

DRUG POLICY

Lymphir™ (denileukin diftitox-cxdl)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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

Compendial Uses

1. Mycosis fungoides (MF) – primary treatment

POLICY

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.

Continuation of Therapy

Cutaneous T-Cell Lymphoma

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

Other

Lymphir (denileukin diftitox-cxdl) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

J9161 – Injection, denileukin diftitox-cxdl, 1 mcg

REFERENCES

Lymphir [package insert]. Cranford, NJ: Citius Pharmaceuticals, Inc.; August 2024.

The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed December 15, 2025.

POLICY HISTORY

Policy #: 05.06.16

Original Effective Date: February 27, 2026

Reviewed: August 2026

Revised:

Current Effective Date: February 27, 2026