PATIENT SUPPORT PROGRAM
ENROLLMENT FORM

Zymfentra™ infliximab-dyyb | subcutaneous 120 mg/mL

CELLTRION CONNECT PATIENT SUPPORT PROGRAM

Monday - Friday, 8 AM - 8 PM ET / Phone: 1-877-81CONNC (1-877-812-6662) / Fax: 833-912-3707 / www.CelltrionConnect.com

INSTRUCTIONS FOR COMPLETION

Celltrion CONNECT® offers 3 options for enrollment:

Option 1: Submit through the portal

At www.CelltrionConnect.com/ZYMFENTRA/hcpportal, a healthcare provider can:

- Enroll a patient into Celltrion CONNECT®
- Instruct a patient to access and sign the patient consent

OR

Option 2: Send an ePrescription

- Select ePrescribe to Phyz via the pharmacy drop-down menu:
  NCPDP: 5928809 | **Phone:** 844-590-5792
- Phyz will facilitate the enrollment process into Celltrion CONNECT®
- Attach the patient's insurance card(s), demographics, chart notes, and clinical documentation
- Celltrion Connect will forward the ZYMFENTRA™ (infliximab-dyyb) prescription to the patient's pharmacy of choice

OR

Option 3: Complete this form

- Attach both sides of the patient's insurance card(s)
- Attach the patient's demographics, chart notes, and clinical documentation
- Have the patient and prescriber sign the form
- Fax the completed form to 833-912-3707

Patients may sign the form electronically by visiting www.CelltrionConnect.com/ZYMFENTRA

Program Offerings

Upon enrolling in the program, Celltrion will assist patients getting started on ZYMFENTRA including benefit investigation, prior authorization and appeal support, determining eligibility for financial assistance, as well as dedicated Nurse Connector™ support.

IS THE PATIENT CURRENTLY RECEIVING INTRAVENOUS (IV) INFLIXIMAB?

Yes

Which IV infliximab product is the patient receiving?

_____

Date of First Dose: MM / DD / YYYY

Date of Last Dose: MM / DD / YYYY

Fill out patient information

OR

No

Would you like Celltrion CONNECT® to verify coverage for IV infliximab? ☐ Yes ☐ No

If yes, please complete the following:

Infusion site name, if different from prescriber: _____

Address: _____ City: _____ State: _____ Zip: _____

Contact Name: _____ Phone: (_____) _____ - _____ Fax: (_____) _____ - _____

Site NPI: _____ Tax ID: _____ Medicare #: _____

Please send statement of coverage to: ☐ Infusion Site ☐ Prescriber ☐ Both

When do you anticipate the patient starting ZYMFENTRA? MM / DD / YYYY

PATIENT INFORMATION ALL FIELDS MARKED WITH AN * ARE REQUIRED

*First Name: _____ M.I.: _____ *Last Name: _____

*Address: _____ *City: _____ *State: _____ *Zip: _____

*Date of Birth: MM / DD / YYYY Sex: ☐ Male ☐ Female ☐ Prefer Not to Answer *Email: _____

*Primary Phone: (_____) _____ - _____ ☐ Cell ☐ Home Secondary Phone: (_____) _____ - _____ ☐ Cell ☐ Home Preferred Contact Method: ☐ Cell ☐ Home

Alternate Contact: _____ Relationship to Patient: _____ Preferred Contact: ☐ Patient ☐ Alternate Contact

Primary Phone: (_____) _____ - _____ ☐ Cell ☐ Home Secondary Phone: (_____) _____ - _____ ☐ Cell ☐ Home

Preferred Language: ☐ English ☐ Other: _____

PATIENT INSURANCE INFORMATION PLEASE ATTACH A COPY OF THE PATIENT'S INSURANCE CARD(S) (FRONT AND BACK). IF NOT AVAILABLE, PLEASE COMPLETE THE FOLLOWING:

☐ Patient Does Not Have Insurance If patient is uninsured, please complete the Patient Assistance Program application available at www.CelltrionConnect.com.

Primary Insurance: _____ Policyholder Name: _____

Primary Policy #: _____ Primary Group #: _____ Policyholder Date of Birth: MM / DD / YYYY

Secondary Insurance: _____ Policyholder Name: _____

Secondary Policy #: _____ Secondary Group #: _____ Policyholder Date of Birth: MM / DD / YYYY

Do you have a separate pharmacy benefit card: ☐ Yes ☐ No

Cardholder Name: _____ Pharmacy Benefit Name: _____

Policy or Identification #: _____ Rx BIN: _____ Rx PCN: _____ Group #: _____

Please see Important Safety Information on last page and accompanying Full Prescribing Information including BOXED WARNING.

PRESCRIBER INFORMATION ALL FIELDS REQUIRED

Prescriber First Name: _____ M.I.: _____ Last Name: _____

Prescriber NPI: _____ Tax ID #: _____ Medicare #: _____

Prescriber Address: _____ City: _____ State: _____ Zip: _____

Phone: (_____) _____ - _____ Fax: (_____) _____ - _____

Practice Name: _____ Practice Contact First Name: _____ Practice Contact Last Name: _____

Title: _____ Phone: (_____) _____ - _____ Practice Email Address: _____

PRESCRIPTION INFORMATION ALL FIELDS REQUIRED

Patient Name: _____ **Patient Date of Birth:** MM / DD / YYYY

Preferred Specialty Pharmacy, if known: _____

ZYMFENTRA™ (infliximab-dyyb)	**Select Indication:**	☐ ICD-10: K50 (Moderately to severely active Crohn's Disease following treatment with an infliximab product administered intravenously) ☐ ICD-10: K51 (Moderately to severely active Ulcerative Colitis following treatment with an infliximab product administered intravenously)		
	Select Quantity and Refill:	120 mg/ml solution in a single-dose **pre-filled pen**, inject SC every 2 weeks	Quantity: ☐ #2 (1 month) ☐ #6 (3 months)	Refills: _____
		120 mg/ml solution in a **pre-filled syringe** with needle shield, inject SC every 2 weeks	Quantity: ☐ #2 (1 month) ☐ #6 (3 months)	Refills: _____

For commercially insured patients experiencing a delay or gap in prescription coverage

Celltrion may provide ZYMFENTRA to eligible patients, including those with commercial insurance experiencing delays or a gap in coverage of ZYMFENTRA. Eligible patients must have been prescribed ZYMFENTRA for an on-label indication and their participation is in no way contingent on any requirement or obligation to purchase ZYMFENTRA or any other Celltrion product or service at any time. Patients who are covered, in whole or part, through a state or federal healthcare program, including but not limited to Medicare, Medicaid, Medigap, CHAMPUS, TRICARE, Veterans Affairs, or Department of Defense are not eligible. Eligibility for continued participation will be verified periodically and patients will not be eligible to continue participating if they no longer satisfy the eligibility criteria, including when initiation of coverage for ZYMFENTRA is approved by the patient's commercial insurance plan. Void where prohibited or restricted by law, and Celltrion reserves the right to rescind, revoke, or amend the terms and conditions at any time without notice.

☐ I authorize Celltrion to determine a patient's eligibility to receive ZYMFENTRA at no cost. I authorize Celltrion to forward this prescription to the designated pharmacy to dispense ZYMFENTRA directly to the above-named patient. I understand that eligibility will be reverified periodically during the program. Patient authorization to share health information is required to receive ZYMFENTRA at no cost to the patient.

If authorized above, complete the prescription below.

ZYMFENTRA™ (infliximab-dyyb)	**Select Dosage Form:**	☐ 120 mg/mL solution in a single-dose **pre-filled pen**, inject subcutaneously every 2 weeks ☐ 120 mg/mL solution in a single-dose **pre-filled syringe** with needle shield, inject subcutaneously every 2 weeks
	Quantity:	1 (# of packs)
	Refills:	12

PRESCRIBER ATTESTATION/AUTHORIZATION

By signing this document the prescriber attests that they have obtained any and all authorizations and consents from the patient or the patient's authorized personal representative necessary under HIPAA and state law to release protected heath information, including that contained on this form, to Celltrion and its employees or agents for the purposes relating to Celltrion's patient support program, including, assisting the patient with benefits verification, prior authorization/appeals assistance, dispensing and delivery of the medication, financial assistance resources and information, such as co-pay support or free drug programs, for which the patient may be eligible, and other support for Celltrion's medication.

The provider certifies that they have obtained consent from the patient or the patient's caregiver to be contacted by Celltrion, Celltrion CONNECT®, and parties acting on their behalf at the phone number(s) provided regarding the purposes described above and for other non-marketing purposes.

The provider certifies that they are the prescriber of ZYMFENTRA to the patient and that the therapy is medically necessary. The provider authorizes Celltrion to act on their behalf to transmit this prescription by any means necessary to the pharmacy chosen by the patient.

Please select one option and sign below:

☐ Dispense As Written/Brand Medically Necessary/Do Not Substitute/No Substitution/DAW/May Not Subsititute

CA, MA, NC & PR: Interchange is mandated unless Prescriber writes the words **"No Substitution"** HERE _____

SIGN & DATE **Prescriber Signature:** _____ **Date:** MM / DD / YYYY

Please see Important Safety Information on last page and accompanying Full Prescribing Information including BOXED WARNING.

PATIENT AUTHORIZATION TO SHARE HEALTH INFORMATION

By signing this form, the patient gives their permission for their physicians, pharmacies, laboratories, and other healthcare providers ("Healthcare Providers") and their health insurers to share their individually identifiable health information with Celltrion USA, Inc., the Celltrion Patient Assistance Foundation, Celltrion affiliates and its vendors (collectively, "Celltrion").

The patient understands that their individually identifiable health information may include their full name, address, date of birth, demographic information, financial information, insurance information and information related to medical condition, treatment, care management, medication history, and prescriptions (collectively, "Health Information"), whether in written or verbal form, including portions of their medical record.

The patient's Health Information will be shared with Celltrion so that Celltrion may provide them with various support and information to help them access a Celltrion medicine, which may include the following, depending on the program (collectively, "Patient Support Activities"):

- Processing this Application;
- Verifying the information provided in this Application;
- Providing benefit investigations/verification and reimbursement support, including:
  - Assisting with identification of prior authorization requirements;
  - Assisting with identification of requirements of their insurer for appeal of a denied claim;
- Determining their eligibility for and helping them access co-pay support or free drug programs;
- Communicating with their Healthcare Providers about a Celltrion medicine and Patient Support Activities;
- Coordinating the dispensing and delivery of medication;
- Providing them with financial assistance resources and information if they are eligible;
- Providing them with disease management and other educational materials, as well as information about Celltrion's products, services, and programs, and may include sending them surveys about their experience with Celltrion products, services, and programs; and
- Providing them with access to Nurse Connectors who can assist in medication and adherence communications, medication dispensing support, and supplemental injection training.

Celltrion also may use their Health Information for auditing for compliance with Program requirements, quality assurance purposes, and to evaluate and improve our operations and services.

The patient understands that they do not have to sign this form, and choosing not to sign will not affect their ability to receive treatment from their Healthcare Providers or payment from their health insurer. However, if they do not sign this form, Celltrion may not be able to provide them with assistance.

The patient understands that once their Health Information is shared, it may no longer be protected by federal privacy law. However, Celltrion agrees to protect their Health Information and to use it for the purposes described in this form or as required or permitted by law. Select pharmacies may receive remuneration from Celltrion in exchange for their Health Information and/or for any Patient Support Activities provided to them. The patient understands that this form will remain in effect for [4] years from the date of their signature or shall otherwise expire at a shorter duration as required under applicable State law, unless they provide written notice that they would like to withdraw their approval to share their Health Information sooner. MARYLAND HEALTHCARE PROVIDERS, under Md. Code, Health - Gen. § 4-303(b)(4), this authorization expires ONE YEAR from the date of signature. If the patient would like to withdraw their approval, they may contact Celltrion at 1-877-81CONNC (1-877-812-6662). This withdrawal will not affect the use or sharing of their Health Information that took place before they withdraw their approval. The patient understands that they may receive a copy of this form.

SIGN & DATE

Patient or Patient Authorized Representative Signature: _____ **Date:** MM / DD / YYYY

If Patient Representative, First Name: _____ If Patient Representative, Last Name: _____

Relationship to Patient: _____

☐ **By checking this box,** the patient elects to **opt out** from nursing support.

PATIENT AUTHORIZATION TO TELEPHONE CONSUMER PROTECTION ACT (TCPA) INFORMATION

By signing up for text messages from Celltrion, the patient agrees that they are the primary owner of the phone number provided and consent to receiving promotional communications in the form of phone calls or text messages relating to Celltrion products and services and/or their condition or treatment. Messages may be sent from an automated system. Consent is not required for the purchase of any goods or services. Message and Data Rates May Apply. Unsubscribe at any time by replying STOP or clicking the unsubscribe link (where available). Text HELP for help. Message frequency varies. To the maximum extent permitted by law: (i) all information contained in SMS text messages is provided "as is" without warranty of any kind, either express or implied, including, but not limited to, the implied warranties of merchantability, fitness for a particular purpose, or non-infringement; and (ii) Celltrion expressly excludes any liability for any direct, indirect, or consequential loss or damage incurred by any user in connection with the receipt, use, failure of, or inability to use, SMS text messages.

The patient also gives their permission to receive communications from Celltrion and parties acting on its behalf, including calls made with an autodialer or prerecorded voice at the phone number(s) provided to determine their eligibility and provide benefits verification, prior authorization/appeals assistance, and financial assistance resources and information, such as co-pay support or free drug programs, Nurse Connectors, supplemental injection training, and/or other non-marketing purposes. The patient understands that they can opt-out of these telephonic communications concerning Patient Support Activities at any time by contacting Celltrion at 1-877-81CONNC (1-877-812-6662), Monday - Friday, 8 AM - 8 PM ET.

Celltrion CONNECT®: View our privacy policy: https://www.celltrionconnect.com/patient-privacy-policy | View our terms of use: https://www.celltrionconnect.com/terms-of-use/

By signing below, the patient expressly consents to the terms of this section.

SIGN & DATE

Patient or Patient Authorized Representative Signature: _____ **Date:** MM / DD / YYYY

If Patient Representative, First Name: _____ If Patient Representative, Last Name: _____

Relationship to Patient: _____

☐ **By checking this box,** the patient accepts receiving SMS messages with the cell phone number provided in the Patient Information section.

Please see Important Safety Information on last page and accompanying Full Prescribing Information including BOXED WARNING.

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.**
- **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.**

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.
- ***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.

Please see accompanying Full Prescribing Information including BOXED WARNING.

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