



LYMPHIR™

(denileukin diftitox-cxdI)

Injection 300 mcg

BILLING AND CODING GUIDE

A resource that provides coding descriptors capturing diagnoses, medical procedures, and product information needed for billing and coding of LYMPHIR and helping payers process and pay claims

This resource is for informational purposes only and does not guarantee the payer will provide reimbursement for LYMPHIR. Coding requirements may vary by payer. Providers should follow payer-specific coding requirements and exercise independent clinical judgment when selecting codes and submitting claims.

INDICATIONS AND USAGE

LYMPHIR (denileukin diftitox-cxdI) is 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.

IMPORTANT SAFETY INFORMATION

WARNING: CAPILLARY LEAK SYNDROME

Capillary leak syndrome (CLS), including life-threatening or fatal reactions, can occur in patients receiving LYMPHIR. Monitor patients for signs and symptoms of CLS during treatment. Withhold LYMPHIR until CLS resolves, or permanently discontinue based on severity.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning.



What is included in this guide?

Suggested codes for billing for LYMPHIR:

- International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes
- Current Procedural Terminology (CPT®) code*
- Revenue code
- Healthcare Common Procedure Coding System (HCPCS) level II codes
- National Drug Code (NDC)

*CPT is a registered trademark of the American Medical Association. The American Medical Association assumes no liability for data contained or not contained herein.

Annotated samples of the 2 most common Centers for Medicare & Medicaid Services (CMS) claim forms used to bill for drugs and services:

- CMS-1500 (print) or 837P (electronic) forms for billing for physician office reimbursement
- CMS-1450 (print), also referred to as UB-04, or 837I (electronic) forms for hospital outpatient reimbursement

For questions or for more information about LYMPHIR, call **844-4-LYMPHIR** (844-459-6744), email **medicalinformation@citiusonc.com**, or visit **LYMPHIRhcp.com**

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

Capillary Leak Syndrome

LYMPHIR can cause capillary leak syndrome (CLS), including life-threatening or fatal reactions. CLS was defined in the clinical trials as the occurrence of at least 2 of the following symptoms at any time during LYMPHIR therapy: hypotension, edema, and serum albumin <3 g/dL. These symptoms were not required to occur simultaneously to be characterized as CLS.

As defined, CLS occurred in 27% of patients in the pooled population across 3 clinical trials, including 8% with Grade 3. There was one (0.8%) fatal occurrence of CLS. Of the patients with CLS, 22% had recurrence. The majority of CLS events (81%) occurred within the first 2 cycles of treatment. The median time to onset from Cycle 1, Day 1 was 6.5 days (range: 1 to 77), the median duration of CLS was 14 days (range: 2 to 40), and 75% of patients had resolution.



ICD-10-CM diagnosis codes

Indication and usage for relapsed or refractory Stage I-III CTCL

LYMPHIR is a fusion protein designed to direct the cytotoxic action of diphtheria toxin (DT) to cells which express the IL-2 receptor. LYMPHIR is 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.¹

Mycosis fungoides is the most common form of CTCL, accounting for approximately 50% of this rare group of blood cancers.² The following diagnosis codes may be submitted to document a diagnosis of CTCL indicated for LYMPHIR.

MYCOSIS FUNGOIDES[†]

C84.0	Mycosis fungoides
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, 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

[†]Be as specific as possible when selecting code(s).

Continued on next page.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Capillary Leak Syndrome (cont'd)

Regularly assess patients for weight gain, new onset or worsening of edema, dyspnea, and hypotension (including orthostatic changes). Monitor serum albumin levels prior to the initiation of each cycle of therapy and more often as clinically indicated.

Withhold, reduce dose, or permanently discontinue based on severity. If LYMPHIR is withheld, resume LYMPHIR following resolution of CLS and when serum albumin is ≥ 3 g/dL.

Visual Impairment

LYMPHIR can cause serious visual impairment, including changes in visual acuity and color vision. In the pooled population across 3 clinical trials, visual impairment occurred in 9%, with Grade 1 in 8% and Grade 2 in 1%. The most commonly reported symptom was blurred vision. Of the patients with visual impairment, 67% had resolution of their visual impairment.

Perform baseline ophthalmic examination and monitor as clinically indicated. If patients experience symptoms of visual impairment, such as changes in visual acuity, changes in color vision, or blurred vision, refer for ophthalmologic evaluation. Withhold LYMPHIR until visual impairment resolves or permanently discontinue based on severity.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning.

ICD-10-CM diagnosis codes (cont'd)

Sézary syndrome is the second most common type of CTCL, accounting for approximately 15% of all CTCL.² The following codes may be used to document a diagnosis indicated for LYMPHIR:

SÉZARY SYNDROME*

Continued from previous page.

C84.1	Sézary disease
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, 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

The ICD-10-CM codes below may be submitted to more broadly document a diagnosis of CTCL indicated for LYMPHIR.

CUTANEOUS T-CELL LYMPHOMA*

C84.A	Cutaneous T-cell lymphoma, unspecified
C84.A0	Cutaneous T-cell lymphoma, unspecified, unspecified site
C84.A1	Cutaneous T-cell lymphoma, unspecified, lymph nodes of head, face, and neck
C84.A2	Cutaneous T-cell lymphoma, unspecified, intrathoracic lymph nodes
C84.A3	Cutaneous T-cell lymphoma, unspecified, intra-abdominal lymph nodes
C84.A4	Cutaneous T-cell lymphoma, unspecified, lymph nodes of axilla and upper limb
C84.A5	Cutaneous T-cell lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C84.A6	Cutaneous T-cell lymphoma, unspecified, intrapelvic lymph nodes
C84.A7	Cutaneous T-cell lymphoma, unspecified, spleen
C84.A8	Cutaneous T-cell lymphoma, unspecified, lymph nodes of multiple sites
C84.A9	Cutaneous T-cell lymphoma, unspecified, extranodal and solid organ sites

*Be as specific as possible when selecting code(s).

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Infusion-Related Reactions

LYMPHIR can cause serious infusion-related reactions. Infusion-related reactions were reported in 69% of patients in the pooled population across 3 clinical trials of patients who received LYMPHIR, with Grade 3 infusion-related reactions in 3.4%. Eighty-three percent of infusion-related reactions occurred in Cycles 1 and 2. The most common symptoms included nausea, fatigue, chills, musculoskeletal pain, vomiting, fever, and arthralgia.



CPT code

Healthcare providers are required to report the administration of an intravenous (IV) infusion of LYMPHIR. The service may be documented using the CPT code below.³

96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug
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Revenue code

The following revenue code may be recorded on the CMS-1450 (UB-04) form.⁴

0636	Pharmacy—drugs requiring detailed coding
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HCPCS level II codes[†]

J-codes are permanent codes used by hospitals, physicians, and other health professionals who bill Medicare and commercial payers for non-orally administered medication and chemotherapy drugs. Prior to the assignment of a permanent product-specific J-code for LYMPHIR, the following miscellaneous J-codes or temporary C-code may be used for administrative and billing purposes.

J9999	Not otherwise classified, antineoplastic
J3490	Unclassified drugs
J3590	Unclassified biologics
C9399	Unclassified drugs or biologics (limited to use in the HOPD or ASC when treating Medicare beneficiaries)

ASC=ambulatory surgery center; HOPD=hospital outpatient department.

[†]CMS and most payers require prescribers to record drug wastage, or lack thereof. A JW modifier is required to report discarded drug (ie, JXXXX-JW), and effective July 1, 2023, a JZ modifier is required to report no discarded drug (ie, JXXXX-JZ).⁵

More information on miscellaneous HCPCS codes

- Miscellaneous HCPCS codes are used when a provider submits a bill for an item or service for which there is no existing national code that adequately describes the item or service being billed⁶
- Using miscellaneous HCPCS codes allows providers to begin billing immediately for a service or item as soon as it is approved by the US Food and Drug Administration (FDA)⁶
- Requirements will vary by payer. Include any supporting documentation for the patient's diagnosis (eg, clinical notes, laboratory results), the brand or generic name, the administered dosage, the route of administration, and the total wastage or lack of wastage
- Miscellaneous HCPCS codes should be used until a product-specific code is assigned for LYMPHIR

LYMPHIR product information¹

LYMPHIR™ (denileukin diftitox-cxd) dose [†]	Configuration	National Drug Code (NDC) [§]
300 mcg	Single-dose vial	52658-7777-01

[†]Please refer to the full Prescribing Information for the recommended dosage of LYMPHIR.

[§]The product's NDC has been "zero-filled" to ensure creation of an 11-digit code that meets general billing standards. The zero-fill location is indicated in bold above.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Infusion-Related Reactions (cont'd)

Premedicate patients for the first 3 cycles prior to starting a LYMPHIR infusion. Monitor patients frequently during infusion. For Grade 2 or higher infusion reactions, premedicate at least 30 minutes prior to each subsequent infusion with a systemic steroid for at least 3 cycles. Interrupt or discontinue LYMPHIR based on severity. Institute appropriate medical management.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning.

Completing a CMS-1500 form*

The CMS-1500 form is used when billing in-office claims. The sample annotated form below provides guidance on completing a CMS-1500 form using a miscellaneous J-code or temporary C-code as well as populating additional fields that health plans require for LYMPHIR reimbursement.

Please confirm the accuracy of the codes you use to bill for LYMPHIR with each payer. If submitting to a Medicare Administrative Contractor (MAC), refer to the specific MAC's guidelines for completion of the reimbursement forms. **This sample claim form is intended for use only as a reference. The codes provided are subject to change and should not be construed as legal or billing advice.**

BOX 19:

LYMPHIR does not currently have a product-specific HCPCS code. When filing claims using a miscellaneous or temporary HCPCS code, most payers require additional information to be entered in Box 19, including the drug name, route of administration, total dosage, NDC, and wastage or lack of wastage.^{7,8} **Please check with the payer to confirm the required additional information.**

BOX 21:

Indicate appropriate diagnosis using ICD-10-CM code(s).⁷

BOX 24A:

Enter a 6-digit or 8-digit (month-date-year) date for each procedure, service, or supply. Include NDC, if required, in the shaded red areas above each date.⁷

BOX 24B:

Enter the appropriate place of service code(s).⁷

BOX 24D:

Enter the appropriate CPT and HCPCS level II codes and modifiers for procedures, services, and supplies.⁷ Because LYMPHIR does not currently have a product-specific HCPCS code, default NOC (Not Otherwise Classified) codes are used instead. Enter miscellaneous HCPCS code J3490, J3590, J9999, or temporary C9399 to represent LYMPHIR.

Additionally, CMS and most payers require you to record drug waste. Until LYMPHIR is assigned a product-specific code, reports of no wastage can be added to Box 19 and entered here using the miscellaneous or temporary HCPCS code and modifier JZ denoting zero waste (ie, JXXXX-JZ). Similarly, reports of wastage can be added to Box 19 and entered here using the miscellaneous or temporary HCPCS code and modifier JW denoting drug waste (ie, JXXXX-JW). Drug wastage should be reported on a separate claim line.^{5,7}

BOX 24E:

Enter the diagnosis code reference number or letter (as appropriate, per form version) as shown in item 21 to relate the date of service and the procedures performed to the primary diagnosis. Enter only 1 reference number/letter per line item. If multiple services were performed, enter the primary reference number/letter for each service.⁷

BOX 24G:

Enter the number of units of LYMPHIR administered. **Miscellaneous HCPCS codes are usually reported with a unit of 1.** Use Box 19 to report the total dosage of LYMPHIR administered.^{7,8}

The image shows a sample CMS-1500 Health Insurance Claim Form with several fields highlighted and annotated with callouts:

- Box 19:** Points to the shaded red area at the top of the form, used for entering drug name, route, dosage, NDC, and wastage.
- Box 21:** Points to the ICD-10-CM diagnosis code field (Item 21).
- Box 24A:** Points to the date of service field (Item 24A).
- Box 24B:** Points to the place of service code field (Item 24B).
- Box 24D:** Points to the CPT and HCPCS code fields (Item 24D).
- Box 24E:** Points to the diagnosis code reference number/letter field (Item 24E).

*CMS 837P (not shown) is the electronic equivalent of CMS-1500 and should be used if you submit your claims electronically.



Completing a CMS-1450 (UB-04) form†

The UB-04 form is used when billing hospital outpatient claims. The sample annotated form below provides guidance on completing a UB-04 form using a miscellaneous J-code or temporary C-code as well as populating additional fields that health plans require for LYMPHIR reimbursement.

Please confirm the accuracy of the codes you use to bill for LYMPHIR with each payer. If submitting to a Medicare Administrative Contractor (MAC), refer to the specific MAC's guidelines for completion of the reimbursement forms. **This sample claim form is intended for use only as a reference. The codes provided are subject to change and should not be construed as legal or billing advice.**

BOX 42:

List revenue codes in ascending order. Be sure to enter the appropriate numeric revenue code on the adjacent line in Box 42 to explain each charge in Box 47.⁹

BOX 43:

Provide a narrative description or standard abbreviation for each revenue code shown in Box 42 on the adjacent line in Box 43. If an NDC is required, submit "N4" followed by the 11-digit NDC.⁹

BOX 44:

Enter the appropriate CPT code for LYMPHIR injection, 96413, and the payer's preferred miscellaneous or temporary HCPCS code to represent LYMPHIR. CMS and most payers require you to record drug waste. Until LYMPHIR is assigned a product-specific code, reports of no wastage can be added to Box 80 and entered here using the miscellaneous or temporary HCPCS code and modifier JZ denoting zero waste (ie, JXXXX-JZ). Similarly, reports of wastage can be added to Box 80 and entered here using the miscellaneous or temporary HCPCS code and modifier JW denoting drug waste (ie, JXXXX-JW). Drug wastage should be reported on a separate claim line.^{5,9}

BOX 46:

Enter the number of units of LYMPHIR administered. **Miscellaneous HCPCS codes are usually reported with a unit of 1.** If drug wastage was reported in Box 44 on a separate claim line with the JW modifier, please indicate the amount of drug wasted here.^{4,5,9}

BOX 67:

Enter the specific ICD-10-CM diagnosis code(s).⁹

BOX 80:

When filing claims using a miscellaneous or temporary HCPCS code, most payers require additional information to be entered in Box 80, including the drug name, route of administration, total dosage, NDC, and wastage or lack of wastage.^{4,5,9} **Please check with the payer to confirm the required additional information.**

†CMS 837I (not shown) is the electronic equivalent of CMS-1450/UB-04 and should be used if you submit your claims electronically.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Hepatotoxicity

LYMPHIR can cause hepatotoxicity. In the pooled safety population, elevated ALT occurred in 70% of patients, with Grade 3 ALT occurring in 22%; elevated AST occurred in 64% of patients, with Grade 3 AST elevation occurring in 9%. For Grade 3 events, median time to onset was 8 days (range: 1 to 15 days); median time to resolution was 15 days (range: 7 to 50 days); all cases of Grade 3 ALT or AST elevations resolved. Elevated total bilirubin occurred in 5% of patients, with Grade 3 occurring in 0.9%.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold, reduce dose, or permanently discontinue LYMPHIR based on severity.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning.

The image shows a sample CMS-1450 (UB-04) form with several fields highlighted and annotated with callouts:

- Box 42:** Points to the revenue code field.
- Box 43:** Points to the narrative description field.
- Box 44:** Points to the CPT and HCPCS code field.
- Box 46:** Points to the number of units administered field.
- Box 67:** Points to the ICD-10-CM diagnosis code field.
- Box 80:** Points to the drug name, route, dosage, NDC, and wastage field.



For questions or for more information about LYMPHIR,
call **844-4-LYMPHIR** (844-459-6744), email
medicalinformation@citiusonc.com, or visit **LYMPHIRhcp.com**

References: 1. LYMPHIR. Prescribing Information. Citius Pharmaceuticals, Inc.; 2024. 2. Cutaneous T-cell lymphoma. Cleveland Clinic. Accessed June 30, 2024. <https://my.clevelandclinic.org/health/diseases/17940-cutaneous-t-cell-lymphoma> 3. CPT® 96413, under injection and intravenous infusion chemotherapy and other highly complex drug or highly complex biologic agent administration. Codify by AAPC. Accessed July 15, 2024. <https://www.aapc.com/codes/cpt-codes/96413> 4. Centers for Medicare & Medicaid Services. Billing and coding: hospital outpatient drugs and biologicals under the Outpatient Prospective Payment System (OPPS). Accessed July 12, 2024. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55913> 5. Centers for Medicare & Medicaid Services. Medicare program. Discarded drugs and biologicals—JW modifier and JZ modifier policy frequently asked questions. Accessed June 30, 2024. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf> 6. Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Level II coding procedures. Accessed June 30, 2024. <https://www.cms.gov/medicare/coding/medhcpcsgeninfo/downloads/2018-11-30-hcpcs-level2-coding-procedure.pdf> 7. Centers for Medicare & Medicaid Services. Medicare claims processing manual. Chapter 26: completing and processing form CMS-1500 data set. Updated June 6, 2024. Accessed July 13, 2024. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf> 8. Centers for Medicare & Medicaid Services. Billing and coding guidelines for drugs and biologics (non-chemotherapy). Accessed July 13, 2024. https://downloads.cms.gov/medicare-coverage-database/lcd_attachments/34741_34/L34741_INJ041_BCG.pdf 9. Centers for Medicare & Medicaid Services. Medicare claims processing manual. Chapter 25: completing and processing the form CMS-1450 data set. Updated December 20, 2023. Accessed June 30, 2024. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Embryo-Fetal Toxicity

Based on its mechanism of action, LYMPHIR can cause fetal harm when administered to a pregnant woman. Verify the pregnancy status of females of reproductive potential prior to the initiation of LYMPHIR. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment and for 7 days following the last dose of LYMPHIR.

ADVERSE REACTIONS

In the pooled safety population, the most common ($\geq 20\%$) adverse reactions, including laboratory abnormalities, were increased transaminases (70%), albumin decreased (53%), nausea (40%), edema (35%), hemoglobin decreased (34%), fatigue (30%), musculoskeletal pain (26%), rash (23%), chills (22%), constipation (22%), pyrexia (21%), and CLS (20%).

USE IN SPECIFIC POPULATIONS

Lactation: Advise women not to breastfeed during treatment with LYMPHIR and for 7 days after the last dose.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Citius Pharmaceuticals at 1-844-459-6744.

Please see accompanying full **Prescribing Information**, including **Boxed Warning** available at **LYMPHIRhcp.com**.



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