Medical Coverage Policy | Yescarta (axicabtagene)

EFFECTIVE DATE:06|01|2018
POLICY LAST UPDATED: 05|15|2018

OVERVIEW

Yescarta (axicabtagene) is used in the treatment of 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, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. It is made from the patient's own white blood cells.

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section

MEDICAL CRITERIA

BlueCHiP for Medicare

Yescarta (axicabtagene) will be approved when ALL of the following are met:

1. One of the following:
    a. The patient has a diagnosis of relapsed or refractory large B-cell lymphoma including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (note: patient must meet all aspects of the diagnosis as indicated)
    OR
    b. The use of the target agent is for an indication that is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic use (approval by the Clinical Review Pharmacist required).

    AND
2. The patient does not have primary central nervous system lymphoma
    AND
3. The prescriber has confirmed the patient has CD19 tumor expression
    AND
4. The patient has relapsed or has refractory large B-cell lymphoma after two or more lines of systemic therapy
    AND
5. The patient does not have active uncontrolled infection including Hepatitis B, Hepatitis C, or HIV infection
    AND
6. The patient does not have any FDA labeled contraindications to the requested agent
    AND
7. The patient has not previously been treated with gene therapy including the requested agent

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare.

POLICY STATEMENT

BlueCHiP for Medicare

Yescarta (axicabtagene) is medically necessary when all of the criteria have been met.

Note: Blue Cross and Blue Shield of Rhode Island reserves the right to request information from the provider regarding the members response to the therapy. Failure to agree may result in denial of the request. Provider agrees to provide documentation of response upon request.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage for applicable physician administered benefits/coverage.

BACKGROUND

Axicabtagene is CD19-directed genetically modified autologous T cell immunotherapy. Efficacy of axicabtagene was studied in a single-arm, open-label, multicenter trial evaluated the efficacy of a single infusion of axicabtagene in adult patients with relapsed or refractory aggressive B-cell non-Hodgkin lymphoma. Eligible patients had refractory disease to the most recent therapy or relapse within 1 year after autologous hematopoietic stem cell transplantation (HSCT). The study excluded patients with prior allogeneic HSCT, any history of central nervous system lymphoma, ECOG performance status of 2 or greater, absolute lymphocyte count less than 100/µL, creatinine clearance less than 60 mL/min, hepatic transaminases more than 2.5 times the upper limit of normal, cardiac ejection fraction less than 50%, or active serious infection.

Efficacy was established based on complete remission (CR) rate and duration of response (DOR), as determined by an independent review committee. The median time to response was 0.9 months (range: 0.8 to 6.2 months). Response durations were longer in patients who achieved CR, as compared to patients with a best response of partial remission (PR) (Table 6). Of the 52 patients who achieved CR, 14 initially had stable disease (7 patients) or PR (7 patients), with a median time to improvement of 2.1 months (range: 1.6 to 5.3 months).

CODING

BlueCHiP for Medicare

For services prior to 4/1/2018, there is not a specific HCPCS code for this drug. Claims should be filed with the unlisted J code and the NDC number

Effective 4/1/2018, claims should be filed with the following code:
Q2041 Axicabtagene Ciloleucel, up to 200 Million Autologous Anti-CD19 CAR T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Infusion

RELATED POLICIES

Prior Authorization of Drugs

PUBLISHED

Provider Update, June 2018
Provider Update, March 2018

REFERENCES:

1. Yescarta prescribing information. Kite Pharma, Inc. October 2017.