Clinical Policy Title:	axicabtagene ciloleucel
Policy Number:	RxA.323
Drug(s) Applied:	Yescarta®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Large B-Cell Lymphoma (must meet all)**:**

1. Diagnosis of one of the following Large B-cell lymphoma (LBCL);
   a. Diffuse large B-cell lymphoma (DLBCL);
   b. Transformed follicular lymphoma (TFL) to DLBCL;
   c. Transformed nodal marginal zone lymphoma (MZL) to DLBCL;
   d. High-grade B-cell lymphomas with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma) or high-grade B-cell lymphomas, not otherwise specified;
   e. Monomorphic post-transplant lymphoproliferative disorders (B-cell type);
   f. AIDS-related DLBCL, primary effusion lymphoma, and HHV8-positive DLBCL;
   g. If request is for third line or later therapy, any of the following:
      i. Primary mediastinal Large B-cell lymphoma (PMBCL);
      ii. Gastric MALT lymphoma;
      iii. Splenic marginal zone lymphoma;
      iv. Nongastric MALT lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Recent (within the last 30 days) absolute lymphocyte count (ALC) ≥100/µL;
5. Member meets one of the following (a or b):
   a. Disease is refractory or member has relapsed after ≥ 2 lines of systemic therapy that includes rituximab and one anthracycline-containing regimen (e.g., doxorubicin);
   b. Disease that is refractory (defined as no complete remission) to or has relapsed (defined as complete remission followed by biopsy-proven disease relapse) no more than 12 months after first-line chemoimmunotherapy that included an antiCD20 monoclonal antibody (e.g., rituximab*) and anthracycline-containing regimen (e.g., doxorubicin);

   *Prior authorization may be required for rituximab;
6. Member does not have active or primary central nervous system (CNS) disease;
7. Member has not previously received treatment with Chimeric antigen receptor (CAR) T-cell immunotherapy (e.g., Abecma®, Carvykti™, Breyanzi®, Kymriah™, Tecartus®);
8. Yescarta is not prescribed concurrently with other Chimeric antigen receptor (CAR) T-cell immunotherapy (e.g., Abecma®, Carvykti™, Breyanzi®, Kymriah™, Tecartus®);
9. Member has not previously been treated with a Chimeric antigen receptor (CAR) T Therapy or axicabtagene ciloleucel;

10. Dose does not exceed 2 x 10^8 chimeric antigen receptor (CAR)-positive viable T cells.

Approval duration
Commercial: 3 months (1 dose only)
Medicaid: 3 months (1 dose only)

B. Follicular Lymphoma (must meet all)**:**

1. Diagnosis of follicular lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Disease is refractory or member has relapsed after ≥ 2 lines of systemic therapy combination of an anti-CD20 monoclonal antibody (e.g., rituximab or Gazyva®) and an alkylating agent (e.g., bendamustine, cyclophosphamide, chlorambucil)*;
   *Prior authorization may be required;
5. Member does not have active or primary central nervous system (CNS) disease;
6. Member has not previously received treatment with Chimeric antigen receptor (CAR) T-cell immunotherapy (e.g., Abecma®, Carvykti™, Breyanzi®, Kymriah™, Tecartus®);
7. Yescarta® is not prescribed concurrently with other Chimeric antigen receptor (CAR) T-cell immunotherapy (e.g., Abecma®, Carvykti™, Breyanzi®, Kymriah™, Tecartus®);
8. Member has not previously been treated with a Chimeric antigen receptor (CAR) T Therapy or axicabtagene ciloleucel;
9. Dose does not exceed 2 x 10^8 chimeric antigen receptor (CAR)-positive viable T cells.

Approval duration
Commercial: 3 months (1 dose only)
Medicaid: 3 months (1 dose only)

II. Continued Therapy Approval

A. All indications in Section I

1. Reauthorization is not permitted as axicabtagene ciloleucel is indicated to be dosed one time only. Members must meet the initial approval criteria, at a minimum of 3 months since initial treatment discontinuation.

Approval duration: Not applicable.

References

1. National Comprehensive Cancer Network. B-cell Lymphomas Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed April 13, 2023.
2. National Comprehensive Cancer Network. Central Nervous System Cancers Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed April 13, 2023.
3. Kite, A Gilead Company. A Phase 2 Multicenter Study Evaluating the Efficacy and Safety of Axicabtagene Ciloleucel as First-Line Therapy in Subjects With High-Risk Large B-Cell Lymphoma (ZUMA-12). Clinicaltrials.gov. Published February 10, 2022. Available at: https://www.clinicaltrials.gov/ct2/show/NCT03761056?term=yescarta++OR+axicabtagene+ciloleucel. Accessed April 13, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed:	06/23/2020	09/14/2020

1. Policy title was updated. 2. References were updated.		
Policy was reviewed: 1. Policy title was updated. 2. FL indication and criteria added. 3. References were updated.	04/29/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.7, I.B.6: Updated to include new trial and failure criteria Member has not previously received treatment with CAR T-cell immunotherapy (e.g., Kymriah™, Breyanzi®). 2. Initial Approval Criteria, I.A.8, I.B.7: Updated to include new combination therapy criteria Yescarta is not prescribed concurrently with other CAR T-cell immunotherapy (e.g., Kymriah, Breyanzi). 3. Initial Approval Criteria, I.B.4: Updated trial and failure criteria from Disease is refractory or member has relapsed after 2 or more lines of systemic therapy to Disease is refractory or member has relapsed after 2 or more lines of systemic therapy combination of an anti-CD20 monoclonal antibody (e.g., rituximab or Gazyva®) and an alkylating agent (e.g., bendamustine, cyclophosphamide, chlorambucil)*. 4. References reviewed and updated.	01/31/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, 1.A.1: Updated to include diagnosis information. 2. References were reviewed and updated.	05/31/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.1.f was updated from AIDS-related B-cell lymphomas to AIDS-related DLBCL, primary effusion lymphoma, and HHV8-positive DLBCL. 2. References were reviewed and updated.	04/13/2023	07/13/2023

Policy was reviewed.	10/19/2023	10/19/2023