Reference number
1862-A

SPECIALTY GUIDELINE MANAGEMENT

VALCHLOR (mechlorethamine gel)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Valchlor is indicated for the topical treatment of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy.

B. Compendial Uses
1. Chronic or smoldering adult T-cell leukemia/lymphoma
2. Mycosis fungoides/Sezary syndrome
3. Primary cutaneous B-cell lymphoma:
    a. Primary cutaneous marginal zone lymphoma
    b. Primary cutaneous follicle center lymphoma
4. Lymphomatoid papulosis

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Mycosis Fungoides/Sezary Syndrome
Authorization of 12 months may be granted for the treatment of mycosis fungoides or Sezary syndrome.

B. Adult T-cell leukemia/lymphoma
Authorization of 12 months may be granted for the treatment of chronic or smoldering adult T-cell leukemia/lymphoma.

C. Primary cutaneous B-cell lymphoma
Authorization of 12 months may be granted for the treatment of primary cutaneous marginal zone or follicle center lymphoma.

D. Lymphomatoid Papulosis
Authorization of 12 months may be granted for the treatment of lymphomatoid papulosis.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Valchlor [package insert]. Iselin, NJ: Helsinn Therapeutics, Inc.; January 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 6, 2021.