Medical Policy

Breyanzi™ (lisocabtagene maraleucel)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_070
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 Medical Policy 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 Breyanzi™ (lisocabtagene maraleucel) therapy.

Medical Policy

POLICY

Clinical Review Criteria

Prior Authorization and Medical Review is required.

Coverage for Breyanzi will be provided for a one-time, single administration and cannot be renewed.
Dosing Limit: The patient's dose will not exceed 1 infusion of up to 110 million autologous anti-cd19 car -positive viable t-cells

1. Patient is 18 years of age or older; AND
2. Breyanzi is prescribed by, or in consultation with, an oncologist; AND
3. Patient has a confirmed diagnosis of large B-cell lymphoma including:
    a. Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma); **OR**
    b. Primary mediastinal large B-cell lymphoma; **OR**
    c. High grade B-cell lymphoma; **OR**
    d. Follicular lymphoma grade 3B; **AND**
4. The B-cells must be CD19-positive as confirmed by testing or analysis; **AND**
5. Patient's disease is relapsed or refractory after two or more lies of systemic therapy; **OR** Patient's disease is refractory to first line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; **OR** Patient's disease is refractory to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and they are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; **AND**
6. Patient has not received a previous treatment course of Breyanzi or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy; **AND**
7. Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
8. 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**
9. Patient will receive lymphodepleting chemotherapy (fludarabine 30 mg/m2/day and cyclophosphamide 300 mg/m2/day concurrently for 3 days) completed 2 to 7 days before administration of Breyanzi; **AND**
10. Patient will be receiving Breyanzi at a treatment center that is certified to administer Breyanzi; **AND**
11. Healthcare facility has enrolled in the Breyanzi REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
12. Patient will be monitored for signs and symptoms of Cytokine Release Syndrome (CRS) and neurological toxicities daily for at least 7 days following treatment, at the Breyanzi infusion center. Monitoring for signs or symptoms of CRS will continue for at least 4 weeks after treatment with Breyanzi and patient will be counselled to seek immediate medical attention should signs and symptoms of CRS or a neurological event occur at any time; **AND**

13. Patient will stay within proximity (within 2 hours) of the Breyanzi infusion center for at least 4 weeks following infusion.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Patients with primary central nervous system (CNS) lymphoma

BACKGROUND

Breyanzi is a CD19-directed genetically modified autologous T cell immunotherapy indicated 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 (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

DEFINITIONS

1. **BREYANZI (**lisocabtagene maraleucel) suspension for intravenous infusion. Initial U.S. Approval: 2021
    a. BREYANZI consists of genetically modified autologous T cells, supplied in vials as separate frozen suspensions of each CD8 component and CD4 component.
    b. Each CD8 or CD4 component is packed in a carton containing up to 4 vials, depending upon the concentration of the cryopreserved drug product CAR-positive viable T cells.

CODING

Applicable NDC Codes	
73153-0900-01	Breyanzi™ (lisocabtagene maraleucel) outer carton containing Carton for CD8 component, with up to 4 single-dose vials Carton for CD4 component, with up to 4 single-dose vials

Applicable Procedure Code	
Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose. Q-Code effective date: 10/01/2021

Applicable ICD-10 Codes	
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

C83.90	Non-follicular (diffuse) lymphoma, unspecified, unspecified site
C83.91	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of head, face, and neck
C83.92	Non-follicular (diffuse) lymphoma, unspecified, intrathoracic lymph nodes
C83.93	Non-follicular (diffuse) lymphoma, unspecified, intra-abdominal lymph nodes
C83.94	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of axilla and upper limb
C83.95	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C83.96	Non-follicular (diffuse) lymphoma, unspecified, intrapelvic lymph nodes
C83.97	Non-follicular (diffuse) lymphoma, unspecified, spleen
C83.98	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of multiple sites
C83.99	Non-follicular (diffuse) lymphoma, unspecified, 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
C82.50	Diffuse follicle center lymphoma, unspecified site
C82.51	Diffuse follicle center lymphoma, lymph nodes of head, face, and neck
C82.52	Diffuse follicle center lymphoma, intrathoracic lymph nodes
C82.53	Diffuse follicle center lymphoma, intra-abdominal lymph nodes
C82.54	Diffuse follicle center lymphoma, lymph nodes of axilla and upper limb
C82.55	Diffuse follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.56	Diffuse follicle center lymphoma, intrapelvic lymph nodes
C82.57	Diffuse follicle center lymphoma, spleen
C82.58	Diffuse follicle center lymphoma, lymph nodes of multiple sites
C82.59	Diffuse follicle center 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
Z51.12	Encounter for antineoplastic immunotherapy

EVIDENCE BASED REFERENCES

Medical Policy

1. Product Information: BREYANZI(R) intravenous suspension, lisocabtagene maraleucel intravenous suspension. Bristol-Myers Squibb (per FDA), Bothell, WA, 2021

POLICY HISTORY

This policy has been approved by the approval body listed below or has received other necessary approval pursuant to Brand New Day/Central Health Medicare Plan policies on clinical criteria and policy development.

Approval Body	Pharmacy and Therapeutics Committee		
Version History	**Approval Date**	**Effective Date**	**Action**
V1	7/19/2021	7/19/2021	New Policy
V2	1/7/2022	1/7/2022	Added Q code (Q2054): Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose. *Effective date: 10/01/2021*
V3	2/28/2023	3/1/2023	Expanded indication—refractory disease to first line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy. (Indication approved by FDA July 2022). *Updated monitoring parameters for CRS per package insert changes June 2022;* Adopted by MA UM Committee 1/01/2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)