SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

The Sentara Health Plans Oncology Program is administered by OncoHealth

- **For any oncology indications**, the most efficient way to submit a prior authorization request is through the **OncoHealth OneUM Provider Portal** at https://oneum.oncohealth.us. Fax to **1-800-264-6128.** OncoHealth can also be contacted by Phone: 1-888-916-2616.
- Commercial customers **NOT** enrolled in the OncoHealth program, please fax requests to Sentara Health plans at fax number 1-844-668-1550.

Drug Requested: Breyanzi® (liscoabtagene maraleucel) **IV (Q2054)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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Quantity Limit:

- **Pharmacy Benefit** – N/A
- **Medical Benefit** – Max Units (per dose and over time): 1 infusion of Breyanzi® only
  - NDC: Breyanzi® suspension for intravenous infusion: 73153-0900-08

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Approval Criteria – Coverage cannot be renewed

- ❑ Member is 18 years of age or older
- ❑ Member does **NOT** have a clinically significant active systemic infection or inflammatory disorder
- ❑ Member has **NOT** received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during treatment, and will not receive live vaccines until immune recovery following treatment
- ❑ Member 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)
- ❑ Prophylaxis for infection has been followed according to local guidelines
- ❑ Healthcare facility has enrolled in the BREYANZI REMS Program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities
- ❑ Member has **NOT** received prior CAR-T therapy
- ❑ Member must meet **ONE** of the following:
  - ❑ Member has **NOT** received prior anti-CD19 therapy, (e.g., tafasitamab)
  - ❑ Member previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease
- ❑ Medication will be used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture)
- ❑ Member does **NOT** have primary central nervous system lymphoma

❑ Diagnosis: B Cell Lymphomas

- ❑ Member must meet **ONE** of the following diagnosis and corresponding treatment failure requirements:
  - ❑ Member has a diagnosis of diffuse large B cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma; high-grade B-cell lymphoma; primary mediastinal B-cell lymphoma (PMBCL); follicular lymphoma Grade 3B
    - ❑ Member must have **ONE** of the following:
      - ❑ Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy (e.g., rituximab with dexamethasone, cytarabine, and cisplatin)

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- ❑ Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy (e.g., rituximab with dexamethasone, cytarabine, and cisplatin) and are **NOT** eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age
- ❑ Relapsed or refractory disease after two or more lines of systemic therapy

❑ Member has a diagnosis of relapsed or refractory follicular lymphoma and has received two (2) or more prior lines of therapy

❑ Diagnosis: Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)

❑ Member has a diagnosis chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

❑ Requested medication will be used for relapsed or refractory disease

❑ Member has received at least 2 prior lines of therapy including **BOTH** of the following:

- ❑ Bruton tyrosine kinase (BTK) inhibitor (e.g., acalabrutinib, ibrutinib, pirtobrutinib, zanubrutinib)
- ❑ B-cell lymphoma 2 (BCL-2) inhibitor (e.g., venetoclax)

❑ Diagnosis: Mantle Cell Lymphoma

❑ Member has a confirmed diagnosis of Mantle Cell Lymphoma, determined to be relapsed or refractory

❑ Member must have received previous systemic therapy with **BOTH** of the following:

- ❑ Bruton tyrosine kinase (BTK) inhibitor (e.g., ibrutinib, acalabrutinib, zanubrutinib)
- ❑ Second systemic therapy (e.g., rituximab-based immunochemotherapy)

Reauthorization Criteria – Coverage cannot be renewed

Medication being provided by: Please check applicable box below.

❑ **Location/site of drug administration:** _____

NPI or DEA # of administering location: _____

OR

❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step-edit/preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee:** ~~5/15/2021; 7/21/2022; 5/23/2024;~~ **7/25/2024**
REVISED/UPDATED/REFORMATTED: ~~9/14/2021; 10/8/2021 7/12/2022; 8/7/2022; 5/20/2024; 6/4/2024; 8/21/2024, 11/18/2024;~~ **2/28/2025**