Carvykti (ciltacabtagene autoleucel)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Carvykti is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:
Chart notes, medical record documentation or claims history supporting previous lines of therapy.

Criteria for Initial Approval

Multiple Myeloma

Authorization of 3 months may be granted for one-time treatment of relapsed or refractory multiple myeloma in members 18 years of age and older when all of the following criteria are met:

A. The member has received prior treatment with at least four prior lines of therapy, including at least one drug from each of the following categories:
    1. Immunomodulatory agent

2. Proteasome inhibitor
3. Anti-CD38 monoclonal antibody

B. The member has not received previous treatment with the requested medication, another CAR-T therapy directed at any target, or any therapy that is targeted to B-cell maturation antigen (BCMA).
C. The member has an ECOG performance status of 0 to 2.
D. The member has adequate and stable kidney, liver, pulmonary and cardiac function.
E. The member does not have known active or prior history of central nervous system (CNS) involvement, including CNS multiple myeloma.
F. The member does not have clinically significant active infection.
G. The member does not have active graft versus host disease.
H. The member does not have an active inflammatory disorder.

Continuation of Therapy

Repeat treatment of Carvykti for any indication is considered investigational, as the safety and efficacy beyond one dose has not been studied. The evidence is insufficient to determine the effects on net health outcomes.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Carvykti approvals will be limited to one treatment per lifetime.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Q2056 – Ciltacabtagene autoleucel, up to 100 million autologuous B-cell maturation antigen (BCMA) directed CAR-positive T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose

REFERENCES

- Carvykti [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2022.
- Berdeja JG, Madduri D, Usmani SZ, et al. Ciltacabtagene autoleucel, a B-cell maturation antigen-directed chimeric antigen receptor T-cell therapy in patients with relapsed or refractory multiple myeloma (CARTITUDE-1): a phase 1b/2 open-label study. Lancet. 2021 Jul 24;398(10297):314-324.

POLICY HISTORY

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