Yescarta (axicabtagene ciloleucel)

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

1. Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.
2. Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), primary mediastinal large B-cell lymphoma, high-grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.
3. Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

Limitations of Use: Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma.

Compendial Use

1) Histologic transformation of indolent lymphomas to DLBCL
2) Human immunodeficiency virus (HIV)-related B-cell lymphomas (including HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specific)
3) Monomorphic post-transplant lymphoproliferative disorder (B-cell type)
4) Marginal zone lymphomas (MZL):

a. Extranodal MZL of the stomach (gastric mucosa associated lymphoid tissue (MALT) lymphoma)
b. Extranodal MZL of nongastric sites (nongastric MALT lymphoma)
c. Nodal MZL
d. Splenic MZL

5) Pediatric primary mediastinal large B-cell lymphoma

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.

Exclusions

Coverage will not be provided for members with any of the following exclusions:

1) Primary central nervous system lymphoma
2) Previous treatment course with the requested medication or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.
3) ECOG performance status greater than or equal to 3 (member is not ambulatory and not capable of all self-care, confined to bed or chair more than 50% of waking hours)
4) Inadequate and unstable kidney, liver, pulmonary or cardiac function
5) Active hepatitis B, active hepatitis C or a clinically significant active systemic infection
6) Active inflammatory disorder

Criteria for Initial Approval

Adult Large B-cell lymphomas

Authorization of 3 months may be granted as a one-time treatment of B-cell lymphomas in members 18 years of age or older when either of the following criteria are met:

A. The member has received prior treatment with either of the following:
    1. Prior treatment with two or more lines of systemic therapy and has any of the following B-cell lymphoma subtypes:
        a. Diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma
        b. Histologic transformation of indolent lymphomas to DLBCL
        c. Diffuse large B-cell lymphoma (DLBCL)
        d. Primary mediastinal large B-cell lymphoma
        e. High-grade B-cell lymphomas (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
        f. Human immunodeficiency virus (HIV)-related B-cell lymphomas (including HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specific)
        g. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)
        h. Follicular lymphoma
        i. Extranodal marginal zone lymphoma of the stomach (gastric MALT)
        j. Extranodal marginal zone lymphoma of nongastric sites (nongastric MALT)
        k. Nodal marginal zone lymphoma
        l. Splenic marginal zone lymphoma
    2. The member has received prior treatment with first-line chemoimmunotherapy and has relapsed/refractory disease with any of the following B-cell lymphoma subtypes:
        a. Diffuse large B-cell lymphoma (DLBCL)
        b. Primary mediastinal large B-cell lymphoma
        c. High-grade B-cell lymphomas (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)

d. Human immunodeficiency virus (HIV)-related B-cell lymphomas (including HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specific)
e. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)

Pediatric Primary Mediastinal Large B-cell lymphomas
Authorization of 3 months (one dose) may be granted for treatment of relapsed/refractory primary mediastinal large B-cell lymphoma in members less than 18 years of age when the member has received prior therapy with at least two prior chemoimmunotherapy regimens and achieved partial response.

Continuation of Therapy
Repeat treatment of Yescarta 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
Yescarta will be provided based on the FDA recommended dosing and administration:

The patient will receive weight-based dosing of 2 x 10^6 CAR-positive viable T-cells per kg body weight intravenously, and will not be treated with more than 2 x 10^8 CAR-positive viable T-cells intravenously.

Quantity Limits
Yescarta 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.

- Q2041 – Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 CAR-positive viable T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose

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POLICY HISTORY

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