

**Clinical Pharmacy Program Guidelines for Valchlor**

Program	Prior Authorization
Medication	Valchlor™ gel for topical use (mechlorethamine)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2014
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

**1. Background:**

Valchlor (mechlorethamine) 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.<sup>1</sup> The National Cancer Comprehensive Network (NCCN) recommends use of topical mechlorethamine in T-cell leukemia/lymphoma, primary cutaneous B-cell lymphoma and primary cutaneous CD30+ T-cell lymphoproliferative disorders.<sup>2</sup>

**2. Coverage Criteria:**

<p><b>A. <u>Primary Cutaneous Lymphomas</u></b></p> <p><b>1. <u>Initial Authorization</u></b></p> <p>a. <b>Valchlor</b> will be approved based on the following criteria:</p> <p>(1) Diagnosis of <b>one</b> of the following:</p> <p>(a) Chronic or smoldering T-cell leukemia/lymphoma  (b) Primary cutaneous marginal zone or follicle center B-cell lymphoma  (c) Lymphomatoid papulosis (LyP) with extensive lesions  (d) Mycosis fungoides (MF)/Sezary syndrome (SS)</p> <p align="center"><b>Authorization will be issued for 12 months.</b></p> <p><b>2. <u>Reauthorization</u></b></p> <p>a. <b>Valchlor</b> will be approved based on the following criterion:</p> <p>(1) Patient does not show evidence of progressive disease while on Valchlor</p>
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**Authorization will be issued for 12 months.**

**B. NCCN Recommended Regimens**

**1. Initial Authorization**

a. **Valchlor** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

**Authorization will be issued for 12 months.**

**2. Reauthorization**

a. **Valchlor** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Valchlor therapy

**Authorization will be issued for 12 months.**

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**

1. Valchlor [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.; January 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [http://www.nccn.org/professionals/drug\\_compendium/content/contents.asp](http://www.nccn.org/professionals/drug_compendium/content/contents.asp). Accessed July 30, 2020.

Program	Prior Authorization - Valchlor gel for topical use (mechlorethamine)
<b>Change Control</b>	
Date	Change
3/2014	New Criteria

12/2015	Annual Review
9/2016	Updated clinical criteria to align with E&I notification policy and updated policy template.
9/2017	Annual Review. Updated criteria for fungoides/sezary syndrome. Updated references.
9/2018	Updated NHL criteria per NCCN. Added NCCN Recommended Regimen review criteria. Updated references.
9/2019	Changed NHL to Primary Cutaneous Lymphomas and revised coverage criteria to align with NCCN. Updated references.
9/2020	Annual review. No changes to coverage criteria. Added Additional Clinical Rules section. Updated references.