Priority Health

MEDICAL POLICY No. 91638-R2

CELLULAR AND GENE THERAPY

Effective Date: June 1, 2024
Date Of Origin: August 23, 2023
Review Dates: 8/23, 11/23, 5/24, 5/25
Status: Current

I. POLICY/CRITERIA

A. Cellular and Gene therapy, including chimeric antigen receptor (CAR) T-cell products, for the treatment of medical conditions is considered medically necessary when all the following are met:

1. Prior authorization is required.
   a. Medical necessity determination is made according to criteria located on Priority Health's website: https://www.priorityhealth.com/formulary.
2. The Cellular or Gene therapy product has clinically appropriate limits for treatment:
   a. The safety and effectiveness of repeat administrations for many Cellular and Gene therapy products has not been evaluated beyond one treatment per lifetime.
3. Dosing is in strict alignment to Food and Drug Administration indication, and requests for off-label dosing will not be approved.
4. The member's benefit plan documents provide coverage of Cellular and Gene therapies.
5. The provider and facility administering treatment must be participating, in-network, and in alignment with the Priority Health Infusion Services & Equipment policy (No. 91414). Cellular and gene therapy referrals are directed to facilities in Priority Health's network or contracted networks. For more information, please refer to the Provider Manual.

B. Medicaid: Members receiving CAR-T therapy whose coverage is carved out to the Fee For Service Medicaid program will be disenrolled from the Medicaid Health Plan (MHP) for approximately three months and put on Medicaid FFS during the time of treatment. The Fee For Service Michigan Medicaid program will manage coverage of the CAR-T therapy and immediate after-therapy and complications. If there are no complications, the member is reinstituted with the MHP after three months.

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, 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, please refer to the Priority Health Provider Manual.

III. APPLICATION TO PRODUCTS

Coverage is subject to 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) and/or the Evidence of Coverage (EOC); 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 to therapy covered by the Medicaid Health Plan. Information on therapy carved out to the FFS Medicaid program can be found here: https://www.michigan.gov/mdhhs/doing-business/providers/providers/medicaid-health-plan-carve-out . 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 applicable Michigan Medicaid Fee Schedule located at: https://www.michigan.gov/mdhhs/doing-business/providers/providers/billingreimbursement/information-specific-to-different-providers. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: https://www.michigan.gov/mdhhs/doing-business/providers/providers/medicaid/policyforms/medicaid-provider-manual, the Michigan Medicaid Provider Manual will govern.***

IV. DESCRIPTION

Gene, Cell, and CAR-T therapies are overlapping fields or types of treatment. The potential for use with these types of therapy is being studied for many types of diseases including cancer, genetic diseases and even infectious diseases.

Gene therapy seeks to modify or change how a gene works in the body to alter the properties of living cells for therapeutic use. Ultimately, gene therapy is a way to modify a person's genes to treat or cure disease. Gene therapy can replace a disease-causing gene with a healthy copy of a gene, turn off a disease-causing gene, or introduce a new or modified gene to a patient's body to treat a disease.

Another term closely related to gene therapy is cell therapy. Both cell and gene therapy work to treat, prevent or possibly cure a disease. Cell therapy differs slightly in that it aims to treat diseases by restoring or altering sets of cells in a body. Cells can be cultivated or modified and placed back into a patient and can come from the patient themselves or from a donor. These modified cells can carry a therapy in the body to ultimately fight, repair or replace old damaged or diseased cells. Note this is different than a stem cell transplant which is addressed in a separate stem cell transplant medical policy (Stem Cell or Bone Marrow Transplantation policy - No. 91066).

One specific type of therapy that contains elements of both these approaches and is commonly mentioned in this field is CAR-T therapy. A chimeric antigen receptor (CAR) can be added to a T cell and this specific type of therapy works by changing a patient's immune cells in a way that allows them to find and kill cancer cells. Think of this as making a "heat seeking missile". These modified T-cells are looking to specifically target the "heat" or cancer cell to ultimately find and destroy the cancer cell.

V. CODING INFORMATION

Cellular and Gene therapy products can be identified by referencing Priority Health's Medical Benefit Drug List (MBDL) and filtering by the Category column to "Gene/Cellular Therapy".

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 (Effective 4/1/19) 0875 - Injection of Modified Cells (Effective 4/1/19)

- **089X:** Pharmacy - Extension of 025X and 063X 0890 - Reserved (Use 0250 For General Classification) (Effective 4/1/19) 0891- Special Processed Drugs - FDA Approved Cell Therapy (Effective 4/1/19) 0892 - Special Processed Drugs – FDA Approved Gene Therapy (Effective 4/1/20)

CPT CODES:

Prior Authorization Required

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

VI. REFERENCES

1. 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 April 4, 2025).
2. High KA, Roncarolo MG, Gene Therapy. New England Journal of Medicine. 2019;381(5):455-464. Doi: https://doi.org/10.1056/nejmra1706910
3. National Comprehensive Cancer Network. Immunotherapy Side Effects – CAR T-Cell Therapy. https://www.nccn.org/patients/guidelines/content/PDF/immunotherapy-se-car-tcell-patient.pdf. (Accessed April 4, 2025)
4. 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 April 4, 2025)
5. US Food and Drug Administration. Long Term Follow-Up After Administration of Human Gene Therapy Products: Guidance for Industry, January 2020. https://www.fda.gov/media/113768/download. (Accessed April 4, 2025)
6. US Food and Drug Administration. What is Gene Therapy? https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy. (Accessed April 4, 2025)
7. US Food and Drug Administration. Approved Cellular and Gene Therapy Products. https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products. (Accessed April 4, 2025)
8. US Food and Drug Administration. Cellular & Gene Therapy Products. https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products. (Accessed April 4, 2025)