Treanda Bendeka Belrapzo

Description

Treanda, Bendeka, Belrapzo (bendamustine)

Background
Treanda, Bendeka, and Belrapzo are bifunctional mechloretamine 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).

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

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 or Bendeka may be considered medically necessary in patients 18 years of age and older with chronic lymphocytic leukemia (CLL), B-cell non-Hodgkin lymphoma (NHL), or refractory or relapsed Hodgkin lymphoma.

Treanda and Bendeka are considered investigational in patients less than 18 years of age and 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
Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits
Same as above

Rationale

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

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2014</td>
<td>Review by PMPC</td>
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<tr>
<td>October 2014</td>
<td>Addition to PA</td>
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<tr>
<td>Date</td>
<td>Event Description</td>
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<tr>
<td>September 2015</td>
<td>Annual editorial review and reference update</td>
</tr>
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<td>Removal of progression of lymphoma during or within 6 months of treatment with</td>
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<td></td>
<td>rituximab or a rituximab-containing regimen from B-cell non-Hodgkin lymphoma</td>
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<tr>
<td>December 2015</td>
<td>Addition of Bendeka</td>
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<tr>
<td>March 2016</td>
<td>Annual review</td>
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<tr>
<td></td>
<td>Policy number changed from 5.04.43 to 5.21.43</td>
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<tr>
<td>June 2016</td>
<td>Annual review</td>
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<tr>
<td>September 2016</td>
<td>Annual review</td>
</tr>
<tr>
<td>June 2017</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>June 2018</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review and reference update</td>
</tr>
<tr>
<td>September 2019</td>
<td>Addition of Belrapzo</td>
</tr>
<tr>
<td>December 2019</td>
<td>Annual review</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.