RXADVANCE
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Clinical Policy Title:	mechlorethamine gel
Policy Number:	RxA.534
Drug(s) Applied:	Valchlor®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
mechlorethamine Gel (Valchlor®)	Stage IA/IB MF	Thin film once daily to affected areas of the skin	One application once daily

Dosage Forms

- Gel: 0.016% w/w (equivalent to 0.02% mechlorethamine HCl) in 60g tubes.

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

Commercial: 6 months
Medicaid: 6 months

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
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
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
Commercial: 6 months
Medicaid: 6 months

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
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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; January 2020. Available at: https://www.valchlor.com/pdfs/Valchlor-022120-USPI-Digital.pdf . Accessed October 14, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org. Accessed October 14, 2020.
3. National Comprehensive Cancer Network. Primary Cutaneous Version 1.2021. Available at: http://www.nccn.org. Accessed October 14, 2020.
4. National Comprehensive Cancer Network. T-Cell Lymphomas Version 1.2021. Available at: http://www.nccn.org. Accessed October 14, 2020.
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/Revision Date	P&T Approval Date

Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title Table was updated. 2. Line of business policy applies was updated to All lines of business. 3. Dosage form was updated to include the tube size. 4. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..." 5. Initial Approval criteria: Medicaid approval duration was updated from Length of Benefit to 6 months. 6. Continued Approval criteria: Medicaid approval duration was updated from Length of Benefit to 6 months. 7. References was reviewed and updated.	10/14/2020	12/07/2020