RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title: **Mechlorethamine Gel (Valchlor)**
Policy Number: **RxA.534**
Drug(s) Applied: **Valchlor**
Last Review Date: **01/2020**
Line of Business: **Commercial, Medicaid**

Background

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

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

Gel: 0.016% w/w (equivalent to 0.02% mechlorethamine HCl)

Clinical Policy

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

I. Initial Approval Criteria

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

1. One of the following diagnoses (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;
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:
Medicaid – 6 months
Commercial – Length of Benefit

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

1. One of the following diagnoses (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;
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).

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

II. Continued Therapy

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

1. Currently receiving medication via RxAdvance benefit, 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).

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

III. Appendices

Appendix A: Abbreviation/Acronym Key

CTCL: cutaneous T-cell lymphoma
FDA: Food and Drug Administration
MCH: mechlorethamine
MF: mycosis fungoides
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®)		
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.

References

1. Valchlor Prescribing Information. Malvern, PA: Ceptarin Therapeutics; November 2018. Available at: www.valchlor.com. Accessed May 2, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org. Accessed May 2, 2019.
3. National Comprehensive Cancer Network. Primary Cutaneous Version 2.2019. Available at: http://www.nccn.org. Accessed May 2, 2019.
4. National Comprehensive Cancer Network. T-Cell Lymphomas Version 2.2019. Available at: http://www.nccn.org. Accessed May 2, 2019.
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.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	03/06/2020