

Medical Drug Clinical Criteria

Subject:	Bendamustine agents		
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Overview

This document addresses the use of bendamustine agents (Bendeka, Treanda, Belrapzo, Vivimusta). Bendamustine is an alkylating agent primarily used to treat types of blood cancers such as leukemias and lymphomas.

The FDA approved indications for bendamustine include first line treatment of chronic lymphocytic leukemia (CLL) as well as indolent B-cell non-Hodgkin's lymphoma (NHL) that has progressed on treatment including rituximab. Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are different manifestations of the same disease and are managed in much the same way. Bendamustine has also been used off-label in combination with rituximab as treatment for cold agglutinin disease or cold antibody-mediated autoimmune hemolytic anemia (Jager 2020).

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of bendamustine. These recommendations include the use alone or in combination for previously treated multiple myeloma for relapse or progressive disease; as well as second-line, subsequent, or palliative therapy for classic Hodgkin lymphoma (HL). NCCN also recommends bendamustine for waldenstrom's macroglobulinemia, systemic light chain amyloidosis, and as part of a conditioning regimen for transplant in patients with non-Hodgkin's lymphoma (NHL) or HL. Bendamustine is recommended by NCCN for various types of non-Hodgkin's lymphoma (NHL) which is a group of blood cancers that includes all types of lymphoma except Hodgkin's lymphoma. NCCN recommends bendamustine in the following types of NHL:

- B-Cell lymphomas:
 - HIV-related B-cell lymphoma
 - Diffuse large B-cell lymphoma
 - Follicular lymphoma
 - High-Grade B-Cell Lymphomas
 - Histologic Transformation of Indolent Lymphomas to Diffuse Large B-cell Lymphoma
 - Mantle cell lymphoma
 - Nodal marginal zone lymphoma
 - Extranodal marginal zone lymphoma
 - Post-transplant lymphoproliferative disorders
 - Splenic marginal zone lymphoma
- T-Cell lymphomas:
 - Adult T-cell leukemia/lymphoma
 - T-cell prolymphocytic leukemia
 - Peripheral T-cell lymphomas
 - Breast Implant-associated Anaplastic Large Cell Lymphoma (ALCL)
 - Hepatosplenic T-cell lymphoma
- Primary Cutaneous Lymphomas
 - Mycosis Fungoides/Sézary Syndrome

Definitions and Measures

Multiple myeloma: A type of cancer that begins in plasma cells (white blood cells that produce antibodies).

Non-Hodgkin Lymphoma (NHL): A heterogeneous group of lymphoproliferative disorders originating from B lymphocytes, T lymphocytes, or natural killer (NK) cells.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Bendamustine Agents (Belrapzo, Bendeka, Treanda, Vivimusta)

Requests for bendamustine agents (Belrapzo, Bendeka, Treanda, Vivimusta) may be approved if the following criteria are met:

I. Individual is under 19 years of age;

OR

II. Individual has a diagnosis of one of the following:

A. Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) (Label, NCCN 2A); **OR**

B. Relapsed, refractory, or progressive classical Hodgkin lymphoma (Label, NCCN 2A); **OR**

C. Non-Hodgkin lymphoma (NHL) (NCCN 2A); **OR**

G-D. Progressive, relapsed or refractory nodular lymphocyte-predominant Hodgkin lymphoma (NCCN 2A); **OR**

D-E. Relapsed, refractory, or progressive Multiple myeloma (NCCN 2A); **OR**

E-F. Relapsed or refractory systemic light chain amyloidosis (NCCN 2A); **OR**

F-G. Waldenstrom's macroglobulinemia (NCCN 2A); **OR**

G-H. Cold agglutinin disease (DP BIIa; Jager 2020).

Requests for bendamustine agents (Belrapzo, Bendeka, Treanda, Vivimusta) may not be approved for the following:

- I. Treatment of metastatic breast cancer; **OR**
- II. Treatment of small cell lung cancer (SCLC); **OR**
- III. When the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

<u>J9033J9036</u>	<u>Injection, bendamustine hydrochloride (Treanda), 1 mg</u> Injection, bendamustine HCL (Belrapzo), 1mg
<u>J9034J9033</u>	<u>Injection, bendamustine hcl (Bendeka), 1 mg</u> Injection, bendamustine HCL, (Treanda), 1 mg
<u>J9036J9034</u>	<u>Injection, bendamustine hydrochloride (Belrapzo/bendamustine), 1mg</u> Injection, bendamustine HCL (Bendeka), 4 mg
<u>J9056J9056</u>	<u>Injection, bendamustine hydrochloride (Vivimusta), 1 mg</u> Injection, bendamustine hydrochloride (Vivimusta), 1 mg

ICD-10 Diagnosis

<u>C81.00</u> C81.10-	<u>Classical/</u> unspecified Hodgkin lymphoma
<u>C81.99</u>	
<u>C82.00-</u>	Follicular lymphoma
<u>C82.99</u> C82.9A	
<u>C83.00-C83.9A</u>	Non-follicular lymphoma
<u>C84.00-C84.9A</u>	Mature T/NK-cell lymphomas
<u>C83.00-C83.09</u>	Small cell B-cell lymphoma
<u>C83.10-C83.19</u>	Mantle cell lymphoma
<u>C83.30-C83.38</u>	Diffuse large B-cell lymphoma
<u>C83.398</u>	Diffuse large B-cell lymphoma of other extranodal and solid organ sites

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C83.80-C83.89	Other non-follicular lymphoma
C83.90-C83.99	Non-follicular (diffuse) lymphoma, unspecified
C84.40-C84.49	Peripheral T-cell lymphoma, not elsewhere classified
C84.60-C84.69	Anaplastic large cell lymphoma, ALK-positive
C84.70-C84.7A	Anaplastic large cell lymphoma, ALK-negative
C84.Z0-C84.Z9	Other mature T/NK-cell lymphomas
C84.90-C84.99	Mature T/NK-cell lymphomas, unspecified
C85.10-C85.9A	Other specified and unspecified types of non-Hodgkin lymphoma
C86.00-C86.61	Other specified types of T/NK-cell lymphoma
C86.10	Hepatosplenic T-cell lymphoma not having achieved remission
C86.20	Enteropathy-type (intestinal) T-cell lymphoma not having achieved remission
C86.50	Angioimmunoblastic T-cell lymphoma not having achieved remission
C88.00	Waldenström's macroglobulinemia not having achieved remission
C88.40	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma] not having achieved remission
C90.00-C90.32	Multiple myeloma and malignant plasma cell neoplasms
C91.10-C91.12	Chronic lymphocytic leukemia of B-cell type
C91.50-C91.52	Adult T-cell lymphoma/leukemia (HTLV-1 associated)
C91.60-C91.62	Prolymphocytic leukemia of T-cell type
D59.12	Cold autoimmune hemolytic anemia
E85.81	Light chain (AL) amyloidosis

Document History

Revised: 11/14/2025

Document History:

- 11/14/2025 – Annual Review: Add nodular lymphocyte-predominant Hodgkin lymphoma per NCCN 2A. Administrative update for age. Coding Reviewed: Updated description for HCPCS J9036. Added ICD-10-CM C81.00-C81.09 to range C81.10-C81.99 and updated description. Removed ICD-10-CM C82.9A, C85.9A, C86.00, C86.01, C86.11, C86.21, C86.30-C86.41, C86.51-C86.61, C88.0, C88.4. Separated range C83.00-C83.9A and removed C83.0A, C83.1A, C83.3A, C83.390, C83.50-C83.7A, C83.8A, C83.9A. Separated range C84.00-C84.9A and removed C84.00-C84.1A, C84.4A, C84.6A, C84.7B, C84.A0-C84.AA, C84.ZA, C84.9A. Added ICD-10-CM C88.00, C88.40, C91.60-C91.62.
- 1/22/2025 – Coding Update: Revised description and split out coding range C82.00-C86.61.
- 11/15/2024 – Annual Review: Update references. Coding Reviewed: Added ICD-10-CM C83.00-C83.9A, D59.12. Revised description for HCPCS J9033 effective 1/1/25. Removed HCPCS J9058 and J9059 effective 12/31/24. Added back (Treanda) to HCPCS J9033.
- 02/23/2024 – Annual Review: Clarify criteria to include progressive Hodgkin lymphoma and refractory multiple myeloma per NCCN. Coding Reviewed: No changes. 02/24/2023 – Annual Review: Update criteria to include new brand agent Vivimusta and to include use in cold agglutinin disease. Coding Reviewed: Added HCPCS J9999. Effective 7/1/2023 Added HCPCS J9056, J9058, J9059. Removed HCPCS J9999.
- 05/20/2022 – Annual Review: Update criteria to include systemic light chain amyloidosis per NCCN; update multiple myeloma to include relapsed or progressive disease per NCCN. Coding Reviewed: Added ICD-10-CM-PCS E85.81.
- 05/21/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/15/2020 – Annual Review: No changes. Coding Review: No changes
- 05/17/2019 – Annual Review: First review of bendamustine clinical criteria. Clarify use in CLL which includes SLL as well. Move list of examples of non-Hodgkin lymphoma to overview section. Wording and formatting updates. Coding Reviewed: No changes currently. Effective 7/1/2019 HCPCS Code J9036 for BELRAPZO, Remove C9042, and J9999 temporary HCPCS codes.

References

- DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 6, 2024.
- DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- Jager U, Barcelini W, Broome C, et al. Diagnosis and treatment of autoimmune hemolytic anemia in adults: Recommendations from the first International Consensus meeting. *Blood Rev.* 2020; 41:100648.

4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed September 2024.
 - a. Chronic Lymphocytic leukemia/small lymphocytic lymphoma. V3.2024. Revised March 26, 2024.
 - b. B-Cell Lymphomas. V3.2024. Revised August 26, 2024.
 - c. T-Cell Lymphomas. V4.2024. Revised May 28, 2024.
 - d. Waldenstrom Macroglobulinemia/Lymphoplasmacytic lymphoma. V2.2024. Revised December 5, 2023.
 - e. Multiple Myeloma. V4.2024. Revised April 26, 2024.
 - f. Hodgkin Lymphoma. V3.2024. Revised March 18, 2024.
 - g. Pediatric Hodgkin Lymphoma. V1.2024. Revised May 14, 2024.
 - h. Systemic Light Chain Amyloidosis. V2.2024. Revised December 12, 2023.
 - i. Hematopoietic Cell Transplantation (HCT). V2.2024. Revised August 30, 2024.
 - j. Primary Cutaneous Lymphomas. V3.2024. Revised August 22, 2024.

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