Clinical Policy: Mechlorethamine Gel (Valchlor)

Reference Number: PA.CP.PHAR.381
Effective Date: 10.17.18
Last Review Date: 07/17/19 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 health plans affiliated with 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 MF stage IA or IB;
2. Prescribed by or in consultation with an oncologist;
3. Failure of at least one skin-directed therapy (*see Appendix B)* unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed one application per day.

Approval duration: 6 months

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

1. Currently receiving medication via Pennsylvania Health and 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, new dose does not exceed one application per day.

Approval duration: 6 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
MCH: mechlorethamine
MF: mycosis fungoides

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®)		
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

Not applicable.

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)

VII. References

1. Valchlor Prescribing Information. Malvern, PA: Ceptarin Therapeutics; December 2016. Available at: www.valchlor.com. Accessed April 2018.
2. National Comprehensive Cancer Network. T-cell lymphomas; Version 3.2018. Available at: http://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Accessed April 2018.
3. 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	10/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	