CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Lymphir Utilization Management Medical Policy
- Lymphir™ (denileukin diftitox-cxdl intravenous infusion – Citius)

REVIEW DATE: 10/23/2024

OVERVIEW

Lymphir, an interleukin (IL)-2 receptor directed cytotoxin, is indicated for the treatment of relapsed or refractory Stage I-III cutaneous T-cell lymphoma in adults after at least one prior systemic therapy.[1]

Dosing

The recommended dose of Lymphir is 9 mcg/kg/day administered by intravenous infusion on the first 5 days of each 21-day cycle.[1] Treatment can continue until disease progression or unacceptable adverse events. Delay administration of Lymphir if the serum albumin is < 3 g/dL.

Guidelines

The National Comprehensive Cancer Network (NCCN) primary cutaneous lymphomas (version 3.2024 – August 22, 2024) guidelines recommend Lymphir for the primary and subsequent treatment of stage IIB mycosis fungoides/Sezary syndrome with generalized tumor lesions as a "Preferred Regimen" in combination with skin-directed therapy.[2,3] NCCN also recommends Lymphir for the primary and subsequent treatment of stage IB to IIA and stage III mycosis fungoides/Sezary syndrome as "Useful in Certain Circumstances" in combination with skin-directed therapy and as "Useful in Certain Circumstances" for stage IIB with limited tumor lesions with or without skin-directed therapy. All recommendations are category 2A.

Safety

Lymphir has a Boxed Warning for capillary leak syndrome, including life-threatening or fatal reactions.[1]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Lymphir. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Lymphir as well as the monitoring required for adverse events and long-term efficacy, approval requires Lymphir to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lymphir is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Cutaneous T-Cell Lymphoma.** Approve for one year if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has Stage I to III disease; AND
   C) Serum albumin is ≥ 3 g/dL; AND
   D) Medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 9 mcg/kg/day of actual body weight given by intravenous infusion no more frequently than five times in each 21-day treatment cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lymphir is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Lymphir intravenous infusion [prescribing information]. Cranford, NJ: Citius Pharmaceuticals; August 2024.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 15, 2024. Search term: denileukin diftitox-cxdl.
3. The NCCN Primary Cutaneous Lymphoma Clinical Practice Guidelines in Oncology (version 3.2024 – August 22, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed October 15, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	10/23/2024