EmblemHealth

Yescarta (axicabtagene ciloleucel)

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Definition

Yescarta (axicabtagene ciloleucel): is a CD19-directed genetically modified autologous T cell immunotherapy that kills CD19-expressing cancer cells. T cells from the patient are harvested and genetically modified ex vivo by retroviral transduction to express a chimeric antigen receptor (CAR), and after infusion back into the patient, results in CD28 and CD3-zeta co-stimulatory domains to activate causing T-cell activation, proliferation, acquisition of effector functions and secretion of inflammatory cytokines and chemokines.

Yescarta (axicabtagene ciloleucel) is FDA approved for 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.

Yescarta (axicabtagene ciloleucel) is available as cell suspension for infusion. Yescarta comprises a suspension of 2 × 106 CAR-positive viable T cells per kg of body weight, with a maximum of 2 × 108 CAR-positive viable T cells in approximately 68 mL.

Guideline

Provider must submit documentation (which may include office notes and lab results) supporting that the patient has met all approval criteria.

Yescarta is considered medically necessary when all the below criteria are met:

- Patient is aged 18 years or greater; **AND**
- Patient has a confirmed diagnosis of large B-cell lymphoma, including:
  - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified; **OR**
  - Primary mediastinal large B-cell lymphoma; **OR**
  - High grade B-cell lymphoma; **OR**
  - DLBCL arising from follicular lymphoma; **AND**

    - The large B-cell lymphoma must be relapsed or refractory after two or more types of systemic therapy.
- Patient's disease is relapsed or refractory defined as one of the following:
    - Relapse within 1 year after autologous hematopoietic stem cell transplantation (HSCT); **OR**
    - Refractory disease to the most recent therapy; **AND**
- Patient did not receive prior allogeneic hematopoietic stem cell transplantation (HSCT); **AND**
- Patient has an ECOG performance status of 0-1; **AND**
- Patient has CD19-positive disease; **AND**
- Patient must not be currently pregnant and sexually-active females of reproductive potential should have pregnancy status verified through a pregnancy test; **AND**
- Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during Yescarta treatment, and will not receive live vaccines until immune recovery following treatment; **AND**
- Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection has been followed according to local guidelines; **AND**
- Patient will be using Yescarta in conjunction with lymphodepleting chemotherapy (fludarabine 30 mg/m^2 daily for 3 days and cyclophosphamide 500 mg/m^2 daily on the fifth, fourth, and third day before infusion of Yescarta ; **AND**
- Healthcare facility has enrolled in the Yescarta REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
- Patient will be using Yescarta (axicabtagene cilileucel) at a treatment center that is certified to administer Yescarta (axicabtagene cilileucel); **AND**
- Patient will be monitored for signs and symptoms of Cytokine Release Syndrome (CRS) for at least 4 weeks after treatment with Yescarta (axicabtagene cilileucel) and will be counselled to seek immediate medical attention should signs and symptoms of CRS or a neurological event occur at any time; **AND**
- Patient will stay within proximity (within 2 hours) of the Yescarta (axicabtagene cilileucel) infusion center for at least 4 weeks following infusion.

Limitations/Exclusions

- Dosing of Yescarta (axicabtagene cilileucel) is based on the number of chimeric antigen receptor (CAR)-positive viable T-cells.
- The target dose is : 2 X 10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2 X 10^8 CAR- positive viable T cells.
- Patient has a diagnosis of primary central nervous system lymphoma
- Patient has previously received CAR-T therapy

Initial Approval

- Approval will be granted for 1 single dose of Yescarta
- Coverage cannot be renewed, a maximum of one dose per lifetime will apply

Applicable Procedure Codes

HCPCS	HCPCS Description
Q2041	Axicabtagene Ciloleucel, up to 200 million autologous Anti-CD19 CAR T Cells, including leukapheresis and dose preparation procedures, per infusion

Applicable ICD-10 Codes

ICD-10	ICD-10 Description
C82.20	Follicular lymphoma grade III, unspecified, unspecified site
C82.21	Follicular lymphoma grade III, unspecified, lymph nodes of head, face and neck
C82.22	Follicular lymphoma, grade III, unspecified, intrathoracic lymph nodes
C82.23	Follicular lymphoma grade III, unspecified, intra-abdominal lymph nodes
C82.24	Follicular lymphoma grade III, unspecified, lymph nodes of axilla and upper limb
C82.25	Follicular lymphoma grade III, unspecified, lymph nodes of inguinal region and lower limb
C82.26	Follicular lymphoma grade III, unspecified, intrapelvic lymph nodes
C82.27	Follicular lymphoma grade III, unspecified, spleen
C82.28	Follicular lymphoma grade III, unspecified, lymph nodes of multiple sites
C82.29	Follicular lymphoma grade III, unspecified, extranodal and solid organ sites
C82.30	Follicular lymphoma grade IIIa, unspecified site
C82.31	Follicular lymphoma grade IIIa, lymph nodes of head, face and neck
C82.32	Follicular lymphoma, grade IIIa, intrathoracic lymph nodes
C82.33	Follicular lymphoma grade IIIa, intra-abdominal lymph nodes
C82.34	Follicular lymphoma grade IIIa, lymph nodes of axilla and upper limb
C82.35	Follicular lymphoma grade IIIa, lymph nodes of inguinal region and lower limb
C82.36	Follicular lymphoma grade IIIa, intrapelvic lymph nodes
C82.37	Follicular lymphoma grade IIIa, spleen
C82.38	Follicular lymphoma grade IIIa, lymph nodes of multiple sites
C82.39	Follicular lymphoma grade IIIa, extranodal and solid organ sites
C82.40	Follicular lymphoma grade IIIb, unspecified site
C82.41	Follicular lymphoma grade IIIb, lymph nodes of head, face and neck
C82.42	Follicular lymphoma, grade IIIb, intrathoracic lymph nodes
C82.43	Follicular lymphoma grade IIIb, intra-abdominal lymph nodes
C82.44	Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb
C82.45	Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb
C82.46	Follicular lymphoma grade IIIb, intrapelvic lymph nodes
C82.47	Follicular lymphoma grade IIIb, spleen

C82.48	Follicular lymphoma grade IIIb, lymph nodes of multiple sites
C82.49	Follicular lymphoma grade IIIb, extranodal and solid organ sites
C83.30	Diffuse large B-cell lymphoma unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C85.80	Other specified types of non-Hodgkin lymphoma, unspecified site
C85.81	Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face and neck
C85.82	Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes
C85.83	Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes
C85.84	Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb
C85.85	Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region of lower limb
C85.86	Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes
C85.87	Other specified types of non-Hodgkin lymphoma, spleen
C85.88	Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
Z85.72	Personal history of non-Hodgkin lymphomas

References

1. Yescarta [package insert]. Santa Monica, CA; Kite Pharma, Inc., October 2017.
2. Clinical Pharmacology Elsevier Gold Standard. 2017.
3. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2017.