Clinical Policy: Lisocabtagene Maraleucel (Breyanzi)

Reference Number: LA.PHAR.483
Effective Date: 09.29.23
Last Review Date: ~~05.01.23~~05.21.24
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Please note: This policy is for medical benefit

Description
Lisocabtagene maraleucel (Breyanzi®) is a CD19-directed genetically modified autologous T-cell immunotherapy.

FDA Approved Indication(s)
Breyanzi is indicated for the treatment of ~~adult~~:

- Adult patients with large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), ~~highgrade~~high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have:
  - Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy
  - Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy 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

  Limitation of use: Breyanzi is not indicated for the treatment of patients with primary central nervous system (CNS) lymphoma.
- Adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase inhibitor (BTKi) and a B-cell lymphoma 2 inhibitor (BCL-2i). This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

All requests reviewed under this policy **require medical director review.**

It is the policy of Louisiana Healthcare Connections® that Breyanzi is **medically necessary** when the following criteria are met:

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I. Initial Approval Criteria

A. Large B-Cell Lymphoma* (must meet all)**:**

**Only for initial treatment dose; subsequent doses will not be covered.*

1. Diagnosis of one of the following LBCL (a – h);
   a. DLBCL;
   b. DLBCL transformed from one of the following (i – v):
      i. Follicular lymphoma;
      ii. Nodal marginal zone lymphoma;
      iii. Gastric mucosa-associated lymphoid tissue (MALT) lymphoma;
      iv. Nongastric MALT Lymphoma (noncutaneous);
      v. Splenic marginal zone lymphoma;
   c. Primary mediastinal ~~large B-cell lymphoma~~LBCL;
   d. Follicular lymphoma grade 3B;
   e. High-grade B-cell lymphomas with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma) or high-grade B-cell lymphomas, not otherwise specified;
   f. Monomorphic post-transplant lymphoproliferative disorders (B-cell type);
   g. ~~AIDS~~HIV-related ~~diffuse large B-cell lymphoma~~DLBCL, primary effusion lymphoma, and HHV8-positive ~~diffuse large B-cell lymphoma;~~DLBCL;
   h. T cell/histiocyte-rich LBCL~~ and request is for second line therapy;~~;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Request is for one of the following (a, b, or c):
   a. Disease is refractory or member has relapsed after ≥ 2 lines of systemic therapy that includes an anti-CD20 therapy (e.g., rituximab) and one anthracycline-containing regimen (e.g., doxorubicin);*****
   b. Disease that is refractory (defined as no complete remission) to or has relapsed (defined as complete remission followed by biopsy-proven disease relapse) no more than 12 months after first-line chemoimmunotherapy that included an anti-CD20 monoclonal antibody (e.g., rituximab*) and anthracycline-containing regimen (e.g., doxorubicin);
   c. Member is not eligible for HSCT due to comorbidities or age (see *Appendix D* for examples) and disease is refractory (defined as no complete remission) to or has relapsed (defined as complete remission followed by biopsy-proven disease relapse) after first-line chemoimmunotherapy that included an anti-CD20 monoclonal antibody (e.g., rituximab*) and anthracycline-containing regimen (e.g., doxorubicin);
   **Prior authorization may be required for rituximab*
5. Member does not have primary CNS disease;
6. Member has not previously received treatment with CAR T-cell immunotherapy (e.g., Abecma®, Carvykti™, Kymriah™, Tecartus™, Yescarta™);
7. Breyanzi is not prescribed concurrently with other CAR T-cell immunotherapy (e.g., Abecma, Carvykti, Kymriah, Tecartus, Yescarta);

8. Dose does not exceed 110 x 10^6 chimeric antigen receptor (CAR)-positive viable T cells.

Approval duration: 3 months ***(1 dose only, with 4 doses of tocilizumab (Actemra) if requested at up to 800 mg per dose)***

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B. Chronic Lymphocytic Leukemia, Small Lymphocytic Lymphoma* (must meet all)**:**

**Only for initial treatment dose; subsequent doses will not be covered.*

1. Diagnosis of relapsed or refractory CLL or SLL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. One of the following (a or b):
   a. Member has measurable disease as evidenced by one of the following assessed within the last 30 days (i, ii, or iii):
      i. Measurable lymph nodes ≥ 1.5 cm in the greatest transverse diameter;
      ii. Hepatomegaly;
      iii. Splenomegaly;
   b. Demonstration of CLL cells in the peripheral blood by flow cytometry;
5. Member has received ≥ 2 prior lines of therapy (*see Appendix B for examples*) that include both of the following (a and b):
   a. One BTKi (e.g., Brukinsa®, Calquence®, Imbruvica®);
   b. One BCL2i (e.g., Venclexta®);
   **Prior authorization may be required.*
6. Member does not have active CNS involvement by malignancy or history or presence of clinically relevant CNS pathology (e.g., epilepsy, generalized seizure disorder, aphasia, stroke with current neurologic sequelae, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, cerebral edema, or psychosis);
7. Member has not previously received treatment with CAR T-cell immunotherapy (e.g., Abecma, Carvykti, Kymriah, Tecartus, Yescarta);
8. Breyanzi is not prescribed concurrently with other CAR T-cell immunotherapy (e.g., Abecma, Carvykti, Kymriah, Tecartus, Yescarta);
9. Dose does not exceed 110 x 10^6 CAR-positive viable T-cells.

Approval duration: 3 months ***(1 dose only, with 4 doses of tocilizumab (Actemra) if requested at up to 800 mg per dose)***

~~B.~~**C. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

A. ~~Large B-Cell Lymphoma~~All Indications in Section I:

1. Continued therapy will not be authorized as Breyanzi is indicated to be dosed one time only.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255 for Medicaid
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – LA.PMN.53 for Medicaid or evidence of coverage documents;

B. Primary CNS disease.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALC: absolute lymphocyte count
BTKi: Bruton tyrosine kinase inhibitor
BCL2i: B-cell lymphoma 2 inhibitor
CLL: chronic lymphocytic leukemia
CAR: chimeric antigen receptor
CNS: central nervous system
CRS: cytokine release syndrome
DLBCL: diffuse large B-cell lymphoma
FDA: Food and Drug Administration
HSCT: hematopoietic stem cell transplantation
LBCL: large B-cell lymphoma
MALT: mucosa-associated lymphoid tissue
SLL: small lymphocytic lymphoma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
LBCL: First-Line Treatment Regimens		
RCHOP (~~Rituxan®~~ ~~(~~rituximab~~),~~ cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
RCEPP (~~Rituxan®~~ ~~(~~rituximab~~),~~ cyclophosphamide, etoposide, prednisone, procarbazine)	Varies	Varies

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
RCDOP (~~Rituxan®~~ ~~(~~rituximab~~),~~ cyclophosphamide, liposomal doxorubicin, vincristine, prednisone)	Varies	Varies
DA-EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + ~~Rituxan®~~ ~~(~~rituximab~~)~~	Varies	Varies
RCEOP (~~Rituxan®~~ ~~(~~rituximab~~),~~ cyclophosphamide, etoposide, vincristine, prednisone)	Varies	Varies
RGCVP (~~Rituxan®~~ ~~,~~rituximab, gemcitabine, cyclophosphamide, vincristine, prednisone)	Varies	Varies
LBCL: **Second-Line Treatment Regimens**		
Bendeka® (bendamustine) ± ~~Rituxan®~~ ~~(~~rituximab~~)~~	Varies	Varies
CEPP (cyclophosphamide, etoposide, prednisone, procarbazine) ± ~~Rituxan®~~ ~~(rituximab~~rituxima)	Varies	Varies
CEOP (cyclophosphamide, etoposide, vincristine, prednisone) ± ~~Rituxan®~~ ~~(~~rituximab~~)~~	Varies	Varies
DA-EPOCH ± ~~Rituxan®~~ ~~(~~rituximab~~)~~	Varies	Varies
GDP (gemcitabine, dexamethasone, cisplatin) ± ~~Rituxan®~~ ~~(~~rituximab~~)~~	Varies	Varies
gemcitabine, dexamethasone, carboplatin ± ~~Rituxan®~~ ~~(~~rituximab~~)~~	Varies	Varies
GemOx (gemcitabine, oxaliplatin) ± ~~Rituxan®~~ ~~(~~rituximab~~)~~	Varies	Varies
gemcitabine, vinorelbine ± ~~Rituxan®~~ ~~(~~rituximab~~)~~	Varies	Varies
lenalidomide ± ~~Rituxan®~~ ~~(~~rituximab~~)~~	Varies	Varies
Rituximab (Riabni™, Rituxan® ~~(rituximab)~~®, Ruxience®, Truxima®)	Varies	Varies
DHAP (dexamethasone, cisplatin, cytarabine) ± ~~Rituxan®~~ ~~(~~rituximab~~)~~	Varies	Varies
DHAX (dexamethasone, cytarabine, oxaliplatin) ± ~~Rituxan®~~ ~~(~~rituximab~~)~~	Varies	Varies
ESHAP (etoposide, methylprednisolone, cytarabine, cisplatin) ± ~~Rituxan®~~ ~~(~~rituximab~~)~~	Varies	Varies
ICE (ifosfamide, carboplatin, etoposide) ± ~~Rituxan®~~ ~~(~~rituximab~~)~~	Varies	Varies
MINE (mesna, ifosfamide, mitoxantrone, etoposide) ± ~~Rituxan®~~ ~~(~~rituximab~~)~~	Varies	Varies
CLL/SLL: First-Line Therapies		
Calquence (acalabrutinib) ± Gazyva® (obinutuzumab)	Varies	Varies
Venclexta® (venetoclax) + Gazyva (obinutuzumab)	Varies	Varies

CLL/SLL: First-Line Therapies		
Brukinsa (zanubrutinib)	160 mg PO BID or 320 mg PO QD	320 mg/day 640 mg/day when used with a moderate CYP3A4 inducer
Imbruvica® (ibrutinib)	420 mg PO QD	420 mg/day
Imbruvica (ibrutinib) + Gazyva (obinutuzumab)	Varies	Varies
Imbruvica (ibrutinib) + rituximab	Varies	Varies
Imbruvica (ibrutinib) + Venclexta (venetoclax)	Varies	Varies
CLL/SLL: Second-Line or Third-Line Therapies		
Calquence (acalabrutinib)	100 mg PO BID	400 mg/day
Venclexta (venetoclax) ± rituximab	Varies	Varies
Brukinsa (zanubrutinib)	160 mg PO BID or 320 mg PO QD	320 mg/day 640 mg/day when used with a moderate CYP3A4 inducer
Imbruvica (ibrutinib)	420 mg PO QD	420 mg/day
CLL/SLL: Therapies for Relapsed or Refractory Disease After Prior BTKi- and BCL2i-Based Regimens		
Copiktra® (duvelisib)	25 mg PO BID	50 mg/day
Zydelig® (idelalisib) ± rituximab	150 mg PO BID	300 mg/day
Jaypirca™ (pirtobrutinib)	200 mg PO QD	200 mg/day
FCR (fludarabine, cyclophosphamide, rituximab)	Varies	Varies
Revlimid® (lenalidomide) ± rituximab	Varies	Varies
Gazyva (obinutuzumab)	100 mg IV on day 1, 900 mg IV on day 2 of cycle 1, then 1,000 mg IV on days 8 and 15 of cycle 1; begin the next cycle of therapy on day 29. For cycles 2 to 6, give 1,000 mg IV on day 1 repeated every 28 days.	See regimen
Campath® (alemtuzumab) ± rituximab	30 mg/day IV three times per week for 12 weeks	See regimen
High-dose methylprednisolone ± rituximab or Gazyva (obinutuzumab)	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): cytokine release syndrome ~~and~~, neurologic toxicities, and secondary hematological malignancies

Appendix D: General Information

- Patients with primary CNS disease were excluded from the TRANSCEND NHL 001 trial. For primary CNS lymphoma, NCCN treatment guidelines for CNS cancers recommend a high-dose methotrexate induction based regimen or whole brain radiation therapy, and consolidation therapy with high-dose chemotherapy with stem cell rescue, high-dose cytarabine with or without etoposide, low dose whole brain radiation therapy, or continuation with monthly high-dose methotrexate-based regimen.
- In the TRANSCEND NHL 001 trial, three of six patients in the efficacy-evaluable set with secondary CNS lymphoma achieved a complete response.
- No prespecified threshold for blood counts, including absolute lymphocyte count, was required for enrollment in the TRANSCEND NHL 001 trial.
- The PILOT study evaluated transplant-ineligible patients with relapsed or refractory LBCL after one line of chemoimmunotherapy. The study required at least one of the following criteria to identify patients who were not eligible for high-dose therapy and autologous HSCT: age ≥ 70 years, adjusted diffusing capacity of the lung for carbon monoxide (DLCO) ≤ 60%; left ventricular ejection fraction (LVEF) < 50%; creatinine clearance < ~~60mL~~60 mL/min; aspartate transaminase (AST) or alanine aminotransferase (ALT) greater than two times the upper limit or normal, or Eastern Cooperative Oncology Group (ECOG) performance status of 2 (capable of all self-care but unable to carry out any work activities; up and about > 50% of waking hours).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
LBCL after two or more lines of therapy	Target dose: 50 to 110 x 10^6 CAR-positive viable T cells	110 x 10^6 CAR-positive viable T cells
LBCL after one line of therapy, CLL/SLL	Target dose: 90 to 110 x 10^6 CAR-positive viable T cells	110 x 10^6 CAR-positive viable T cells

VI. Product Availability

Single-dose 5 mL vial: frozen suspension of genetically modified autologous T-cells labeled for the specific recipient

VII. References

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~~iv.~~4. National Comprehensive Cancer Network. B-cell Lymphomas Version ~~5.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed July 19, 2022~~1.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed January 22, 2024.

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~~5.~~National Comprehensive Cancer Network Drug and Biologics Compendium. ~~Available at http://www.nccn.org/professionals/drug_compendium. Accessed February 1, 2022.~~

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~~vii.~~7. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT03575351, A Study to Compare the Efficacy and Safety of JCAR017 to Standard of Care in Adult Subjects With High-risk, Transplant-eligible Relapsed or Refractory Aggressive B-cell Non-Hodgkin Lymphomas (TRANSFORM); ~~10, June 2021.~~15, November 2023. Available at: ~~https://www.clinicaltrials.gov/ct2/show/NCT03575351.~~https://www.clinicaltrials.gov/ct2/show/NCT03575351. Accessed ~~March 9, 2022~~January 22, 2024.

~~viii.~~8. Kamdar M, Solomon SR, Arnason JE, et al. Lisocabtagene Maraleucel Versus Standard of Care with Salvage Chemotherapy Followed By Autologous Stem Cell Transplantation As Second-Line Treatment in Patients with Relapsed or Refractory Large B-Cell Lymphoma~~:~~ (TRANSFORM): Results from an interim analysis of an open-label, randomized, phase 3 trial. Lancet 2022; 399: 2294-308.

~~ix.~~9. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT03483103, Lisocabtagene Maraleucel (JCAR017) as Second-Line Therapy (TRANSCEND-PILOT-017006); ~~25, April 2022.~~20, December 2023. Available at: ~~https://clinicaltrials.gov/ct2/show/NCT03483103.~~https://clinicaltrials.gov/ct2/show/NCT03483103. Accessed ~~July 7, 2022~~January 22, 2024.

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Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-CD 19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Policy created	05.01.23	08.28.23
Annual review: for T-cell/histiocyte-rich LBCL removed requirement for use as second line therapy; references reviewed and updated; added new indication for CLL/SLL; updated boxed warnings to include secondary hematological malignancies per updated prescribing information.	03.25.24 and 05.21.24	

Important Reminder

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This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.