

## Kymriah® (tisagenlecleucel) (Intravenous)

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### I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for one treatment course (1 dose).
- Renewal: Prior authorization validity may NOT be renewed.

### II. Dosing Limits

**Max Units (per dose and over time) [HCPCS Unit]:**

- 1 billable unit (1 infusion of up to 600 million CAR-positive viable T-cells)

### III. Initial Approval Criteria <sup>1,4-7</sup>

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. 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. Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity is provided in the following conditions:

- Patient does not have an active 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 tisagenlecleucel 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 local guidelines; **AND**
- Patient has not received prior chimeric antigen receptor (CAR)-T cell therapy; **AND**
- Patient has not received other anti-CD19 therapy (e.g., blinatumomab, tafasitamab, 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**

**Adult B-Cell Precursor Acute Lymphoblastic Leukemia (ALL) † Φ<sup>1,8,10-13,18</sup>**

- Patient is 18 to 25 years of age; **AND**
  - Patient has Philadelphia chromosome (Ph)-positive disease; **AND**
    - Disease is refractory or in second or later relapse; **AND**
    - Used following therapy that has included two (2) tyrosine kinase inhibitors (i.e., dasatinib, imatinib, ponatinib, nilotinib, or bosutinib); **OR**
  - Patient has Philadelphia chromosome (Ph)-negative disease; **AND**
    - Disease is refractory or in second or later relapse

**Pediatric B-Cell Precursor Acute Lymphoblastic Leukemia (ALL) † ‡ Φ<sup>1,8,10-13,18</sup>**

- Patient is 2 to 17 years of age; **AND**
  - Patient has BCR::ABL1-positive disease; **AND**
    - Disease is intolerant or refractory to at least two (2) tyrosine kinase inhibitors (i.e., dasatinib, imatinib, etc.); **OR**
    - Patient has relapsed disease post-hematopoietic stem cell transplant (HSCT); **OR**
  - Patient has BCR::ABL1-negative disease; **AND**
    - Disease is refractory or in second or later relapse

**B-Cell Lymphomas † ‡ Φ<sup>1,3,8,9,14-17</sup>**

- Patient is at least 18 years of age; **AND**
- Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1; **AND**
- Patient does not have primary central nervous system lymphoma; **AND**
  - Patient has follicular lymphoma (grade 1, 2, or 3A); **AND**
    - Patient has received at least two (2) prior lines of systemic therapy which must have included an anti-CD20 antibody and an alkylating agent, unless contraindicated; **AND**
    - Patient has had partial or no response OR has relapsed, refractory, or progressive disease; **OR**

- Patient has histologic transformation of an indolent lymphoma (follicular lymphoma or marginal zone lymphoma) to diffuse large B-cell lymphoma (DLBCL) OR Richter’s transformation of Chronic Lymphocytic Leukemia (CLL) to DLBCL; **AND**
  - Patient has received at least two (2) prior lines of chemoimmunotherapy for indolent disease prior to histologic transformation which must have included an anthracycline and rituximab, unless contraindicated; **OR**
- Patient has DLBCL, high-grade B-cell lymphoma, HIV-related B-cell lymphoma (i.e., HIV-related DLBCL or HHV8-positive DLBCL, not otherwise specified), or monomorphic post-transplant lymphoproliferative disorder (B-cell type); **AND**
  - Patient has received at least two (2) prior lines of therapy which must have included an anthracycline and rituximab, unless contraindicated; **AND**
    - Used as additional therapy for relapsed disease >12 months after completion of first-line therapy if partial response following second-line therapy; **OR**
    - Used for treatment of disease that is in second or greater relapse in patients with partial response, relapse, or progressive disease following therapy for relapsed or refractory disease

**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.**

**Enhanced Oncology Value (EOV) Program – Redacted indications**

Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity.

Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

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

## IV. Renewal Criteria

Duration of authorization has not been exceeded (*refer to Section I*)

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

| Indication   | Dose   |
|--|--|
| B-Cell<br>Precursor ALL  | <p><b><u>Lymphodepleting chemotherapy:</u></b></p> <ul style="list-style-type: none"> <li>Administer fludarabine (30 mg/m<sup>2</sup> intravenously daily for 4 days) and cyclophosphamide (500 mg/m<sup>2</sup> intravenously daily for 2 days starting with the first dose of fludarabine).</li> </ul> <p><b><u>Kymriah infusion:</u></b></p> <ul style="list-style-type: none"> <li>Infuse 2 to 14 days after completion of lymphodepleting chemotherapy</li> <li>Kymriah is provided in a single-dose unit containing chimeric antigen receptor (CAR)-positive viable T cells* based on the patient weight reported at the time of leukapheresis:               <ul style="list-style-type: none"> <li>Patients ≤ 50 kg: administer 0.2 to 5.0 x 10<sup>6</sup> CAR-positive viable T cells per kg body weight</li> <li>Patients &gt; 50 kg: administer 0.1 to 2.5 x 10<sup>8</sup> CAR-positive viable T cells</li> </ul> </li> </ul>   |
| B-Cell<br>Lymphomas  | <p><b><u>Lymphodepleting chemotherapy (<i>lymphodepleting chemotherapy may be omitted if a patient's white blood cell [WBC] count is less than 1 x 10<sup>9</sup>/L within 1 week prior to Kymriah infusion</i>):</u></b></p> <ul style="list-style-type: none"> <li>Administer fludarabine (25 mg/m<sup>2</sup> intravenously daily for 3 days) and cyclophosphamide (250 mg/m<sup>2</sup> intravenously daily for 3 days starting with the first dose of fludarabine); <b>OR</b></li> <li>Administer bendamustine (90 mg/m<sup>2</sup> intravenously daily for 2 days) if the patient experienced a previous Grade 4 hemorrhagic cystitis with cyclophosphamide or demonstrates resistance to a previous cyclophosphamide containing regimen</li> </ul> <p><b><u>Kymriah infusion:</u></b></p> <ul style="list-style-type: none"> <li>Follicular Lymphoma: Infuse 2 to 6 days after completion of lymphodepleting chemotherapy.</li> <li>All other B-Cell Lymphomas: Infuse 2 to 11 days after completion of lymphodepleting chemotherapy</li> <li>Kymriah is provided in a single-dose unit containing chimeric antigen receptor (CAR)-positive viable T cells* based on the patient weight reported at the time of leukapheresis:               <ul style="list-style-type: none"> <li>Administer 0.6 to 6.0 x 10<sup>8</sup> CAR-positive viable T cells</li> </ul> </li> </ul> |
| <p><b>For autologous use only. For intravenous use only.</b></p> <ul style="list-style-type: none"> <li>Kymriah is prepared from the patient's peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure</li> <li>One treatment course consists of lymphodepleting chemotherapy followed by a single infusion of Kymriah</li> <li>Confirm Kymriah availability prior to starting the lymphodepleting regimen.</li> <li>Confirm the patient's identity with the patient identifiers on each KYMRIAH infusion bag(s).</li> <li>Delay the infusion of Kymriah after lymphodepleting chemotherapy for unresolved serious adverse reactions from preceding chemotherapies (including pulmonary toxicity, cardiac toxicity, or hypotension), active uncontrolled infection, active graft versus host disease (GVHD), or worsening of leukemia burden.</li> </ul> |  |
| <p><b><u>Premedication:</u></b></p> <ul style="list-style-type: none"> <li>Premedicate with acetaminophen and diphenhydramine (or another H1-antihistamine) 30-60 minutes prior to infusion. Avoid prophylactic system corticosteroids which may interfere with Kymriah activity.</li> </ul>   |  |
| <p><b><u>Monitoring after infusion:</u></b></p>  |  |

- Monitor patients daily during the first week following KYMRIAH infusion for signs and symptoms of cytokine release syndrome (CRS) and neurologic toxicities.
  - Instruct patients to remain within proximity of a healthcare facility for at least 2 weeks following infusion.
  - Instruct patients to refrain from driving for at least 2 weeks following infusion.
- \*See the Certificate of Analysis (CoA) for the actual number of chimeric antigen receptor (CAR)-positive T cells in the product.
  - Store infusion bag(s) in the vapor phase of liquid nitrogen (less than or equal to minus 120°C) in a temperature-monitored system. Thaw prior to infusion.
  - In case of manufacturing failure, a second manufacturing may be attempted.
  - Additional bridging chemotherapy may be necessary between leukapheresis and lymphodepleting chemotherapy.
  - Tocilizumab must be available on site prior to infusion if needed for the treatment of CRS (2 doses minimum)
  - Biosafety guidelines must be followed. Product contains human cells genetically modified with a lentivirus. Employ universal precautions when handling.

## VI. Billing Code/Availability Information

### HCPCS Code:

- Q2042 – Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

### NDC(s):

- Kymriah suspension for intravenous infusion (Ped ALL); 1 infusion bag (10 to 50 mL): 00078-0846-xx
- Kymriah suspension for intravenous infusion (DLBCL and FL); 1 infusion bag (10 to 50 mL): 00078-0958-xx

## VII. References (STANDARD)

1. Kymriah [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corp., June 2025. Accessed November 2025.
2. Porter DL, Hwang WT, Frey NV, et al. Chimeric antigen receptor T cells persist and induce sustained remissions in relapsed refractory chronic lymphocytic leukemia. *Sci Transl Med.* 2015 Sep 2;7(303):303ra139. doi: 10.1126/scitranslmed.aac5415.
3. Schuster S, Bishop MR, Constantine T, et al. Global Pivotal Phase 2 Trial of the CD19-Targeted Therapy CTL019 In Adult Patients with Relapsed or Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL)—An Interim Analysis. *Clinical Lymphoma, Myeloma and Leukemia, Volume 17, S373 - S374.*
4. 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
5. 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.

6. 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.
7. Majzner RG, Mackall CL. Tumor Antigen Escape from CAR T-cell Therapy. *Cancer Discov* 2018;8:1219-1226.
8. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) tisagenlecleucel. National Comprehensive Cancer Network, 2025. 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 November 2025.
9. Schuster SJ, Bishop MR, Tam CS, et al; JULIET Investigators. Tisagenlecleucel in adult relapsed or refractory diffuse large B-cell lymphoma. *N Engl J Med*. 2019;380(1):45-56. doi:10.1056/NEJMoa1804980.
10. Lee DW, Kochenderfer JN, Stetler-Stevenson M, et al. T cells expressing CD19 chimeric antigen receptors for acute lymphoblastic leukaemia in children and young adults: a phase 1 dose-escalation trial. *Lancet*. 2015;385(9967):517-528.
11. Maude SL, Frey N, Shaw PA, et al. Chimeric antigen receptor T cells for sustained remissions in leukemia. *N Engl J Med*. 2014;371(16):1507-1517.
12. Maude SL, Laetsch TW, Buechner J, et al. Tisagenlecleucel in Children and Young Adults with B-Cell Lymphoblastic Leukemia. *N Engl J Med*. 2018;378(5):439-448.
13. Fitzgerald JC, Weiss SL, Maude SL, et al. Cytokine release syndrome after chimeric antigen receptor T cell therapy for acute lymphoblastic leukemia. *Crit Care Med*. 2017;45(2):e124-e131.
14. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version 1.2026. National Comprehensive Cancer Network, 2025. 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 November 2025.
15. 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.
16. Thudium Mueller K, Grupp SA, Maude SL, et al. Tisagenlecleucel immunogenicity in relapsed/refractory acute lymphoblastic leukemia and diffuse large B-cell lymphoma. *Blood Adv*. 2021 Dec 14;5(23):4980-4991. doi: 10.1182/bloodadvances.2020003844.
17. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas Version 3.2025. National Comprehensive Cancer Network, 2025. 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 November 2025.

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## VIII. References (ENHANCED)

- 1e. Kantarjian H, Stein A, Gökbüget N, et al. Blinatumomab versus Chemotherapy for Advanced Acute Lymphoblastic Leukemia. *N Engl J Med* 2017; 376:836-847.
- 2e. Kantarjian HM, DeAngelo DJ, Stelljes M, et al. Inotuzumab Ozogamicin versus Standard Therapy for Acute Lymphoblastic Leukemia. *N Engl J Med*. 2016;375(8):740–753.
- 3e. Neelapu S, Locke F, Bartlett N, et al. Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma. *N Engl J Med* 2017; 377:2531-2544.
- 4e. 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.
- 5e. 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.
- 6e. 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.
- 7e. 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.
- 8e. Shah BD, Ghobadi A, Oluwole OO, et al. KTE-X19 for relapsed or refractory adult B-cell acute lymphoblastic leukaemia: phase 2 results of the single-arm, open-label, multicentre ZUMA-3 study. *Lancet*. 2021 Aug 7;398(10299):491-502. doi: 10.1016/S0140-6736(21)01222-8. Epub 2021 Jun 4.
- 9e. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Pediatric Acute Lymphoblastic Leukemia, Version 1.2026. National Comprehensive Cancer Network, 2025. 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 NCCN Guidelines, go online to NCCN.org. Accessed October 2025.

- 10e. Martinelli G, Boissel N, Chevallier P, et al. Complete Hematologic and Molecular Response in Adult Patients With Relapsed/Refractory Philadelphia Chromosome-Positive B-Precursor Acute Lymphoblastic Leukemia Following Treatment With Blinatumomab: Results From a Phase II, Single-Arm, Multicenter Study. *J Clin Oncol*. 2017 Jun 1;35(16):1795-1802. doi: 10.1200/JCO.2016.69.3531. Epub 2017 Mar 29.
- 11e. Salles G, Schuster SJ, Dreyling M, et al. Efficacy comparison of tisagenlecleucel vs usual care in patients with relapsed or refractory follicular lymphoma. *Blood Adv*. 2022 Nov 22;6(22):5835-5843.
- 12e. 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.
- 13e. 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.
- 14e. 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.
- 15e. Dreyling, M., Santoro, A., Mollica, L., et al. (2017) COPANLISIB IN PATIENTS WITH RELAPSED OR REFRACTORY INDOLENT B-CELL LYMPHOMA (CHRONOS-1). *Hematological Oncology*, 35(S2): 119–120. doi: 10.1002/hon.2437\_107.
- 16e. Morschhauser F, Tilly H, Chaidos A, et al. Tazemetostat for patients with relapsed or refractory follicular lymphoma: an open-label, single-arm, multicentre, phase 2 trial. *Lancet Oncol* 2020;21:1433-1442.
- 17e. Bartlett NL, Sehn LH, Matasar MJ, et al. Mosunetuzumab Monotherapy Demonstrates Durable Efficacy with a Manageable Safety Profile in Patients with Relapsed/Refractory Follicular Lymphoma Who Received  $\geq 2$  Prior Therapies: Updated Results from a Pivotal Phase II Study [abstract]. *Blood* 2022;140:1467-1470.
- 18e. Laetsch TW, Maude SL, Rives S, et al. Three-Year Update of Tisagenlecleucel in Pediatric and Young Adult Patients With Relapsed/Refractory Acute Lymphoblastic Leukemia in the ELIANA Trial. *J Clin Oncol*. 2023;41(9):1664-1669.
- 19e. Roddie C, Sandhu KS, Tholouli E, et al. Obecabtagene Autoleucel in Adults with B-Cell Acute Lymphoblastic Leukemia. *N Engl J Med* 2024;391(23):2219-2230.
- 20e. Luskin MR, Murakami MA, Keating J, et al. Asciminib plus dasatinib and prednisone for Philadelphia chromosome-positive acute leukemia. *Blood*. 2025;145(6):577-589.
- 21e. 1.Thieblemont C, Dreyling M, Dickinson MJ, et al. Clinical Outcomes of Patients with High-Risk Relapsed/Refractory Follicular Lymphoma Treated with Tisagenlecleucel: Phase 2 ELARA 4-Year

Update. Blood. 2024;144(Supplement 1):3034-3034. doi:<https://doi.org/10.1182/blood-2024-201730>.

22e. Landsburg DJ, Frigault MJ, Heim M, Foley SR, Hill B, Schofield G, et al. Real-world outcomes with tisagenlecleucel in aggressive B-cell lymphoma: subgroup analyses from the CIBMTR registry. Journal for ImmunoTherapy of Cancer. 2025;13:e009890.

23e. Prime Therapeutics Management. Kymriah Clinical Literature Review Analysis. Last updated November 2025. Accessed November 2025.

## Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime’s assessment led to for each.

| Factor                     | Conclusion            |
|----------------------------|-----------------------|
| Indication                 | Yes: Consider for PA  |
| Safety and efficacy        | Yes: Consider for PA  |
| Potential for misuse/abuse | No: PA not a priority |
| Cost of drug               | Yes: Consider for PA  |

## 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  |

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| 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                   |
| C83.30  | 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                 |
| C83.398 | Diffuse large B-cell lymphoma of other extranodal and solid organ sites        |

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| C83.50 | Lymphoblastic (diffuse) lymphoma, unspecified site                                       |
| C83.51 | Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck                    |
| C83.52 | Lymphoblastic (diffuse) lymphoma, intrathoracic lymph nodes                              |
| C83.53 | Lymphoblastic (diffuse) lymphoma, intra-abdominal lymph nodes                            |
| C83.54 | Lymphoblastic (diffuse) lymphoma, lymph nodes of axilla and upper limb                   |
| C83.55 | Lymphoblastic (diffuse) lymphoma, lymph nodes of inguinal region and lower limb          |
| C83.56 | Lymphoblastic (diffuse) lymphoma, intrapelvic lymph nodes                                |
| C83.57 | Lymphoblastic (diffuse) lymphoma, spleen   |
| C83.58 | Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites                          |
| C83.59 | Lymphoblastic (diffuse) lymphoma, 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                 |

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| 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             |
| C91.00 | Acute lymphoblastic leukemia not having achieved remission                                  |
| C91.01 | Acute lymphoblastic leukemia, in remission  |
| C91.02 | Acute lymphoblastic leukemia, in relapse  |
| 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/LCD/LCA): 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                                      |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |   |  |
|---|---|--|
| Jurisdiction  | Applicable State/US Territory   | Contractor                               |
| 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                  |