Marqibo (vincristine liposome injection)

Background
Marqibo is used for the treatment of adults with Philadelphia chromosome negative (Ph-) acute lymphoblastic leukemia (ALL). Marqibo is approved for patients whose leukemia has relapsed two or more times, or whose leukemia has progressed following two or more regimens of anti-leukemia therapy. Marqibo contains vincristine, which is a chemical that stops cancer cells from dividing. The vincristine is encased within a liposome, a drug delivery vehicle composed of material similar to that of cell membranes, which delivers the drug direct to cancer cells (1).

Regulatory Status
FDA-approved indication: Marqibo is a vinca alkaloid indicated for the treatment of adult patients with Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies (1).

Marqibo has a boxed warning that the drug must only be given intravenously. Death has occurred with intrathecal use. Patients must be monitored for neurologic and myelosuppression symptoms such as neuropathy, neutropenia, thrombocytopenia, and anemia. Marqibo is contraindicated in patients with demyelinating conditions including Charcot-Marie-Tooth syndrome (1).

The safety and effectiveness of Marqibo has not been established in pediatric patients (1).
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.

Marqibo may be considered medially necessary in patients that are 18 years of age and older with acute lymphoblastic leukemia (ALL) and if the conditions indicated below are met.

Marqibo is 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

Diagnosis

Patient must have ALL of the following:

1. Acute lymphoblastic leukemia (ALL)
   a. Philadelphia chromosome-negative (Ph-)
   b. Two or more relapses or disease progression following two or more anti-leukemia therapies

Prior – Approval Renewal Requirements

Age 18 years of age or older

Diagnosis

Patient must have ALL of the following:

1. Acute lymphoblastic leukemia (ALL)
   a. Philadelphia chromosome-negative (Ph-)
Pre - PA Allowance
None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Duration 12 months

**Rationale**

**Summary**
Marqibo is a new liposome-encapsulated formulation of vincristine sulfate. It is indicated for patients 18 years of age and older with Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL). Marqibo is contraindicated in demyelinating conditions including Charcot-Marie-Tooth syndrome (1).

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

**References**

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2012</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>March 2013</td>
<td>PMPC Review</td>
</tr>
<tr>
<td>September 2014</td>
<td>Annual criteria review and reference update</td>
</tr>
<tr>
<td>March 2015</td>
<td>Annual criteria review and reference update</td>
</tr>
<tr>
<td>June 2016</td>
<td>Annual editorial review and reference update</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>
</tbody>
</table>
This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.