Bendamustine:

Treanda®; Bendeka®; Belrapzo®; Vivimusta™; Bendamustine Ψ (Intravenous)

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I. Length of Authorization ^{1-6,9,14,18}

- Waldenström's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL):
 - Coverage will be provided for six months and may NOT be renewed, unless otherwise specified.
 - May be renewed for an additional six months for relapsed disease if previously used as primary therapy.
- Non-Hodgkin Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL), Hodgkin Lymphoma, Systemic Light Chain Amyloidosis:
 - o Coverage will be provided for six months and may NOT be renewed.
- <u>Multiple Myeloma:</u>
 - o Coverage will be provided for eight months and may NOT be renewed.
- HSCT Conditioning:
 - o Coverage will be provided for one time only and may NOT be renewed.

II. Dosing Limits

- A. Quantity Limit (max daily dose) [NDC Unit]:
 - Treanda 100 mg single-dose vial: 6 vials every 21 days
 - Treanda 25 mg single-dose vial: 3 vials every 21 days
 - Bendeka 100 mg/4 mL multi-dose vial: 6 vials every 21 days
 - Belrapzo 100 mg/4 mL RTD multi-dose vial: 6 vials every 21 days
 - Vivimusta 100 mg/4 mL multi-dose vial: 6 vials every 21 days
- B. Max Units (per dose and over time) [HCPCS Unit]:

NHL:

• 600 billable units every 21 days

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WM/LPL:

• 450 billable units every 28 days

Hodgkin Lymphoma:

• 600 billable units every 28 days

CLL/SLL, Systemic Light Chain Amyloidosis & Multiple Myeloma:

• 500 billable units every 28 days

HSCT Conditioning:

• 1000 billable units one time only

III. Initial Approval Criteria 1-4

Coverage is provided in the following conditions:

For Treanda® (J9033) requests: Patient must have had an inadequate response to an adequate trial of one of the following drugs: Bendeka® (J9034) OR Belrapzo® (J9036), unless contraindicated or not tolerated

- Patient is at least 18 years of age, unless otherwise specified; AND
- Patient must not have received bendamustine in a previous line of therapy, unless otherwise specified; AND

Non-Hodgkin Lymphoma (NHL) † Φ 1-5,16

- Coverage is provided for B-Cell Lymphomas when:
 - Used as subsequent therapy †; AND
 - In combination with rituximab for:
 - AIDS-Related Diffuse Large B-cell Lymphoma (DLBCL), primary effusion lymphoma, or HHV8-positive DLBCL, not otherwise specified (NOS)
 - Follicular Lymphoma (grade 1-2)
 - Gastric MALT Lymphoma
 - High-grade B-cell Lymphomas
 - Mantle Cell Lymphoma (may also be used as a component of RBAC500 [rituximab, bendamustine, and cytarabine])
 - Nodal Marginal Zone Lymphoma
 - Non-Gastric MALT Lymphoma (Noncutaneous)
 - Monomorphic Post-Transplant Lymphoproliferative Disorder (B-cell type)
 - Splenic Marginal Zone Lymphoma; OR
 - Used as a single agent for:
 - AIDS-Related B-cell Lymphomas (i.e., DLBCL, primary effusion lymphoma, HHV8-positive DLBCL NOS, or plasmablastic lymphoma in non-candidates for transplant)
 - Follicular Lymphoma (grade 1-2)
 - High-grade B-cell Lymphomas
 - Monomorphic Post-Transplant Lymphoproliferative Disorder (B-cell type); **OR**

- In combination with obinutuzumab for:
 - Follicular Lymphoma (grade 1-2)
 - Gastric MALT Lymphoma
 - Nodal Marginal Zone Lymphoma
 - Non-Gastric MALT Lymphoma (Noncutaneous)
 - Splenic Marginal Zone Lymphoma; OR
- In combination with polatuzumab (with or without rituximab) for:
 - AIDS-Related DLBCL, primary effusion lymphoma, or HHV8-positive DLBCL, NOS
 - AIDS-Related plasmablastic lymphoma in non-candidates for transplant (excluding use with rituximab)
 - DLBCL
 - Follicular Lymphoma (grade 1-2)
 - Histologic transformation of indolent lymphomas to DLBCL
 - High-grade B-cell Lymphomas
 - Monomorphic Post-Transplant Lymphoproliferative Disorder (B-cell type); **OR**
- Used as first line therapy ‡; AND
 - In combination with rituximab for:
 - Follicular Lymphoma (grade 1-2)
 - Gastric MALT Lymphoma
 - Mantle Cell Lymphoma (may also be used as a component of RBAC500 [rituximab, bendamustine, and cytarabine])
 - Nodal Marginal Zone Lymphoma
 - Non-Gastric MALT Lymphoma (Noncutaneous)
 - Splenic Marginal Zone Lymphoma; OR
 - In combination with obinutuzumab for:
 - Follicular Lymphoma
 - Nodal Marginal Zone Lymphoma
- Used as CAR T-cell bridging therapy after leukapheresis ‡; AND
 - In combination with polatuzumab (with or without rituximab) for:
 - AIDS-Related DLBCL, primary effusion lymphoma, or HHV8-positive DLBCL, NOS
 - AIDS-Related plasmablastic lymphoma in non-candidates for transplant (excluding use with rituximab)
 - High-grade B-cell Lymphomas
 - DLBCL
 - Monomorphic Post-Transplant Lymphoproliferative Disorder (B-cell type)
- Coverage is provided for the following T-Cell Lymphomas ‡
 - o Adult T-Cell Leukemia/Lymphoma

- Used as subsequent therapy for non-responders to first-line therapy as a single agent for acute or lymphoma subtypes
- o Breast Implant-Associated Anaplastic Large Cell Lymphoma (ALCL)
 - Used as subsequent therapy as a single agent for relapsed or refractory disease
- o Hepatosplenic T-Cell Lymphoma
 - Used as subsequent therapy as a single agent for refractory disease after two firstline therapy regimens
- Peripheral T-Cell Lymphoma (includes peripheral T-cell not otherwise specified, enteropathy-associated T-cell, monomorphic epitheliotropic intestinal T-cell, angioimmunoblastic T-cell, nodal peripheral T-cell with TFH phenotype, follicular T-cell, or anaplastic large cell lymphomas)
 - Used as a single agent; AND
 - Used as subsequent therapy for relapsed or refractory disease; **OR**
 - Used as initial palliative intent therapy in transplant ineligible patients

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) † Φ 1-5,17

- Used as first-line therapy; **AND**
 - O Used as a single agent †; OR
 - Used in combination with rituximab or obinutuzumab for disease without del(17p)/TP53 mutations (excluding use in frail patients [i.e., not able to tolerate purine analogs]); OR
- Used as subsequent therapy, after prior Bruton Tyrosine Kinase inhibitor- and venetoclax-based regimens; **AND**
 - Used in combination with rituximab for disease without del(17p)/TP53 mutations in patients <65 years of age without significant comorbidities

Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL) ‡ 5

- Used as a single agent or in combination with rituximab; AND
 - o Used as primary therapy; **OR**
 - $\circ~$ Used for relapse, if previously used as primary therapy that was well tolerated and elicited a prolonged response; OR
 - \circ Used as alternative therapy for previously treated disease that does not respond to primary therapy; \mathbf{OR}
 - Used for progressive or relapsed disease

Adult Hodgkin Lymphoma ‡ 5,6

- Patient has classic Hodgkin Lymphoma (cHL); AND
 - o Used as second-line or subsequent therapy for relapsed or refractory disease; AND
 - Used in combination with gemcitabine and vinorelbine; OR
 - Used in combination with brentuximab vedotin; OR
 - Used as subsequent fourth-line therapy for relapsed or refractory disease; AND
 - Used as a single agent; OR

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- Used in combination with carboplatin and etoposide; OR
- Used as palliative therapy as a single agent for relapsed or refractory disease in patients
 >60 years of age; OR
- Patient has Nodular Lymphocyte-Predominant Hodgkin Lymphoma (NLPHL); AND
 - o Used as subsequent therapy for progressive, relapsed, or refractory disease; AND
 - Used in combination with rituximab

Pediatric Hodgkin Lymphoma ‡ 5,6

- Patient age is 18 years and under*; AND
- Used as re-induction therapy or subsequent therapy for relapsed or refractory disease; AND
- Used in combination with brentuximab vedotin
- * Pediatric Hodgkin Lymphoma may be applicable to adolescent and young adult (AYA) patients up to the age of 39 years.

Multiple Myeloma ‡ 5

- Used for relapsed or progressive (after at least 3 prior therapies) disease; AND
 - o Used as a single agent; OR
 - Used in combination with dexamethasone and either lenalidomide or bortezomib

Systemic Light Chain Amyloidosis ‡ 5,18

- Patient has relapsed or refractory disease; AND
- Used in combination with dexamethasone

Hematopoietic Cell Transplantation^{‡ 5,19}

- Used as conditioning for autologous transplant; AND
- Used in combination with etoposide, cytarabine and melphalan (BEAM); AND
- Patient has Non-Hodgkin Lymphoma without CNS disease or Hodgkin Lymphoma
- † FDA-labeled indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

IV. Renewal Criteria 1-5

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe myelosuppression, infections, progressive multifocal leukoencephalopathy (PML), anaphylaxis, severe infusion reactions, tumor lysis syndrome (TLS), fatal and serious skin

reactions, fatal and serious hepatotoxicity, secondary malignancies, extravasation injury, etc.; AND

Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (if bendamustine was previously used as primary therapy)

• Refer to Section III for criteria (see WM/LPL)

All Other Indications

Coverage may not be renewed.

V. Dosage/Administration ^{1-6,9,14,18}

Indication	Dose
Non-Hodgkin Lymphoma	Up to 120 mg/m² intravenously on days 1 and 2 of a 21-day cycle, up to 8 cycles
CLL/SLL & Systemic Light Chain Amyloidosis	Up to 100 mg/m² intravenously on days 1 and 2 of a 28-day cycle, up to 6 cycles
Waldenström's Macroglobulinemia/ Lymphoplasmacytic Lymphoma	Up to 90 mg/m² intravenously on days 1 and 2 of a 28-day cycle, up to 6 cycles *May be repeated for relapsed disease if primary therapy was well tolerated and elicited a prolonged response.
Hodgkin Lymphoma	Up to 120 mg/m² intravenously on days 1 and 2 of a 28-day cycle, up to 6 cycles
Multiple Myeloma	Up to 100 mg/m² intravenously on days 1 and 2 of a 28-day cycle, up to 8 cycles
Conditioning for HSCT	Up to 200 mg/m² intravenously on days -7 and -6 leading up to transplant.

VI. Billing Code/Availability Information

HCPCS Code:

- J9033 Injection, bendamustine hcl (treanda), 1 mg; 1 billable unit = 1 mg
- J9034 Injection, bendamustine hcl (bendeka), 1 mg; 1 billable unit = 1 mg
- J9036 Injection, bendamustine hcl, (belrapzo/bendamustine), 1 mg; 1 billable unit = 1 mg
- J9058 Injection, bendamustine hydrochloride (apotex), 1 mg; 1 billable unit = 1 mg (*Effective 07/01/2023*)
- J9059 Injection, bendamustine hydrochloride (baxter), 1 mg; 1 billable unit = 1 mg (Effective 07/01/2023)
- J9056 Injection, bendamustine hydrochloride (vivimusta), 1 mg; 1 billable unit = 1 mg (*Effective 07/01/2023*)

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- J9999 Not otherwise classified, antineoplastic drugs (Applicable to other unclassified 505(b)(2) NDA not listed, inclusive of Vivimusta, ONLY) Ψ (Discontinue of J9999 for Vivimusta on 07/01/2023)
- C9399 Unclassified drugs or biologicals (Applicable to other unclassified 505(b)(2) NDA not listed, inclusive of Vivimusta, ONLY) Ψ (Discontinue of C9399 for Vivimusta on 07/01/2023)

NDC(s):

- Treanda 100 mg lyophilized powder in a single-dose vial for reconstitution: 63459-0391-xx
- Treanda 25 mg lyophilized powder in a single-dose vial for reconstitution: 63459-0390-xx
- Treanda 45 mg/0.5 mL solution in a single dose vial: 63459-0395-xx * §
- Treanda 180 mg/2 mL solution in a single dose vial: 63459-0396-xx * §
- Bendeka 100 mg/4 mL solution in a multi-dose vial: 63459-0348-xx § Ψ
- Belrapzo 100 mg/4 mL ready-to-dilute multi-dose vial: 42367-0521-xx Ψ
- Vivimusta 100 mg/4 mL solution in a multi-dose vial: 71225-0120-xx Ψ
- * No longer commercially available;
- § Available generically from various manufacturers;

 Ψ Designated products approved by the FDA as a 505(b)(2) NDA of the innovator product. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book and are therefore considered single source products based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. For a complete list of all approved 505(b)(2) NDA products please reference the latest edition of the Orange Book:

Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book | FDA

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description	
C81.00	Nodular lymphocyte predominant Hodgkin lymphoma, unspecified site	
C81.01	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of head, face, and neck	
C81.02	Nodular lymphocyte predominant Hodgkin lymphoma, intrathoracic lymph nodes	
C81.03	Nodular lymphocyte predominant Hodgkin lymphoma, intra-abdominal lymph nodes	
C81.04	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of axilla and upper limb	
C81.05	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of inguinal region and lower	
C81.06	Nodular lymphocyte predominant Hodgkin lymphoma, intrapelvic lymph nodes	
C81.07	Nodular lymphocyte predominant Hodgkin lymphoma, spleen	
C81.08	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of multiple sites	
C81.09	Nodular lymphocyte predominant Hodgkin lymphoma, extranodal and solid organ sites	
C81.10	Nodular sclerosis Hodgkin lymphoma, unspecified site	
C81.11	Nodular sclerosis Hodgkin lymphoma, lymph nodes of head, face, and neck	
C81.12	Nodular sclerosis Hodgkin lymphoma, intrathoracic lymph nodes	
C81.13	Nodular sclerosis Hodgkin lymphoma, intra-abdominal lymph nodes	
C81.14	Nodular sclerosis Hodgkin lymphoma, lymph nodes of axilla and upper limb	
C81.15	Nodular sclerosis Hodgkin lymphoma, lymph nodes of inguinal region and lower limb	
C81.16	Nodular sclerosis Hodgkin lymphoma, intrapelvic lymph nodes	
C81.17	Nodular sclerosis Hodgkin lymphoma, spleen	
C81.18	Nodular sclerosis Hodgkin lymphoma, lymph nodes of multiple sites	
C81.19	Nodular sclerosis Hodgkin lymphoma, extranodal and solid organ sites	

ICD-10	ICD-10 Description		
C81.20	Mixed cellularity Hodgkin lymphoma, unspecified site		
C81.21	Mixed cellularity Hodgkin lymphoma, lymph nodes of head, face, and neck		
C81.22	Mixed cellularity Hodgkin lymphoma, intrathoracic lymph nodes		
C81.23	Mixed cellularity Hodgkin lymphoma, intra-abdominal lymph nodes		
C81.24	Mixed cellularity Hodgkin lymphoma, lymph nodes of axilla and upper limb		
C81.25	Mixed cellularity Hodgkin lymphoma, lymph nodes of inguinal region and lower limb		
C81.26	Mixed cellularity Hodgkin lymphoma, intrapelvic lymph nodes		
C81.27	Mixed cellularity Hodgkin lymphoma, spleen		
C81.28	Mixed cellularity Hodgkin lymphoma, lymph nodes of multiple sites		
C81.29	Mixed cellularity Hodgkin lymphoma, extranodal and solid organ sites		
C81.30	Lymphocyte depleted Hodgkin lymphoma, unspecified site		
C81.31	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of head, face, and neck		
C81.32	Lymphocyte depleted Hodgkin lymphoma, intrathoracic lymph nodes		
C81.33	Lymphocyte depleted Hodgkin lymphoma, intra-abdominal lymph nodes		
C81.34	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of axilla and upper limb		
C81.35	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of inguinal region and lower limb		
C81.36	Lymphocyte depleted Hodgkin lymphoma, intrapelvic lymph nodes		
C81.37	Lymphocyte depleted Hodgkin lymphoma, spleen		
C81.38	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of multiple sites		
C81.39	Lymphocyte depleted Hodgkin lymphoma, extranodal and solid organ sites		
C81.40	Lymphocyte-rich Hodgkin lymphoma, unspecified site		
C81.41	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of head, face, and neck		
C81.42	Lymphocyte-rich Hodgkin lymphoma, intrathoracic lymph nodes		
C81.43	Lymphocyte-rich Hodgkin lymphoma, intra-abdominal lymph nodes		
C81.44	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of axilla and upper limb		
C81.45	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of inguinal region and lower limb		
C81.46	Lymphocyte-rich Hodgkin lymphoma, intrapelvic lymph nodes		
C81.47	Lymphocyte-rich Hodgkin lymphoma, spleen		
C81.48	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of multiple sites		
C81.49	Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites		
C81.70	Other Hodgkin lymphoma unspecified site		
C81.71	Other Hodgkin lymphoma lymph nodes of head, face, and neck		
C81.72	Other Hodgkin lymphoma intrathoracic lymph nodes		
C81.73	Other Hodgkin lymphoma intra-abdominal lymph nodes		

ICD-10	ICD-10 Description		
C81.74	Other Hodgkin lymphoma lymph nodes of axilla and upper limb		
C81.75	Other Hodgkin lymphoma lymph nodes of inguinal region and lower limb		
C81.76	Other Hodgkin lymphoma intrapelvic lymph nodes		
C81.77	Other Hodgkin lymphoma spleen		
C81.78	Other Hodgkin lymphoma lymph nodes of multiple sites		
C81.79	Other Hodgkin lymphoma extranodal and solid organ sites		
C81.90	Hodgkin lymphoma, unspecified, unspecified site		
C81.91	Hodgkin lymphoma, unspecified, lymph nodes of head, face, and neck		
C81.92	Hodgkin lymphoma, unspecified, intrathoracic lymph nodes		
C81.93	Hodgkin lymphoma, unspecified, intra-abdominal lymph nodes		
C81.94	Hodgkin lymphoma, unspecified, lymph nodes of axilla and upper limb		
C81.95	Hodgkin lymphoma, unspecified, lymph nodes of inguinal region and lower limb		
C81.96	Hodgkin lymphoma, unspecified, intrapelvic lymph nodes		
C81.97	Hodgkin lymphoma, unspecified, spleen		
C81.98	Hodgkin lymphoma, unspecified, lymph nodes of multiple sites		
C81.99	Hodgkin lymphoma, unspecified, extranodal and solid organ sites		
C82.00	Follicular lymphoma grade I, unspecified site		
C82.01	Follicular lymphoma grade I, lymph nodes of head, face and neck		
C82.02	Follicular lymphoma, grade I, intrathoracic lymph nodes		
C82.03	Follicular lymphoma grade I, intra-abdominal lymph nodes		
C82.04	Follicular lymphoma grade I, lymph nodes of axilla and upper limb		
C82.05	Follicular lymphoma grade I, lymph nodes of inguinal regional and lower limb		
C82.06	Follicular lymphoma grade I, intrapelvic lymph nodes		
C82.07	Follicular lymphoma grade I, spleen		
C82.08	Follicular lymphoma grade I, lymph nodes of multiple sites		
C82.09	Follicular lymphoma grade I, extranodal and solid organ sites		
C82.10	Follicular lymphoma grade II, unspecified site		
C82.11	Follicular lymphoma grade II, lymph nodes of head, face and neck		
C82.12	Follicular lymphoma, grade II, intrathoracic lymph nodes		
C82.13	Follicular lymphoma grade II, intra-abdominal lymph nodes		
C82.14	Follicular lymphoma grade II, lymph nodes of axilla and upper limb		
C82.15	Follicular lymphoma grade II, lymph nodes of inguinal region and lower limb		
C82.16	Follicular lymphoma grade II, intrapelvic lymph nodes		
C82.17	Follicular lymphoma grade II, spleen		

ICD-10	ICD-10 Description		
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		

ICD-10	ICD-10 Description	
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	

ICD-10	ICD-10 Description		
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		
C83.37	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		
C83.80	Other non-follicular lymphoma, unspecified site		

ICD-10	ICD-10 Description		
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		
C84.40	Peripheral T-cell lymphoma, not classified, unspecified site		
C84.41	Peripheral T-cell lymphoma, not classified, lymph nodes of head, face, and neck		
C84.42	Peripheral T-cell lymphoma, not classified, intrathoracic lymph nodes		
C84.43	Peripheral T-cell lymphoma, not classified, intra-abdominal lymph nodes		
C84.44	Peripheral T-cell lymphoma, not classified, lymph nodes of axilla and upper limb		
C84.45	Peripheral T-cell lymphoma, not classified, lymph nodes of inguinal region and lower limb		
C84.46	Peripheral T-cell lymphoma, not classified, intrapelvic lymph nodes		
C84.47	Peripheral T-cell lymphoma, not classified, spleen		
C84.48	Peripheral T-cell lymphoma, not classified, lymph nodes of multiple sites		
C84.49	Peripheral T-cell lymphoma, not classified, extranodal and solid organ sites		
C84.60	Anaplastic large cell lymphoma, ALK-positive, unspecified site		
C84.61	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of head, face, and neck		
C84.62	Anaplastic large cell lymphoma, ALK-positive, intrathoracic lymph nodes		
C84.63	Anaplastic large cell lymphoma, ALK-positive, intra-abdominal lymph nodes		
C84.64	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of axilla and upper limb		

ICD-10	ICD-10 Description		
C84.65	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of inguinal region and lower limb		
C84.66	Anaplastic large cell lymphoma, ALK-positive, intrapelvic lymph nodes		
C84.67	Anaplastic large cell lymphoma, ALK-positive, spleen		
C84.68	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of multiple sites		
C84.69	Anaplastic large cell lymphoma, ALK-positive, extranodal and solid organ sites		
C84.7A	Anaplastic large cell lymphoma, ALK-negative, breast		
C84.70	Anaplastic large cell lymphoma, ALK-negative, unspecified site		
C84.71	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of head, face, and neck		
C84.72	Anaplastic large cell lymphoma, ALK-negative, intrathoracic lymph nodes		
C84.73	Anaplastic large cell lymphoma, ALK-negative, intra-abdominal lymph nodes		
C84.74	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of axilla and upper limb		
C84.75	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of inguinal region and lower limb		
C84.76	Anaplastic large cell lymphoma, ALK-negative, intrapelvic lymph nodes		
C84.77	Anaplastic large cell lymphoma, ALK-negative, spleen		
C84.78	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of multiple sites		
C84.79	Anaplastic large cell lymphoma, ALK-negative, extranodal and solid organ sites		
C84.90	Mature T/NK-cell lymphomas, unspecified, unspecified site		
C84.91	Mature T/NK-cell lymphomas, unspecified, lymph nodes of head, face and neck		
C84.92	Mature T/NK-cell lymphomas, unspecified, intrathoracic lymph nodes		
C84.93	Mature T/NK-cell lymphomas, unspecified, intra-abdominal lymph nodes		
C84.94	Mature T/NK-cell lymphomas, unspecified, lymph nodes of axilla and upper limb		
C84.95	Mature T/NK-cell lymphomas, unspecified, lymph nodes of inguinal region and lower limb		
C84.96	Mature, T/NK-cell lymphomas, unspecified, intrapelvic lymph nodes		
C84.97	Mature T/NK-cell lymphomas, unspecified, spleen		
C84.98	Mature T/NK-cell lymphomas, unspecified, lymph nodes of multiple sites		
C84.99	Mature T/NK-cell lymphomas, unspecified, extranodal and solid organ sites		
C84.Z0	Other mature T/NK-cell lymphomas, unspecified site		
C84.Z1	Other mature T/NK-cell lymphomas, lymph nodes of head, face and neck		
C84.Z2	Other mature T/NK-cell lymphomas, intrathoracic lymph nodes		
C84.Z3	Other mature T/NK-cell lymphomas, intra-abdominal lymph nodes		
C84.Z4	Other mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb		
C84.Z5	Other mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb		
C84.Z6	Other mature T/NK-cell lymphomas, intrapelvic lymph nodes		
C84.Z7	Other mature T/NK-cell lymphomas, spleen		

ICD-10	ICD-10 Description		
C84.Z8	Other mature T/NK-cell lymphomas, lymph nodes of multiple sites		
C84.Z9	Other mature T/NK-cell lymphomas, 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		
C86.1	Hepatosplenic T-cell lymphoma		
C86.2	Enteropathy-type (intestinal) T-cell lymphoma		

ICD-10	ICD-10 Description	
C86.5	Angioimmunoblastic T-cell lymphoma	
C88.0	Waldenström macroglobulinemia	
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue (MALT-	
C90.00	Multiple myeloma not having achieved remission	
C90.02	Multiple myeloma in relapse	
C90.10	Plasma cell leukemia not having achieved remission	
C90.12	Plasma cell leukemia in relapse	
C90.20	Extramedullary plasmacytoma not having achieved remission	
C90.22	Extramedullary plasmacytoma in relapse	
C90.30	Solitary plasmacytoma not having achieved remission	
C90.32	Solitary plasmacytoma 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	
C91.50	Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission	
C91.52	Adult T-cell lymphoma/leukemia (HTLV-1-associated) in relapse	
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)	
E85.3	Secondary systemic amyloidosis	
E85.4	Organ-limited amyloidosis	
E85.81	Light chain (AL) amyloidosis	
E85.89	Other amyloidosis	
E85.9	Amyloidosis, unspecified	
Z85.71	Personal history of Hodgkin lymphoma	
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues	
Z94.81	Bone marrow transplant status	
Z94.89	Other transplanted organ and tissue status	
Z94.9	Transplanted organ and tissue status, unspecified	

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.	
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	