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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Gene Therapy Policy

Indication/Usage:

The goal of gene therapy is to create a treatment with the potential to save or transform lives by modifying a defective gene or replacing it with a more functional one. Gene therapy works by adding or replacing a defective or missing gene in a patient's cells with a healthy version of that gene. New genetic material is delivered into the cells by either an ex-vivo vector or an in-vivo vector. Gene therapy has the potential to be life changing for people with rare genetic diseases or cancer. Each disease with a certain gene variation requires a specific treatment plan including lab work, inpatient or outpatient hospitalizations and post therapy care. Gene therapy should be handled on a case-bycase basis. EviCore reviews all CART- gene therapy requests. Check the website to determine if a non-CAR-T therapy agent is reviewed by EviCore. SummaCare pharmacy and the medical director will review any non-CAR-T requests not reviewed by EviCore.
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Medical Indications for Authorization

Non CAR-T Gene Therapy

- Non CAR-T gene therapy introduces genetic material into cells, genome editing introduces molecular tools to change the existing DNA in the cell to treat or prevent disease. This type of gene therapy is given primarily in an outpatient setting. All requests for inpatient and/or OON network must be pre-authorized.

- FDA-approved gene therapies are available at this time for the following Hemophilia B Melanoma Retinal Dystrophy Childhood Cerebral Adrenoleukodystrophy - X-linked Spinal Muscular Atrophy Beta Thalassemia.

CAR-T Gene Therapy

- Car-T will be approved by eviCore. Inpatient hospital, OON and post care will be authorized through the medical director. Contracting will be involved for OON facilities.

- CAR-T Gene Therapy is a type of treatment in which a patient's T cells are changed in the laboratory so they will attack cancer cells.

- T cells are taken from the member's blood through leukapheresis.

- The gene for a chimeric antigen receptor special receptor (CAR) that binds to a protein on the patient's cancer cells is added to the T cells in the laboratory.

- Large numbers of CAR-T cells takes several weeks to manufacture in the lab
- Chemotherapy given several days prior to infusion of CAR –T.

- Members are monitored for at least 7 days post infusion and must be within a 2 hour drive for 4 weeks post infusion

Precertification of ALL gene therapy is required

SummaCare.com can be referenced for a complete list of drugs and precertification process. You can also access this webpage by clicking on the link below or copying and pasting this into your web browser**.**

Prior Authorization for Drugs Covered Under the Medical Benefit | Prior Authorization | Providers | SummaCare

Approval of gene therapy is required prior to any inpatient admission or OON request.

Limitations

Gene therapy targets rare diseases and there is a small number of people with the disease. This means it can take longer and be more difficult to gather enough research data on potential treatments or to find enough people that are eligible to participate in a clinical trial. People may have changes in different genes but still have the same disease. In this situation, they would likely need different gene therapy approaches each targeted to their gene variation. Producing safe, effective, and reproducible gene therapies can be more complicated due to varying treatment plans and cost of new FDA approved medications and limited outcomes. Health care costs of complex administration methods such as the ex-vivo processing and reintroduction of genetically altered stem cells, which could require as much as a month-long hospital stay. Estimating the cost impact of gene therapies is very complicated due to it being unclear how many patients with a particular condition may be treated with a given therapy or exactly how much the treatment will cost. Despite the potential of gene therapies, they are still new approaches to treatment and could carry significant health risks. Safety and delayed adverse events associated with gene therapy have been a concern since the first clinical trials 20 years ago. Some of the risks include life-threatening immune responses, certain types of cancer, allergic reactions, or damage to organs or tissues. It is too early to tell if patients will be cured or if the disease will return. Even if results decrease over time, gene therapy may still be a better and more cost- efficient treatment option to improve the length and quality of life for patients with genetic disorders.

Coverage Decisions

Coverage decisions made per CMS, Hayes, and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

Definition of CAR T-cell therapy - NCI Dictionary of Cancer Terms - NCI

CAR T-cell Therapy and Its Side Effects | American Cancer Society