

Marketplace National Regional Benefit Interpretation Document

Benefit Name	GENETIC TESTING/THERAPY
Applicable State	California, Florida, Idaho, Illinois, Kentucky, Michigan, Mississippi, Nevada, New Mexico, Ohio, South Carolina, Texas, Utah, Washington, Wisconsin
Benefit Definition	<p>This policy addresses genetic testing and counseling.</p> <p>Covered benefits are listed in three (3) Sections - A, B and C. All services must be medically necessary. Each benefit plan contains its own specific provisions for coverage, limitations and exclusions as stated in the member's Evidence of Coverage (EOC)/Schedule of Benefits (SOB). If there is a discrepancy between this policy and the member's EOC/SOB, the member's EOC/SOB provision will govern.</p> <p>Genetic testing is defined by the National Human Genome Research Institute as an array of techniques including analysis of human DNA, RNA, or protein. Genetic tests are used as a health care tool to detect gene variants associated with a specific disease or condition, as well as for non-clinical uses such as paternity testing and forensics. In the clinical setting, genetic tests can be performed to determine the genetic cause of a disease, confirm a suspected diagnosis, predict future illness, detect when an individual might pass a genetic mutation to his or her children, and predict response to therapy. They are also performed to screen newborns, fetuses, or embryos used in in vitro fertilization for genetic defects.</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> A. FEDERAL/STATE MANDATED REGULATIONS </div> <p>Note: The most current federal/state mandated regulations for each state can be found in the links below.</p> <p>FEDERAL: CMS ACA Implementation FAQ XXVI (Coverage of BRCA Testing)</p> <p>CALIFORNIA: California Health & Safety Code §1367.7: Prenatal Diagnosis of Genetic Disorders of Fetus: On and after January 1, 1980, every health care service plan contract that covers hospital, medical, or surgical expenses on a group basis, and which offers maternity coverage in such groups, shall also offer coverage for prenatal diagnosis of genetic disorders of the fetus by means of diagnostic procedures in cases of high-risk pregnancy. Every health care service plan</p>

shall communicate the availability of such coverage to all group contract holders and to all groups with whom they are negotiating.

SB 535 (APL 21-025):

Prohibits plans, on or after July 1, 2022, from requiring prior authorization for

- 1) biomarker testing for an enrollee with advanced or metastatic stage 3 or 4 cancer or
- 2) biomarker testing for cancer progression or recurrence in the enrollee with advanced or metastatic stage 3 or 4 cancer.

Allows a plan to require prior authorization for biomarker-testing that is not for an FDA-approved therapy for advanced or metastatic stage 3 or 4 cancer.

SB 496 - Biomarker testing- Effective 7/1/2024, the CA health plan must cover medically necessary biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment decisions. Biomarker testing includes, but is not limited to, single-analyte tests, multiplex panel tests, and whole genome sequencing.

KENTUCKY:

[Ky. Rev. Stat. § 304.17A-263](#): Coverage under health benefit plan for biomarker testing

B. STATE MARKET PLAN ENHANCEMENTS

None

C. COVERED BENEFITS

IMPORTANT NOTE: Covered benefits are listed in Sections A, B and C. Always refer to Sections A and B for additional covered benefits not listed in this Section.

Refer to the member's Evidence of Coverage (EOC) and Schedule of Benefits (SOB) to determine coverage eligibility.

MHI uses eviCore healthcare and MCG criteria for evaluation of all genetic testing requests. Please refer to Clinical Policy for additional criteria information.

GENETIC TESTING/THERAPY

CALIFORNIA, ILLINOIS, MICHIGAN, MISSISSIPPI, NEVADA, NEW MEXICO, OHIO, SOUTH CAROLINA, TEXAS, WASHINGTON, WISCONSIN:

Molina covers limited gene therapy services in accordance with Molina's medical policies and subject to Prior Authorization (Not listed FL, ID, UT EOC)

KENTUCKY:

Passport will also cover genetic tests for cancer risk which are recommended by a physician, physician assistant, genetic counselor, or advanced practice registered nurse. You will not be required to pay a co-pay or deductible for a genetic cancer risk test.

BIOMARKER TESTING
CALIFORNIA:

Cancer Treatment: Molina provides the following coverages for cancer care and treatment, including, but not limited to:

- Preventive cancer screening and testing (please refer to the BI Policy titled Preventive Care Services for more information)
- Biomarker testing with no requirement for Prior Authorization for a Member with advanced or metastatic stage 3 or 4 cancer

ILLINOIS:

Cancer Treatment: Molina provides the following coverages for cancer care and treatment, including, but not limited to:

- Biomarker testing

KENTUCKY:

Passport will cover biomarker testing when ordered by a qualified health care provider operating within the provider's scope of practice for the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of an insured's disease or condition when the test is supported by medical and scientific evidence.

NEW MEXICO:

Biomarker Services: Molina covers biomarker testing for the purpose of diagnosis, treatment, appropriate management or ongoing monitoring of a member's disease or condition when the test is supported by medical and scientific evidence, including:

- labeled indications for a United States food and drug administration-approved or -cleared test;
- indicated tests for a United States food and drug administration-approved drug;
- warnings and precautions on United States food and drug administration labels;

- federal centers for Medicare and Medicaid services national coverage determinations or Medicare administrative contractor local coverage determinations; or
- nationally recognized clinical practice guidelines.

Molina ensures coverage is provided in a manner that limits disruptions in care, including coverage for multiple biopsies or biospecimen samples; and a member and their provider who prescribes biomarker testing have clear, accessible and convenient processes to request an appeal of a benefit denial by Molina please refer to the Member Grievance and Appeal Procedure section in this agreement for more details on appeals. Imaging cost share applies.

WASHINGTON:

Cancer Treatment: Molina provides the following coverages for cancer prevention, screening, care, and treatment, including, but not limited to:

- Biomarker testing services, when prescribed by a Participating Provider, are not subject to Prior Authorization requirements for Members with stage 3 or 4 cancer or for Members with recurrent, relapsed, refractory, or metastatic cancer.

D. NOT COVERED

Refer to the member's Evidence of Coverage (EOC) and Schedule of Benefits (SOB) to determine coverage eligibility.

GENE THERAPY

FLORIDA (not in the 2024 EOC):

Gene Therapy: Most gene therapy, including prescription drug gene therapy, is not covered. Molina covers limited gene therapy services in accordance with Molina's medical policies and subject to Prior Authorization.

CALIFORNIA, IDAHO, ILLINOIS, MICHIGAN, MISSISSIPPI, NEVADA, NEW MEXICO, OHIO, SOUTH CAROLINA, TEXAS, UTAH, WASHINGTON, WISCONSIN:

Gene Therapy, Cell Therapy, and Cell-based Gene Therapy: Most gene therapy, cell therapy, and cell-based gene therapy, including any prescription drugs, procedures, or health care services related to these therapies are not covered. Molina covers limited gene therapy, cell therapy, and cell-based gene therapy services in accordance with Molina's medical policies and subject to Prior Authorization.

KENTUCKY:

Gene Therapy, Cell Therapy, and Cell-based Gene Therapy: Gene therapy, cell therapy, and cell-based gene therapy, including any prescription drugs,

procedures, or health care services related to these therapies are not covered. Coverage for other health care services relating to a condition, for which these types of treatments are available, is in accordance with this Agreement and any limitations outlined in applicable medical policy. As such, certain services may be subject to Prior Authorization.

E. DEFINITIONS

[See Glossary](#)

F. REFERENCES

1. Centers for Medicare & Medicaid Services (CMS) Medicare Coverage Database Homepage. Accessed at: <http://www.cms.gov/medicare-coverage-database/>
2. National Institutes of Health. Genetic Testing: How it is used for healthcare, fact sheet. February 14, 2011, Updated June, 2018.
3. Genetic Testing Registry. [website] National Center for Biotechnology Information, U.S. National Library of Medicine. Accessed at: <http://www.ncbi.nlm.nih.gov/gtr/>
4. Centers for Disease Control and Prevention. Genomic Testing. July, 2017. Accessed at: <http://www.cdc.gov/genomics/gtesting/>
5. National Human Genome Research Institute. [website]:
 - a. Coverage and Reimbursement of Genetic Tests. Aug, 2019. Accessed at: <https://www.genome.gov/19016729/coverage-and-reimbursement-of-genetic-tests/>
 - b. Regulation of Genetic Tests. Jan, 2018. Accessed at: <https://www.genome.gov/10002335/regulation-of-genetic-tests/>
6. U.S. National Library of Medicine. What is a gene mutation and how do mutations occur? March 13, 2011. Updated Aug, 2019. Accessed at: <http://ghr.nlm.nih.gov/handbook/mutationsanddisorders/genemutation>

G. POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
7/1/2023	<ul style="list-style-type: none"> • Added NV 2024 EOC Language

Prior Authorization

For the MHI PA Matrix, if a code is NOT listed, it could EITHER be:

- a. Covered and No PA Required
- b. Not Covered

You cannot use the MHI PA Matrix to make coverage determinations.

	PA Lookup Tool			
Approval	Departments	Product	CIM	Clinical Management
	Date	11/2/2021	3/11/2022	11/5/2021
	Revised (for 1/1/2023)	11/10/2022	4/5/2023	11/10/2022
	Revised (for 1/1/2024)	12/15/2023		12/8/2023