DRAFT

BlueCross BlueShield of Alabama

"Unless otherwise noted, coverage for specific indications is effective the date of the FDA approval of that indication."
"Please check Approved by Governing Bodies for FDA approval date."

Name of Blue Advantage Policy:
Yescarta™ (axicabtagene ciloleucel)

Policy #: 676
Category: Pharmacy
Effective Date: 07/01/2018
Latest Review Date: December 2017

Background:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Description of Procedure or Service:

Yescarta is a CD-19 directed genetically modified autologous T cell immunotherapy which involves the reprogramming of T cells with a transgene encoding a chimeric antigen receptor (CAR) to identify and eliminate CD-19-expressing malignant and normal cell. CD-19 is an antigen expressed on the surface of B-cells and tumors derived from B-cells. Upon binding to CD-19 expressing cells, the CAR transmits a signal to promote T-cell expansion, activation, acquisition of effector functions and secretion of inflammatory cytokines and chemokines. This sequence of events leads to killing of CD19-expressing cells.

Yescarta™ has a black box warning because of the risk of cytokine release syndrome and neurologic toxicities that include fatal or life-threatening reactions. It should not be administered to patients with active infection or inflammatory disorders. It is recommended that severe or life-threatening cytokine release syndrome should be treated with tocilizumab. Patients should be monitored for neurologic events after treatment.

Policy:

Effective for dates of service on or after July 1, 2018:

Blue Advantage will treat **Yescarta™ (axicabtagene ciloleucel)** as a **covered benefit** for the treatment of **relapsed or refractory non-Hodgkin's lymphoma (NHL)** when documentation is provided to support **all** of the following criteria are met:

- 18 years of age or older at the time of infusion; **and**
- Histologically confirmed diagnosis of **one** of the following types of aggressive NHL:
  - Diffuse large B-cell lymphoma (DLBCL); **or**
  - Primary mediastinal large B-cell lymphoma; **or**
  - High-grade B-cell lymphoma; **or**
  - Diffuse large B-cell lymphoma arising from follicular lymphoma; **or**
- Relapsed or refractory disease, as defined below:
  - Relapsed disease defined as progression after two or more lines of systemic therapy (which may or may not include therapy supported by autologous stem cell transplant); **or**
  - Refractory disease defined as not having achieved an initial complete remission after 2 cycles of standard chemotherapy regiment or in second or greater relapse; **and**
- Received adequate prior therapy including, at a minimum, **all** of the following:
  - Anti-CD20 monoclonal antibody for CD20-positive tumor; **and**
  - An anthracycline containing chemotherapy regimen; **and**
- Have not received prior treatment with Yescarta or any other gene therapy or are being considered for treatment with any other gene therapy; **and**
- Have not received radiation therapy or systemic therapy within 2 weeks of leukapheresis or planned CAR-T infusion; **and**
- *ECOG performance status of 0-1; **and**
- Documentation of **all** of the following clinical findings within 2 weeks of planned leukapheresis:

    - Absolute neutrophil count (ANC) ≥1000/µL; **and**
    - Absolute lymphocyte count (ALC) >300/µL; **and**
    - Platelet count ≥75,000/µL; **and**
    - Hemoglobulin > 8.0g/dl; **and**
- Yescarta™ can be administered during inpatient hospitalization only; **and**
- Yescarta™ will be given as a one-time, single administration treatment; **and**
- Have adequate organ function with no significant deterioration in organ function expected within 4 weeks after apheresis, as evidence by, including, but not limited to the following:
    - Serum creatinine ≤ 1.5mg/dL
    - ALT/AST ≤ 5 times the upper limit of normal
    - Total bilirubin ≤ 2 mg/dL
    - Cardiac ejection fraction ≥45% confirmed by echocardiogram
    - No evidence of pericardial effusion as evident by echocardiogram
    - No clinically significant pleural effusion
    - Minimum level of pulmonary reserve defined as < Grade 1 dyspnea and pulse oxygenation > 91% on room air
- Do not have any of the following:
    - CNS lymphoma
    - Any central nervous system (CNS) disease (i.e., history or presence of CNS disorders such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, autoimmune disease with CNS involvement)
    - History of or active HIV, hepatitis B, or hepatitis C
    - Any uncontrolled infection requiring IV antimicrobials for management
    - Active inflammatory disorder (ongoing use of systemic corticosteroids or other immunosuppressive treatment).
    - Active autoimmune disease requiring systemic treatment in the previous 2 years (excluding replacement therapy)
    - History of malignancy except carcinoma in situ (e.g. skin, cervix)
    - History of other invasive malignancy (unless the patient is currently disease-free and in complete remission for > 5 years)
    - Autologous stem cell transplant within 6 weeks prior to request for CAR-T
    - History of allogeneic stem cell transplantation
    - Unstable angina and/or myocardial infarction within 6 months prior to screening
    - Cardiac arrhythmia not controlled with medical management
    - Taking oral anticoagulation medication
    - Investigational medicinal product or medical device product within the last 30 days prior to screening
    - Recent monoclonal antibody treatment including anti-CD20 therapy within 4 weeks prior to infusion or 5 half-lives of the respected antibody; whichever is longer.

Blue Advantage will treat **Yescarta (axicabtagene ciloleucel)** as a **non-covered benefit** and as **investigational** when the above criteria are not met and for all other indications.

Effective for dates of service January 1, 2018 through June 30, 2018:
Blue Advantage will treat **Yescarta™ (axicabtagene ciloleucel)** as a **covered benefit** for the treatment of **relapsed or refractory non-Hodgkin's lymphoma (NHL)** when **all** of the following criteria are met:

- 18 years of age or older at the time of infusion; **and**
- Histologically confirmed diagnosis of **one** of the following types of aggressive NHL:
    - Diffuse large B-cell lymphoma (DLBCL); **or**
    - Primary mediastinal large B-cell lymphoma; **or**
    - High-grade B-cell lymphoma; **or**
    - Diffuse large B-cell lymphoma arising from follicular lymphoma
- Relapsed or refractory disease, as defined below:
    - Relapsed disease defined as progression after two or more lines of systemic therapy (which may or may not include therapy supported by autologous stem cell transplant); **or**
    - Refractory disease defined as not having achieved an initial complete remission after 2 cycles of standard chemotherapy regiment or in second or greater relapse; **and**
- Received adequate prior therapy including, at a minimum, **all** of the following:
    - Anti-CD20 monoclonal antibody for CD20-positive tumor; **and**
    - An anthracycline containing chemotherapy regimen; **and**
- *ECOG performance status of 0-1; **and**
- Documentation of **all** of the following clinical findings:
    - Absolute neutrophil count (ANC) ≥1000/µL; **and**
    - Absolute lymphocyte count (ALC) >100/µL; **and**
    - Platelet count ≥75,000/µL; **and**
- Have not received prior treatment with Yescarta or any other gene therapy or are being considered for treatment with any other gene therapy; **and**
- Yescarta™ can be administered during inpatient hospitalization only; **and**
- Yescarta™ will be given as a one-time, single administration treatment; **and**
- Have not received radiation therapy or systemic therapy within 2 weeks of leukapheresis; **and**
- Have adequate organ function with no significant deterioration in organ function expected within 4 weeks after apheresis, as evidence by, including, but not limited to the following:
    - Serum creatinine ≤ 1.5mg/dL
    - ALT/AST ≤ 2.5 times the upper limit of normal
    - Total bilirubin ≤ 1.5mg/dL
    - Cardiac ejection fraction ≥50%
    - No clinically significant pleural effusion
    - No evidence of pericardial effusion as evident by echocardiogram
- Do not have any of the following:
    - CNS lymphoma

- Any central nervous system (CNS) disease (i.e., history or presence of CNS disorders such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, autoimmune disease with CNS involvement)
- History of or active HIV, hepatitis B, or hepatitis C
- Any uncontrolled infection requiring IV antimicrobials for management
- Active inflammatory disorder (ongoing use of systemic corticosteroids or other immunosuppressive treatment).
- Active autoimmune disease requiring systemic treatment in the previous 2 years (excluding replacement therapy)
- History of malignancy except carcinoma in situ (e.g. skin, cervix)
- Autologous stem cell transplant within 6 weeks prior to request for CAR-T
- History of allogeneic stem cell transplantation

Blue Advantage will treat **Yescarta (axicabtagene ciloleucel)** as a **non-covered benefit** and as **investigational** when the above criteria are not met and for all other indications.

Effective for dates of service prior to January 1, 2018:
Adoptive immunotherapy, using adoptive cellular therapy (ACT) for the administration of cytotoxic T-lymphocytes, cytokine-induced killer (CIK) cells, lymphokine-activated killer (LAK) cells, **chimeric antigen receptor therapy (CAR-T)**, tumor-infiltrating lymphocytes (TIL), or antigen-loaded autologous dendritic cells (ADC) **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered as **investigational**.

Additional Policy Guidelines
Autologous lymphocytes used as part of adoptive immunotherapy may be harvested in a pheresis procedure or may be isolated from resected tumor tissue.

Yescarta™ is available only through a restricted program under a risk evaluation and mitigation strategy (REMS) called the Yescarta REMS. The requirement for the REMS components are as follows:

- Health care facilities that dispense and administer Yescarta™ must be enrolled and comply with the REMS requirements.
- Certified health care facilities must have onsite, immediate access to tocilizumab, and ensure that a minimum of 2 doses of tocilizumab are available for each patient for administration within 2 hours after Yescarta™ infusion, if needed for treatment of cytokine release syndrome.
- Certified health care facilities must ensure that health care providers, who prescribe, dispense or administer Yescarta™ are trained about the management of cytokine release syndrome and neurologic toxicities.

*Eastern Cooperative Oncology Group (ECOG) Performance Status

GRADE	ECOG Performance Status
0	Fully active, able to carry on all pre0disease performance without restriction
1	Restricted in physically strenuous active, but ambulatory and able to carry out work if a light sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all self-care, but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair
5	Dead

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

Diffuse Large B-cell Lymphoma

Diffuse large B-cell lymphoma (DLBCL) is the most common histologic subtype of non-Hodgkin lymphoma and accounts for approximately 25% of non-Hodgkin lymphoma cases. DLBCL exhibits large heterogeneity in morphologic, genetic, and clinical aspects and multiple clinicopathologic entities are defined by 2016 World Health Organization (WHO) classification that are sufficiently distinct to be considered separate diagnostic categories.

It has been estimated that 27,650 estimated new cases of DLBCL were diagnosed in the United States in 2016. Treatment in first-line setting (particularly rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone [R-CHOP]) is associated with a 5-year survival rate ranging from 60% to 70%. However, based on number of prognostic factors, 20% to 50% of DLBCL cases are refractory or relapse after first-line chemotherapy. The response to subsequent salvage chemotherapy and consolidation with autologous cell transplantation is suboptimal. A recently published retrospective analysis of SCHOLAR-1 study that pooled data from 2 phase 3 clinical trials and 2 observational cohorts that included 636 patients with refractory DLBCL, the objective response rate to the next line of therapy was 26% with 7% achieving a complete response. Median overall survival was 6.3 months and 2-year survival was 20%. Refractory DLBCL was defined as progressive disease or stable disease as best response at any point during chemotherapy (>4 cycles of first-line or 2 cycles of later-line therapy) or relapsed at 12 or fewer months from autologous cell transplantation.

Genetically Engineered T Cells

Peripheral T Lymphocytes

For individuals with cancers who receive autologous peripheral T lymphocytes containing tumor antigen-specific T-cell receptors, the evidence includes multiple small observational studies. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related mortality and morbidity. Multiple observational studies have examined autologous peripheral T lymphocytes containing tumor antigen-specific T-cell receptors in melanoma, Hodgkin and non-Hodgkin lymphoma, prostate tumors, and neuroblastoma. Because of the non-comparative nature of the available evidence with a small sample size, it is difficult to draw any meaningful conclusion. To establish efficacy, the following is needed: larger, well-conducted, multicentric trials with adequate randomization procedures, blinded assessments, centralized oversight, and the use of an appropriate standard of care as the control arm showing treatment benefit. The evidence is insufficient to determine the effects of the technology on health outcomes.

Axicabtagene Ciloleucel

For individuals who are adults with histologically confirmed diagnosis of aggressive NHL that includes diffuse large B-cell lymphoma, not otherwise specified, high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and transformed follicular lymphoma who receive axicabtagene ciloleucel, the evidence includes a single-arm prospective trial. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related mortality and morbidity. The pivotal single-arm trial reported a 72% overall response rate (measured by complete or partial remission) in heavily pretreated patients. After a median follow-up of 7.9 months, the median duration of response was 9.2 months. The observed benefits were offset by a high frequency and severity of adverse reactions. Cytokine release syndrome was observed in more than half (63%) of the patients, and 44% had an adverse event at grade 3 or higher. Long-term follow-up and real-world evidence is required to assess the generalizability of axicabtagene ciloleucel efficacy and safety outside of the clinical trial setting. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Pivotal Trial

The approval was based on the results of a single open-label, multicenter phase 1/2 study called ZUMA-1 based on the complete remission rate and duration of response demonstrated in the phase 2 portion of the study. This trial has not been published; information was obtained from the Food and Drug Administration documents and approved label. Adults with aggressive B-cell non-Hodgkin lymphoma that was primary refractory, refractory to second or greater line of therapy, or relapsed within 1 year after autologous hematopoietic cell transplantation were enrolled in the study. Patients with prior allogeneic hematopoietic cell transplantation, any history of central nervous system lymphoma, ECOG Performance Status score 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 were excluded. Majority (74%) of patients had de novo DLBCL and 32% had double- or triple-hit lymphoma. The median age was 58 with 24% being aged 65 years or older; the median number of prior therapies was 3; 77% had refractory disease to a second or greater line of therapy; and 21% had relapsed within 1 year after autologous HCT.

All patients received a lymphodepleting regimen consisted of cyclophosphamide and fludarabine prior to infusion of axicabtagene ciloleucel. Of the 111 patients who underwent leukapheresis, 101 received the infusion (9 not treated due to progressive disease or serious adverse reactions following leukapheresis and there was manufacturing failure in case of 1 patients). Study protocol mandated hospitalization of patients for infusion and 7 days after infusion. Bridging chemotherapy between leukapheresis and lymphodepleting chemotherapy was not permitted. The median time from leukapheresis to product delivery was 17 days (range, 14-51 days). The primary end point was objective response rate based on a modified intention-to-treat population, which was defined as all patients treated with at least 1.0 × 106 CAR-positive T cells per kilogram. Results are summarized in Table 1.

Table 1. Summary of Efficacy Results of the Pivotal Study

Outcomes	Results, n (%) (95% Confidence Interval)
Primary end point	N=101
Objective remission rate (CR+ PR)[a]	73 (72) (62 to 81)
CR	52 (51) (41 to 62)
PR	21 (21) (13 to 30)
Secondary end points	N=73
Median duration of response, mo[b,c]	
All patients	9.2 (5.4 to NE)
CR only	NE (8.1 to NE)
PR only	2.1 (1.3 to 5.3)
Median follow-up for duration of response, mo[b,c]	7.9

CR: complete response; NE: not estimable; PR: partial response.
[a]Per 2007 revised International Working Group criteria, as assessed by the independent review committee
[b] Duration of response was measured form the date of the first objective response to the date of progression or death from relapse or toxicity.
[c] Kaplan-Meir estimates

Safety

Safety data included a total of 108 patients who were treated with axicabtagene ciloleucel. Adverse events of special interest are summarized in Table 2. All patients experienced at least 1 adverse event following infusion and 94% (n=102) experienced grade 3 or higher events. Serious adverse events were observed in 56 (52%) of patients, and serious adverse events that were grade 3 or higher occurred in 48 (44%) patients. Overall, 34 deaths were reported from the time of informed consent to the data cutoff for the study (January 27, 2017). Thirty patients died of progressive disease and 4 deaths were attributed to the product as per FDA analysis of which 3 occurred within 30 days of infusion.

The median time to onset for CRS was 2 days (range, 1-12 days), and the median time to resolution was 7 days (range for CRS duration, 2-58 days). Forty-five percent (49/108) of patients received tocilizumab for CRS management. The median time to onset of neurologic toxicity was 4 days (range, 1-43 days). The median duration was 17 days. Prolonged encephalopathy lasting up to 173 days was noted. Most common neurologic toxicities included encephalopathy, headache, tremor, dizziness, aphasia, delirium, insomnia, and anxiety.

Neurologic toxicities were managed with supportive care and/or corticosteroids. Almost all neurologic toxicities at grade 2 or higher occurred within 7 days following infusion.

Table 2. Summary of Serious Adverse Events of Special Interest in the Pivotal Study (N=108)

Adverse Events	All Grades, n (%)	Grades ≥3, n (%)
Cytokine release syndrome	101 (63)	14 (13)
Neurologic toxicities[a]	94 (21)	34 (31)
Serious Infections	41 (38)	25 (23)
Febrile Neutropenia	39 (36)	35 (32)
Prolonged cytopenia not resolved by day 30	-	30 (28)
Hypogammaglobulinemia	16 (15)	0

[a] 98% of all neurologic toxicities occurred within first 8 weeks of axicabtagene ciloleucel infusion

Current guidelines from the National Comprehensive Cancer Network® (NCCN) for B-cell lymphomas recommend (category 2A) axicabtagene ciloleucel as a treatment option for:

- Diffuse large B-cell lymphoma, primary mediastinal large B-cell lymphoma, or double/triple hit lymphoma that is refractory or in 2 or second relapse or greater.
- Subsequent therapy for patients with histologic transformation to diffuse large B-cell lymphoma (DLBCL)

Summary

For individuals who are adults with histologically confirmed diagnosis of aggressive NHL that includes diffuse large B-cell lymphoma, not otherwise specified, high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma and transformed follicular lymphoma who receive axicabtagene ciloleucel, the evidence includes 1 single-arm prospective trial. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related mortality and morbidity. The pivotal single-arm trials reported 72% overall response rate (measured by complete or partial remission) in heavily pretreated patients. After a median follow-up of 7.9 months, the median duration of response was 9.2 months. The observed benefits were offset by a high frequency and severity of adverse reactions. Cytokine release syndrome was observed in more than half (63%) of the patients, and approximately 44% had an adverse event at grade 3 or higher. Long-term follow-up and real-world evidence is required to assess the generalizability of axicabtagene ciloleucel efficacy and safety outside of a clinical trial setting. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Key Words:

Yescarta, axicabtagene ciloleucel, CAR-T, chimeric antigen receptor therapy, DLBCL, diffuse large b-cell lymphoma, gene therapy, primary mediastinal large B-cell lymphoma, follicular lymphoma,

Approved by Governing Bodies:

On October 18, 2017, axicabtagene ciloleucel (Yescarta™; Kite Pharma) was approved by the FDA for the treatment of adults with relapsed or refractory large B-cell lymphoma after 2 or more lines of systemic therapy, including diffuse large B-cell lymphoma not otherwise specified, primary mediastinal large B-cell lymphoma, high-grade B-cell lymphoma, and diffuse large B-cell lymphoma arising from follicular lymphoma.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

Current Coding:

CPT Codes:

Q2041	axicabtagene ciloleucel, up to 200 million autologous Anti-CD19 CAR T Cells, including leukapheresis and dose preparation procedures, per infusion **(Effective 04/01/2018)**

Previous Coding:

CPT Codes:

J9999	Not otherwise classified, antineoplastic drugs [when specified as axicabtagene ciloleucel]

References:

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Policy History:

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