

# Breyanzi® (lisocabtagene maraleucel) (Intravenous)

Document Number: EOCCO-0590

Last Review Date: 07/02/2024

Date of Origin: 03/01/2021

Dates Reviewed: 03/2021, 07/2021, 10/2021, 11/2021, 08/2022, 11/2023, 04/2024, 06/2024, 07/2024

## I. Length of Authorization

Coverage will be provided for one treatment course (1 dose of Breyanzi) and may not be renewed.

## II. Dosing Limits

### A. Quantity Limit (max daily dose) [NDC Unit]:

- 1 carton (1 to 4 vials) of up to 110 million autologous anti-CD19 CAR-positive viable T-cells

### B. Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit (1 infusion of up to 110 million autologous anti-CD19 CAR-positive viable T-cells)

## III. Initial Approval Criteria <sup>1</sup>

Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); **AND**
- Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during lisocabtagene maraleucel treatment and until immune recovery following treatment; **AND**
- 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**
- Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**

- Healthcare facility must be enrolled in and comply with the requirements of the BREYANZI REMS Program; **AND**
- Patient has not received prior CAR-T therapy; **AND**
- Patient has not received other anti-CD19 therapy (e.g., tafasitamab, blinatumomab, loncastuximab tesirine, etc.) OR patient previously received other anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or bridging chemotherapy while awaiting manufacture); **AND**
- Patient does not have primary central nervous system lymphoma; **AND**

#### **B-Cell Lymphomas † ‡ Φ <sup>1,7,11</sup>**

- Patient has diffuse large B cell lymphoma (DLBCL), high-grade B-cell lymphoma, primary mediastinal B-cell lymphoma (PMBCL), follicular lymphoma (FL) grade 3b, HIV-related B-cell lymphoma (i.e., HIV-related DLBCL, primary effusion lymphoma, and HHV8-positive DLBCL, not otherwise specified), or monomorphic post-transplant lymphoproliferative disorder (PTLD) (B-cell type); **AND**
  - Used for primary refractory disease (partial response, no response, or progression) or relapsed disease within 12 months after completion of first-line therapy; **OR**
  - Used for relapsed or refractory disease after first-line chemoimmunotherapy in patients NOT eligible for hematopoietic stem cell transplantation (HSCT) (*Note: Excludes HIV-related B-cell lymphoma and monomorphic PTLT*); **OR**
  - Used as second-line therapy for relapsed or refractory disease >12 months after completion of first-line therapy if no intention to proceed to transplant; **OR**
  - Used as additional therapy for relapsed or refractory disease >12 months after completion of first-line therapy and a partial response following second-line therapy (*Note: For DLBCL, FL grade 3b, or PMBCL, patient must also have no intention to proceed to transplant*); **OR**
  - Used for relapsed or refractory disease after two (2) or more lines of systemic therapy; **OR**
- Patient has Follicular Lymphoma Grade 1, 2, or 3a; **AND**
  - Patient has relapsed or refractory disease; **AND**
  - Patient has received at least two (2) prior lines of therapy; **OR**
- Patient has Mantle Cell Lymphoma; **AND**
  - Patient has relapsed or refractory disease; **AND**
  - Patient has received at least two (2) prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor (e.g., acalabrutinib, ibrutinib, pirtobrutinib, zanubrutinib, etc.); **OR**
- Patient has Richter's transformation of CLL to DLBCL; **AND**

- Patient received at least two (2) prior lines of chemoimmunotherapy for indolent or transformed disease which must have included an anthracycline or anthracenedione-based regimen, unless contraindicated; **OR**
- Patient has histologic transformation of an indolent lymphoma (follicular lymphoma or marginal zone lymphoma) to DLBCL; **AND**
  - Disease is refractory to first-line chemoimmunotherapy or has relapsed within 12 months of first-line chemoimmunotherapy; **AND**
    - Patient is a candidate for autologous hematopoietic stem cell transplant (HSCT); **OR**
  - Disease is relapsed or refractory after first-line chemoimmunotherapy and patient is NOT eligible for HSCT; **OR**
  - Patient received at least two (2) prior lines of chemoimmunotherapy for indolent or transformed disease which must have included an anthracycline or anthracenedione-based regimen, unless contraindicated

**Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (CLL/SLL) † ‡ Φ<sup>1,7,8</sup>**

- Used for relapsed or refractory disease; **AND**
- Patient has received at least 2 prior lines of therapy including a Bruton tyrosine kinase (BTK) inhibitor (e.g., acalabrutinib, ibrutinib, pirtobrutinib, zanubrutinib, etc.) AND a B-cell lymphoma 2 (BCL-2) inhibitor (e.g., venetoclax, etc.)

**Pediatric Aggressive Mature B-Cell Lymphomas ‡<sup>1,7,12</sup>**

- Patient is ≤ 18 years of age; **AND**
- Patient has primary mediastinal large B-Cell lymphoma; **AND**
- Used as consolidation or additional therapy in patients with a partial response after therapy for relapsed or refractory disease; **AND**
- Patient has previously received ≥ 2 prior chemoimmunotherapy regimens

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

## IV. Renewal Criteria<sup>1</sup>

Coverage cannot be renewed.

## V. Dosage/Administration<sup>1</sup>

Indication	Dose
B-Cell Lymphomas and Pediatric	<p><b><u>Lymphodepleting chemotherapy:</u></b></p> <ul style="list-style-type: none"> <li>● Administer cyclophosphamide 300 mg/m<sup>2</sup> and fludarabine 30 mg/m<sup>2</sup> intravenously daily for three days.</li> </ul> <p><b><u>Breyanzi infusion for relapsed/refractory disease after receiving at least ONE line of therapy:</u></b></p>

<p>Aggressive Mature B-Cell Lymphomas</p>	<ul style="list-style-type: none"> <li>• Infuse 2 to 7 days after completion of lymphodepleting chemotherapy.</li> <li>• A single dose of Breyanzi contains 90 to 110 × 10<sup>6</sup> CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose vials.</li> </ul> <p><b><u>Breyanzi infusion for relapsed/refractory Follicular Lymphoma Grade 1, 2, or 3a OR Mantle Cell Lymphoma after receiving at least TWO lines of therapy</u></b></p> <ul style="list-style-type: none"> <li>• Infuse 2 to 7 days after completion of lymphodepleting chemotherapy.</li> <li>• A single dose of Breyanzi contains 90 to 110 × 10<sup>6</sup> CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose vials.</li> </ul> <p><b><u>Breyanzi infusion for relapsed/refractory disease after receiving at least TWO lines of therapy (Note: Does NOT apply to Follicular Lymphoma Grade 1, 2, or 3a OR Mantle Cell Lymphoma)</u></b></p> <ul style="list-style-type: none"> <li>• Infuse 2 to 7 days after completion of lymphodepleting chemotherapy.</li> <li>• A single dose of Breyanzi contains 50 to 110 × 10<sup>6</sup> CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose vials.</li> </ul>
<p>CLL/SLL</p>	<p><b><u>Lymphodepleting chemotherapy:</u></b></p> <ul style="list-style-type: none"> <li>• Administer cyclophosphamide 300 mg/m<sup>2</sup> and fludarabine 30 mg/m<sup>2</sup> intravenously daily for three days.</li> </ul> <p><b><u>Breyanzi infusion for relapsed/refractory disease after receiving at least TWO lines of therapy:</u></b></p> <ul style="list-style-type: none"> <li>• Infuse 2 to 7 days after completion of lymphodepleting chemotherapy.</li> <li>• A single dose of Breyanzi contains 90 to 110 × 10<sup>6</sup> CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose vials.</li> </ul>
<p><b>For autologous use only. For intravenous use only.</b></p> <ul style="list-style-type: none"> <li>• Breyanzi is prepared from the patient’s T-cells, which are obtained via a standard leukapheresis procedure.</li> <li>• One treatment course consists of lymphodepleting chemotherapy followed by a single infusion of Breyanzi.</li> <li>• Confirm Breyanzi availability prior to starting the lymphodepleting regimen.</li> <li>• Confirm the patient’s identity with the patient identifiers on the shipper and the respective Certificate of Release for Infusion (RFI Certificate) prior to infusion.</li> <li>• Delay the infusion of Breyanzi if the patient has unresolved serious adverse events from preceding chemotherapies, active uncontrolled infection, or active graft-versus-host disease (GVHD).</li> </ul>	
<p><b><u>Premedication:</u></b></p> <ul style="list-style-type: none"> <li>• Premedicate with 650 mg acetaminophen and 25-50 mg diphenhydramine (or another H1-antihistamine) 30-60 minutes prior to treatment with Breyanzi. Avoid prophylactic use of systemic corticosteroids, as they may interfere with the activity of Breyanzi.</li> </ul>	
<p><b><u>Monitoring after infusion:</u></b></p> <ul style="list-style-type: none"> <li>• Monitor patients daily at a REMS-certified healthcare facility for at least 7 days following Breyanzi infusion for signs and symptoms of CRS and neurologic toxicities.</li> <li>• Instruct patients to remain within proximity of the certified healthcare facility for at least 4 weeks following infusion.</li> <li>• Instruct patients to refrain from driving or hazardous activities for 8 weeks following infusion.</li> </ul>	
<ul style="list-style-type: none"> <li>• Store vials in the vapor phase of liquid nitrogen (less than or equal to minus 130°C). Thaw prior to infusion.</li> <li>• In case of manufacturing failure, a second manufacturing may be attempted.</li> <li>• Additional bridging chemotherapy (not the lymphodepletion) may be necessary while the patient awaits the product.</li> <li>• Ensure that 2 doses of tocilizumab and emergency equipment are available prior to infusion and during the recovery period.</li> <li>• Breyanzi contains human blood cells that are genetically modified with replication incompetent self-inactivating lentiviral vector. Follow universal precautions and local biosafety guidelines for handling and disposal to avoid potential transmission of infectious diseases.</li> </ul>	

## VI. Billing Code/Availability Information

### HCPCS 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

### NDC:

- Breyanzi suspension for intravenous infusion [Each vial contains between  $6.9 \times 10^6$  and  $322 \times 10^6$  CAR-positive viable T cells in 4.6 mL cell suspension (between  $1.5 \times 10^6$  and  $70 \times 10^6$  CAR-positive viable T cells/mL)]: 73153-0900-xx

## VII. References

1. Breyanzi [package insert]. Bothell, WA; Juno Therap., Inc., May 2024. Accessed May 2024.
2. Abramson JS, Palomba ML, Gordon LI, et al. Lisocabtagene maraleucel for patients with relapsed or refractory large B-cell lymphomas (TRANSCEND NHL 001): a multicentre seamless design study. *Lancet*. 2020 Sep 19;396(10254):839-852. doi: 10.1016/S0140-6736(20)31366-0. Epub 2020 Sep 1.
3. Mejstrikova E, Hrusak O, Borowitz MJ, et al. CD19-negative relapse of pediatric B-cell precursor acute lymphoblastic leukemia following blinatumomab treatment. *Blood Cancer J*. 2017; 659. DOI 10.1038/s41408-017-0023-x
4. Ruella M, Maus MV. Catch me if you can: Leukemia Escape after CD19-Directed T Cell Immunotherapies. *Computational and Structural Biotechnology Journal* 14 (2016) 357–362.
5. Braig F, Brandt A, Goebeler M, et al. Resistance to anti-CD19/CD3 BiTE in acute lymphoblastic leukemia may be mediated by disrupted CD19 membrane trafficking. *Blood*; 129:1, 2017 Jan.
6. Majzner RG, Mackall CL. Tumor Antigen Escape from CAR T-cell Therapy. *Cancer Discov* 2018;8:1219-1226.
7. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) lisocabtagene maraleucel. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2024.
8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version 3.2024. National Comprehensive Cancer Network, 2024. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed March 2024.

9. Kamdar M, Solomon SR, Arnason J, et al.; TRANSFORM Investigators. 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, randomised, phase 3 trial. *Lancet*. 2022 Jun 18;399(10343):2294-2308. doi: 10.1016/S0140-6736(22)00662-6.
10. Sehgal AR, Hildebrandt G, Ghosh N, et al. Lisocabtagene maraleucel (liso-cel) for treatment of second-line (2L) transplant noneligible (TNE) relapsed/refractory (R/R) aggressive large B-cell non-Hodgkin lymphoma (NHL): Updated results from the PILOT study. *Journal of Clinical Oncology* 2020 38:15\_suppl, 8040-8040. DOI: 10.1200/JCO.2020.38.
11. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas Version 5.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed October 2023.
12. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pediatric Aggressive Mature B-Cell Lymphomas Version 1.2023 National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed October 2023.
13. Abramson JS, Solomon SR, Arnason JE, et al. Lisocabtagene maraleucel as second-line therapy for large B-cell lymphoma: primary analysis of phase 3 TRANSFORM study. *Blood* 2023;141:1675-1684.
14. Sehgal A, Hoda D, Riedell PA, et al. Lisocabtagene maraleucel as second-line therapy in adults with relapsed or refractory large B-cell lymphoma who were not intended for haematopoietic stem cell transplantation (PILOT): an open-label, phase 2 study. *Lancet Oncol* 2022;23:1066-1077.
15. Siddiqi T, Maloney DG, Kenderian SS, et al. Lisocabtagene maraleucel in chronic lymphocytic leukaemia and small lymphocytic lymphoma (TRANSCEND CLL 004): a multicentre, open-label, single-arm, phase 1-2 study. *Lancet*. 2023 Aug 19;402(10402):641-654. doi: 10.1016/S0140-6736(23)01052-8. Epub 2023 Jun 6. PMID: 37295445.
16. Wang M, Siddiqi T, Gordon LI, et al. Lisocabtagene Maraleucel in Relapsed/Refractory Mantle Cell Lymphoma: Primary Analysis of the Mantle Cell Lymphoma Cohort From TRANSCEND NHL 001, a Phase I Multicenter Seamless Design Study. *J Clin Oncol*. 2024 Apr 1;42(10):1146-1157. doi: 10.1200/JCO.23.02214. Epub 2023 Dec 10. PMID: 38072625.
17. Morschhauser F, Dahiya S, Palomba ML, et al; TRANSCEND FL: Phase 2 Study Primary Analysis of Lisocabtagene Maraleucel as Second-Line Therapy in Patients with High-Risk Relapsed or

Refractory Follicular Lymphoma. Blood 2023; 142 (Supplement 1): 602. doi:  
<https://doi.org/10.1182/blood-2023-179474>.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C82.00	Follicular lymphoma grade I, unspecified site
C82.01	Follicular lymphoma grade I, lymph nodes of head, face and neck
C82.02	Follicular lymphoma, grade I, intrathoracic lymph nodes
C82.03	Follicular lymphoma grade I, intra-abdominal lymph nodes
C82.04	Follicular lymphoma grade I, lymph nodes of axilla and upper limb
C82.05	Follicular lymphoma grade I, lymph nodes of inguinal regional and lower limb
C82.06	Follicular lymphoma grade I, intrapelvic lymph nodes
C82.07	Follicular lymphoma grade I, spleen
C82.08	Follicular lymphoma grade I, lymph nodes of multiple sites
C82.09	Follicular lymphoma grade I, extranodal and solid organ sites
C82.10	Follicular lymphoma grade II, unspecified site
C82.11	Follicular lymphoma grade II, lymph nodes of head, face and neck
C82.12	Follicular lymphoma, grade II, intrathoracic lymph nodes
C82.13	Follicular lymphoma grade II, intra-abdominal lymph nodes
C82.14	Follicular lymphoma grade II, lymph nodes of axilla and upper limb
C82.15	Follicular lymphoma grade II, lymph nodes of inguinal region and lower limb
C82.16	Follicular lymphoma grade II, intrapelvic lymph nodes
C82.17	Follicular lymphoma grade II, spleen
C82.18	Follicular lymphoma grade II, lymph nodes of multiple sites
C82.19	Follicular lymphoma grade II, extranodal and solid organ sites
C82.20	Follicular lymphoma grade III, unspecified, unspecified site
C82.21	Follicular lymphoma grade III, unspecified, lymph nodes of head, face and neck
C82.22	Follicular lymphoma, grade III, unspecified, intrathoracic lymph nodes
C82.23	Follicular lymphoma grade III, unspecified, intra-abdominal lymph nodes
C82.24	Follicular lymphoma grade III, unspecified, lymph nodes of axilla and upper limb
C82.25	Follicular lymphoma grade III, unspecified, lymph nodes of inguinal region and lower limb
C82.26	Follicular lymphoma grade III, unspecified, intrapelvic lymph nodes
C82.27	Follicular lymphoma grade III, unspecified, spleen
C82.28	Follicular lymphoma grade III, unspecified, lymph nodes of multiple sites

C82.29	Follicular lymphoma grade III, unspecified, extranodal and solid organ sites
C82.30	Follicular lymphoma grade IIIa, unspecified site
C82.31	Follicular lymphoma grade IIIa, lymph nodes of head, face and neck
C82.32	Follicular lymphoma, grade IIIa, intrathoracic lymph nodes
C82.33	Follicular lymphoma grade IIIa, intra-abdominal lymph nodes
C82.34	Follicular lymphoma grade IIIa, lymph nodes of axilla and upper limb
C82.35	Follicular lymphoma grade IIIa, lymph nodes of inguinal region and lower limb
C82.36	Follicular lymphoma grade IIIa, intrapelvic lymph nodes
C82.37	Follicular lymphoma grade IIIa, spleen
C82.38	Follicular lymphoma grade IIIa, lymph nodes of multiple sites
C82.39	Follicular lymphoma grade IIIa, 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
C82.60	Cutaneous follicle center lymphoma, unspecified site
C82.61	Cutaneous follicle center lymphoma, lymph nodes of head, face and neck



C82.62	Cutaneous follicle center lymphoma, intrathoracic lymph nodes
C82.63	Cutaneous follicle center lymphoma, intra-abdominal lymph nodes
C82.64	Cutaneous follicle center lymphoma, lymph nodes of axilla and upper limb
C82.65	Cutaneous follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.66	Cutaneous follicle center lymphoma, intrapelvic lymph nodes
C82.67	Cutaneous follicle center lymphoma, spleen
C82.68	Cutaneous follicle center lymphoma, lymph nodes of multiple sites
C82.69	Cutaneous follicle center lymphoma, extranodal and solid organ sites
C82.80	Other types of follicular lymphoma, unspecified site
C82.81	Other types of follicular lymphoma, lymph nodes of head, face and neck
C82.82	Other types of follicular lymphoma, intrathoracic lymph nodes
C82.83	Other types of follicular lymphoma, intra-abdominal lymph nodes
C82.84	Other types of follicular lymphoma, lymph nodes of axilla and upper limb
C82.85	Other types of follicular lymphoma, lymph nodes of inguinal region and lower limb
C82.86	Other types of follicular lymphoma, intrapelvic lymph nodes
C82.87	Other types of follicular lymphoma, spleen
C82.88	Other types of follicular lymphoma, lymph nodes of multiple sites
C82.89	Other types of follicular lymphoma, extranodal and solid organ sites
C82.90	Follicular lymphoma, unspecified, unspecified site
C82.91	Follicular lymphoma, unspecified, lymph nodes of head, face and neck
C82.92	Follicular lymphoma, unspecified, intrathoracic lymph nodes
C82.93	Follicular lymphoma, unspecified, intra-abdominal lymph nodes
C82.94	Follicular lymphoma, unspecified, lymph nodes of axilla and upper limb
C82.95	Follicular lymphoma, unspecified lymph nodes of inguinal region and lower limb
C82.96	Follicular lymphoma, unspecified, intrapelvic lymph nodes
C82.97	Follicular lymphoma, unspecified, spleen
C82.98	Follicular lymphoma, unspecified, lymph nodes of multiple sites
C82.99	Follicular lymphoma, unspecified, extranodal and solid organ sites
C83.00	Small cell B-cell lymphoma, unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb

C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C83.10	Mantle cell lymphoma, unspecified site
C83.11	Mantle cell lymphoma, lymph nodes of head, face and neck
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites
C83.19	Mantle cell lymphoma, extranodal and solid organ sites
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
C83.80	Other non-follicular lymphoma, unspecified site
C83.81	Other non-follicular lymphoma, lymph nodes of head, face and neck
C83.82	Other non-follicular lymphoma, intrathoracic lymph nodes
C83.83	Other non-follicular lymphoma, intra-abdominal lymph nodes
C83.84	Other non-follicular lymphoma, lymph nodes of axilla and upper limb
C83.85	Other non-follicular lymphoma, lymph nodes of inguinal region and lower limb
C83.86	Other non-follicular lymphoma, intrapelvic lymph nodes
C83.87	Other non-follicular lymphoma, spleen

C83.88	Other non-follicular lymphoma, lymph nodes of multiple sites
C83.89	Other non-follicular lymphoma, extranodal and solid organ sites
C83.90	Non-follicular (diffuse) lymphoma, 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
C85.10	Unspecified B-cell lymphoma, unspecified site
C85.11	Unspecified B-cell lymphoma, lymph nodes of head, face, and neck
C85.12	Unspecified B-cell lymphoma, intrathoracic lymph nodes
C85.13	Unspecified B-cell lymphoma, intra-abdominal lymph nodes
C85.14	Unspecified B-cell lymphoma, lymph nodes of axilla and upper limb
C85.15	Unspecified B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.16	Unspecified B-cell lymphoma, intrapelvic lymph nodes
C85.17	Unspecified B-cell lymphoma, spleen
C85.18	Unspecified B-cell lymphoma, lymph nodes of multiple sites
C85.19	Unspecified B-cell 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
C85.80	Other specified types of non-Hodgkin lymphoma, unspecified site

C85.81	Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face and neck
C85.82	Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes
C85.83	Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes
C85.84	Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb
C85.85	Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region of lower limb
C85.86	Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes
C85.87	Other specified types of non-Hodgkin lymphoma, spleen
C85.88	Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA

<b>Medicare Part B Administrative Contractor (MAC) Jurisdictions</b>		
<b>Jurisdiction</b>	<b>Applicable State/US Territory</b>	<b>Contractor</b>
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC