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5.21.043

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	October 1, 2014
Subject:	Treanda Bendeka Belrapzo Vivimusta	**Page:**	1 of 4

Last Review Date: March 8, 2024

Treanda Bendeka Belrapzo Vivimusta

Description

Treanda, Bendeka, Belrapzo, Vivimusta (bendamustine)

Background
Treanda, Bendeka, Belrapzo, and Vivimusta are bifunctional mechlorethamine derivatives used to treat chronic lymphocytic leukemia and B-cell Non-Hodgkin lymphoma. Mechlorethamine and its derivatives have alkylating groups which cause damage to the formation of DNA cross-links in the cancer cells. In leukemia, cancerous white blood cells grow and multiply, preventing normal blood cells from working properly. The bifunctional covalent linkage can cause cancer cell death via several pathways. Treanda, Bendeka, and Belrapzo are active against both dormant and dividing cells (1-4).

Bendeka will be replacing Treanda in the market place.

Regulatory Status
FDA-approved indications: Treanda, Bendeka, Belrapzo, and Vivimusta are alkylating drugs indicated for treatment of patients with: (1-4)

1. Chronic lymphocytic leukemia (CLL). The efficacy relative to first-line therapies other than chlorambucil has not been established.
2. Indolent B-cell Non-Hodgkin lymphoma (NHL) that has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen.

Off-Label Uses:

Treanda, Bendeka, Belrapzo, and Vivimusta have been used for the treatment of indolent B-cell Non-Hodgkin lymphoma (NHL) as first-line therapy and for refractory or relapsed Hodgkin lymphoma (5).

Safety concerns with these medications include myelosuppression, infection, infusion reactions/anaphylaxis, tumor lysis syndrome, hepatotoxicity, and skin reactions. Pre-malignant and malignant diseases have been reported with Treanda, Bendeka, Belrapzo, and Vivimusta. Precautions should be taken to avoid extravasation when using Treanda, Bendeka, Belrapzo, or Vivimusta. Treanda, Bendeka, Belrapzo, and Vivimusta can cause fetal harm in pregnant women (1-4).

The safety and effectiveness of these medications in patients less than 18 years of age have not been established (1-4).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Treanda, Bendeka, Belrapzo, and Vivimusta may be considered **medically necessary** if the conditions indicated below are met.

Treanda, Bendeka, Belrapzo, and Vivimusta may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Chronic lymphocytic leukemia (CLL)
2. B-cell non-Hodgkin lymphoma (NHL)
3. Refractory or relapsed Hodgkin lymphoma

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Treanda, Bendeka, Belrapzo, and Vivimusta are alkylating agents indicated for the treatment of patients with chronic lymphocytic leukemia (CLL), for B-cell non-Hodgkin lymphoma (NHL), and refractory or relapsed Hodgkin lymphoma. The safety and effectiveness of these medications in patients less than 18 years of age have not been established (1-4).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Treanda, Bendeka, Belrapzo, or Vivimusta while maintaining optimal therapeutic outcomes.

References

1. Treanda [package insert]. North Wales, PA: Teva Pharmaceuticals; October 2022.
2. Bendeka [package insert]. North Wales, PA: Teva Pharmaceuticals; January 2024.
3. Belrapzo [package insert]. Woodcliff Lake, NJ: Eagle Pharmaceuticals, Inc.; June 2022.
4. Vivimusta [package insert]. Princeton, NJ: Slayback Pharma LLC; November 2023.
5. NCCN Drugs & Biologics Compendium® Bendamustine 2024. National Comprehensive Cancer Network, Inc. Accessed on February 8, 2024.

Policy History

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Date	Action
September 2014	Review by PMPC
October 2014	Addition to PA
September 2015	Annual editorial review and reference update Removal of progression of lymphoma during or within 6 months of treatment with rituximab or a rituximab-containing regimen from B-cell non-Hodgkin lymphoma
December 2015	Addition of Bendeka
March 2016	Annual review Policy number changed from 5.04.43 to 5.21.43
June 2016	Annual review
September 2016	Annual review
June 2017	Annual editorial review and reference update
June 2018	Annual editorial review and reference update
June 2019	Annual review and reference update
September 2019	Addition of Belrapzo
December 2019	Annual review
June 2020	Annual review and reference update
December 2020	Annual review
December 2021	Annual review and reference update
December 2022	Annual review and reference update. Changed policy number to 5.21.043
December 2023	Annual review and reference update
January 2024	Addition of Vivimusta to policy
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.