PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 12/18/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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 2.2024 – July 19, 2024) recommend Valchlor for the topical treatment of unifocal Langerhans cell histiocytosis with isolated skin disease.[2,5]
- **Primary cutaneous lymphomas:** Guidelines (version 1.2025 – November 11, 2024) recommend Valchlor for the topical treatment of primary cutaneous B-cell lymphoma, mycosis fungoides/Sezary syndrome, and primary cutaneous CD30+ T-cell lymphoproliferative disorders.[2,3]
- **T-cell lymphomas:** Guidelines (version 1.2023 – January 5, 2023) recommend Valchlor for the topical treatment of adult T-cell leukemia/lymphoma – smoldering subtype.[2,4]

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: Includes mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders.

Other Uses with Supportive Evidence

2. **Adult T-Cell Leukemia/Lymphoma**. Approve for 1 year if the patient has smoldering subtype of adult T-cell leukemia/lymphoma.

3. **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 experimental, investigational or unproven for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Valchlor® topical gel [prescribing information]. Iselin, NJ: Helsinnkm; January 2020.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 16, 2024. Search term: mechlorethamine.
3. The NCCN Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (version 1.2025 – November 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 16, 2024.
4. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 1.2025 – November 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 16, 2024.
5. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – July 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 16, 2024.

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