BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.21.040

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

Last Review Date: September 6, 2024

Valchlor

Description

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** if the conditions indicated below are met.

Valchlor may be considered **investigational** 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
    a. Mycosis fungoides type
    b. Stage IA or IB

AND ALL of the following:

a. Patient has had prior skin directed therapy such as topical corticosteroids, topical retinoids or photo therapy
b. Physician agrees to monitor for non-melanoma skin cancer during and after treatment
c. 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

Same as above

Rationale

Summary

Valchlor is a topical alkylating agent use 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

1. Valchlor [package insert]. Iselin, NJ: Helsinn Pharmaceuticals US, Inc.; January 2020.
2. NCCN Drugs & Biologics Compendium® Mechlorethamine 2024. National Comprehensive Cancer Network, Inc. Accessed on July 16, 2024.

Policy History

Date	Action
March 2014	New addition to PA
December 2014	Annual editorial and reference update Removed: dermatitis monitoring
June 2015	Annual editorial review and reference update Policy code changed from 5.04.40 to 5.21.40
June 2017	Annual editorial review and reference update Addition of age limit in renewal section
June 2018	Annual editorial review
June 2019	Annual review
June 2020	Annual review and reference update
December 2021	Annual review and reference update
December 2022	Annual review and reference update. Changed policy number to 5.21.040
September 2023	Annual review and reference update
September 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.