TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Denileukin diftitox-cxdl (Lymphir®)	**CRITERIA ID:** TX.CC.PHAR.57
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 04/14/2026	**PRODUCT(S):** STAR, STAR+PLUS, STAR Kids, STAR Health, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: N/A	**REGULATOR MOST RECENT APPROVAL DATE(S):** N/A

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for denileukin diftitox-cxdl (Lymphir®)

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
N/A

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of denileukin diftitox-cxdl (Lymphir®); procedure code: J9161.

Description/Mechanism of Action:
Denileukin diftitox-cxdl is a fusion protein designed to direct the cytocidal action of diphtheria toxin (DT) to cells which express the IL2 receptor. Denileukin diftitox-cxdl is a fusion protein designed to direct the cytocidal action of diphtheria toxin (DT) to cells which express the IL2 receptor. It is composed of the amino acid sequences for diphtheria toxin (DT) fragments A and B-His and the sequence for human interleukin-1 (IL-2). The DT fragment is cleaved after cellular uptake, with the free DT fragments inhibiting protein synthesis

and resulting in cell death. It has demonstrated the ability to deplete immunosuppressive regulatory T lymphocytes and has antitumor activity through direct cytocidal action on IL-2R-expressing tumors.

FDA Approved Indications:
Lymphir is an IL2-receptor-directed cytotoxin indicated for the treatment of adult patients with relapsed or refractory Stage I-III cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy.

Formulations:
300 mcg lyophilized cake in a single-dose vial.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Approval Criteria

A. Cutaneous T-cell lymphoma (CTCL)

1. Client is 18 years or older.
2. Client has a confirmed diagnosis of cutaneous T-cell lymphoma (CTCL).
    a. Client's lymphoma is categorized as Stage I to III
    b. Client's CTCL is relapsed or refractory after at least one prior systemic treatment.
3. The client's serum albumin level must be greater than 3 g/dL prior to treatment cycle.
4. The prescriber attests to counseling female clients of childbearing age regarding the use of an effective method of contraception during treatment with Lymphir (denileukin diftitox-cxdl), as there may be a potential risk to the fetus.
5. Prescriber attests to the following:
    a. Monitor for signs and symptoms of Capillary Leak Syndrome (e.g., low blood pressure, severe swelling)
    b. Monitor client's liver enzymes and bilirubin at baseline and during treatment as hepatotoxicity may occur.
    c. Monitor client's renal function prior to starting each treatment. If serum albumin is less than 3 g/dL, delay administration of Lymphir until serum albumin is greater than or equal to 3 g/dL.
    d. Monitor and evaluate for any visual impairment throughout treatment.

Approval duration: 12 months

II. Continuation Criteria

A. Cutaneous T-cell lymphoma (CTCL)

1. Client met initial requirements for prior authorization and is currently treated with denileukin diftitox-cxdl with the absence of severe adverse reactions or unacceptable toxicity (e.g., visual impairment, infusion related reactions, or hepatotoxicity).
2. Client demonstrates partial/complete response to treatment or stabilization of disease, as shown by a decrease in spread or size of the tumor.

Approval duration: 12 months

III. Appendices/General information

Appendix A: Diagnosis code for CTCL (Mycosis Fungoides or Sézary Syndrome)

C84.00	C84.01	C84.02	C84.03	C84.04	C84.05
C84.06	C84.07	C84.08	C84.09	C84.10	C84.11
C84.12	C84.13	C84.14	C84.15	C84.16	C84.17
C84.18	C84.19	C84.A0	C84.A1	C84.A2	C84.A3
C84.A4	C84.A5	C84.A6	C84.A7	C84.A8	C84.A9
C84.AA					

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document		04/14/2026