

## Kymriah® (tisagenlecleucel) (Intravenous)

Document Number: IC-0319

Last Review Date: 10/24/2022

Date of Origin: 09/19/2017

Dates Reviewed: 09/2017, 06/2018, 11/2018, 10/2019, 12/2019, 11/2020, 11/2021, 07/2022, 11/2022

### I. Length of Authorization

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

### II. Dosing Limits

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

- 1 infusion bag of up to 600 million CAR-positive viable T-cells

#### B. 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 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 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**

- Healthcare facility has enrolled in the Kymriah REMS Program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
- Patient has not received prior CAR-T therapy; **AND**
- Patient has not received prior anti-CD19 therapy, (e.g., blinatumomab, etc.) OR patient previously received 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 1,8,10-13**

- Patient is 18 to 25 years of age; **AND**
- Patient has a performance status (Karnofsky/Lansky)  $\geq 50$ ; **AND**
  - Patient has Philadelphia chromosome (Ph)-positive disease; **AND**
    - Patient has refractory disease; **OR**
    - Disease is in second or greater relapse with failure of two (2) tyrosine kinase inhibitors (e.g., dasatinib, imatinib, ponatinib, nilotinib, bosutinib, etc.); **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 1,8,10-13**

- Patient is 2 to 17 years of age; **AND**
- Patient has a performance status (Karnofsky/Lansky)  $\geq 50$ ; **AND**
  - Patient has Philadelphia chromosome (Ph)-positive disease; **AND**
    - Disease is tyrosine kinase inhibitor (TKI) intolerant or refractory; **OR**
    - Patient has relapsed disease post-hematopoietic stem cell transplant (HSCT); **OR**
  - Patient has Philadelphia chromosome (Ph)-negative disease; **AND**
    - Disease is refractory or in second or later relapse

#### **B-Cell Lymphomas † ‡ Φ 1,3,8,9,14-16**

- Patient is at least 18 years of age; **AND**
- Patient has not received prior allogeneic hematopoietic stem cell transplantation (HSCT); **AND**
- Patient has an 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; **AND**
    - Patient has had partial or no response OR has relapsed, refractory, or progressive disease; **OR**

- Patient has histologic transformation of follicular lymphoma or nodal marginal zone lymphoma to diffuse large B-cell lymphoma (DLBCL) OR Richter's transformation of CLL to DLBCL; **AND**
  - Patient has received at least two (2) prior lines of chemoimmunotherapy which must have included an anthracycline or anthracenedione-based regimen, unless contraindicated; **OR**
- Patient has diffuse large B-cell lymphoma, AIDS-related B-cell lymphoma (e.g., diffuse large B-cell lymphoma, primary effusion lymphoma, and HHV8-positive diffuse large B-cell lymphoma, not otherwise specified), high-grade B-cell lymphomas, or monomorphic post-transplant lymphoproliferative disorder (B-cell type); **AND**
  - Patient has received at least two (2) prior lines of therapy; **AND**
    - Used as additional therapy for relapsed or refractory disease >12 months after completion of first-line therapy in patients with intention to proceed to transplant who have a partial response following second-line therapy (*Note: Intention to proceed to transplant does NOT apply to monomorphic post-transplant lymphoproliferative disorder*); **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

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s); Ⓢ Orphan Drug

#### IV. Renewal Criteria

Coverage cannot be renewed.

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

| Indication           | Dose                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| B-Cell 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> intravenous daily for 4 days) and cyclophosphamide (500 mg/m<sup>2</sup> intravenous 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 Lymphomas     | <p><b><u>Lymphodepleting chemotherapy (<i>lymphodepleting chemotherapy may be omitted if a patient's white blood cell [WBC] count is less than or equal to 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> intravenous daily for 3 days) and cyclophosphamide (250 mg/m<sup>2</sup> intravenous daily for 3 days starting with the first dose of fludarabine);<br/><b>OR</b></li> <li>Administer bendamustine (90 mg/m<sup>2</sup> intravenous 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 KYMRIA H 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> <ul style="list-style-type: none"> <li>Monitor patients 2-3 times during the first week following KYMRIA H infusion at the certified healthcare facility 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 at least 8 weeks following infusion.</li> </ul>                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <ul style="list-style-type: none"> <li>*See the Certificate of Analysis (CoA) for the actual number of chimeric antigen receptor (CAR)-positive T cells in the product.</li> <li>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.</li> <li>In case of manufacturing failure, a second manufacturing may be attempted.</li> <li>Additional bridging chemotherapy may be necessary between leukapheresis and lymphodepleting chemotherapy.</li> <li>Tocilizumab must be available on site prior to infusion if needed for the treatment of CRS (2 doses minimum)</li> <li>Biosafety guidelines must be followed. Product contains human cells genetically modified with a lentivirus. Employ universal precautions when handling.</li> </ul>                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

## VI. Billing Code/Availability Information

### HCP CS 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

1. Kymriah [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corp., May 2022. Accessed October 2022.
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, 2022. 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 October 2022.
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 1.2023. National Comprehensive Cancer Network, 2022. 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 2022.
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.

## 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                     |

### KYMRIA® (tisagenlecleucel) Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2022, Magellan Rx Management



|        |                                                                                           |
|--------|-------------------------------------------------------------------------------------------|
| 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                    |
| C83.30 | 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                  |
| C83.50 | 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              |
| 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             |
| C91.00 | 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)

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered 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.                 |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |                                                                                             |                                          |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------|------------------------------------------|
| Jurisdiction                                                  | Applicable State/US Territory                                                               | Contractor                               |
| J (10)                                                        | TN, GA, AL                                                                                  | Palmetto GBA, LLC                        |
| M (11)                                                        | NC, SC, WV, VA (excluding below)                                                            | Palmetto GBA, LLC                        |
| 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                  |

## Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provide free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact us at the phone number shown on the inside cover of this contract, your id card, or [aspirushealthplan.com](http://aspirushealthplan.com).

If you believe that we have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, you can file a grievance with:

Nondiscrimination Grievance Coordinator  
Aspirus Health Plan, Inc.  
PO Box 1062  
Minneapolis, MN 55440  
Phone: 1.866.631.5404 (TTY: 711)  
Fax: 763.847.4010  
Email: [customerservice@aspirushealthplan.com](mailto:customerservice@aspirushealthplan.com)

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

## Language Assistance Services

**Albanian:** KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

**Arabic:** تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلی رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

**French:** ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

**German:** ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

**Hindi:** \_यान द\_ : य\_द आप िहंदी बोलते ह\_ तो आपके िलए मु\_त म\_ भाषा सहायता सेवाएं उपल\_ध ह\_। 1.866.631.5404 (TTY: 711) पर कॉल कर\_।

**Hmong:** LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

**Korean:** 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

**Polish:** UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

**Russian:** ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

**Spanish:** ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

**Tagalog:** PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

**Traditional Chinese:** 注意: 如果您使用繁體中文, 您可以免費獲得語言援助服務。請致電 1.866.631.5404 (TTY: 711)。

**Vietnamese:** CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

**Pennsylvania Dutch:** Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

**Lao:** ໄປດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY: 711).