

## Sample Coding: CD and UC



Not shown in actual size

### Indications and Usage<sup>1</sup>

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

### Coding Resources

This sample coding sheet 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 <sup>2</sup>	<b>K50</b> Crohn's disease	✓	✓	✓	✓
	<b>K50.00</b> Crohn's disease of small intestine without complications	✓	✓	✓	✓
	<b>K50.01</b> Crohn's disease of small intestine with complications	✓	✓	✓	✓
	<b>K50.10</b> Crohn's disease of large intestine without complications	✓	✓	✓	✓
	<b>K50.11</b> Crohn's disease of large intestine with complications	✓	✓	✓	✓
	<b>K50.80</b> Crohn's disease of both small and large intestine without complications	✓	✓	✓	✓
	<b>K50.81</b> Crohn's disease of both small and large intestine with complications	✓	✓	✓	✓
	<b>K50.90</b> Crohn's disease, unspecified, without complications	✓	✓	✓	✓
<b>K50.91</b> Crohn's disease, unspecified, with complications	✓	✓	✓	✓	

Code Set	Code and Description – UC	Site of Care			
		PO	FIC	HIS	HO
ICD-10 CM <sup>2</sup>	<b>K51</b> Ulcerative colitis	✓	✓	✓	✓
	<b>K51.00</b> Ulcerative (chronic) pancolitis without complications	✓	✓	✓	✓
	<b>K51.01</b> Ulcerative (chronic) pancolitis with complications	✓	✓	✓	✓

### 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.**

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.

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Code Set	Code and Description – UC	Site of Care			
		PO	FIC	HIS	HO
ICD-10 CM <sup>2</sup>	<b>K51.20</b> Ulcerative (chronic) proctitis without complications	✓	✓	✓	✓
	<b>K51.21</b> Ulcerative (chronic) proctitis with complications	✓	✓	✓	✓
	<b>K51.30</b> Ulcerative (chronic) rectosigmoiditis without complications	✓	✓	✓	✓
	<b>K51.31</b> Ulcerative (chronic) rectosigmoiditis with complications	✓	✓	✓	✓
	<b>K51.50</b> Left sided colitis without complications	✓	✓	✓	✓
	<b>K51.51</b> Left sided colitis with complications	✓	✓	✓	✓
	<b>K51.80</b> Other ulcerative colitis without complications	✓	✓	✓	✓
	<b>K51.81</b> Other ulcerative colitis with complications	✓	✓	✓	✓
	<b>K51.90</b> Ulcerative colitis, unspecified, without complications	✓	✓	✓	✓
	<b>K51.91</b> Ulcerative colitis, unspecified, with complications	✓	✓	✓	✓

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

Code Set	Code and Description – UC	Site of Care			
		PO	FIC	HIS	HO
NDC <sup>1</sup>	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 NDC is required on the claim form. The NDC unit of measure (UOM) qualifier and quantity may also be required. Check payer-specific reporting requirements.

Code Set	Code and Description – UC	Site of Care			
		PO	FIC	HIS	HO
CPT <sup>®3</sup>	<b>96372</b> Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	✓	✓	✓	✓

### Important Safety Information continued

**WARNING: SERIOUS INFECTIONS and MALIGNANCY** continued

- **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.**
- **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; 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 Important Safety Information on following pages, and [full Prescribing Information](#), including **BOXED WARNING**.



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### 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.**
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- **Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, including infliximab.**
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#### Contraindications

- ZYMFENTRA is contraindicated in patients with a history of a severe hypersensitivity reaction to other infliximab products, any of its ingredients, 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.
- **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.

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

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

## Important Safety Information *continued*

- **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, upper respiratory tract infection, headache, injection site reaction, diarrhea, increased alanine aminotransferase, and increased blood creatine phosphokinase, neutropenia, hypertension, urinary tract infection, 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.

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### References:

1. ZYMFENTRA™ Prescribing Information, Celltrion, Inc., 2023.
2. Centers for Medicare & Medicaid Services. FY2023 ICD-10-CM tabular. Updated September 6, 2023. Accessed January 10, 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.

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



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