Clinical Policy Title:	mechlorethamine gel
Policy Number:	RxA.534
Drug(s) Applied:	Valchlor®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

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. Trial & Failure of at least one skin-directed therapy 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).

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

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, c or d):
   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);
   d. Unifocal Langerhans Cell Histiocytosis;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Trial & Failure of at least one skin-directed therapy 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).*

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

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).

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

Approval Duration
Commercial: 6 months
Medicaid: 6 months

References

1. National Comprehensive Cancer Network. Primary Cutaneous Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf Accessed September 14, 2022.
2. National Comprehensive Cancer Network. T-Cell Lymphomas Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed September 14, 2022.
3. National Comprehensive Cancer Network. Histiocytic Neoplasms Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf. Accessed September 14, 2022.

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. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..." 4. Initial Approval criteria: Medicaid approval duration was updated from Length of Benefit to 6 months. 5. Continued Approval criteria: Medicaid approval duration was updated from Length of Benefit to 6 months. 6. References was reviewed and updated.	10/14/2020	12/07/2020

Policy was reviewed: 1. Initial Approval Criteria I.B.1.d & I.B.1.e added to include off label indications “Unifocal Langerhans Cell Histiocytosis”. 2. References was reviewed and updated.	09/25/2021	12/07/2021
Policy was reviewed: 1. References were reviewed and updated.	09/13/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023