Clinical Policy: Mechlorethamine Gel (Valchlor)

Reference Number: ERX.SPA.238
Effective Date: 09.01.18
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Valchlor is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Mycosis Fungoides/Sezary Syndrome (must meet all)**:**

1. Diagnosis of one of the following (a, b, or c):
   a. MF, stage IA-III;
   b. Sezary syndrome (SS), stage IV;
   c. Large cell transformation (associated with MF and SS);
2. Prescribed by or in consultation with an oncologist;
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*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

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

1. Diagnosis of one of the following (a, b, or c):
   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);
2. Prescribed by or in consultation with an oncologist;

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. 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*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

C. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Valchlor for a covered indication and has received this medication for at least 30 days;
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*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CTCL: cutaneous T-cell lymphoma
FDA: Food and Drug Administration
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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Skin-Directed Therapies		
Topical corticosteroids (e.g., betamethasone, clobetasol)	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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/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)

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 March 17, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org. Accessed March 17, 2021.
3. National Comprehensive Cancer Network. Primary Cutaneous Lymphomas Version 2.2021. Available at: http://www.nccn.org. Accessed March 17, 2021.
4. National Comprehensive Cancer Network. T-Cell Lymphomas Version 1.2021. Available at: http://www.nccn.org. Accessed March 17, 2021.
5. 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.	05.08.18	08.18
3Q 2019 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.; added Medicaid line of business with 6/12 month approval durations; references reviewed and updated.	05.14.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	05.12.20	08.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2021 annual review: no significant changes; references reviewed and updated.	03.17.21	08.21

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.