



PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology – Valchlor Prior Authorization Policy
- Valchlor® (mechlorethamine topical gel – Helsinn)

REVIEW DATE: 12/17/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Valchlor, a nitrogen mustard, is 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

Guidelines

Valchlor is addressed in National Comprehensive Cancer Network guidelines:

- **Histiocytic neoplasms:** Guidelines (version 2.2025 – November 21, 2025) recommend Valchlor for the topical treatment of unifocal Langerhans cell histiocytosis with isolated skin disease (category 2A).^{2,5}
- **Cutaneous lymphomas:** Guidelines (version 1.2026 – December 9,, 2025) recommend Valchlor for the topical treatment of primary cutaneous B-cell lymphoma, mycosis fungoides/Sezary syndrome, and primary cutaneous CD30+ T-cell lymphoproliferative disorders (category 2A).^{2,3}

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Valchlor. All approvals are provided for the duration noted below.

• **Valchlor® (mechlorethamine topical gel – Helsinn)** is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. Cutaneous Lymphomas. Approve for 1 year if the patient is ≥ 18 years of age.
Note: Cutaneous lymphomas include mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders.

Other Uses with Supportive Evidence

2. Langerhans Cell Histiocytosis. Approve for 1 year if, according to the prescriber, patient has unifocal Langerhans cell histiocytosis with isolated skin disease.

CONDITIONS NOT COVERED

• **Valchlor® (mechlorethamine topical gel – Helsinn)** is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Valchlor® topical gel [prescribing information]. Iselin, NJ: Helsinn; January 2020.
2. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 3, 2025. Search term: mechlorethamine.
3. The NCCN Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (version 1.2026 – December 9, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 12, 2025.
4. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 2.2025 – November 21, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed December 3, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/13/2023

Annual Revision	Adult T-Cell Leukemia/Lymphoma: Removed the descriptor "chronic" from the requirement; approve for 1 year if the patient has smoldering subtype of adult T-cell leukemia/lymphoma.	12/18/2024
Annual Revision	Adult T-Cell Leukemia/Lymphoma: This condition for approval was removed.	12/17/2025

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2025 The Cigna Group.