Prior Authorization Approval Criteria

Valchlor (mechlorethamine)

Generic name: mechlorethamine
Brand name: Valchlor
Medication class: Antineoplastic
FDA-approved uses: Topical treatment of stage 1A and 1B mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy
Available dosage forms: 0.016% w/w gel in 60g tubes
Usual dose: Applied once daily to affected areas of the skin
Approximate cost: $3,600 per tube (based on AWP)
Duration of therapy: Until disease progression or unacceptable toxicity occurs

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records
- Clinically diagnosed with Stage 1A or 1B mycosis fungoides-type cutaneous T-cell lymphoma
- Patient was intolerant or refractory to at least one prior therapy
- Patient has contraindication to the use of both the ointment formulation of mechlorethamine and the aqueous formulation of mechlorethamine

Criteria for continuation of therapy:
- Patient responding to treatment
- Patient tolerating treatment

Caution:
- Mucosal or eye injury
- Secondary exposure
- Dermatitis
- Non-melanoma skin cancer
- Embryo-fetal toxicity
- Flammable gel

Contraindication:
- Hypersensitivity to mechlorethamine

Not approved if:
- Does not meet above criteria
- Has any contraindications to treatment
Special considerations:

- Efficacy and safety were assessed in a randomized, multicenter, observer-blind, active-controlled, non-inferiority clinical trial. Aquaphor-based mechlorethamine 0.02% ointment was used as the active-control.
- Must be refrigerated

Adopted: 12/11/2013