Clinical Policy: Mechlorethamine Gel (Valchlor)

Reference Number: PA.CP.PHAR.381
Effective Date: 10/2018
Last Review Date: 07/2023 Revision Log

Description
Mechlorethamine (MCH) gel (Valchlor®) is an alkylating drug also known as nitrogen mustard.

FDA Approved Indication(s)
Valchlor is indicated for the topical treatment of Stage IA and IB mycosis fungoides (MF)-type cutaneous T-cell lymphoma (CTCL) in patients who have received prior skin-directed therapy.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Valchlor is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Mycosis Fungoides (must meet all)**:**

1. Diagnosis of one of the following (a, b, or c):
   a. MF, stage IA-III;
   b. Sezary syndrome (SS), stage IVA;
   c. Large cell transformation (associated with MF and SS);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Failure of at least one skin-directed therapy* (*see Appendix B)* unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for skin directed therapy*
5. Request meets one of the following (a or b):
   a. Dose does not exceed one application per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 6 months

B. NCCN Recommended Uses (off-label) (must meet all)**:**

1. Diagnosis of one of the following (a, b, c, d, or e):
   a. Primary cutaneous B-cell lymphoma (subtype i or ii):
      i. Marginal zone lymphoma;
      ii. Follicle center lymphoma;
   b. Primary cutaneous CD30+ T-cell lymphoproliferative disorder (the following subtype only: lymphomatoid papulosis);
   c. Adult T-cell leukemia/lymphoma (chronic or smoldering subtype);

d. Langerhans cell histiocytosis (LCH) with isolated skin disease;
e. Other category 1, 2A, or 2B NCCN recommended uses;

2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed one application per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CTCL: cutaneous T-cell lymphoma
FDA: Food and Drug Administration
LCH: Langerhans call histiocytosis
MCH: mechlorethamine
MF: mycosis fungoides
NCCN: National Comprehensive Cancer Network
SS: Sezary syndrome

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Skin-Directed Therapies		
Topical corticosteroids (e.g., betamethasone, clobetasol)	Varies	Varies
Local radiation		
Topical retinoids (Targretin® [bexarotene], tazarotene [Avage®, Fabior®, Tazorac®])		
Phototherapy (UVB, NB-UVB, PUVA)		
Topical imiquimod (Aldara®)		
Topical carmustine		
Total skin electron beam therapy		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): severe hypersensitivity to mechlorethamine
- Boxed warning(s): none reported

Appendix D: General Information
The Valchlor pivotal trial was designed to assess non-inferiority of Valchlor (0.02% MCH gel) versus 0.02% MCH as a compounded ointment (historically used for MF in the absence of FDA labeled topical MCH alternatives). Inclusion criteria included persistent or recurrent stage IA, IB and IIA disease. Prior skin-directed therapies included but were not limited to topical corticosteroids, phototherapy, topical and oral bexarotene and other retinoids, interferons, methotrexate, radiation, and topical MCH (the latter not within two years prior to study enrollment). Non-inferiority was confirmed.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Stage IA/IB MF	Thin film QD to affected areas of the skin	One application QD

VI. Product Availability
Gel: 0.016% w/w (equivalent to 0.02% mechlorethamine HCl), 60g tube

VII. References
1. Valchlor Prescribing Information. Malvern, PA: Ceptarin Therapeutics; January 2020. Available at: https://www.valchlor.com/pdfs/Valchlor-022120-USPI-Digital.pdf. Accessed May 10, 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org. Accessed May 10, 2023.

3. National Comprehensive Cancer Network. Primary Cutaneous Lymphomas Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed May 10, 2023.
4. National Comprehensive Cancer Network. T-Cell Lymphomas Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed May 10, 2023.
5. National Comprehensive Cancer Network. Histiocytic Neoplasms Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf. Accessed May 10, 2023.
6. Lessin SR, Duvic M, Guitart J, et al. Topical chemotherapy in cutaneous T-cell lymphoma: positive results of a randomized, controlled, multicenter trial testing the efficacy and safety of a novel mechlorethamine, 0.02%, gel in mycosis fungoides. JAMA Dermatol. 2013; 149(1): 25-32.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created	10/2018	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/2019	
3Q 2020 annual review: NCCN recommended uses expand MS from stage IA to IB to stage IA to III; other NCCN recommended uses added to section I.A and as a new section I.B.; continuation duration extended to 12 months to align with other lines of business; references reviewed and updated.	07/2020	
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021	
3Q 2022 annual review: added Langerhans cell histiocytosis to section B as NCCN recommended use (off label); references reviewed and updated.	07/2022	
3Q 2023 annual review: updated SS staging from “IV” to “IVA” per NCCN compendium; added “topical carmustine” as an alternative skin-therapy agent in Appendix B; references reviewed and updated.	07/2023	