



Breyanzi® (lisocabtagene maraleucel) (Intravenous)

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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 ¹

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. Medical records may be submitted 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 † ‡ ◻ 1,7,11,16,17,18e

- Patient has diffuse large B cell lymphoma (DLBCL), high-grade B-cell lymphoma, primary mediastinal B-cell lymphoma (PMBCL), or follicular lymphoma (FL) grade 3b; **AND**
 - Patient received previous treatment with an anthracycline and anti-CD20 agent; **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 as second-line therapy for relapsed or refractory disease >12 months after completion of first-line therapy if no intention to proceed to transplant; **AND**
 - Patient is not eligible for HSCT due to one of the following: age \geq 70 years, adjusted diffusing capacity of the lung for carbon monoxide (DLCO) \leq 60%, LVEF < 50%, CrCl < 60 mL/min, AST or ALT > 2 \times ULN, or ECOG 2; **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 treatment of disease that is in second or greater relapse in patients with partial response, no response, or progressive disease following therapy for relapsed or refractory disease; **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, including an anti-CD20 agent and an alkylating agent; **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.), an anti-CD20 agent, and an alkylating agent; **OR**
- Patient has histologic transformation of an indolent lymphoma (follicular lymphoma or marginal zone lymphoma) to DLBCL; **AND**
 - Patient received previous treatment with an anthracycline and anti-CD20 agent; **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; **AND**
 - Patient is not eligible for HSCT due to one of the following: age ≥ 70 years, adjusted diffusing capacity of the lung for carbon monoxide (DLCO) $\leq 60\%$, LVEF $< 50\%$, CrCl $< 60\text{mL/min}$, AST or ALT $> 2 \times \text{ULN}$, or ECOG 2; **OR**
 - Patient received at least two (2) prior lines of chemoimmunotherapy for indolent or transformed disease

Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (CLL/SLL) † Φ 1,7,8

- Used for relapsed or refractory disease; **AND**
- Patient has received 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.); **AND**
 - Patient has high-risk features defined as having complex cytogenetic abnormalities (>3 chromosomal abnormalities), del (17p), mutated TP53, or unmutated immunoglobulin heavy-chain variable region **AND** failed ≥ 2 prior lines of therapy; **OR**
 - Patient has standard-risk features **AND** has failed ≥ 3 prior lines of therapy

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

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

IV. Renewal Criteria ¹

Coverage cannot be renewed.

V. Dosage/Administration ¹

Indication	Dose
B-Cell Lymphomas	<p><u>Lymphodepleting chemotherapy:</u></p> <ul style="list-style-type: none"> Administer cyclophosphamide 300 mg/m² and fludarabine 30 mg/m² intravenously daily for three days. <p><u>Breyanzi infusion for relapsed/refractory disease after receiving at least ONE line of therapy:</u></p> <ul style="list-style-type: none"> Infuse 2 to 7 days after completion of lymphodepleting chemotherapy. A single dose of Breyanzi contains 90 to 110 × 10⁶ 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. <p><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></p> <ul style="list-style-type: none"> Infuse 2 to 7 days after completion of lymphodepleting chemotherapy. A single dose of Breyanzi contains 90 to 110 × 10⁶ 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. <p><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></p> <ul style="list-style-type: none"> Infuse 2 to 7 days after completion of lymphodepleting chemotherapy. A single dose of Breyanzi contains 50 to 110 × 10⁶ 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.
CLL/SLL	<p><u>Lymphodepleting chemotherapy:</u></p> <ul style="list-style-type: none"> Administer cyclophosphamide 300 mg/m² and fludarabine 30 mg/m² intravenously daily for three days. <p><u>Breyanzi infusion for relapsed/refractory disease after receiving at least TWO lines of therapy:</u></p> <ul style="list-style-type: none"> Infuse 2 to 7 days after completion of lymphodepleting chemotherapy. A single dose of Breyanzi contains 90 to 110 × 10⁶ 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.
<p>For autologous use only. For intravenous use only.</p> <ul style="list-style-type: none"> Breyanzi is prepared from the patient's T-cells, which are obtained via a standard leukapheresis procedure One treatment course consists of lymphodepleting chemotherapy followed by a single infusion of Breyanzi. Confirm Breyanzi availability prior to starting the lymphodepleting regimen. 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. 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). 	
<p><u>Premedication:</u></p>	

- 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.

Monitoring after infusion:

- 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.
- Instruct patients to remain within proximity of the certified healthcare facility for at least 4 weeks following infusion.
- Instruct patients to refrain from driving or hazardous activities for 8 weeks following infusion.
- Store vials in the vapor phase of liquid nitrogen (less than or equal to minus 130°C). Thaw prior to infusion.
- In case of manufacturing failure, a second manufacturing may be attempted.
- Additional bridging chemotherapy (not the lymphodepletion) may be necessary while the patient awaits the product.
- Ensure that 2 doses of tocilizumab and emergency equipment are available prior to infusion and during the recovery period.
- 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.

VI. Billing Code/Availability Information

HCPSC 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 6.9×10^6 and 322×10^6 CAR-positive viable T cells in 4.6 mL cell suspension (between 1.5×10^6 and 70×10^6 CAR-positive viable T cells/mL)]: 73153-0900-xx

VII. References (STANDARD)

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*. 20177; 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,

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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 April 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 1.2024. 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 April 2024.
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, 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 April 2024.
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>.

VIII. References (ENHANCED)

- 1e. Schuster SJ, Bishop MR, Tam CS, et al. Tisagenlecleucel in Adult Relapsed or Refractory Diffuse Large B-Cell Lymphoma. *N Engl J Med* 2019;380:45-56.
- 2e. Neelapu SS, Locke FL, Bartlett NL, et al. Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma. *N Engl J Med*. 2017;377(26):2531-2544. doi:10.1056/NEJMoa1707447.
- 3e. Caimi PF, Ai WZ, Alderuccio JP, et al. Loncastuximab tesirine in relapsed or refractory diffuse large B-cell lymphoma (LOTIS-2): a multicentre, open-label, single-arm, phase 2 trial. *Lancet Oncol* 2021;22:790-800.
- 4e. Kalakonda N, Maerevoet M, Cavallo F, et al. Selinexor in patients with relapsed or refractory diffuse large B-cell lymphoma (SADAL): a single-arm, multinational, multicentre, open-label, phase 2 trial. *Lancet Haematol*. 2020 Jul;7(7):e511-e522. doi: 10.1016/S2352-3026(20)30120-4.
- 5e. Salles G, Duell J, González Barca E, et al. Tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicentre, prospective, single-arm, phase 2 study. *Lancet Oncol*. 2020 Jul;21(7):978-988. doi: 10.1016/S1470-2045(20)30225-4.
- 6e. Locke FL, Miklos DB, Jacobson CA, et al. Axicabtagene Ciloleucel as Second-Line Therapy for Large B-Cell Lymphoma. *N Engl J Med*. 2022 Feb 17;386(7):640-654.
- 7e. Sehn LH, Herrera AF, Flowers CR, et al. Polatuzumab Vedotin in Relapsed or Refractory Diffuse Large B-Cell Lymphoma. *J Clin Oncol*. 2020 Jan 10;38(2):155-165.
- 8e. Mounier N, El Gnaoui T, Tilly H, et al. Rituximab plus gemcitabine and oxaliplatin in patients with refractory/relapsed diffuse large B-cell lymphoma who are not candidates for high-dose therapy. A phase II Lymphoma Study Association trial. *Haematologica*. 2013 Nov;98(11):1726-31.
- 9e. Thieblemont C, Phillips T, Ghesquieres H, et al. Epcoritamab, a Novel, Subcutaneous CD3xCD20 Bispecific T-Cell-Engaging Antibody, in Relapsed or Refractory Large B-Cell Lymphoma: Dose Expansion in a Phase I/II Trial. *J Clin Oncol*. 2023 Apr 20;41(12):2238-2247.
- 10e. Dickinson MJ, Carlo-Stella C, Morschhauser F, et al. Glofitamab for Relapsed or Refractory Diffuse Large B-Cell Lymphoma. *N Engl J Med* 2022;387:22220-2231.

- 11e. Furman RR, Sharman JP, Coutre SE, et al. Idelalisib and Rituximab in Relapsed Chronic Lymphocytic Leukemia. New England Journal of Medicine. 2014;370(11):997-1007. doi:https://doi.org/10.1056/nejmoa1315226
- 12e. Flinn IW, Hillmen P, Montillo M, et al. The phase 3 DUO trial: duvelisib vs ofatumumab in relapsed and refractory CLL/SLL. Blood. 2018;132(23):2446-2455. doi:https://doi.org/10.1182/blood-2018-05-850461
- 13e. Badoux X, Keating MJ, Wen S, et al. Phase II Study of Lenalidomide and Rituximab As Salvage Therapy for Patients With Relapsed or Refractory Chronic Lymphocytic Leukemia. 2013;31(5):584-591. doi:https://doi.org/10.1200/jco.2012.42.8623
- 14e. Bowen DA, Call TG, G. Douglas Jenkins, et al. Methylprednisolone-rituximab is an effective salvage therapy for patients with relapsed chronic lymphocytic leukemia including those with unfavorable cytogenetic features. Leukemia & Lymphoma. 2007;48(12):2412-2417. doi:https://doi.org/10.1080/10428190701724801
- 15e. Robak T, Dmoszynska A, Solal-Céligny P, et al. Rituximab Plus Fludarabine and Cyclophosphamide Prolongs Progression-Free Survival Compared With Fludarabine and Cyclophosphamide Alone in Previously Treated Chronic Lymphocytic Leukemia. Journal of Clinical Oncology. 2010;28(10):1756-1765. doi:https://doi.org/10.1200/jco.2009.26.4556
- 16e. Cartron G, de Guibert S, Dilhuydy MS, et al. Obinutuzumab (GA101) in relapsed/refractory chronic lymphocytic leukemia: final data from the phase 1/2 GAUGUIN study. Blood. 2014;124(14):2196-2202. doi:https://doi.org/10.1182/blood-2014-07-586610
- 17e. Mato AR, Woyach JA, Brown JR, et al. Pirtobrutinib after a Covalent BTK Inhibitor in Chronic Lymphocytic Leukemia. 2023;389(1):33-44. doi:https://doi.org/10.1056/nejmoa2300696
- 18e. 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.
- 19e. Jacobson CA, Chavez JC, Sehgal AR, et al. Interim analysis of ZUMA-5: A phase II study of axicabtagene ciloleucel (axi-cel) in patients (pts) with relapsed/refractory indolent non-Hodgkin lymphoma (R/R iNHL). Journal of Clinical Oncology 2020 38:15_suppl, 8008-8008.
- 20e. Fowler NH, Dickinson M, Dreyling M, et al. Tisagenlecleucel in adult relapsed or refractory follicular lymphoma: the phase 2 ELARA trial. Nat Med. 2022 Feb;28(2):325-332. doi: 10.1038/s41591-021-01622-0.
- 21e. Magellan Rx Management. Breyanzi Clinical Literature Review Analysis. Last updated May 2024. Accessed May 2024.

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
C83.10	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
C83.90	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

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
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