

**Bendamustine**  
(Belrapzo™, Bendeka™, Treanda®, Vivimusta™)

**Place of Service**  
Office Administration  
Outpatient Facility Infusion  
Administration  
Infusion Center Administration

**HCPCS**

J9033 per 1 mg (Treanda)  
J9034 per 1 mg (Bendeka)  
J9036 per 1 mg (Belrapzo)  
J9999 (Vivimusta)

**NDC for Vivimusta:** 71225-120-01

**Conditions listed in policy (*see criteria for details*)**

- [B-cell lymphomas \(\*see section for specific subtypes covered\*\)](#)
- [Chronic lymphocytic leukemia](#)
- [Conditioning for hematopoietic cell transplantation for non-Hodgkin lymphoma without CNS disease or Hodgkin lymphoma](#)
- [Hodgkin lymphoma, relapsed/refractory](#)
- [Multiple myeloma, relapsed/refractory](#)
- [Primary cutaneous lymphomas CD30+ T-Cell Lymphoproliferative Disorders](#)
- [Small lymphocytic lymphoma](#)
- [Systemic light chain amyloidosis, previously treated](#)
- [T-cell lymphomas \(\*see section for specific subtypes covered\*\)](#)
- [Waldenstrom's macroglobulinemia / lymphoplasmacytic lymphoma](#)

**AHFS therapeutic class:** Antineoplastic agent

**Mechanism of action:** Bifunctional mechlorethamine derivative/ alkylating antineoplastic agent.

**(1) Special Instructions and pertinent Information**

**Covered under the Medical Benefit,** please submit clinical information for prior authorization review via fax.

**(2) Prior Authorization/Medical Review is required for the following condition(s)**

**All requests for bendamustine not listed in section (3) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

**B-cell lymphomas**

1. Meets one of the following:

B-cell subtypes	ICD-10
Diffuse large B-cell lymphoma	C83.30-C83.39, C85.20-C85.29, C83.90-C83.99
Extranodal marginal zone lymphoma of nongastric sites (noncutaneous)	C83.80-C83.89, C85.80-C85.89, C88.4

Extranodal marginal zone lymphoma (EMZL) of the stomach	C83.80-C83.89, C85.80-C85.89, C88.4
Follicular lymphoma	C82.00-C82.09, C82.10-C82.19, C82.20-C82.29, C82.30-C82.39, C82.40-C82.49, C82.50-C82.59, C82.60-C82.69, C82.80-C82.89, C82.90-C82.99, C83.30-C83.39, C85.20-C85.29
High-grade B-cell lymphoma	C83.30-C83.39, C85.10 - C85.19
Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma	C83.30- C83.39, C85.20-C85.29
HIV related B-cell lymphoma	B20 with C83.30-C83.39, C83.80-C83.89, C83.90-C83.99, or C85.80-C85.89
Mantle cell lymphoma	C83.10-C83.19
Nodal marginal zone lymphoma	C83.00, C83.08, C83.80-C83.86, C83.33, C83.88
Post-transplant lymphoproliferative disorder	D47.Z1
Splenic marginal zone lymphoma	C83.00-C83.09, C85.80-C85.89

**AND**

2. **Effective 7/31/2023 and after:** For the non-preferred products (Bendeka, Belrapzo or Vivimusta), will require an intolerance or contraindication to bendamustine (generic Treanda, HCPCS J9033) that is not expected with the requested non-preferred product

**Covered Doses**

Up to 120 mg/m<sup>2</sup> IV on two days of each 21-day or 28-day cycle

**ICD-10:** See above table

**Chronic lymphocytic leukemia (CLL) or Small lymphocytic lymphoma (SLL)**

1. Diagnosis, **AND**
2. **Effective 7/31/2023 and after:** For the non-preferred products (Bendeka, Belrapzo or Vivimusta), will require an intolerance or contraindication to bendamustine (generic Treanda, HCPCS J9033) that is not expected with the requested non-preferred product

**Covered Doses**

Up to 120 mg/m<sup>2</sup> IV on two days of each 21-day or 28-day cycle

**ICD-10:**

C83.00-C83.09, C91.10, C91.12

### Conditioning for hematopoietic cell transplantation for non-Hodgkin lymphoma without CNS disease or Hodgkin lymphoma

1. For the non-preferred products (Bendeka, Belrapzo or Vivimusta), will require an intolerance or contraindication to bendamustine (generic Treanda, HCPCS J9033) that is not expected with the requested non-preferred product

#### **Covered Doses**

Up to 200 mg/m<sup>2</sup> IV for a total of two days

#### **ICD-10:**

Z94.81, Z94.89, Z94.9

### Hodgkin Lymphoma, relapsed/refractory

1. Diagnosis, **AND**
2. **Effective 7/31/2023 and after.** For the non-preferred products (Bendeka, Belrapzo or Vivimusta), will require an intolerance or contraindication to bendamustine (generic Treanda, HCPCS J9033) that is not expected with the requested non-preferred product

#### **Covered Doses**

Up to 120 mg/m<sup>2</sup> IV on two days of each 21-day cycle or 28-day cycle

#### **ICD-10:**

C81.00-C81.09, C81.10-C81.19, C81.20-C81.29, C81.30-C81.39, C81.40-C81.49, C81.70-C81.79, C81.90-C81.99, Z85.71

### Multiple myeloma, relapsed/refractory

1. Diagnosis, **AND**
2. **Effective 7/31/2023 and after.** For the non-preferred products (Bendeka, Belrapzo or Vivimusta), will require an intolerance or contraindication to bendamustine (generic Treanda, HCPCS J9033) that is not expected with the requested non-preferred product

#### **Covered Doses**

Up to 150 mg/m<sup>2</sup> IV on two days of each 28-day cycle

#### **ICD-10:**

C90.00, C90.02, C90.10, C90.12, C90.20, C90.22, C90.30, C90.32, Z85.79

### Primary cutaneous lymphomas

1. Diagnosis of Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders, **AND**
2. **Effective 7/31/2023 and after.** For the non-preferred products (Bendeka, Belrapzo or Vivimusta), will require an intolerance or contraindication to bendamustine (generic Treanda, HCPCS J9033) that is not expected with the requested non-preferred product

#### **Covered Doses**

Up to 120 mg/m<sup>2</sup> IV on two days of each 21-day or 28-day cycle

#### **ICD-10:**

**Systemic Light Chain Amyloidosis, previously treated**

1. Diagnosis, **AND**
2. **Effective 7/31/2023 and after.** For the non-preferred products (Bendeka, Belrapzo or Vivimusta), will require an intolerance or contraindication to bendamustine (generic Treanda, HCPCS J9033) that is not expected with the requested non-preferred product

**Covered Doses**Up to 120 mg/m<sup>2</sup> IV on two days of each 21-day or 28-day cycle**ICD-10:**

E85.81, E85.89, E85.9

**T-cell lymphomas**

1. Meets one of the following:

T-cell subtypes	ICD-10
Adult T-cell leukemia/lymphoma	C91.50, C91.52
Breast Implant-Associated ALCL	C84.60-C84.69, C84.7A, C84.70-C84.79
Hepatosplenic Gamma-Delta T-Cell Lymphoma	C84.90-C84.99, C84.Z0-C84.Z9, C86.1
Peripheral T-cell lymphoma	C84.40-C84.49, C84.60-C84.69, C84.70-C84.79, C86.2, C86.5

**AND**

2. **Effective 7/31/2023 and after.** For the non-preferred products (Bendeka, Belrapzo or Vivimusta), will require an intolerance or contraindication to bendamustine (generic Treanda, HCPCS J9033) that is not expected with the requested non-preferred product

**Covered Doses**Up to 120 mg/m<sup>2</sup> IV on two days of each 21-day or 28-day cycle**ICD-10:**

See above

**Waldenstrom's macroglobulinemia / Lymphoplasmacytic lymphoma**

1. Diagnosis of Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders, **AND**
2. **Effective 7/31/2023 and after:** For the non-preferred products (Bendeka, Belrapzo or Vivimusta), will require an intolerance or contraindication to bendamustine (generic Treanda, HCPCS J9033) that is not expected with the requested non-preferred product

**Covered Doses**Up to 120 mg/m<sup>2</sup> IV on two days of each 21-day cycle or 28-day cycle

ICD-10:

C88.0

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

All requests for bendamustine must be sent for clinical review and receive authorization prior to drug administration or claim payment.

**(4) This Medication is NOT COVERED for the following condition(s)**

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**

How supplied:

Bendeka, Belrapzo, Vivimusta: 100 mg/4 mL (solution, multiple dose vial)

Treanda:

- 25 mg, 100 mg (powder, single-use vial)
- 45 mg, 180 mg (solution, single use vial)

**(6) References**

- AHFS®. Available by subscription at <http://www.lexi.com>
- Belrapzo™ (bendamustine) [Prescribing Information]. Woodcliff Lake, NJ: Eagle Pharmaceuticals, Inc. 10/2021.
- Bendeka® (bendamustine) [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals, Inc. 10/2021.
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- National Comprehensive Cancer Network Drugs & Biologics Compendium. Bendamustine (2023).
- Available by subscription at: [www.nccn.org](http://www.nccn.org).
- National Comprehensive Cancer Network. B-cell Lymphomas (Version 2.2023). Available at <http://www.nccn.org>.
- National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (Version 2.2023). Available at <http://www.nccn.org>.
- National Comprehensive Cancer Network. Hematopoietic Cell Transplantation (Version 3.2022). Available at <http://www.nccn.org>.
- National Comprehensive Cancer Network. Hodgkin Lymphoma (Version 2.2023). Available at <http://www.nccn.org>.
- National Comprehensive Cancer Network. Multiple Myeloma (Version 3.2023). Available at <http://www.nccn.org>.
- National Comprehensive Cancer Network. Pediatric Hodgkin Lymphoma (Version 2.2023). Available at <http://www.nccn.org>.
- National Comprehensive Cancer Network. Primary Cutaneous Lymphomas (Version 2.2021). Available at <http://www.nccn.org>.
- National Comprehensive Cancer Network. Waldenstrom's Macroglobulinemia/ Lymphoplasmacytic Lymphoma (Version.1.2023). Available at <http://www.nccn.org>.

- Treanda® (bendamustine) [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; 6/2021.
- Vivimusta (bendamustine) [Prescribing Information]. Princeton, NJ: Slayback Pharma LLC; 12/2022.

### (7) Policy Update

Date of last review: 2Q2023

Date of next review: 2Q2024

Changes from previous policy version:

- Section (2): All indications - **Effective 7/31/2023 and after**, will require an intolerance or contraindication to bendamustine (generic Treanda) that is not expected with Bendeka, Belrapzo or Vivimusta

*Rationale: Bendamustine (generic Treanda) is a cost-effective therapeutic alternative*

- New indication in Section (2): Added coverage for conditioning for hematopoietic cell transplantation for NHL or Hodgkin lymphoma.

*Rationale: NCCN category 2A support*

*BSC Drug Coverage Criteria to Determine Medical Necessity  
Reviewed by P&T Committee*