Gazyva® (obinutuzumab)
(Intravenous)

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I. Length of Authorization [1,7-13,16,18]

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

- Initial:
  - Prior authorization validity will be provided initially for eight (8) 21-day cycles for the following:
    - ❖ Use as single-agent therapy
    - ❖ Use in combination with atezolizumab and venetoclax for Richter transformation
  - Prior authorization validity for all other regimens will be provided initially for six (6) 28-day cycles.
- Renewal: Prior authorization validity may NOT be renewed.

B-Cell Lymphomas:

- Initial: Prior authorization validity will be provided initially for 6 months, unless otherwise specified.
  - Use as pretreatment for glofitamab-gxbm: Prior authorization validity will be provided initially for a single dose.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter for up to a maximum of two (2) years of maintenance therapy, unless otherwise specified.
  - Use as pretreatment for glofitamab-gxbm: Prior authorization validity may NOT be renewed.

Castleman Disease:

- Initial: Prior authorization validity will be provided initially for six (6) months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter for up to a maximum of two (2) years of maintenance therapy.

Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma:

- Initial: Prior authorization validity will be provided initially for six (6) 21-day cycles.
- Renewal: Prior authorization validity may NOT be renewed.

Hairy Cell Leukemia:

- Initial:

- Combination therapy with vemurafenib: Prior authorization validity will be provided initially for three (3) 28-day cycles.
- Single agent therapy: Prior authorization validity will be provided initially for six (6) 28-day cycles.

- Renewal: Prior authorization validity may NOT be renewed.

Lupus Nephritis:

- Initial: Prior authorization validity will be provided initially for 12 months.
- Renewal: Prior authorization validity may be renewed every 12 months thereafter.

II. Dosing Limits

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

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

- Initial cycle: 10 billable units day 1, 90 billable units day 2, 100 billable units day 3, 200 billable units days 8 and 15 (21 days)
- Subsequent cycles: 200 billable units every 21 days

B-Cell Lymphomas & Castleman Disease:

- Initial cycle: 100 billable units every 7 days x 4 doses
- Subsequent cycles: 100 billable units every 21 days

Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL):

- Initial cycle: 100 billable units on days 1, 8, and 15 (21 days)
- Subsequent cycles: 100 billable units every 21 days

Hairy Cell Leukemia:

- Initial cycle: 100 billable units on days 1, 8, and 15 (28 days)
- Subsequent cycles: 100 billable units every 28 days

Lupus Nephritis:

- Initial: 100 billable units weeks 0, 2, 24, and 26
- Maintenance: 100 billable units every 6 months

III. Initial Approval Criteria [1]

Prior authorization validity 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) † ‡ Φ [1,2,14]

- 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**; **OR**
  - Used in combination with venetoclax and acalabrutinib; **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 as a single agent; **AND**
    - Used for relapsed or refractory disease after prior covalent BTK inhibitor (e.g., ibrutinib, acalabrutinib, zanubrutinib) and BCL2i (e.g., venetoclax) based regimens; **OR**
  - Used in combination with high-dose methylprednisolone; **AND**
    - Used for disease with del(17p)/TP53; **AND**
    - Used for relapsed or refractory disease after prior covalent BTK inhibitor (e.g., ibrutinib, acalabrutinib, zanubrutinib) and BCL2i (e.g., venetoclax) based regimens; **OR**
  - Used in combination with venetoclax; **AND**
    - Used as treatment for relapse after a period of remission; **OR**
- Patient has histologic transformation (Ritcher); **AND**
  - Used in combination with atezolizumab and venetoclax; **AND**
    - Used as additional therapy for partial response, refractory disease, or progression while on prior treatment; **OR**
    - Used as initial treatment of Richter transformation if previously treated for CLL; **OR**
    - Used as continuation therapy for complete response until progression

***Consider only when covalent BTK inhibitor (e.g., ibrutinib, acalabrutinib, zanubrutinib) and BCL2i (e.g., venetoclax) are not available or not feasible*

B-Cell Lymphomas † ‡ [1,2,15,18-19,23-24]

- Follicular Lymphoma **† ‡ Φ**
  - 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, CHOP, or CVP]; **OR**
        - Used in combination with lenalidomide; **OR**
        - Used as a single agent; **OR**
    - Used as third-line and subsequent therapy for no response, relapsed, or progressive disease; **AND**
        - Used in combination with zanubrutinib; **OR**
    - Used as a single agent for maintenance therapy; **AND**
        - Used as first-line extended therapy following chemoimmunotherapy; **OR**
        - Used as second-line extended therapy for rituximab-refractory disease; **OR**
    - Used as a substitute for rituximab in patients with intolerance to rituximab (including those experiencing severe hypersensitivity reactions requiring discontinuation of rituximab) or experiencing rare complications such as mucocutaneous reactions
- Extranodal Marginal Zone Lymphoma (of Non-Gastric Sites [Noncutaneous] or of the Stomach) or Marginal Zone Lymphoma (Splenic or Nodal) ‡
    - Used in combination with chemotherapy (e.g., bendamustine, CHOP, or CVP); **AND**
        - Used as first-line therapy (*Applies to Nodal Marginal Zone Lymphoma only*); **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 (*Applies to Splenic Marginal Zone Lymphoma only*); **OR**
        - Used as subsequent therapy for relapsed, refractory, or progressive disease; **OR**
    - Used as a single agent for maintenance as second-line extended therapy for rituximab-refractory patients treated with obinutuzumab and bendamustine for recurrent disease; **OR**
    - Used as a substitute for rituximab in patients with intolerance to rituximab (including those experiencing severe hypersensitivity reactions requiring discontinuation of rituximab) or experiencing rare complications such as mucocutaneous reactions
- Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma ‡
    - Used as pretreatment prior to glofitamab-gxbm administration; **AND**
        - Used as third-line and subsequent therapy as a single agent; **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

- Burkitt Lymphoma ‡
  - 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
- Diffuse Large B-Cell lymphoma (DLBCL), High-Grade B-Cell Lymphomas (HGBL), HIV-Related B-Cell Lymphomas, Post-Transplant Lymphoproliferative Disorders ‡
  - Used as pretreatment prior to glofitamab-gxbm administration; **AND**
    - Used as second-line and subsequent treatment; **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
- Mantle Cell Lymphoma (MCL) ‡
  - Used as pretreatment prior to glofitamab-gxbm administration; **AND**
    - Used as second-line and subsequent treatment; **OR**
  - Used as induction therapy for classical or indolent TP53 mutated disease in combination with venetoclax and zanubrutinib when clinical trial is not available; **OR**
  - Used as a substitute for rituximab at the discretion of the treating physician

Castleman Disease ‡ [2]

- 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

Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL) ‡ [2]

- Patient is unable to tolerate rituximab

Hairy Cell Leukemia ‡ [2,21]

- Used in combination with vemurafenib; **AND**
  - Used as initial therapy; **AND**
  - Patient is unable to tolerate purine analogs including frail patients and those with active infection; **OR**
- Used as a single agent; **AND**
  - Used for treatment of progression after therapy for relapsed/refractory disease; **OR**
  - Patient is unable to receive purine analogs; **AND**
    - Used for incomplete hematologic recovery after initial therapy; **OR**
    - Used for relapse within 2 years of full hematologic recovery consistent with complete response following initial therapy; **OR**
    - Used for relapse ≥ 2 years after initial treatment

Lupus Nephritis (LN) † [1,25-26]

- Patient has a diagnosis of active class III, IV, or V lupus nephritis as confirmed via kidney biopsy; **AND**
- Patient will be using background immunosuppressive LN therapy (e.g., corticosteroids plus mycophenolate, azathioprine, or cyclophosphamide) in combination; **AND**
- Patient does not have severe active central nervous system (CNS) lupus; **AND**
- One of the following:
  - The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors, etc.); **OR**
  - The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
    - The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent; **AND**
    - There is support for the use of combination therapy (submitted copies of clinical trials, phase III studies, or guidelines required)

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

IV. Renewal Criteria [1]

Prior authorization validity 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**
- Duration of authorization has not been exceeded (*refer to Section I*); **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), 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**

Oncology Indications

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

Lupus Nephritis

- The patient has experienced a clinical benefit with the requested agent; **AND**
- The patient has a diagnosis of active lupus nephritis (LN) and BOTH of the following:

- The patient is currently treated with background immunosuppressive LN therapy (e.g., corticosteroids plus mycophenolate, azathioprine, or cyclophosphamide); **AND**
- The patient will continue background immunosuppressive LN therapy (e.g., corticosteroids plus mycophenolate, azathioprine, or cyclophosphamide) in combination with the requested agent; **AND**

- The patient does NOT have severe active central nervous system (CNS) lupus; **AND**
- ONE of the following:
  - The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors); **OR**
  - The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
    - The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent; **AND**
    - There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required)

V. Dosage/Administration [1,7-13,16-18,20-24]

Indication	Dose
CLL/SLL	<u>In combination with atezolizumab and venetoclax for Richter transformation:</u> • 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 <u>Single Agent therapy:</u> • 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 -OR- • 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 <u>All other regimens:</u> • 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

B-Cell Lymphomas & Castleman Disease	<u>Initial combination therapy with chemotherapy:</u>
	• Combination chemotherapy with bendamustine:
	  ○ 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 6 cycles of CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), followed by 2 additional 21-day cycles of Gazyva alone
	  ○ Cycle 1 (21-day cycle): 1000 mg days 1, 8, and 15
	  ○ Cycles 2-6 (21-day cycle): 1000 mg day 1
	  ○ Cycles 7-8 (21-day cycle): 1000 mg day 1
	• Combination chemotherapy with CVP (cyclophosphamide, vincristine, prednisone)
	  ○ Cycle 1 (21-day cycle): 1000 mg days 1, 8, and 15

<table>
<tr><td></td><td>
Cycles 2-8 (21-day cycle): 1000 mg day 1
<u>Initial combination therapy with lenalidomide:</u>
Cycle 1 (28-day cycle): 1000 mg days 8, 15, and 22
Cycles 2-6 (28-day cycle): 1000 mg day 1
<u>Initial combination therapy with zanubrutinib:</u>
Cycle 1 (28-day cycle): 1000 mg days 1, 8, and 15
Cycle 2-6 (28-day cycle): 1000 mg day 1
<u>Single agent subsequent treatment:</u>
1000 mg once a week for 4 weeks on days 1, 8, 15, and 22
<u>Induction therapy for MCL in combination with zanubrutinib and venetoclax:</u>
Cycle 1 (28-day cycle): 1000 mg days 1, 8, and 15
Cycle 2-8 (28-day cycle): 1000 mg day 1
<u>Single agent maintenance therapy for follicular or marginal zone lymphoma:</u>
1000 mg every 8 weeks for up to two years (12 doses)
<u>Pretreatment for glofitamab-gxbm</u>
Cycle 1: 1000 mg as a single dose on day 1
</td></tr>
<tr><td>WM/LPL</td><td>
Cycle 1 (21-day cycle): 1000 mg on days 1, 8, and 15
Cycles 2-6 (21-day cycle): 1000 mg on day 1
</td></tr>
<tr><td>Hairy Cell Leukemia</td><td>
<u>Initial combination therapy with vemurafenib:</u>
Cycle 2 (28-day cycle): 1000 mg on days 1, 8, and 15
Cycles 3-4 (28-day cycle): 1000 mg on day 1
<u>Single agent therapy:</u>
Cycle 1 (28-day cycle): 1000 mg on days 1, 8, and 15
Cycles 2-6 (28-day cycle): 1000 mg on day 1
</td></tr>
<tr><td>Lupus Nephritis</td><td>
The recommended dose is 1,000 mg intravenously according to the table below:
<table>
<tr><th>Dose Number</th><th>Timing of treatment</th><th>Dose of obinutuzumab</th></tr>
<tr><td>1</td><td>Initial infusion</td><td>1,000 mg</td></tr>
<tr><td>2</td><td>Week 2 (two weeks after Dose 1)</td><td>1,000 mg</td></tr>
<tr><td>3</td><td>Week 24</td><td>1,000 mg</td></tr>
<tr><td>4</td><td>Week 26 (two weeks after Dose 3)</td><td>1,000 mg</td></tr>
<tr><td>5* and thereafter</td><td>Every 6 months</td><td>1,000 mg</td></tr>
</table>
*Dose 5 should be administered six months after Dose 4
Refer to Prescribing Information for rates of infusion and modifications for infusion-related reactions.
</td></tr>
</table>

VI. Billing Code/Availability Information

<u>HCPCS Code:</u>

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

NDC:

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

VII. References

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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 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
C83.398	Diffuse large B-cell lymphoma of other 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
C88.00	Waldenström macroglobulinemia not having achieved remission
C88.40	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma] not having achieved remission
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
M32.14	Glomerular disease in systemic lupus erythematosus
M32.15	Tubulo-interstitial nephropathy in systemic lupus erythematosus

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
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