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Federal Employee Program.

TREANDA / BENDEKA / BELRAPZO (bendamustine)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Treanda, Bendeka, and Belrapzo 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 causing 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 (1-3).

Bendeka will be replacing Treanda in the market place.

Regulatory Status

FDA-approved indications: Treanda, Bendeka, and Belrapzo are alkylating drugs indicated for treatment of patients with: (1-3)

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, and Belrapzo 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 (4).

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, and Belrapzo. Precautions should be taken to avoid extravasation when using Treanda, Bendeka, or Belrapzo. Treanda can cause fetal harm in pregnant women (1-3).



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The safety and effectiveness of these medications in patients less than 18 years of age have not been established (1-3).

Summary

Treanda, Bendeka, and Belrapzo are alkylating agents indicated for chronic lymphocytic leukemia: 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 (1-3).

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

References

1. Treanda [package insert]. North Wales, PA: Teva Pharmaceuticals; November 2019.
2. Bendeka [package insert]. North Wales, PA: Teva Pharmaceuticals; October 2019.
3. Belrapzo [package insert]. Woodcliff Lake, NJ: Eagle Pharmaceuticals, Inc.; December 2018.
4. "National Comprehensive Cancer Network." *NCCN Drugs & Biologics Compendium*®. 2020.