UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1123-12
Program	Prior Authorization/Notification
Medication	Valchlor® gel for topical use (mechlorethamine)
P&T Approval Date	4/2014, 11/2014, 11/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 10/2021, 10/2022, 10/2023
Effective Date	1/1/2024

1. Background:

Valchlor gel for topical use (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.[1] The National Cancer Comprehensive Network (NCCN) recommends use of topical mechlorethamine in T-cell leukemia/lymphoma, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders, and Langerhans Cell Histiocytosis (LCH).[2]

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Primary Cutaneous Lymphomas</u>

1. **<u>Initial Authorization</u>**

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

      (1) Diagnosis of **<u>one</u>** of the following:

         (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)

   Authorization will be issued for 12 months.

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2. **Reauthorization**

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

      (1) Patient does not show evidence of progressive disease while on Valchlor

   Authorization will be issued for 12 months.

C. <u>Histiocytic Neoplasms</u>

1. **<u>Initial Authorization</u>**

   a. **Valchlor** will be approved based on **both** of the following criteria:

      (1) Diagnosis of Langerhans Cell Histiocytosis (LCH)

      -AND–

      (2) Skin disease is unifocal and isolated

   Authorization will be issued for 12 months.

2. **Reauthorization**

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

      (1) Patient does not show evidence of progressive disease while on Valchlor

   Authorization will be issued for 12 months.

D. <u>NCCN Recommended Regimens</u>

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

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.
   - Supply limits may be in place.

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4. References:

1. Valchlor [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; January 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia. Accessed September 1, 2023.

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Change Control	
4/2014	New criteria.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
11/2014	Annual review. Updated references.
11/2015	Annual review. Added additional NHL indications to coverage criteria and updated MF/SS criteria. Updated background & references.
9/2016	Annual review. Updated references.
9/2017	Annual review. Updated criteria for mycosis fungoides/sezary syndrome. Updated references.
9/2018	Annual review. Updated criteria based on NCCN Compendium. Updated references.
9/2019	Annual review. Renamed NHL to Primary Cutaneous Lymphomas. Revised coverage rationale based on NCCN Compendium. Updated references. Added general NCCN recommended review criteria.
9/2020	Annual review. No changes to coverage criteria.
10/2021	Annual review. Added coverage rationale for LCH according to NCCN Compendium. Updated references.
10/2022	Annual review. No changes to coverage criteria. Added state mandate. Updated references.
10/2023	Annual review. No changes to coverage criteria. Updated references.

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