**Prior Authorization Approval Criteria**

**Valchlor (mechlorethamine)**

**Generic name:** mechlorethamine  
**Brand name:** Valchlor  
**Medication class:** Antineoplastic  
**FDA-approved uses:** Topical treatment of stage 1A and 1B mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy

**Criteria for use (bullet points below are all inclusive unless otherwise noted):**

- Clinically diagnosed with Stage 1A or 1B mycosis fungoides-type cutaneous T-cell lymphoma
- Patient was intolerant or refractory to at least one prior skin-directed therapy (such as topical corticosteroids, phototherapy, bexarotene (Targretin) gel, or topical nitrogen mustard)

**Criteria for continuation of therapy:**

- Patient is tolerating treatment
- Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient’s condition)

**Caution:**

- Mucosal or eye injury
- Secondary exposure
- Dermatitis
- Non-melanoma skin cancer
- Embryo-fetal toxicity
- Flammable gel

**Approval Duration:**

- Initial 6 months
- Renewal 1 year

**Benefit Type:**

- Pharmacy

****Off-label Use:**

Fallon may authorize coverage of the requested medication for use in other cancer diagnoses with submitted documentation that the drug is recognized as a “Medically Accepted Indication” according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus.

If the requested off-label use is not acknowledged by the NCCN Drugs and Biologics Compendium, Fallon will abide by the Centers for Medicare and Medicaid Services (CMS) guidance or Massachusetts

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
regulations¹ accepting documentation of recommended off-label use of the requested medication in any one of the following:

1. One of the following standard reference compendia:
   - American Hospital Formulary Service – Drug information (AHFS-DI)
   - Thomson Micromedex DrugDex
   - Clinical Pharmacology (Gold Standard)
   - Wolters Kluwer Lexi-Drugs

2. Peer-reviewed published medical literature determined by Fallon that sufficient evidence exists to support use.

¹Reference: [https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47K](https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47K) accessed 7/7/2017

Date: 12/11/2013

Adopted: Reviewed: 12/13/17- updated criteria for use & continuation of therapy, removed not approved if, contraindications & special considerations, added approval duration, benefit type & FDA off label use statement

References: