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. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (including AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specified)
3. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)

4. Marginal zone lymphomas:
    a. Gastric mucosa associated tissue (MALT) lymphoma
    b. Nongastric MALT lymphoma
    c. Nodal marginal zone lymphoma
    d. Splenic marginal zone 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.

Criteria for Initial Approval

Adult 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 all of the following criteria are met:

A. 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 (also known as histologic transformation of follicular lymphoma to DLBCL)
        b. Hitologic 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. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (including AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specified)
        g. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)
        h. Follicular lymphoma
        i. Gastric MALT lymphoma
        j. Nongastric MALT lymphoma
        k. Nodal marginal zone lymphoma
        l. Splenic marginal zone lymphoma
    2. Prior treatment with first-line chemoimmunotherapy and has 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. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (including AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specified)
        e. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)
B. The member does not have primary central nervous system lymphoma.
C. The member has not received a previous treatment course of the requested medication or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.

D. Member has an ECOG performance status 0 to 2. (Member is ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours).
E. The member has adequate bone marrow reserve defined by all of the following:
    a. Absolute neutrophil count (ANC) ≥ 1000 cells/µL
    b. Absolute lymphocyte count (ALC) ≥ 100 cells/µL
    c. Platelet count ≥ 75000 cells/µL
F. The member has adequate and stable kidney, liver, pulmonary and cardiac function as demonstrated by all of the following:
    a. Creatinine clearance ≥ 60 mL/minute
    b. Serum alanine aminotransferase (ALT)/aspartate aminotransferase (AST) ≤ 2.5 times upper limit of normal for age
    c. Total bilirubin < 1.5 mg/dL with the exception of patients with Gilbert-Meulengracht syndrome; patients with Gilbert-Meulengracht syndrome may be included if their total bilirubin is < 3.0 times the upper limit of normal
    d. Left ventricular ejection fraction ≥ 50% and there is no evidence of pericardial effusion as determined by an echocardiogram
G. The member does not have any active infections including hepatitis B (HBsAG negative) or hepatitis C virus (anti-HCV negative); (a history of hepatitis B or hepatitis C virus is permitted if the viral load is undetectable per quantitative PCR and/or nucleic acid testing).
H. The member does not have an active inflammatory disorder.
I. The member will receive Yescarta at a treatment center that is certified to administer Yescarta per Yescarta and Tecartus REMS requirements.

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 2×10^6 CAR-positive viable T-cells per kg body weight intravenously, and will not be treated with more than 2×10^8 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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