

Lymphir™ (denileukin diftitox-cxdl) (Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 6000 billable units per 21-day cycle

III. Initial Approval Criteria¹

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria ¹

- Member's serum albumin is greater than or equal to 3 g/dL; **AND**
- Member will be regularly assessed for signs and symptoms of capillary leak syndrome (e.g., more than one of the following: hypotension, edema, serum albumin <3 g/dL); **AND**
- Member will have an ophthalmic examination at baseline and periodically throughout therapy as clinically indicated; **AND**
- Used as single agent systemic therapy; **AND**

Cutaneous T-Cell Lymphoma (CTCL) - Mycosis Fungoides/Sezary Syndrome † ‡ § ^{1-4,2e,6e}

- Used as subsequent therapy for relapsed or refractory disease after at least one prior systemic therapy; **AND**

- Member has stage I, II, or III disease; **AND**

- Member demonstrated an inadequate response to bexarotene or mogamulizumab as subsequent systemic therapy, if clinically appropriate and not previously used, unless there is a contraindication or intolerance, prior to approval of denileukin diftiox-cxdl

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Enhanced Oncology Value (EOV) Program – Redacted indications

Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity.

Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹

Prior authorization validity can be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: capillary leak syndrome (CLS), severe visual impairment, severe infusion-related reactions, severe hepatotoxicity, etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

V. Dosage/Administration ¹

Indication	Dose
Cutaneous T-Cell Lymphoma (CTCL) - Mycosis Fungoides/Sezary Syndrome	Administer 9 mcg/kg/day actual body weight intravenously on Days 1 through 5 of a 21-day treatment cycle until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

- J9161 – Injection, denileukin diftitox-cxdL, 1 mcg; 1 billable unit = 1 mcg

NDC:

- Lymphir 300 mcg lyophilized cake for reconstitution in a single-dose vial: 52658-7777-xx

VII. References (STANDARD)

1. Lymphir [package insert]. Cranford, NJ; Citius Pharmaceuticals, Inc.; August 2024. Accessed March 2026.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) denileukin diftitox-cxdL. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2026.
3. Foss FM, Kim YH, Prince HMM, et al. Efficacy and Safety of E7777 (improved purity Denileukin diftitox [ONTAK]) in Patients with Relapsed or Refractory Cutaneous T-Cell Lymphoma: Results from Pivotal Study 302. Blood 2022; 140 (Supplement 1): 1491–1492. doi: <https://doi.org/10.1182/blood-2022-166916>.
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VIII. References (ENHANCED)

- 1e. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Cutaneous Lymphomas, Version 2.2026. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2026.
- 2e. Kim YH, Bagot M, Pinter-Brown L, et al; MAVORIC Investigators. Mogamulizumab versus vorinostat in previously treated cutaneous T-cell lymphoma (MAVORIC): an international, open-label, randomised, controlled phase 3 trial. Lancet Oncol. 2018 Sep;19(9):1192-1204. doi: 10.1016/S1470-2045(18)30379-6. Epub 2018 Aug 9. Erratum in: Lancet Oncol. 2018 Nov;19(11):e581. doi: 10.1016/S1470-2045(18)30772-1. PMID: 30100375.

- 3e. Prince HM, Kim YH, Horwitz SM, et al; ALCANZA study group. Brentuximab vedotin or physician's choice in CD30-positive cutaneous T-cell lymphoma (ALCANZA): an international, open-label, randomised, phase 3, multicentre trial. *Lancet*. 2017 Aug 5;390(10094):555-566. doi: 10.1016/S0140-6736(17)31266-7. Epub 2017 Jun 7. PMID: 28600132.
- 4e. Duvic M, Tetzlaff MT, Gangar P, et al. Results of a Phase II Trial of Brentuximab Vedotin for CD30+ Cutaneous T-Cell Lymphoma and Lymphomatoid Papulosis. *J Clin Oncol*. 2015 Nov 10;33(32):3759-65. doi: 10.1200/JCO.2014.60.3787. Epub 2015 Aug 10. PMID: 26261247; PMCID: PMC4737859.
- 5e. Kim YH, Tavallaei M, Sundram U, et al. Phase II Investigator-Initiated Study of Brentuximab Vedotin in Mycosis Fungoides and Sézary Syndrome With Variable CD30 Expression Level: A Multi-Institution Collaborative Project. *J Clin Oncol*. 2015 Nov 10;33(32):3750-8. doi: 10.1200/JCO.2014.60.3969. Epub 2015 Jul 20. PMID: 26195720; PMCID: PMC5089160.
- 6e. Duvic M, Hymes K, Heald P, et al; Bexarotene Worldwide Study Group. Bexarotene is effective and safe for treatment of refractory advanced-stage cutaneous T-cell lymphoma: multinational phase II-III trial results. *J Clin Oncol*. 2001 May 1;19(9):2456-71. doi: 10.1200/JCO.2001.19.9.2456. PMID: 11331325.
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- 11e. Kuzel TM, Roenigk HH Jr, Samuelson E, et al. Effectiveness of interferon alfa-2a combined with phototherapy for mycosis fungoides and the Sézary syndrome. *J Clin Oncol*. 1995 Jan;13(1):257-63.
- 12e. Pulini S, Rupoli S, Goteri G, et al. Pegylated liposomal doxorubicin in the treatment of primary cutaneous T-cell lymphomas. *Haematologica*. 2007 May;92(5):686-9.
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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C84.00	Mycosis fungoides, unspecified site
C84.01	Mycosis fungoides, lymph nodes of head, face, and neck
C84.02	Mycosis fungoides, intrathoracic lymph nodes
C84.03	Mycosis fungoides, intra-abdominal lymph nodes
C84.04	Mycosis fungoides, lymph nodes of axilla and upper limb
C84.05	Mycosis fungoides, lymph nodes of inguinal region and lower limb
C84.06	Mycosis fungoides, intrapelvic lymph nodes
C84.07	Mycosis fungoides, spleen
C84.08	Mycosis fungoides, lymph nodes of multiple sites
C84.09	Mycosis fungoides, extranodal and solid organ sites
C84.10	Sézary disease, unspecified site
C84.11	Sézary disease, lymph nodes of head, face, and neck
C84.12	Sézary disease, intrathoracic lymph nodes
C84.13	Sézary disease, intra-abdominal lymph nodes
C84.14	Sézary disease, lymph nodes of axilla and upper limb
C84.15	Sézary disease, lymph nodes of inguinal region and lower limb
C84.16	Sézary disease, intrapelvic lymph nodes

C84.17	Sézary disease, spleen
C84.18	Sézary disease, lymph nodes of multiple sites
C84.19	Sézary disease, extranodal and solid organ sites

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC