

# 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
  - Peripheral T-cell lymphomas
  - Breast Implant-associated Anaplastic Large Cell Lymphoma (ALCL)
  - Hepatosplenic T-cell lymphoma

## 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 has a diagnosis of one of the following:
  - A. Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL); **OR**
  - B. Relapsed, ~~or~~ refractory, or progressive classical Hodgkin lymphoma (NCCN 2A); **OR**
  - C. Non-Hodgkin lymphoma (NHL); **OR**
  - D. Relapsed, refractory, or progressive Multiple myeloma (NCCN 2A); **OR**
  - E. Relapsed or refractory systemic light chain amyloidosis; **OR**
  - F. Waldenstrom's macroglobulinemia (NCCN 2A); **OR**
  - G. 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

|       |  |
|-------|--|
| J9036 | Injection, bendamustine HCL (Belrapzo), 1mg (Effective 7/1/2019) |
| J9033 | Injection, bendamustine HCL (Treanda), 1 mg                      |
| J9034 | Injection, bendamustine HCL (Bendeka), 1 mg                      |
| J9056 | Injection, bendamustine hydrochloride (vivimusta), 1 mg          |
| J9058 | Injection, bendamustine hydrochloride (apotex), 1 mg             |
| J9059 | Injection, bendamustine hydrochloride (baxter), 1 mg             |

### ICD-10 Diagnosis

|               |   |
|---------------|---|
| C81.10-C81.99 | Classical/unspecified Hodgkin lymphoma  |
| C82.00-C86.6  | Non-Hodgkin lymphoma  |
| C88.0         | Waldenström's macroglobulinemia   |
| C88.4         | Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma] |
| 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)  |
| E85.81        | Light chain (AL) amyloidosis  |

## Document History

Revised: 02/23/2024

Document History:

- 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

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 5, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Jager U, Barcellini 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 January 2024.
  - a. Chronic Lymphocytic leukemia/small lymphocytic lymphoma. V1.2024. Revised November 3, 2023.
  - b. B-Cell Lymphomas. V6.2023. Revised October 10, 2023.
  - c. T-Cell Lymphomas. V1.2023. Revised January 5, 2023.
  - d. Waldenstrom Macroglobulinemia/Lymphoplasmacytic lymphoma. V2.2024. Revised December 5, 2023.
  - e. Multiple Myeloma. V2.2024. Revised November 1, 2023.
  - f. Hodgkin Lymphoma. V1.2024. Revised October 12, 2023.
  - g. Pediatric Hodgkin Lymphoma. V2.2023. Revised March 9, 2023.
  - h. Systemic Light Chain Amyloidosis. V2.2024. Revised December 12, 2023.
  - i. Hematopoietic Cell Transplantation (HCT). V3.2023. Revised October 9, 2023.

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