Marketplace Benefit Interpretation

Marketplace National Regional Benefit Interpretation Document

Benefit Name	GENE THERAPY
Applicable State	California, Florida, Idaho, Illinois, Kentucky, Michigan, Mississippi, Nevada, New Mexico, Ohio, South Carolina, Texas, Utah, Washington, Wisconsin
Benefit Definition	This policy addresses gene therapy. 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. 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. **A. FEDERAL/STATE MANDATED REGULATIONS** **Note: The most current federal/state mandated regulations for each state can be found in the links below.** **MICHIGAN:** SB 738: A bill to amend 1956 PA 218, entitled "The insurance code of 1956," by amending section 3406e (MCL 500.3406e), as amended by 2016 PA 276: As used in this section, "genetic therapy and immunotherapy" includes, but is not limited to, CAR-T cell therapy. **B. STATE MARKET PLAN ENHANCEMENTS**

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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.

Gene Therapy aims to treat diseases by directly introducing a functional gene into a patient's cells to replace a faulty one.

GENE THERAPY:

MICHIGAN:
In alignment with State Law, the benefit exclusion listed in the not covered section does not apply to therapies, drugs, procedures, or health care services related to the treatment of cancer.

D. NOT COVERED

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

GENE THERAPY

CALIFORNIA:
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 and treatment options relating to a condition – for which these excluded therapies have been developed – is in accordance with this Agreement and any limitations outlined in applicable medical policy. As such, certain services may be subject to Prior Authorization.

FLORIDA:
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

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limitations outlined in applicable medical policy. As such, certain services may be subject to Prior Authorization.

IDAHO:
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.

ILLINOIS:
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 and treatment options relating to a condition - for which these excluded therapies have been developed - is in accordance with this Agreement and any limitations outlined in applicable medical policy. As such, certain services may be 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.

MICHIGAN:
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 is not covered. Coverage for other health care services and treatment options relating to a condition - for which these excluded therapies have been developed - is in accordance with this Agreement and any limitations outlined in applicable medical policy. In alignment with State Law, this benefit exclusion does not apply to therapies, drugs, procedures, or health care services related to the treatment of cancer. As such, certain services may be subject to Prior Authorization.

MISSISSIPPI:

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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 and treatment options relating to a condition - for which these types of excluded therapies have been developed - is in accordance with this Agreement and any limitations outlined in applicable medical policy. As such, certain services may be subject to Prior Authorization.

NEVADA:
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 and treatment options relating to a condition – for which these excluded therapies have been developed – is in accordance with this Agreement and any limitations outlined in applicable medical policy. As such, certain services may be subject to Prior Authorization.

NEW MEXICO:
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 and treatment options relating to a condition – for which these excluded therapies have been developed – is in accordance with this Agreement and any limitations outlined in applicable medical policy. As such, certain services may be subject to Prior Authorization.

OHIO:
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.

SOUTH CAROLINA:
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 and treatment options relating to a condition - for which these types of excluded therapies have been developed - is in accordance with this Agreement and any limitations outlined in applicable medical policy. As such, certain services may be subject to Prior Authorization.

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TEXAS:
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 and treatment options relating to a condition – for which these excluded therapies have been developed – is in accordance with this Agreement and any limitations outlined in applicable medical policy. As such, certain services may be subject to Prior Authorization.

UTAH:
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.

WASHINGTON:
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 limit outlined in applicable medical policy. As such, certain services may be subject to subject to Prior Authorization.

WISCONSIN:
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

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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	• Added NV 2024 EOC Language

Codification	Marketplace Benefit Interpretation Policies Codification
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

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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 1/1/2025)	12/11/2024	-	12/11/2024

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