Valchlor (mechlorethamine)

**Background**
Valchlor is a topical gel that is applied directly to the skin to treat Stage 1A and 1B mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received previous skin-directed treatment. The active ingredient, mechlorethamine, also known as nitrogen mustard, is an alkylating agent which inhibits rapidly proliferating cancer cells and prevents its replication (1).

**Regulatory Status**
FDA-approved indication: Valchlor is an alkylating drug indicated for the topical treatment of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy (1).

Valchlor is a cytotoxic drug and should be handled and disposed of appropriately. Valchlor exposure to mucous membranes, especially of the eyes, can cause mucosal injury which may be severe. Blindness and severe irreversible anterior eye injury may occur. If eye exposure occurs, immediate irrigation for at least 15 minutes and seek medical consultation (1).

Patients should be monitored for non-melanoma skin cancers during and after treatment with Valchlor (1).

Valchlor can cause fetal harm when administered to a pregnant woman. Women should be advised to avoid becoming pregnant while using Valchlor. If this drug is used during pregnancy
or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus (1).

The safety and effectiveness of Valchlor in pediatric patients have not been established (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.

Valchlor may be considered medically necessary in patients that are 18 years of age and older with Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma and if the conditions indicated below are met.

Valchlor is considered investigational in patients that are 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 the following:
  1. Cutaneous T-cell Lymphoma
     - Mycosis fungoides type
     - Stage IA or IB

   **AND ALL** of the following:
   - Patient has had prior skin directed therapy such as topical corticosteroids, topical retinoids or photo therapy
   - Physician agrees to monitor for non-melanoma skin cancer during and after treatment
   - Physician agrees that patients or caregivers will be counseled on the applicable special handling and disposal procedure
Prior – Approval *Renewal* Requirements

**Age**

18 years of age or older

**Diagnosis**

Patient must have the following:

1. Cutaneous T-cell Lymphoma
   a. Mycosis fungoides type
   b. Stage IA or IB

   **AND ALL** of the following:
   a. Patient has **NOT** developed non-melanoma skin cancer and physician will continue to monitor for non-melanoma skin cancer
   b. Patient has had improvement with treatment based either on CAILS score or decrease in severity of scaling, plaque elevation or surface area

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Duration**

12 Months

**Prior – Approval *Renewal* Limits**

**Duration**

12 Months

**Rationale**

**Summary**

Valchlor is a topical alkylating agent used to treat Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma. It is only indicated for patients who have received prior skin
directed therapy. Special handling and disposal procedures must be followed in order to avoid potential mucosal or eye injury and/or secondary exposures. Patients must be monitored for non-melanoma skin cancers during and after treatment which may occur on any area of the skin, including untreated areas (1).

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

References

Policy History

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<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>March 2014</td>
<td>New addition to PA</td>
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<tr>
<td>December 2014</td>
<td>Annual editorial and reference update</td>
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<td>Removed: dermatitis monitoring</td>
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<tr>
<td>June 2015</td>
<td>Annual editorial review and reference update</td>
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<td>Policy code changed from 5.04.40 to 5.21.40</td>
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<td>June 2017</td>
<td>Annual editorial review and reference update</td>
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<td>Addition of age limit in renewal section</td>
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<td>June 2018</td>
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<td>June 2019</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.