



Submitted by:  
Kaleen Barbary, Pharm D  
Bristol Myers Squibb  
86 Morris Avenue  
Summit, NJ 07901

Date of Request: February 8th, 2021

Dear NCCN B-Cell Lymphomas Guidelines Panel:

On behalf of Bristol Myers Squibb, we respectfully request the NCCN Guidelines Panel for B-Cell Lymphoma review the enclosed Prescribing Information for BREYANZI® (lisocabtagene maraleucel) suspension for intravenous infusion.

**Specific Changes:**

We respectfully request the panel's consideration of the enclosed data and inclusion of BREYANZI within the B-Cell Lymphomas guidelines (Pages BCEL-C) as a Category 2A recommendation as well as an update to the appropriate discussion sections.

**FDA Clearance:**

On February 5, 2021 the US Food and Drug Administration (FDA) granted approval of BREYANZI for the treatment of patients with relapsed or refractory large B-cell Lymphoma after two or more lines of systemic therapy. The indication is as follows:

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.<sup>1</sup>

BREYANZI is not indicated for the treatment of patients with primary central nervous system lymphoma.

Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving BREYANZI. Do not administer BREYANZI to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab with or without corticosteroids.

Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving BREYANZI, including concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with BREYANZI. Provide supportive care and/or corticosteroids as needed.

BREYANZI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BREYANZI REMS.

Please see the enclosed full Prescribing Information.

**Rationale:**

This information is being submitted in response to a standing request from NCCN for new data.

A previous submission to NCCN regarding clinical data from the TRANSCEND NHL 001 study, evaluating the safety and efficacy of lisocabtagene maraleucel in patients with relapsed/refractory Large B-Cell Lymphoma was submitted on October 7<sup>th</sup>, 2020.

As part of this submission, the following resources are included for your review:

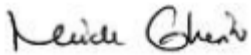
1. BREYANZI® (lisocabtagene maraleucel) [Package Insert]. Bothell, WA: Juno Therapeutics Inc., a Bristol-Myers Squibb Company; 2021

Your consideration of this submission is greatly appreciated.

Sincerely,

A handwritten signature in black ink, appearing to read "Kaleen Barbary". The signature is fluid and cursive, with the first name "Kaleen" and last name "Barbary" clearly distinguishable.

Kaleen Barbary, PharmD  
Director, Worldwide Scientific Content & US Market Capabilities Hematology

A handwritten signature in black ink, appearing to read "Mecide Gharibo". The signature is cursive and somewhat stylized, with the first name "Mecide" and last name "Gharibo" visible.

Mecide Gharibo, MD  
Executive Director, US Medical Affairs, Lymphoma