CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Bendamustine Products Utilization Management Medical Policy
- Belrapzo® (bendamustine intravenous infusion – Eagle)
- Bendeka® (bendamustine intravenous infusion – Teva)
- Treanda® (bendamustine intravenous infusion – Cephalon)
- Vivimusta® (bendamustine intravenous – Slayback, Latina)
- Bendamustine intravenous infusion – various manufacturers

REVIEW DATE: 07/29/2026

OVERVIEW
Bendamustine, an alkylating agent, is indicated for the following uses:[1-4]
- **B-cell non-Hodgkin lymphoma, indolent**, that has progressed during or within 6 months of treatment with rituximab or a rituximab containing regimen.
- **Chronic lymphocytic leukemia**. Efficacy compared to first-line agents other than chlorambucil has not been established.

Guidelines
The use of bendamustine is recommended across multiple National Comprehensive Cancer Network (NCCN) guidelines and the use of the NCCN Compendium.[5-14] Recommendations with a category of evidence of 2B or higher support the approval criteria outlined below.

POLICY STATEMENT
Prior Authorization is recommended for medical benefit coverage of bendamustine. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with bendamustine as well as the monitoring required for adverse events and long-term efficacy, approval requires bendamustine to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of bendamustine is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **B-Cell Non-Hodgkin Lymphoma.** Approve for 6 months if the patient meets ALL of the following (A, B, and C):
   Note: Examples include follicular lymphoma, marginal zone lymphoma, mantle cell lymphoma, diffuse large B-cell lymphoma (DLBCL), histologic transformation of indolent lymphomas to diffuse

large B-cell lymphoma (DLBCL), high-grade B-cell lymphoma, HIV-Related B-Cell Lymphomas, and Post-Transplant Lymphoproliferative Disorders.

A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
  i. Patient has follicular lymphoma, marginal zone lymphoma, or mantle cell lymphoma; OR
  ii. Patient meets BOTH of the following (a and b):
    a) Patient has diffuse large B-cell lymphoma (DLBCL), histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma (DLBCL), high-grade B-cell lymphoma, HIV-related B-cell lymphoma, or post-transplant lymphoproliferative disorder; AND
    b) The medication is used as second-line or subsequent therapy; AND
C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 120 mg/m^2 administered by intravenous infusion no more frequently than twice in each 21-day treatment cycle.

2. **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.** Approve for 6 months if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 100 mg/m^2 administered by intravenous infusion no more frequently than twice in each 28-day treatment cycle.

Other Uses with Supportive Evidence

3. **Hematopoietic Cell Transplantation.** Approve for 1 month if the patient meets ALL of the following (A, B, C, and D):
   A) The medication is used as conditioning prior to autologous hematopoietic cell transplantation; AND
   B) Patient has ONE of the following conditions (i or ii):
     i. Non-Hodgkin lymphoma without central nervous system disease; OR
     ii. Hodgkin lymphoma; AND
   C) The medication is used in combination with etoposide, cytarabine, and melphalan.
   D) The medication is prescribed by or in consultation with an oncologist or a physician who specializes in hematopoietic cell transplantation.

   Dosing. Approve up to 200 mg/m^2 administered by intravenous infusion no more frequently than twice prior to autologous hematopoietic cell transplantation.

4. **Hodgkin Lymphoma.** Approve for 6 months if the patient meets BOTH of the following (A and B):
   A) The medication is used as second-line or subsequent therapy; AND
   B) The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 120 mg/m^2 administered by intravenous infusion no more frequently than twice in each 21-day or 28-day treatment cycle.

5. Multiple Myeloma. Approve for 6 months if the patient meets ALL of the following (A, B, and C):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i or ii):
  - **i.** Patient has been treated with at least 3 prior regimens; OR
  - **ii.** Patient meets BOTH of the following (a and b):
    - a) Patient has central nervous disease; AND
    - b) The medication is used as part of a multimodality therapy; AND
      Note: Examples of multimodality therapies include radiation and systemic therapy.
- **C)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 150 mg/m^2 administered by intravenous infusion no more frequently than twice in each 28-day treatment cycle.

6. Systemic Light Chain Amyloidosis. Approve for 6 months if the patient meets ALL of the following (A, B, C, and D):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has relapsed or refractory disease; AND
- **C)** The medication is used in combination with dexamethasone; AND
- **D)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 100 mg/m^2 administered by intravenous infusion no more frequently than twice in each 28-day treatment cycle.

7. T-Cell Lymphoma. Approve for 6 months if the patient meets ALL of the following (A, B, and C):
Note: Examples of T-cell lymphoma include peripheral T-cell lymphoma not otherwise specified, enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, angioimmunoblastic T-cell lymphoma, nodal peripheral T-cell lymphoma, follicular helper T-cell lymphoma, follicular T-cell lymphoma, anaplastic large cell lymphoma, breast implant-associated anaplastic large cell lymphoma, T-cell prolymphocytic leukemia, adult T-cell leukemia/lymphoma, hepatosplenic T-cell lymphoma, and CD30+ peripheral T-cell lymphoma.
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i, ii, or iii):
  - **i.** Patient has peripheral T-cell lymphoma not otherwise specified, enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, angioimmunoblastic T-cell lymphoma, nodal peripheral T-cell lymphoma, follicular helper T-cell lymphoma, follicular T-cell lymphoma, or anaplastic large cell lymphoma; OR
  - **ii.** Patient meets BOTH of the following (a and b):
    - a) Patient has CD30+ peripheral T-cell lymphoma, breast implant-associated anaplastic large cell lymphoma, T-cell prolymphocytic leukemia, or adult T-cell leukemia/lymphoma; AND
    - b) The medication is used as second-line or subsequent therapy; OR
  - **iii.** Patient meets BOTH of the following (a and b):
    - a) Patient has hepatosplenic T-cell lymphoma; AND
    - b) The medication is used as subsequent therapy after two systemic regimens; AND
      Note: Examples of systemic regimens include ICE (ifosfamide, carboplatin, etoposide), DHAP (dexamethasone, cytarabine, cisplatin), DHAX (dexamethasone, cytarabine, oxaliplatin), IVAC (ifosfamide, etoposide, cytarabine).

C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 120 mg/m^2 administered by intravenous infusion no more frequently than twice in each 21-day treatment cycle.

8. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma. Approve for 6 months if the patient meets BOTH of the following (A and B):
A) Patient is ≥ 18 years of age; AND
B) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 90 mg/m^2 administered by intravenous infusion no more frequently than twice in each 28-day treatment cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of bendamustine is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

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2. Treanda® intravenous infusion [prescribing information]. Frazer, PA: Cephalon; October 2022.
3. Belrapzo® intravenous infusion [prescribing information]. Woodcliff Lake, NJ: Eagle Pharmaceuticals; January 2024.
4. Vivimusta® intravenous infusion [prescribing information]. Princeton, NJ: Slayback and Sermoneta, Italy: Latina Pharma; March 2025.
5. The NCCN Drugs and Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 23, 2026. Search term: bendamustine.
6. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 2.2026 – December 22, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 23, 2026.
7. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2026 – May 20, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 23, 2026.
8. The NCCN Hodgkin Lymphoma Clinical Practice Guidelines in Oncology (version 2.2026 – July 1, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 23, 2026.
9. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 5.2026– January 9, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 23, 2026.
10. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2026 – February 13, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 23, 2026.
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13. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (version 12.2026 – March 16, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 23, 2026.
14. The NCCN Hematopoietic Cell Transplantation (HCT) Clinical Practice Guidelines in Oncology (version 2.2026 – April 3, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 23, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Vivimusta:** Added Vivimusta to list of bendamustine products; the same criteria apply as those for the other bendamustine products. **Mycosis Fungoides/Sezary Syndrome:** New condition of approval was added.	07/17/2024
Annual Revision	**B-Cell Non-Hodgkin Lymphoma:** Added a requirement that the medication is used as second-line or subsequent therapy for diffuse large B-cell lymphoma, histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma, high-grade B-cell lymphoma, HIV-related B-cell lymphoma, and post-transplant lymphoproliferative disorder. **Hematopoietic Cell Transplantation:** Added a requirement that the medication is used in combination with etoposide, cytarabine, and melphalan. **Multiple Myeloma:** Changed the requirement from "more than three prior regimens" to "at least three prior regimens.". Added another option for approval, which includes that the patient has central nervous disease and the medication is used as part of a multimodal therapy. **Mycosis Fungoides/Sezary Syndrome:** Removed as a condition of approval. **T-Cell Lymphoma**: Added a requirement that the medication is used as second-line or subsequent therapy for CD30+ peripheral T-cell lymphoma, breast implant-associated anaplastic large cell lymphoma, T-cell prolymphocytic leukemia, or adult T-cell leukemia/lymphoma. Added a requirement that the medication is used as subsequent therapy after two systemic regimens for hepatosplenic T-cell lymphoma. Removed the requirement that Bendamustine is used as a single agent.	07/16/2025
Annual Revision	No criteria changes.	07/29/2026