Reference number(s)
6612-A

SPECIALTY GUIDELINE MANAGEMENT

LYMPHIR (denileukin diftitox-cxdl)

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 Indications
Adult patients with relapsed or refractory Stage I-III cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy.

B. Compendial Uses
Mycosis fungoides (MF) or Sézary syndrome (SS) – primary treatment

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

II. CRITERIA FOR INITIAL APPROVAL

Cutaneous T-cell lymphoma
Authorization of 12 months may be granted for treatment of stage I-III cutaneous T-cell lymphoma.

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. Lymphir [package insert]. Cranford, NJ: Citius Pharmaceuticals, Inc.; August 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed August 22, 2024.