6PD* deficiency, genetic disorders of immune function, aminoacidopathies).
2. Testing cancer cells of an affected individual to benefit the individual
 - a. Diagnostic: To determine the origin of a cancer or to determine a clinically relevant subgroup into which a cancer is classified.
 - b. Prognostic: To determine the risk of progression, recurrence, or mortality for a cancer that is already diagnosed.
 - c. Therapeutic: To determine the likelihood that a patient will respond to a targeted cancer therapy that is based on the presence or absence of a specific variant.
 3. Testing an asymptomatic individual to determine future risk of disease. To detect genetic variants associated with disorders that appear after birth, usually later in life. Such testing is intended for individuals with a family history of a genetic disorder, but who themselves have no features of the disorder, at the time of testing, in order to determine their risk for developing the disorder.
 4. Testing of an affected individual's germline to benefit family member(s). To focus and direct family testing of asymptomatic relatives, by testing an individual with known disease but in whom the presence or absence of a pathogenic variant has not been determined.

MEDICAL NECESSITY CRITERIA

The criteria listed below for medical necessity represent minimum criteria that must be met in each category to conclude that a test is medically necessary.

Genetic testing is considered **medically necessary** for a genetic or heritable disorder when the following are met.

For ALL genetic testing, the condition being tested for must have either:

- Reduced life expectancy OR
- At least moderate-to-severe morbidity.³

For the specific categories of testing, the following criteria must also be met:

1. Testing of an affected (symptomatic) individual's germline to benefit the individual (excluding reproductive testing)
 - a. Diagnostic
 - i. An association between the marker and the disorder has been established AND

- ii. Symptoms of the disease are present AND
 - iii. A definitive diagnosis cannot be made based on history, physical examination, pedigree analysis, and standard diagnostic studies/tests AND
 - iv. The clinical utility of identifying the variant has been established
 - 1) Leads to changes in clinical management of the condition that improve outcomes OR
 - 2) Eliminates the need for further clinical workup or invasive testing OR
 - 3) Leads to discontinuation of interventions that are unnecessary and/or ineffective,
 - b. Prognostic
 - i. An association between the marker and the natural history of the disease has been established AND
 - ii. Clinical utility of identifying the variant has been established
 - 1) Provides incremental prognostic information above that of standard testing AND
 - 2) Reclassifies patients into clinically relevant prognostic categories for which there are different treatment strategies AND
 - 3) Reclassification leads to changes in management that improve outcomes.
 - c. Therapeutic
 - i. Genetic testing identifies variants of a phenotype/metabolic state that relate to different pharmacokinetics, drug efficacy, or adverse drug reactions AND
 - ii. Clinical utility of identifying the variant has been established
 - 1) Leads to initiation of effective medication(s) OR
 - 2) Leads to discontinuation of medications that are ineffective or harmful OR
 - 3) Leads to clinical meaningful change in dosing of medication that is likely to improve outcomes.
2. Testing cancer cells of an affected individual to benefit the individual
- a. Diagnostic
 - i. Genetic testing can establish the cell origin of a cancer when the origin is uncertain following standard workup AND
 - ii. Clinical utility of identifying the variant has been established:
 - 1) Start effective treatment OR
 - 2) Discontinue ineffective or harmful treatment
 - b. Prognostic
 - i. An association between the marker and the natural history of the disease has been established AND
 - ii. Clinical utility of identifying the variant has been established:
 - 1) Provides incremental prognostic information above that of standard testing AND
 - 2) Reclassifies patients into clinically relevant prognostic categories for which there are different treatment strategies AND
 - 3) Reclassification leads to changes in management that improve outcomes.
 - c. Therapeutic

- i. Association between a variant and treatment response to a particular drug has been established AND
 - ii. Clinical utility has been established (see Appendix 2):
 - 1) The patient is a candidate for targeted drug therapy associated with a specific variant AND
 - 2) There is a clinically meaningful improvement in outcomes when targeted therapy is given for the condition.
3. Testing an asymptomatic individual to determine future risk of disease
- i. An association between the marker and future disorder has been established AND
 - ii. Clinical utility has been established:
 - 1) There is a presymptomatic phase for this disorder and interventions or surveillance are available AND
 - 2) Interventions in the presymptomatic phase are likely to improve outcomes:
 - a. Prevent or delay onset of disease OR
 - b. Detect disease at an earlier stage during which treatment is more effective OR
 - c. Discontinuation of ineffective or unnecessary interventions.

CLINICAL UTILITY CRITERIA

For the following category, focusing on the benefit of testing for another individual, the definition of medical necessity may not apply. When an individual is tested to benefit a family member, and there is no benefit for the individual being tested, eligibility for coverage depends on individual plan benefit language. Individual plans may differ whether benefit structure allows testing of an individual to benefit an unaffected family member.

For these reasons, the following criteria are considered for clinical utility of testing and not for medical necessity.

- 4. Testing of an affected individual's germline to benefit family members
 - i. An association between the genetic variant and clinical disease has been established AND
 - ii. Family members are available who may be at risk for the disorder AND
 - iii. The individual tested has a clinical diagnosis of the condition (or represents the family member who is most likely to harbor the pathogenic variant), but genetic testing has not been performed AND
 - iv. There is a presymptomatic phase for the disorder in which interventions are available AND
 - v. Interventions in the presymptomatic phase are likely to improve outcomes in one of the following ways:
 - 1) Prevent or delay onset of disease;
 - 2) Detect disease at an earlier stage during which treatment is more effective;
 - 3) Discontinuation of interventions that are ineffective or unneeded.

LIMITATIONS OF GENETIC TESTING

- The testing methods may not detect all variants that may occur in a gene.
- Genetic testing may identify variants of uncertain significance.
- Genetic testing may not necessarily determine the clinical outcome.
- Different genes can cause the same disease (genetic heterogeneity).
- A variant in a gene may cause different phenotypes (phenotypic heterogeneity).
- Some disease-causing genes may not yet be identified.
- Genetic testing is subject to laboratory error.

SUMMARY OF EVIDENCE

This conceptual framework addresses genetic testing in nonreproductive settings. Genetic testing in reproductive settings is addressed separately. For categories of genetic testing for which the benefit of testing is the individual, criteria for medical necessity apply. When the benefit of testing is not for the individual, but for a family member, medical necessity criteria may not apply, and the criteria are developed for clinical utility.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

No guidelines or statements were identified.

Government Regulations

National:

According to the Social Security Act of 1862(a)(1)(A)

“Notwithstanding any other provision of this title, no payment may be made...for items or services - which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” This has been interpreted historically to prohibit payment for screening and prevention, unless Congress creates specific exceptions, which it has done periodically, e.g., for colorectal cancer screening. Thus, Medicare’s ability to consider payment for genomic services is currently limited to such uses that are neither screening nor preventive in nature.

Medicare does not have a broad national coverage policy on genomic testing. Therefore, local Medicare contractors may make policies that apply only within their own jurisdictions. However, since many genomic tests are provided in a single location, i.e., all specimens are sent to a single laboratory, the decision of the local contractor having oversight of that laboratory has national implications.

Medicare does not pay for preventive screening tests except for those specifically authorized by statute (e.g., prostate-specific antigen test). Since CMS considers predictive tests to be screening tests, genetic tests for this purpose are not covered by Medicare. However, genetic tests used to diagnose or determine treatment in the presence of signs and symptoms of disease can be covered by Medicare. A common use of genetic tests in the Medicare population is to assist in determining cancer treatment. Genetic tests can be used to predict optimal chemotherapy regimens and avoid exposing patients to ineffective or overly toxic regimens.

Medicare uses a combination of national and local coverage determinations for making coverage decisions for genetic tests. National coverage determinations (NCD) are made at the

Federal level and apply to all Medicare beneficiaries and Medicare administrative contractors (MAC). Currently, only two NCDs related to genetic tests have been established: (1) testing to predict patient responsiveness to the drug warfarin sodium, and (2) cytogenetic studies. MACs make local coverage determinations (LCD), which apply only to beneficiaries in the contractor's jurisdiction. Of the nearly 9,000 LCDs, only 11 are related to genetic tests. For example, one MAC covers BRCA1 and BRCA2 genetic testing for beneficiaries who meet certain criteria.

Medicare National Coverage Determinations Manual, Section 190.3, Cytogenetic Studies; CIM 50-29, p 8-9:

The term "cytogenetic studies" is used to describe the microscopic examination of the physical appearance of human chromosomes. Medicare covers these tests when they are reasonable and necessary for the diagnosis or treatment of the following conditions:

- Genetic disorders (e.g., mongolism) in a fetus (See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §20.1
- Failure of sexual development; or
- Chronic myelogenous leukemia.
- Acute leukemias lymphoid (FAB L1-L3), myeloid (FAB M0-M7), and unclassified; or
- Myelodysplasia.

Local:

WPS GHA policy staff review and revise Local Coverage Determinations (LCDs) and Local Coverage Articles to ensure that all information remains accurate and up-to-date. When new LCDs and articles are created, and when current LCDs and articles are revised or retired, a summary of these updates is made available the WPS website.

A list of WPS policy numbers and their effective dates can be located at the following link:
https://www.wpsgha.com/wps/portal/mac/site/policies/news-and-updates/2017-january-policy-article-updates!/ut/p/z0/jY_LTsMwFER_pV1kaV03fW4LKoqqRGWFqjflOJfkFmO7tkJv564GyRe6nJGozMzIKA_GYeQ7tTKSNVIP-IEsnu6LYIFMVrzc5RXn6-ruYbpZITd8k8MWxJ-B7XI2TwTaHw5iDUJZE_EjQn1yYXQRJo7QtJpCl_HOvmHGHfqQmumMDUtWAuS-uaq1aEE7GjpF5sVD_zP235DL1d5DBU2DSNOzoGhXkQJ3zyZLtpTIK3zNnNameSR9JafwKXfsqWkeKqc_FDP7xLNMKQ8e-1Gb-m1r2K5356Lgvdjj8Bezr1TQ!!/

Moldx Expansion to J5 and J8

Reference the following link for coding molecular diagnostic testing coding:

https://www.wpsgha.com/wps/portal/mac/site/policies/guides-and-resources/moldx-expansion!/ut/p/z1/pVRdc6lwFP0r7YOPmQQQCY_YcWUdaTt0qcrLDoal6UBCISr66zfrJ3cKaMtDBi65H-fcey6M4RLGPNmzLJFM8CRX36t49Pfv90e-gdH8xQwQ8oJf79YEz8doYsJFfwULTS0Y3-KPWh4P9fm_wxjGhMtSbuHqUNYPRHBJuXygPMtZvR0gKUpGAFE2Wg1QKXJGGK0HKNuxlNYg4Sm_oaC12FdHWQuRpA2hTJrxWFOjoJWEpXLmG5ZAhdKFKXRsmBfWGkWMD0yXmxnAt6oy62TiXG3eDnV3DnUbPY-QZL-HUnIRWGCLdD_bx-RI7CrQG2ki4_BL1RISFgrMVBb2c2tWsgqcgU4gSuQWMBwRcXn6dz1kX1zg0WiJ8xSNcfuA14ELxLIIK_UkF2hSrvPFW3Y7juHMkTVrT2rSNf66ZM7RvL-jCZkmrWouDnWjawsnVIU5e32bW7fm1ISES7OruoL-D4XdZIIICOONZdwl9yt9Mck8A7xm6_30XW4966lPKislaaedBwcu9oweYMSV4NTCfltzY_h9GSLzhxl6wts_DF8WUVRg6wji9bHBx8Ze2_l-vgkkPlqnOV28lv5p_AymT2t8-OM9Pv4D1FV5oA!!/dz/d5/L2dBISevZ0FBIS9nQSEh/

Medicare LCD L36807, Molecular Diagnostic Testing, revised 12/30/2021, available at

<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36807&ver=7&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Mi>

MolDX will reimburse

- approved tests covered for dates of service consistent with the effective date of the coverage determination.

Covered Tests

Please refer to the MolDX website www.palmettogba.com/MolDX for covered and excluded tests' specific coding and billing information.

To obtain a unique identifier for a test and, to submit information for a technical assessment go to McKesson Diagnostics Exchange™: <https://app.mckesson.com/#login>.

For additional MolDX Program information, go to the Medicare home page at PalmettoGBA.com/MolDX.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Genetic and Lab Testing for 5-Fluorouracil
- Genetic and Protein Biomarkers for the Diagnosis and Risk Assessment of Prostate Cancer
- Genetic Testing – JAK2 and MPL Mutation Analysis
- Genetic Testing – Marfan Syndrome
- Genetic Testing and Counseling
- Genetic Testing for Adolescent Idiopathic Scoliosis
- Genetic Testing for Alpha₁-Antitrypsin Deficiency
- Genetic Testing for Alzheimer's Disease
- Genetic Testing for Amyotrophic Lateral Sclerosis
- Genetic Testing for Analysis of MGMT Promoter Methylation
- Genetic Testing for ARVC
- Genetic Testing for Bloom Syndrome
- Genetic Testing for BRAF for Melanoma Targeted Therapy
- Genetic Testing for Cadasil Syndrome
- Genetic Testing for Cancer Susceptibility
- Genetic Testing for Cancers Unknown Primary (CUP)
- Genetic Testing for Cardiac Ion Channelopathies
- Genetic Testing for Carrier Status Genetic Testing for CHEK2 Mutations
- Genetic Testing-Circulating DNA Colon Cancer Recurrence
- Genetic Testing-Circulating Tumor DNA and Circulating Tumor Cells
- Genetic Testing-Circulating Tumor DNA for Management of NSCLC
- Genetic Testing for Cystic Fibrosis
- Genetic Testing for Cytochrome p450 Polymorphisms
- Genetic Testing for Dilated Cardiomyopathy

- Genetic Testing for Duchenne and Becker Muscular Dystrophy
- Genetic Testing for Epilepsy
- Genetic Testing-Gene Expression Profile Decision Making Breast Cancer
- Genetic and Molecular Tests E/I
- Genetic and Lab Testing
- Genetic Testing for Familial Cutaneous Melanoma
- Genetic Testing for FMR1 Mutations Including Fragile X
- Genetic Tests for FLT3, NPM1 and CEBPH
- Genetic Testing for Hereditary Breast-Ovarian CA
- Genetic Testing for Hereditary Hearing Loss
- Genetic Testing for Hereditary Hemochromatosis
- Genetic Testing for HLA-B 1502 before Carbamazepine
- Genetic Testing for Inherited Hypertrophic Cardiomyopathy
- Genetic Testing for Inherited Peripheral Neuropathies
- Genetic Testing for Inherited Thrombophilias
- Genetic Testing for Lynch Syndrome
- Genetic Testing for Macular Degeneration
- Genetic Testing for Mitochondrial Disorders
- Genetic Testing for Myotonic Muscular Dystrophy
- Genetic Testing for Noonan Spectrum Disorder
- Genetic Testing for Pharmacologic Testing for Pain Management
- Genetic Testing for Prader Willi and Angelman Syndromes
- Genetic Testing for PTEN Hamartoma Tumor Syndrome
- Genetic Testing for Retinal Dystrophy
- Genetic Testing for Rett Syndrome
- Genetic Testing for Specified Conditions Using Testing Panels
- Genetic Testing for Tay Sachs Disease
- Genetic Testing for the Prognosis of Breast Cancer
- Genetic Testing for Warfarin Dosing
- Genetic Testing-BCR-ABL1 in BML and AML
- Genetic Testing-Chromosomal Microarray Analysis for Developmental Delay/Autism
- Genetic Testing-Chromosomal Microarray Analysis for Early Pregnancy Loss
- Genetic Testing-Expanded Molecular Panel Testing
- Genetic Testing-Fetal RhD Genotyping Using Maternal Plasma
- Genetic Testing-Gene Expression Profile Analysis-Prostate Cancer
- Genetic Testing-Gene Expression Profiling for Uveal Melanoma
- Genetic Testing-Gene Expression Testing to Predict CAD
- Genetic Testing-Germline-BRCA1, BRCA2, PALB2 for Hereditary Breast Ovarian
- Genetic Testing-Hereditary Hearing Loss
- Genetic Testing-Hereditary Hemochromatosis
- Genetic Testing-Heterozygous Hypercholesterolemia
- Genetic Testing-HLA Testing for Celiac
- Genetic Testing-Human Platelet Antigen Genotyping
- Genetic Testing-Huntington's Disease
- Genetic Testing-Inherited Peripheral Neuropathies
- Genetic Testing-KRAS, NRAS, BRAF in Metastatic Colorectal Cancer
- Genetic Testing-LiFraumeni Syndrome

- Genetic Testing-Lynch Syndrome
 - Genetic Testing-Marfan Syndrome, Ehlers Danlos, TAAD
 - Genetic Testing-Misc and Genetic and Molecular Diagnostic Tests
 - Genetic Testing-Molecular Analysis for Targeted Therapy
 - Genetic Testing-Molecular Markers in Fine Needle Aspirates of Thyroid
 - Genetic Testing-Multimarker Serum based Testing R/T Ovarian Cancer
 - Genetic Testing-Multigene Assay in Colon Cancer
 - Genetic Testing-NGS for Measurable Residual-Hematological
 - Genetic Testing NGS for Solid and Hematolymphoid Conditions
 - Genetic Testing-Noninvasive Prenatal Screening
 - Genetic Testing-Pathfinder-Molecular Anatomic Pathology
 - Genetic Testing-Preimplantation
 - Genetic Testing-Whole Exome-Whole Genome Sequencing
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References

1. ACMG Board of Directors. Clinical utility of genetic and genomic services: a position statement of the American College of Medical Genetics and Genomics. *Genet Med*. Jun 2015;17(6):505-507. PMID 25764213
2. Teutsch SM, Bradley LA, Palomaki GE, et al. The Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Initiative: methods of the EGAPP Working Group. *Genet Med*. Jan 2009;11(1):3-14. PMID 18813139
3. Beltran-Sanchez H, Razak F, Subramanian SV. Going beyond the disability-based morbidity definition in the compression of morbidity framework. *Glob Health Action*. Sep 2014;7:24766. PMID 25261699
4. Blue Cross Blue Shield Association. General approach to genetic testing. Medical Policy Reference Manual. 2.04.91. Published February 2013. Updated December 2017.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January 2024, the date the research was completed.

Joint I/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/07	7/30/07	8/29/07	Joint policy established
9/1/09	6/16/09	6/16/09	Routine maintenance
11/1/11	8/16/11	8/16/11	Routine maintenance-updated related policies and references
11/1/13	8/22/13	8/27/13	Routine maintenance; added numerous new molecular pathology codes to policy.
11/1/14	8/19/14	8/25/14	Routine maintenance, new codes added. Expanded definitions and background as well as list of related policies.
11/1/15	8/18/15	10/19/15	Routine maintenance. Removed references to carrier testing; refer to related policy, "Genetic Testing for Carrier Status."
11/1/16	9/23/16	9/23/16	Routine maintenance. 2016 codes added (81162, 81219, 81272, 81273, 81276, 81311, 81314, 81432, 81433, 81434, 81437, 81438, 81442, 81490, 81493, 81525, 81535, 81536, 81538, 81540, 81545, 81595. No change in policy status.
5/1/17	2/21/17	2/21/17	2017 code update, deleted 81280-81282. Added 81327, 81413, 81414, 81422, 81439, 81539, 0001U and 0003U. No change in policy status.
5/1/18	2/20/18	2/20/18	Added codes 0004U and 0005U as E/I. Eliminated listing of individual codes and listed code ranges. Reformatting of all sections.
5/1/19	2/19/19		Routine policy maintenance, codes 81163-81167, 81187, 81234, 81236, 81237, 81239, 81333, 81443 and 81518 added to policy.
5/1/20	2/18/20		Routine policy maintenance. No change in policy status.

5/1/21	2/16/21		Routine policy maintenance, no change in policy status. Code 96040 removed from policy as it is no longer a payable procedure code.
5/1/22	2/15/22		Clarification of exclusion section. No change in policy status.
5/1/23	2/21/23		<ul style="list-style-type: none"> • Routine policy maintenance, no change in policy status. • Added codes 81418 as established. • Added codes 0332U, 0345U, 0347U, 0348U, 0349U and 0350U as E/I. (ds)
5/1/24	2/20/24		<ul style="list-style-type: none"> • Deleted all PLA codes from policy. • Routine policy maintenance, no change in status. • Vendor managed: N/A (ds)

Next Review Date: 1st Qtr. 2025

**BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: GENETIC TESTING AND COUNSELING**

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Specific tests may be covered; criteria apply.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.