Reference number(s)
4513-A

SPECIALTY GUIDELINE MANAGEMENT

BREYANZI (lisocabtagene maraleucel)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
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 (NOS) (including DLBCL arising from indolent lymphoma), high grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

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

B. Compendial Uses
1. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (including AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specific)
2. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Chart notes, medical record documentation or claims history supporting previous lines of therapy.

III. CRITERIA FOR INITIAL APPROVAL

Adult Large B-cell lymphomas
Authorization of 3 months may be granted for treatment of B-cell lymphomas in members 18 years of age or older when all of the following criteria are met:
A. The member has any of the following B-cell lymphoma subtypes:
1. Diffuse large b-cell lymphoma (DLBCL) [including DLBCL NOS, Follicular lymphoma grade 3, DLBCL arising from indolent lymphomas (including follicular lymphoma, nodal marginal zone lymphoma, gastric MALT lymphoma, non-gastric MALT lymphoma, splenic marginal zone lymphoma)]
2. High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
3. Primary mediastinal large B-cell lymphoma

4. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (including AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specific)
5. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)

B. The member has received prior treatment with two or more lines of systemic therapy.
C. The member does not have primary central nervous system lymphoma.
D. The member has not received a previous treatment course of the requested medication or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.
E. The member has an ECOG performance status of 0 to 2 (member is ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours).
F. The member has adequate and stable kidney, liver, pulmonary and cardiac function.
G. The member does not have active hepatitis B, active hepatitis C or any active uncontrolled infection.
H. The member does not have active graft versus host disease.
I. The member does not have an active inflammatory disorder.

IV. REFERENCES

1. Breyanzi [package insert]. Bothell, WA: Juno Therapeutics Inc.; February 2021.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 05, 2021.
3. Abramson J, Palomba ML, Gordon L, et al. Lisocabtagene maraleucel for patients with relapsed or refractory large B-cell lymphomas (TRANSCEND NHL 001): a multicenter seamless design study. Lancet. 2020;396 (10254):839-852.