Brand New Day
HEALTHCARE YOU CAN FEEL GOOD ABOUT

CENTRAL HEALTH MEDICARE PLAN

Medical Policy

Yescarta® (axicabtagene ciloleucel)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_029
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Yescarta® (axicabtagene ciloleucel) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Yescarta® (axicabtagene ciloleucel) is considered medical necessary when all the bellow criteria are met:

1. Patient is 18 years of age or greater; **AND**
2. Patient has a confirmed diagnosis of large B-cell lymphoma including:
    a. Diffuse large B-cell lymphoma (DLBCL) not otherwise specified, **OR**
    b. Primary mediastinal large B-cell lymphoma; **OR**
    c. High grade B-cell lymphoma; **OR**

   d. DLBCL arising from follicular lymphoma; **AND**
   e. The large B-cell lymphoma must be relapsed or refractory after two or more types of systemic therapy.
3. Patient's disease is relapsed, or refractory, defined as one of the following:
   a. Relapse within 1 year after autologous hematopoietic stem cell transplantation (HSCT); **OR**
   b. Refractory disease to the most recent therapy; **AND**
4. Patient did not receive prior allogeneic hematopoietic stem cell transplantation (HSCT); **AND**
5. Patient has an ECOG performance status of 0-1; **AND**
6. Patient has CD19-positive disease; **AND**
7. Patient must not be currently pregnant and sexually active females of reproductive potential should have pregnancy status verified through a pregnancy test; **AND**
8. Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
9. 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**
10. 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**
11. Prophylaxis for infection has been followed according to local guidelines; **AND**
12. Patient will be using Yescarta in conjunction with lymphodepleting chemotherapy (fludarabine 30 mg/m2 daily for 3 days and cyclophosphamide 500 mg/m2 daily on the fifth, fourth, and third day before infusion of Yescarta; **AND**
13. 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**
14. Patient will be using Yescarta at a treatment center that is certified to administer Yescarta; **AND**
15. Patient will be monitored for signs and symptoms of Cytokine Release Syndrome (CRS) for at least 4 weeks after treatment with Yescarta and will be counselled to seek immediate medical attention should signs and symptoms of CRS or a neurological event occur at any time; **AND**
16. Patient will stay within proximity (within 2 hours) of the Yescarta infusion center for at least 4 weeks following infusion; **AND**
17. Approval will be granted for 1 single dose of Yescarta; **AND**
18. Coverage may not be renewed. Maximum of one dose per lifetime will apply.

LIMITATIONS/EXCLUSIONS

1. Dosing of Yescarta is based on the number of chimeric antigen receptor (CAR)-positive viable T-cells.
2. 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.
3. Patient has a diagnosis of primary central nervous system lymphoma.

4. Patient has previously received CAR-T therapy.

BACKGROUND

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.

DEFINITIONS

1. 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.

CODING

Applicable NDC Codes	
00078-0846-19	00078-0958-19

Applicable Procedure Code	
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	
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

Medical Policy

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

EVIDENCE BASED 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.

POLICY HISTORY

Original Effective Date	December 7, 2020
Revised Date	November 1, 2021 – Annual Review and approval (no policy revisions made) February 2, 2022 – Annual Review and approval (no policy revisions made) March 1, 2023 – Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics Committee on 2/2/2022