

Clinical Policy: Mechlorethamine Gel (Valchlor)

Reference Number: CP.PHAR.381

Effective Date: 11.16.16

Last Review Date: 08.19

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.

It is the policy of health plans affiliated with Centene Corporation[®] that Valchlor is **medically necessary** when the following criteria are met:

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 \geq 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 \geq 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

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene 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

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CTCL: cutaneous T-cell lymphoma MF: mycosis fungoides
 FDA: Food and Drug Administration SS: Sezary syndrome
 MCH: mechlorethamine

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
<i>Skin-Directed Therapies</i>		
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.

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; 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template; removed topical mechlorethamine from redirect options as there is no generic Valchlor	1.12.17	8.17
3Q 2018 annual review: policies combined for Centene Medicaid (new) and Commercial lines of business; age and specialist requirements added; continuation of care statement added; therapeutic alternatives updated per NCCN (App. B); references reviewed and updated.	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.; references reviewed and updated.	05.14.19	08.19

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and

limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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