



Gazyva® (obinutuzumab) (Intravenous)

Document Number: IC-0184

Last Review Date: 06/01/2023

Date of Origin: 01/02/2014

Dates Reviewed: 08/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 03/2016, 05/2016, 08/2016, 11/2016, 02/2017, 05/2017, 08/2017, 11/2017, 02/2018, 05/2018, 09/2018, 12/2018, 03/2019, 06/2019, 09/2019, 12/2019, 03/2020, 06/2020, 09/2020, 12/2020, 03/2021, 06/2021, 09/2021, 12/2021, 03/2022, 06/2022, 09/2022, 12/2022, 03/2023, 06/2023

I. Length of Authorization ^{1,7-13}

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL):

- Combination therapy is limited to six (6) 28-day cycles and may NOT be renewed.
- Single-agent therapy is limited to eight (8) 21-day cycles and may NOT be renewed.

B-Cell Lymphomas:

- Coverage is provided for six (6) months and may be renewed for up to a maximum of two (2) years of maintenance therapy.

Hairy Cell Leukemia:

- Combination therapy with vemurafenib is limited to three (3) 28-day cycles and may NOT be renewed.

II. Dosing Limits

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

- Gazyva 1000 mg/40 mL single-dose vial: 2 vials every 21 days (6 vials for the initial 21-day cycle only)

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

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL):

- Loading Dose: 10 billable units day 1, 90 billable units day 2, 100 billable units day 3, 200 billable units days 8 and 15 of Cycle 1 (21 days)
- Maintenance Dose: 200 billable units every 21 days

B-Cell Lymphomas:

- Loading Dose: 100 billable units x 3 weekly doses for Cycle 1 (21 days)

- Maintenance Dose: 100 billable units every 21 days for 8 cycles; then every 2 months for 2 years

Hairy Cell Leukemia

- Cycle 2 (28-day cycle): 100 billable units x 3 weekly doses
- Cycles 3-4 (28-day cycle): 100 billable units every 28 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ¹

- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient has been screened for the presence of hepatitis B virus (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) † ‡ ◊ ^{1-3,14}

- Used as first-line therapy; **AND**
 - Used in combination with chlorambucil †; **OR**
 - Used in combination with acalabrutinib; **OR**
 - Used in combination with venetoclax; **OR**
 - Used as a single agent *[excluding use in patients without del(17p)/TP53 mutation who are <65 years of age without significant comorbidities (e.g., creatinine clearance <70 mL/min)]*; **OR**
 - Used in combination with bendamustine for disease without del(17p)/TP53 mutation *(excluding use in frail patients)*; **OR**
- Used as subsequent therapy; **AND**
 - Used for disease without del(17p)/TP53 mutation; **AND**
 - Used as a single agent (if not given as first-line therapy); **AND**
 - Used for relapsed or refractory disease after prior BTK inhibitor (e.g., ibrutinib, acalabrutinib, etc.)- and venetoclax-based regimens; **OR**
 - Used in combination with venetoclax (if previously used as first-line therapy); **AND**
 - Used as retreatment for relapsed disease after a period of remission

B-Cell Lymphomas † ‡ ^{1,2,4-6,15}

- Follicular Lymphoma (Grade 1-2) † ◊

- Used as first-line therapy; **AND**
 - Used in combination with chemotherapy [e.g., bendamustine or CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or CVP (cyclophosphamide, vincristine, prednisone)]; **OR**
- Used as subsequent therapy for no response, relapsed, refractory, or progressive disease (if not previously given); **AND**
 - Used in combination with chemotherapy [e.g., bendamustine or CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or CVP (cyclophosphamide, vincristine, prednisone)]; **OR**
 - Used as a single agent; **OR**
 - Used in combination with lenalidomide; **OR**
- Used as a single agent for maintenance therapy; **AND**
 - Used as first-line consolidation therapy or extended dosing following chemoimmunotherapy; **OR**
 - Used as second-line consolidation therapy or extended dosing for rituximab-refractory disease; **OR**
- Used as a substitute for rituximab in patients with intolerance (including those experiencing severe hypersensitivity reactions requiring discontinuation of rituximab) or experiencing rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis
- Extranodal Marginal Zone Lymphoma (of Non-Gastric Sites [Non-Cutaneous] or of the Stomach) or Marginal Zone Lymphoma (Splenic or Nodal) ‡
 - Used as first-line therapy (*Nodal Marginal Zone Lymphoma only*); **AND**
 - Used in combination with chemotherapy [e.g., bendamustine or CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or CVP (cyclophosphamide, vincristine, prednisone)]; **OR**
 - Used in combination with bendamustine (if not previously treated with bendamustine) or lenalidomide; **AND**
 - Used as second-line therapy for disease recurrence following initial management of splenomegaly with rituximab (*Splenic Marginal Zone Lymphoma only*); **OR**
 - Used as subsequent therapy for relapsed, refractory, or progressive disease (*Extranodal Marginal Zone Lymphoma of Non-Gastric Sites [Non-Cutaneous] or of the Stomach and Nodal Marginal Zone Lymphoma only*); **OR**
 - Used as a single agent for maintenance therapy as second-line consolidation therapy or extended dosing in rituximab-refractory patients treated with obinutuzumab and bendamustine for recurrent disease; **OR**
 - Used as a substitute for rituximab in patients with intolerance (including those experiencing severe hypersensitivity reactions requiring discontinuation of rituximab) or experiencing rare complications such as mucocutaneous reactions including

paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis

- Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma, Mantle Cell Lymphoma, Diffuse Large B-Cell Lymphoma, High-Grade B-Cell Lymphomas, Burkitt Lymphoma, HIV-Related B-Cell Lymphomas, Post-Transplant Lymphoproliferative Disorders, or Castleman Disease †
 - Used as a substitute for rituximab in patients with intolerance (including those experiencing severe hypersensitivity reactions requiring discontinuation of rituximab) or experiencing rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis

Hairy Cell Leukemia †²

- Used as initial therapy; **AND**
- Used in combination with vemurafenib; **AND**
- Patient is unable to tolerate purine analogs including frail patients and those with active infection

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

IV. Renewal Criteria¹

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe neutropenia/febrile neutropenia, severe thrombocytopenia, severe infusion-related reactions, hypersensitivity reactions including serum sickness, tumor lysis syndrome (TLS), serious infections (bacterial, fungal, or viral), disseminated intravascular coagulation (DIC), etc.; **AND**
- Patient has been evaluated for the presence of progressive multifocal leukoencephalopathy (PML) and has been found to be negative; **AND**

CLL/SLL

- Coverage may NOT be renewed

B-Cell Lymphomas (maintenance treatment)

- Patient has not exceeded a maximum of two (2) years of therapy

Hairy Cell Leukemia

- Coverage may NOT be renewed

V. Dosage/Administration ^{1,7-13}

Indication	Dose
CLL/SLL	<p><u>Combination therapy:</u></p> <ul style="list-style-type: none"> • Cycle 1 (28-day cycle): 100 mg day 1, 900 mg day 2, then 1000 mg days 8 and 15 • Cycles 2-6 (28-day cycle): 1000 mg on day 1 <p><u>Monotherapy:</u></p> <ul style="list-style-type: none"> • Cycle 1 (21-day cycle): 100 mg day 1, 900 mg day 2, then 1000 mg days 8 and 15 • Cycles 2-8 (21-day cycle): 1000 mg on day 1 <p>-OR-</p> <ul style="list-style-type: none"> • Cycle 1 (21-day cycle): 100mg day 1, 900 mg day 2, 1000 mg day 3, 2000 mg days 8 and 15 • Cycles 2-8 (21-day cycle): 2000 mg on day 1
B-Cell Lymphomas	<p><u>Initial combination therapy with chemotherapy:</u></p> <ul style="list-style-type: none"> • Combination chemotherapy with bendamustine: <ul style="list-style-type: none"> ○ Cycle 1 (28-day cycle): 1000 mg days 1, 8, and 15 ○ Cycles 2-6 (28-day cycle): 1000 mg day 1 • Combination chemotherapy with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), followed by 2 additional 21-day cycles of Gazyva alone <ul style="list-style-type: none"> ○ Cycle 1 (21-day cycle): 1000 mg days 1, 8, and 15 ○ Cycles 2-6 (21-day cycle): 1000 mg day 1 • Combination chemotherapy with CVP (cyclophosphamide, vincristine, prednisone) <ul style="list-style-type: none"> ○ Cycle 1 (21-day cycle): 1000 mg days 1, 8, and 15 ○ Cycles 2-8 (21-day cycle): 1000 mg day 1 <p><u>Initial combination therapy with lenalidomide:</u></p> <ul style="list-style-type: none"> • Cycle 1 (28-day cycle): 1000 mg days 8, 15, and 22 • Cycles 2-6 (28-day cycle): 1000 mg day 1 <p><u>Initial monotherapy:</u></p> <ul style="list-style-type: none"> • 1000 mg once a week for 4 weeks on days 1, 8, 15, and 22 <p><u>Maintenance therapy for use after initial combination therapy or monotherapy:</u></p> <ul style="list-style-type: none"> • 1000 mg every 2 months for up to two years as monotherapy • NOTE: When initial therapy is given in combination with lenalidomide, the first year of maintenance therapy will be given with lenalidomide, followed by an additional year of monotherapy
Hairy Cell Leukemia	<p><u>Initial combination therapy with vemurafenib:</u></p> <ul style="list-style-type: none"> • Cycle 2 (28-day cycle): 1000 mg on days 1, 8, and 15 • Cycles 3-4 (28-day cycle): 1000 mg on day 1

VI. Billing Code/Availability Information

HCPCS Code:

- J9301 – Injection, obinutuzumab, 10 mg; 1 billable unit = 10 mg

NDC:

- Gazyva 1000 mg/40 mL single-dose vial: 50242-0070-xx

VII. References

1. Gazyva [package insert]. South San Francisco, CA; Genentech, Inc; July 2022. Accessed May 2023.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) obinutuzumab. National Comprehensive Cancer Network, 2023. 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 May 2023.
3. Goede V, Fischer K, Busch R, et al. Chemoimmunotherapy with GA101 plus chlorambucil in patients with chronic lymphocytic leukemia and comorbidity: results of the CLL11 (BO21004) safety run-in. *Leukemia*. 2013 Apr; 27(5):1172-4. Doi: 10.1038/leu.2012.252. Epub 2012 Aug 31.
4. Sehn LH, Chua N, Mayer J, et al. Obinutuzumab plus bendamustine versus bendamustine monotherapy in patients with rituximab-refractory indolent non-Hodgkin lymphoma (GADOLIN): a randomised, controlled, open-label, multicentre, phase 3 trial. *Lancet Oncol*. 2016 Jun 23. Pii: S1470-2045(16)30097-3.
5. Cheson BD, Chua N, Mayer J, et al. Overall Survival Benefit in Patients With Rituximab-Refractory Indolent Non-Hodgkin Lymphoma Who Received Obinutuzumab Plus Bendamustine Induction and Obinutuzumab Maintenance in the GADOLIN Study. *J Clin Oncol*. 2018 36:22, 2259-2266.
6. Marcus R, Davies A, Ando K, et al. Obinutuzumab for the First-Line Treatment of Follicular Lymphoma. *N Engl J Med* 2017; 377:1331.
7. Morschhauser F, Le Gouill S, Feugier P, et al. Obinutuzumab combined with lenalidomide for relapsed or refractory follicular B-cell lymphoma (GALEN): a multicentre, single-arm, phase 2 study. *Lancet Haematol*. 2019;6(8):e429-e437. Doi:10.1016/S2352-3026(19)30089-4.
8. Fischer K, Al-Sawaf O, Bahlo J, et al. Venetoclax and Obinutuzumab in Patients with CLL and Coexisting Conditions. *N Engl J Med*. 2019;380(23):2225-2236. Doi:10.1056/NEJMoa1815281.
9. Sharman JP, Banerji V, Fogliatto LM, et al. ELEVATE TN: Phase 3 Study of Acalabrutinib Combined with Obinutuzumab (O) or Alone Vs O Plus Chlorambucil (Clb) in Patients (Pts) with Treatment-Naive Chronic Lymphocytic Leukemia (CLL) [abstract]. *Blood* 2019;134:Abstract 31.
10. Sharman JP, Yimer HA, Boxer M, et al. Results of a phase II multicenter study of obinutuzumab plus bendamustine in pts with previously untreated chronic lymphocytic leukemia (CLL). *J Clin Oncol*. 2017;35(15_suppl):7523-7523.

11. Byrd JC, Flynn JM, Kipps TJ, et al. Randomized phase 2 study of obinutuzumab monotherapy in symptomatic, previously untreated chronic lymphocytic leukemia. *Blood*. 2016;127(1):79-86. Doi:10.1182/blood-2015-03-634394.
12. Cartron G, de Guibert S, Dilhuydy MS, et al. Obinutuzumab (GA101) in relapsed/refractory chronic lymphocytic leukemia: final data from the phase 1/2 GAUGUIN study. *Blood*. 2014; 2196-2202.
13. Sehn LH, Goy A, Offner FC, et al. Randomized Phase II Trial Comparing Obinutuzumab (GA101) With Rituximab in Patients With Relapsed CD20+ Indolent B-Cell Non-Hodgkin Lymphoma: Final Analysis of the GAUSS Study. *J Clin Oncol*. 2015;33(30):3467-3474. Doi:10.1200/JCO.2014.59.2139.
14. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, Version 2.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed May 2023.
15. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas, Version 2.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed May 2023.
16. Park JH, Winder ES, Huntington SF, et al. First Line Chemo-Free Therapy with the BRAF Inhibitor Vemurafenib Combined with Obinutuzumab Is Effective in Patients with HCL [abstract]. *Blood* 2021; 138; Abstract 43.

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 region 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 site
C82.21	Follicular lymphoma grade III lymph nodes of head, face, and neck
C82.22	Follicular lymphoma grade III intrathoracic lymph nodes
C82.23	Follicular lymphoma grade III intra-abdominal lymph nodes
C82.24	Follicular lymphoma grade III lymph nodes of axilla and upper limb
C82.25	Follicular lymphoma grade III lymph nodes of inguinal region and lower limb
C82.26	Follicular lymphoma grade III intrapelvic lymph nodes
C82.27	Follicular lymphoma grade III spleen
C82.28	Follicular lymphoma grade III lymph nodes of multiple sites
C82.29	Follicular lymphoma grade III 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 lymph nodes of multiple sites
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 site
C82.91	Follicular lymphoma, unspecified lymph nodes of head, face, and neck
C82.92	Follicular lymphoma, unspecified intrathoracic lymph nodes
C82.93	Follicular lymphoma, unspecified intra-abdominal lymph nodes
C82.94	Follicular lymphoma, unspecified lymph nodes of axilla and upper limb
C82.95	Follicular lymphoma, unspecified lymph nodes of inguinal region and lower limb
C82.96	Follicular lymphoma, unspecified intrapelvic lymph nodes
C82.97	Follicular lymphoma, unspecified spleen

C82.98	Follicular lymphoma, unspecified lymph nodes of multiple sites
C82.99	Follicular lymphoma, unspecified extranodal and solid organ sites
C83.00	Small cell B-cell lymphoma unspecified site
C83.01	Small cell B-cell lymphoma lymph nodes of head, face, and neck
C83.02	Small cell B-cell lymphoma intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma spleen
C83.08	Small cell B-cell lymphoma lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma extranodal and solid organ sites
C83.10	Mantle cell lymphoma, unspecified site
C83.11	Mantle cell lymphoma, lymph nodes of head, face, and neck
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites
C83.19	Mantle cell lymphoma, extranodal and solid organ sites
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C83.70	Burkitt lymphoma, unspecified site
C83.71	Burkitt lymphoma, lymph nodes of head, face, and neck
C83.72	Burkitt lymphoma, intrathoracic lymph nodes
C83.73	Burkitt lymphoma, intra-abdominal lymph nodes
C83.74	Burkitt lymphoma, lymph nodes of axilla and upper limb
C83.75	Burkitt lymphoma, lymph nodes of inguinal region and lower limb

C83.76	Burkitt lymphoma, intrapelvic lymph nodes
C83.77	Burkitt lymphoma, spleen
C83.78	Burkitt lymphoma, lymph nodes of multiple sites
C83.79	Burkitt 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, 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 and 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
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma]
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
C91.40	Hairy cell leukemia not having achieved remission
C91.42	Hairy cell leukemia, in relapse
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)
D47.Z2	Castleman disease

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)

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