NO. 91638

CELLULAR AND GENE THERAPY

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Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This policy outlines general considerations and administrative requirements for cellular and gene therapy products, including chimeric antigen receptor (CAR) T-cell therapies, for the treatment of specific medical conditions.

Related policies:

- Stem Cell or Bone Marrow Transplantation Policy No. 91066
- Infusion Services & Equipment Policy No. 91414

I. POLICY CRITERIA

A. Cellular and gene therapy products, including chimeric antigen receptor (CAR) T-cell therapies, are subject to the following requirements:

1. Prior authorization
   a. Prior Authorization is required
   b. Coverage determinations are made according to product-specific criteria located on Priority Health's website via the Approved Drug List page.

2. Limits for Treatment
   a. Cellular and gene therapy products must have clinically appropriate limits for treatment.

b. The safety and effectiveness of repeat administrations for many cellular and gene therapy products have not been evaluated beyond a single treatment per lifetime.

3. FDA-Approved Use
   a. Dosing and administration must be strictly aligned with the Food and Drug Administration (FDA) approved indication.
   b. Requests for off-label dosing or use will not be approved.

4. Benefit Coverage
   a. Coverage of cellular and gene therapy products is subject to the member's benefit plan documents.

5. Provider and Facility Requirements
   a. The provider and facility administering treatment must be participating, in-network, and in alignment with Priority Health's Reimbursement Requirements for Outpatient Medical Drugs Billing Policy No. 092.
   b. Cellular and gene therapy referrals are directed to facilities in Priority Health's network or contracted networks.
   c. For additional information, please refer to the Priority Health's medical benefit drug information page.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
NCD - Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24)	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None Identified
First Coast Service Options, Inc.	None Identified
National Government Services, Inc.	None Identified
Noridian Healthcare Solutions	None Identified
Novitas Solutions, Inc.	None Identified
Palmetto GBA	None Identified
WPS Insurance Corporation	None Identified

III. BACKGROUND

Cellular therapy, gene therapy, and chimeric antigen receptor T-cell (CAR-T) therapy are related but distinct therapeutic approaches that use living cells or genetic material to treat disease. These therapies are an area of active clinical development and are being studied and applied across a range of conditions, including cancer, inherited genetic disorders, and select infectious diseases.

Gene therapy is a technique that modifies or manipulates the expression of a gene or alters the biological properties of living cells for therapeutic use. According to the U.S. Food and Drug Administration (FDA), gene therapy seeks to treat or potentially cure disease by modifying a person's genes. Gene therapies may work through several mechanisms, including replacing a disease-causing gene with a functional copy, inactivating or silencing a gene that is not functioning properly, or introducing a new or modified gene into the body to help treat disease. Gene therapy products are being studied to treat diseases such as cancer, genetic diseases, and infectious diseases (FDA, 2018).

There are multiple types of gene therapy products, including plasmid DNA therapies, viral vector-based therapies, bacterial vector-based therapies, human gene-editing technologies, and patient-derived cellular gene therapy products. In patient-derived cellular gene therapy, cells are collected from the patient, genetically modified, often using a viral vector and then returned to the patient for therapeutic effect (FDA, 2018).

Cell therapy involves the administration of living cells to restore, repair, or replace damaged or dysfunctional cells or tissues. Cells used for therapy may be autologous (derived from the patient) or allogeneic (derived from a donor) and may be expanded, activated, or otherwise manipulated prior to administration. Some cell therapies incorporate genetic modification, while others do not. **Cell therapy and gene therapy are distinct from hematopoietic stem cell or bone marrow transplantation**, which involves the replacement of blood-forming stem cells and is addressed separately under the Stem Cell or Bone Marrow Transplantation medical policy (No. 91066).

CAR-T therapy is a specialized form of cellular immunotherapy that incorporates elements of both gene therapy and cell therapy. In CAR-T therapy, a patient's T cells are collected and genetically modified ex vivo to express a chimeric antigen receptor (CAR) that enables the cells to recognize specific antigens on cancer cells. The modified T cells are then reinfused into the patient, where they can identify and destroy targeted malignant cells. CAR-T therapies are currently used primarily in the treatment of certain hematologic malignancies and are associated with unique clinical considerations related to administration, monitoring, and management of therapy-related toxicities.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
International Society for Cell & Gene Therapy	Consensus Guidelines for the Monitoring and Management of Metachromatic Leukodystrophy in the United States (2025)

American Society of Clinical Oncology (ASCO)	Management of Immune-Related Adverse Events in Patients Treated with Chimeric Antigen Receptor T-Cell Therapy: ASCO Guideline | Journal of Clinical Oncology (2021)
American Society for Transplantation and Cellular Therapy (ASTCT)	ASTCT Clinical Practice Recommendations for Transplantation and Cellular Therapies in Diffuse Large B Cell Lymphoma (2023) Use of Chimeric Antigen Receptor T Cell Therapy in Clinical Practice for Relapsed/Refractory Aggressive B Cell Non-Hodgkin Lymphoma: An Expert Panel Opinion from the American Society for Transplantation and Cellular Therapy (2019) Clinical Practice Recommendations for Hematopoietic Cell Transplantation and Cellular Therapies in Follicular Lymphoma: A Collaborative Effort on Behalf of the American Society for Transplantation and Cellular Therapy and the European Society for Blood and Marrow Transplantation (2024)
National Comprehensive Cancer Network (NCCN)	NCCN Guidelines Version 2026-B-Cell Lymphomas NCCN Guidelines Version 2026- Acute Lymphoblastic Leukemia NCCN Guidelines Version 2026- Multiple Myeloma

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

Cellular and gene therapy products are regulated by the U.S. Food and Drug Administration (FDA) through the Office of Tissues and Advanced Therapies (OTAT).

OTAT maintains a list of FDA-approved and licensed cellular and gene therapy products, which can be located on the FDA website: Approved Cellular and Gene Therapy Products.

Inclusion on the FDA list does not imply coverage under this policy, as some products may fall outside the scope of this policy or be subject to separate coverage determinations.

VI. CODING

Cellular and Gene therapy products can be identified by referencing Priority Health's Drug Information page.

Relevant revenue codes may include but are not limited to:

- **087X: Cell/Gene Therapy**
  - 0870-General
  - 0871-Cell Collection
  - 0872-Specialized Biologic Processing and Storage - Prior To Transport
  - 0873-Storage and Processing After Receipt of Cells from Manufacturer
  - 0874-Infusion of Modified Cells
  - 0875-Injection of Modified Cells

- **089X: Pharmacy – (Extension of 025X and 063X)**
  - 0890-Reserved (Use 0250 For General Classification)
  - 0891-Special Processed Drugs - FDA Approved Cell Therapy
  - 0892-Special Processed Drugs – FDA Approved Gene Therapy

CPT/HCPCS Codes

38225	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
38226	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
38227	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration
38228	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

Professional and Society Guidelines

1. Adang LA, Bonkowsky JL, Boelens JJ, Mallack E, Ahrens-Nicklas R, Bernat JA, Bley A, Burton B, Darling A, Eichler F, Eklund E, Emrick L, Escolar M, Fatemi A, Fraser JL, Gaviglio A, Keller S, Patterson MC, Orchard P, Orthmann-Murphy J, Santoro JD, Schöls L, Sevin C, Srivastava IN, Rajan D, Rubin JP, Van Haren K, Wasserstein M, Zerem A, Fumagalli F, Laugwitz L, Vanderver A. Consensus guidelines for the monitoring and management of metachromatic leukodystrophy in the United States. Cytotherapy. 2024 Jul;26(7):739-748. doi: 10.1016/j.jcyt.2024.03.487. Epub 2024 Apr 1. PMID: 38613540; PMCID: PMC11348704.
2. American Society of Gene and Cell Therapy. Gene and Cell Therapy FAQ's. https://asgct.org/education/more-resources/gene-and-cell-therapy-faqs Accessed May 1, 2026).
3. Epperla N, Kumar A, Abutalib SA, et al. ASTCT clinical practice recommendations for transplantation and cellular therapies in diffuse large B-cell lymphoma. *Transplant Cell Ther.* 2023;29(9):548-555. doi:10.1016/j.jtct.2023.06.013.
4. High KA, Roncarolo MG, Gene Therapy. New England Journal of Medicine. 2019;381(5):455-464. https://doi.org/10.1056/nejmra1706910
5. Iqbal M, Hamadani M, Kumar A, Sureda A, d'Amore F, Montoto S, LaCasce AS, Gopal AK, Epperla N, Dreger P, Moskowitz CH, Sureda A, Shadman M. Clinical practice recommendations for hematopoietic cell transplantation and cellular therapies in follicular lymphoma: a collaborative effort on behalf of the American Society for Transplantation and Cellular Therapy and the European Society for Blood and Marrow Transplantation. Transplant Cell Ther. 2024 Sep;30(9):832-843.
6. Jain T, Bar M, Kansagra AJ, Chong EA, Hashmi SK, Neelapu SS, Ghosh N, Chavez JC, Ghosh N, Hamadani M, Porter DL, Nastoupil LJ, Oluwole OO, Locke FL. Use of chimeric antigen receptor T-cell therapy in clinical practice for relapsed/refractory

aggressive B-cell non-Hodgkin lymphoma: an expert panel opinion from the American Society for Transplantation and Cellular Therapy. Biol Blood Marrow Transplant. 2019 Dec;25(12):2305-2321. doi:10.1016/j.bbmt.2019.08.015.
7. Kharfan-Dabaja MA, Kumar A, Pinilla-Ibarz J, Brown JR, Shadman M, Awan FT, Kenderian SS, Siddiqi T, Abramson JS, Al-Juhaishi T, Brander DM, Coombs CC, Furman RR, Jain N, Khan N, Saba NS, Collins JM, Beitinjaneh A, Stephens DM, Woyach J, Hamadani M. Clinical practice recommendations on the role of allogeneic hematopoietic cell transplantation and chimeric antigen receptor T-cell therapy in patients with chronic lymphocytic leukemia on behalf of the American Society for Transplantation and Cellular Therapy. Transplant Cell Ther**.** 2025 Aug;31(8):494-504.
8. National Comprehensive Cancer Network (NCCN). Immunotherapy Side Effects CAR T-Cell Therapy. https://www.nccn.org/patients/guidelines/content/PDF/immunotherapy-se-car-tcell-patient.pdf (Accessed May 1, 2026).
9. National Comprehensive Cancer Network (NCCN). Acute lymphoblastic leukemia. NCCN Clinical Practice Guidelines in Oncology. Version 01.2026. Fort Washington, PA: National Comprehensive Cancer Network; 2025. Available from: NCCN Clinical Practice Guidelines in Oncology- Acute Lymphoblastic Leukemia. [cited 2026 May 1].
10. National Comprehensive Cancer Network (NCCN). B-cell lymphomas. NCCN Clinical Practice Guidelines in Oncology. Version 02.2026. Fort Washington, PA: National Comprehensive Cancer Network; 2026. Available from: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf [cited 2026 Mar 3]
11. National Comprehensive Cancer Network (NCCN). Multiple myeloma. NCCN Clinical Practice Guidelines in Oncology. Version 5.2026. Fort Washington, PA: National Comprehensive Cancer Network; 2026. Available from: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf [cited 2026 Mar 3].

General

1. Novartis. What is cell and gene therapy. https://www.novartis.com/about/innovative-medicines/novartis-pharmaceuticals/novartis-gene-therapies/what-cell-and-gene-therapy (Accessed May 1, 2026).
2. Santomasso BD, Nastoupil LJ, Adkins S, Lacchetti C, Schneider BJ, Anadkat M, Atkins MB, Brassil KJ, Caterino JM, Chau I, Davies MJ, Ernstoff MS, Fecher L, Funchain P, Jaiyesimi I, Mammen JS, Naidoo J, Naing A, Phillips T, Porter LD, Reichner CA, Seigel C, Song JM, Spira A, Suarez-Almazor M, Swami U, Thompson JA, Vikas P, Wang Y, Weber JS, Bollin K, Ghosh M. Management of immune-related adverse events in patients treated with chimeric antigen receptor T-cell therapy: ASCO guideline**.** *J Clin Oncol.* 2021;39(35):3978-3992. doi:10.1200/JCO.21.01992.
3. US Food and Drug Administration (FDA). Approved Cellular and Gene Therapy Products. https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products (Accessed March 3, 2026)
4. US Food and Drug Administration (FDA). Cellular & Gene Therapy Products. https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products (Accessed March 3, 2026).
5. US Food and Drug Administration (FDA). Long Term Follow-Up After Administration of Human Gene Therapy Products: Guidance for Industry, January 2020. https://www.fda.gov/media/113768/download (Accessed May 1, 2026).

6. U.S. Food and Drug Administration (FDA). What is gene therapy? Silver Spring (MD): U.S. Food and Drug Administration; [updated 2018 Jul 25; cited 2026 Mar 3]. Available from: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy.

SUMMARY OF CHANGES

Deletions:

- Removed Medicaid enrollment administrative language for multi-state compatibility

Changes

- Converted policy to new standardized template.

Clarifications:

- Refined and streamlined the background section to improve clarity and reflect current regulatory and clinical context.
- Updated website links to pharmacy drug webpage and site of service information webpage

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Past committee review dates: 08/2023, 11/2023, 05/2024, 05/2025, 05/2026