

Sample Billing and Coding: CD and UC



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INDICATIONS AND USAGE

ZYMFENTRA™ is indicated in adults for the maintenance treatment of moderately to severely active UC or moderately to severely active CD following an IV infliximab product.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS and MALIGNANCY

- Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis) and infections due to other opportunistic pathogens.
- Discontinue ZYMFENTRA if a patient develops a serious infection or sepsis.
- Perform test for latent TB; if positive, start treatment for TB prior to starting ZYMFENTRA. Monitor all patients for active TB during treatment, even if initial latent TB test is negative.
- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, including infliximab products.
- Postmarketing cases of fatal hepatosplenic T-cell lymphoma (HSTCL) have been reported in patients treated with TNF blockers including infliximab products. Almost all had received azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. The majority of cases were reported in patients with Crohn's disease or ulcerative colitis, most of whom were adolescent or young adult males.

CD, Crohn's disease; UC, ulcerative colitis.

Please see additional Important Safety Information on page 7, and [full Prescribing Information](#), including **BOXED WARNING**.

Sample Billing and Coding: CD and UC

Coding Resources

This sample coding guide serves as an educational reference for codes that may be appropriate for reporting ZYMFENTRA and related services. Medical record documentation must support the codes reported on the claim. These codes may be appropriate when ZYMFENTRA is administered to patients with CD or UC in the following sites of care: physician's office (**PO**), freestanding infusion center (**FIC**), home infusion services (**HIS**), and hospital outpatient (**HO**).

Code Set	Code and Description – CD	Site of Care			
		PO	FIC	HIS	HO
ICD-10-CM ²	K50 Crohn's disease	✓	✓	✓	✓
	K50.00 Crohn's disease of small intestine without complications	✓	✓	✓	✓
	K50.011-K50.019 Crohn's disease of small intestine with complications	✓	✓	✓	✓
	K50.10 Crohn's disease of large intestine without complications	✓	✓	✓	✓
	K50.111-K50.119 Crohn's disease of large intestine with complications	✓	✓	✓	✓
	K50.80 Crohn's disease of both small and large intestine without complications	✓	✓	✓	✓
	K50.811-K50.819 Crohn's disease of both small and large intestine with complications	✓	✓	✓	✓
	K50.90 Crohn's disease, unspecified, without complications	✓	✓	✓	✓
	K50.911-K50.919 Crohn's disease, unspecified, with complications	✓	✓	✓	✓

IMPORTANT SAFETY INFORMATION (continued)

Contraindications

- ZYMFENTRA is contraindicated in patients with a history of a severe hypersensitivity reaction to infliximab-dyyb, other infliximab products, any of the inactive ingredients in ZYMFENTRA, or any murine proteins. Reactions have included anaphylaxis.

Warnings and Precautions

- **Serious infections:** Avoid in patients with active infection. If infection develops, conduct a prompt/complete diagnostic workup appropriate for immunocompromised patients and initiate antimicrobials. If systemic illness develops in patients who reside or travel to regions where mycoses are endemic, consider empiric antifungals.
- **Malignancies:** Malignancies, including lymphoma, were greater in TNF-blocker-treated patients. Consider the higher risk of hepatosplenic T-cell lymphoma (HSTCL) with combination therapy versus increased risk of immunogenicity and hypersensitivity reactions with monotherapy.

CD, Crohn's disease; FIC, freestanding infusion center; HIS, home infusion services; HO, hospital outpatient; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; PO, physician's office; UC, ulcerative colitis.

Please see additional Important Safety Information on pages 7 and 8, and [full Prescribing Information](#), including **BOXED WARNING**.

 **Zymfentra**[™]
 infliximab-dyyb | subcutaneous
 120 mg/mL

(Continued from previous page)

Code Set	Code and Description – UC	Site of Care			
		PO	FIC	HIS	HO
ICD-10-CM ²	K51 Ulcerative colitis	✓	✓	✓	✓
	K51.00 Ulcerative (chronic) pancolitis without complications	✓	✓	✓	✓
	K51.011-K51.019 Ulcerative (chronic) pancolitis with complications	✓	✓	✓	✓
	K51.20 Ulcerative (chronic) proctitis without complications	✓	✓	✓	✓
	K51.211-K51.219 Ulcerative (chronic) proctitis with complications	✓	✓	✓	✓
	K51.30 Ulcerative (chronic) rectosigmoiditis without complications	✓	✓	✓	✓
	K51.311-K51.319 Ulcerative (chronic) rectosigmoiditis with complications	✓	✓	✓	✓
	K51.50 Left sided colitis without complications	✓	✓	✓	✓
	K51.511-K51.519 Left sided colitis with complications	✓	✓	✓	✓
	K51.80 Other ulcerative colitis without complications	✓	✓	✓	✓
	K51.811-K51.819 Other ulcerative colitis with complications	✓	✓	✓	✓
	K51.90 Ulcerative colitis, unspecified, without complications	✓	✓	✓	✓
	K51.911-K51.919 Ulcerative colitis, unspecified, with complications	✓	✓	✓	✓

One or more codes may be appropriate on a claim. Please review payer policy requirements for guidance on diagnosis codes.

Code Set	Code and Description – UC	Site of Care			
		PO	FIC	HIS	HO
NDC ¹	72606-025-01 Single-dose prefilled pen x 1	✓	✓	✓	✓
	72606-025-02 Single-dose prefilled pen x 2	✓	✓	✓	✓
	72606-025-10 Single-dose prefilled syringe with needle shield x 2	✓	✓	✓	✓

The 10-digit National Drug Code (NDC) is required on the claim form. The NDC unit of measure qualifier and quantity may also be required. Check payer-specific reporting requirements.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- **Hepatitis B virus (HBV) reactivation:** Test for HBV infection before starting treatment. Monitor HBV carriers during and several months after therapy for active HBV infection. If reactivation occurs, stop ZYMFENTRA and begin anti-viral therapy.
- **Hepatotoxicity:** Severe hepatic reactions, some fatal or necessitating liver transplantation have occurred in patients receiving infliximab products. Monitor hepatic enzymes and liver function tests every 3-4 months during treatment; investigate liver enzyme elevations and interrupt treatment if drug-induced liver injury is suspected. Instruct patients to seek immediate medical attention if symptoms develop.
- **Congestive heart failure (CHF):** New onset or worsening symptoms may occur. Avoid in patients with CHF. Monitor for new/worsening symptoms when administering ZYMFENTRA.

FIC, freestanding infusion center; HIS, home infusion services; HO, hospital outpatient; ICD-10-CM, *International Classification of Diseases*, Tenth Revision, Clinical Modification; NDC, National Drug Code; PO, physician's office; UC, ulcerative colitis.

Please see additional Important Safety Information on pages 7 and 8, and [full Prescribing Information](#), including **BOXED WARNING**.

 **Zymfentra**[™]
 infliximab-dyyb | subcutaneous
 120 mg/mL

Administration & Billing Codes

This section reviews general coding guidelines for drug administration services coded by physician offices using the CMS-1500 claim form and by hospital outpatient departments using the CMS-1450 (UB-04) claim form.

Drug administration services are reported on claims forms in both the physician office and hospital outpatient sites of care using the Current Procedural Terminology (CPT®) coding system.

Code Set	Code and Description	Location on CMS-1500 Form	Location on CMS-1450 (UB-04) Form
CPT®³	96372 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Field 24D	Field 44

Drugs are typically reported using product-specific Healthcare Common Procedure Coding System (HCPCS) codes (eg, J-codes) assigned by the Centers for Medicare & Medicaid Services (CMS). HCPCS units are determined by the specific HCPCS descriptor. The descriptor is not necessarily the same as the package or therapeutic dose, so the dose must be converted to billable HCPCS units to accurately complete a claim.

HCPCS Level II code(s)*

Code Set	Code and Description	Location on CMS-1500 Form	Location on CMS-1450 (UB-04) Form
HCPCS⁴	J1748 Injection, infliximab-dyyb (zymfentra), 10 mg	Field 24D	Field 44

*J1748 effective July 1, 2024

Effective August 18, J1748 will be added to Medicare's Self-Administered Drug (SAD) list and will not be covered by Medicare. This primarily affects traditional Fee-For-Service Medicare. Commercial Medicare can make their own independent decisions to follow Traditional Medicare or make their own coverage criteria. For Medicare Advantage and Medicare Part D, please work with your Celltrion Field Reimbursement Manager (FRM) for Zymfentra Benefits verification.

Modifiers^{5,6}

Modifier	Description	Location on CMS-1500 Form	Location on CMS-1450 (UB-04) Form
JZ	No amount of drug was discarded from a single-vial/dose drug and not administered to any patient	Field 24D	Field 44
JW	Amount of drug discarded/not administered to any patient		
JG	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes		
TB	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities		

Note on product and administration coding:

If you order ZYMFENTRA™ through a specialty pharmacy or the Celltrion CONNECT® Patient Support Program, you should not seek reimbursement for the product; however, your patient's health plan may still require that you include the J-code on the claim with a zero or nominal charge in order for them to reimburse the drug administration procedure.

Remember to submit a claim for reimbursement for services associated with ZYMFENTRA.

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 **Zymfentra™**
 infliximab-dyyb | subcutaneous
 120 mg/mL

Sample CMS-1500 Claim Form—Physician Office

The sample claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate health care setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE ☐ MEDICAID ☒ TRICARE ☐ CHAMPVA ☐ GROUP HEALTH PLAN ☐ FECA ☐ OTHER ☐

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)
Doe, Jane S.

3. PATIENT'S BIRTH DATE
02/12/70 SEX ☐ M ☒ F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)
Doe, Jane S.

5. PATIENT'S ADDRESS (No., Street)
123 Main Street

6. PATIENT RELATIONSHIP TO INSURED
Self ☒ Spouse ☐ Child ☐ Other ☐

7. INSURED'S ADDRESS (No., Street)
123 Main Street

8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE: I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE: I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP)
MM DD YY QUAL

15. OTHER DATE
MM DD YY QUAL

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION
FROM MM DD YY TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE
John Smith, MD

17a. NPI **321 654 7890**

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES
FROM MM DD YY TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? ☐ YES ☒ NO

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)
A. **K50.80**

22. RESUBMISSION CODE

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. EPST Family Plan I. ID. QUAL. J. RENDERING PROVIDER ID. #

1. **N407260602501** **J1748** **JZ** **A** **12** **321 654 7890**

2. **96372** **A** **1** **321 654 7890**

3. **NPI**

4. **NPI**

5. **NPI**

6. **NPI**

25. FEDERAL TAX ID. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) ☐ YES ☒ NO

28. TOTAL CHARGE \$

29. AMOUNT PAID \$

30. Rev'd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREE OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH # ()

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

Field 21: Indicate the most medically appropriate diagnosis code. (ICD-10-CM)

Field 23: If required, report the prior authorization number here.

Field 24D: Indicate appropriate HCPCS as required by the payer. Include the appropriate CPT® code to report the administration procedure.

Field 24E: Enter the diagnosis code reference letter as shown in box 21. Enter only 1 diagnosis pointer.

Field 24G: Enter the number of HCPCS units.

Field 24A

If line item NDC information is required, it will be entered in the shaded portion of Item 24A. For example:

	24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. EPST Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #	SUPPLIER INFORMATION
1	N407260602501			J1748 JZ	A		12		NPI	321 654 7890	
2									NPI		
3									NPI		

Please see additional Important Safety Information on pages 7 and 8, and [full Prescribing Information](#), including **BOXED WARNING**.

Zymfentra™
infliximab-dyyb subcutaneous
120 mg/mL

Sample CMS-1450 (UB-04) Claim Form—Hospital Outpatient Departments

The sample claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate health care setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

1 Facility Name Street Address City, State, Zip		2 Pay-to name Street Address City, State, Zip		3a PAT. CNTL. NO. 3b NDC 3c FISC. TAX NO.		4 TYPE OF BILL	
8 PATIENT NAME a Jane S. Doe		9 PATIENT ADDRESS a 123 Main Street		10 BIRTHDATE 03/23/1970		11 SEX F	
12 DATE OF ADMISSION 13 HR. 14 TYPE 15 SRC 16 DHR		17 STAT 18 19 20 21		22 CONDITION CODES 23 24 25 26 27 28		29 ACCT. STATE AZ	
30 OCCURRENCE DATE 31 CODE		32 OCCURRENCE DATE 33 CODE		34 OCCURRENCE DATE 35 CODE		36 OCCURRENCE DATE 37 CODE	
38		39		40		41	
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / NPIPS CODE		45 SERV. DATE	
0636		Injection, infliximab-dyyb (zymfentra), 10 mg NDC# 07260602501		J1748 JZ		MM-DD-YY 12	
0500		Outpatient Clinic		96372		MM-DD-YY 1	
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Help secure access to ZYMFENTRA™ for appropriate patients



Discover Celltrion CONNECT®

Services include benefits verification, prior authorization assistance, co-pay assistance and, other support options for your ZYMFENTRA patients.

www.celltrionconnect.com



INDICATIONS AND USAGE

ZYMFENTRA™ is indicated in adults for the maintenance treatment of moderately to severely active UC or moderately to severely active CD following an IV infliximab product.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS and MALIGNANCY

SERIOUS INFECTIONS

Patients treated with TNF blockers, including ZYMFENTRA, are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue ZYMFENTRA if a patient develops a serious infection or sepsis.

Reported infections include:

- Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Test patients for latent tuberculosis before ZYMFENTRA use and during therapy. Initiate treatment for latent infection prior to ZYMFENTRA use.
- Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.
- Bacterial, viral and other infections due to opportunistic pathogens, including Legionella and Listeria.

Carefully consider the risks and benefits of treatment with ZYMFENTRA prior to initiating therapy in patients with chronic or recurrent infection.

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with ZYMFENTRA, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including infliximab products.

Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including infliximab products. These cases have had a very aggressive disease course and have been fatal. Almost all patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. The majority of reported cases have occurred in patients with Crohn's disease or ulcerative colitis and most were in young adult males.

Contraindications

- ZYMFENTRA is contraindicated in patients with a history of a severe hypersensitivity reaction to infliximab-dyyb, other infliximab products, any of the inactive ingredients in ZYMFENTRA, or any murine proteins. Reactions have included anaphylaxis.



IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions

- **Serious infections:** Avoid in patients with active infection. If infection develops, conduct a prompt/complete diagnostic workup appropriate for immunocompromised patients and initiate antimicrobials. If systemic illness develops in patients who reside or travel to regions where mycoses are endemic, consider empiric antifungals.
- **Malignancies:** Malignancies, including lymphoma, were greater in TNF-blocker-treated patients. Consider the higher risk of hepatosplenic T-cell lymphoma (HSTCL) with combination therapy versus increased risk of immunogenicity and hypersensitivity reactions with monotherapy.
- **Hepatitis B virus (HBV) reactivation:** Test for HBV infection before starting treatment. Monitor HBV carriers during and several months after therapy for active HBV infection. If reactivation occurs, stop ZYMFENTRA and begin anti-viral therapy.
- **Hepatotoxicity:** Severe hepatic reactions, some fatal or necessitating liver transplantation have occurred in patients receiving infliximab products. Monitor hepatic enzymes and liver function tests every 3-4 months during treatment; investigate liver enzyme elevations and interrupt treatment if drug-induced liver injury is suspected. Instruct patients to seek immediate medical attention if symptoms develop.
- **Congestive heart failure (CHF):** New onset or worsening symptoms may occur. Avoid in patients with CHF. Monitor for new/worsening symptoms when administering ZYMFENTRA.
- **Hematologic reactions:** Advise patients to seek immediate medical attention if signs and symptoms of cytopenia develop; consider stopping if significant hematologic abnormalities develop.
- **Hypersensitivity and other administration reactions:** Serious hypersensitivity reactions, including anaphylaxis have occurred with intravenous formulations of infliximab; discontinue ZYMFENTRA and start appropriate therapy.
- **Neurologic reactions:** Exacerbation or new onset CNS demyelinating disorders may occur; consider discontinuation of ZYMFENTRA.
- **Risk of infection with concurrent administration of other biological products:** Concurrent use with other immunosuppressive biologics may increase risk of infection.
- **Risk of additive immunosuppressive effects from prior biological products:** Consider the half-life and mode of action of prior biologics.
- **Autoimmunity:** Formation of autoantibodies and development of lupus-like syndrome may occur; discontinue ZYMFENTRA if symptoms develop.
- **Vaccinations and use of live vaccines/therapeutic infectious agents:** Prior to initiating ZYMFENTRA bring patients up to date with vaccinations. Live vaccines or therapeutic infectious agents should not be given with ZYMFENTRA. A 6-month waiting period following birth is recommended before the administration of live vaccines to infants exposed in utero to infliximab.

Common Adverse Reactions (≥3%)

- **Ulcerative Colitis:** COVID-19, anemia, arthralgia, injection site reaction, increased alanine aminotransferase, and abdominal pain.
- **Crohn's Disease:** COVID-19, headache, upper respiratory tract infection, injection site reaction, diarrhea, increased blood creatine phosphokinase, arthralgia, increased alanine aminotransferase, hypertension, urinary tract infection, neutropenia, dizziness, and leukopenia.

Drug Interactions

- Concurrent use with immunosuppressive biologics used to treat UC and CD is not recommended due to risk of infection.
- Formation of CYP450 enzymes may be suppressed by increased levels of cytokines during chronic inflammation. ZYMFENTRA could normalize the formation of CYP450 enzymes potentially resulting in decreased exposure of CYP450 substrates and requiring dose adjustments.

Please see [full Prescribing Information](#), including **BOXED WARNING**.

References:

1. ZYMFENTRA. Prescribing information. Celltrion, Inc., 2023. https://zymfentra.b-cdn.net/zymfentra_prescribing_information_final.pdf 2. Centers for Medicare & Medicaid Services. Accessed February 1, 2024. <https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm>. 3. American Medical Association. CPT® 2024 Professional Edition. American Medical Association; 2023. 4. Centers for Medicare & Medicaid Services. Billing and Coding: Hospital Outpatient Drugs and Biologicals Under the Outpatient Prospective Payment System (OPPS). Revised April 4, 2020. Accessed March 5, 2024. <http://www.cms.gov/medicarecoverage-database/view/article.aspx?articleid=52423> 5. Centers for Medicare & Medicaid Services. Billing and Coding: JW and JZ Modifier billing guidelines. Revised January 10, 2023. Accessed January 22, 2024. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55932> 6. Centers for Medicare & Medicaid Services. Medicare-FFS Program Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS) Frequently Asked Questions. Revised March 3, 2023. Accessed March 5, 2024. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf>

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