PATIENT ASSISTANCE PROGRAM
APPLICATION

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

Required fields indicated with an asterisk.

Complete online and print, then sign form. Fax all pages to Celltrion CONNECT®: 833-912-3707

PATIENT INFORMATION ALL FIELDS MARKED WITH AN * ARE REQUIRED

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

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

*Date of Birth: ____/____/____ 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

☐ Patient Does Not Have Insurance

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 #: _____

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 benefits 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 PO BOX 610 Columbus, OH 43216. 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

Patient Representative First Name: _____ Patient Representative Last Name: _____

Relationship to Patient: _____

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

PATIENT ASSISTANCE PROGRAM (PAP) CONSENT

I certify that I cannot afford my medication, and I affirm that my answers and my proof-of-income documents are complete, true, and accurate to the best of my knowledge. I will promptly contact the Celltrion Patient Assistance Program within thirty (30) days if my financial status or health insurance coverage changes. I will not seek to have this medicine or any cost from it counted in my Medicare Part D out-of-pocket expenses for prescription drugs. I will not seek reimbursement or credit for the medicine(s) from my prescription insurance provider, payor, or government health benefit program, including Medicare Part D plans, for Celltrion medications that I receive from the Celltrion Patient Assistance Foundation. I will notify my insurance provider of the receipt of any medicines through the Celltrion Patient Assistance Program. I have a signed copy of a current and completed Patient Authorization to Share Health Information on record with my healthcare provider so that my healthcare provider may share health information about me with Celltrion's assistance programs, Celltrion USA, Inc., and the Celltrion Patient Assistance Foundation.

The information you provide will be used by Celltrion, the Celltrion Patient Assistance Foundation, and parties acting on their behalf to determine eligibility, to manage and improve Celltrion's assistance programs, to communicate with you about your experience with Celltrion's assistance programs, to help you understand your insurance coverage and help you access certain Celltrion medicines through your insurance, and/or to send you materials and other helpful information and updates relating to Celltrion programs.

I understand that: Completing this enrollment form does not guarantee that I will qualify for Celltrion's assistance programs. Celltrion may contact my insurer, to help me understand my insurance coverage for certain products and may provide me support to obtain coverage through my insurer, including prior authorization and appeals support (if necessary and available). Celltrion may verify the accuracy of the information I have provided and may ask for more financial and insurance information. Any medicines supplied by Celltrion's assistance programs shall not be sold, traded, bartered, or transferred. Celltrion reserves the right to change or cancel Celltrion's assistance programs, or terminate my enrollment, at any time, except that if I am enrolled in a Medicare Part D plan, my benefits will continue until the end of the calendar year. I understand that if I am currently enrolled in a Medicare Part D plan, I cannot utilize my Part D plan benefits for medications received through the Celltrion Patient Assistance Foundation for the duration of my enrollment. The support provided through this program is not contingent on any future purchase. If I decide to enroll in a Medicare Part D plan and am eligible for the Celltrion Patient Assistance Program, I will inform the Celltrion Patient Assistance Foundation by calling 1-877-81CONNC (1-877-812-6662). If I receive notice that I have been auto enrolled in a Medicare Part D plan, I will immediately notify the Celltrion Patient Assistance Foundation.

☐ **By checking this box**, the patient agrees to PAP consent and agrees to the Terms and Conditions specified here.

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, or in writing at PO BOX 610 Columbus, OH 43216.

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

Cell Phone: (_____) _____ - _____

PATIENT FINANCIAL VERIFICATION AUTHORIZATION

I understand that by checking the "I Agree" box immediately following this notice, I am providing "written instructions" to Celltrion CONNECT® and/or its agents and contractors under applicable federal and/or state law authorizing them to perform electronic income verification by obtaining information from my personal credit profile or other information from Experian Health. I authorize Celltrion CONNECT® and/or their agents and contractors to obtain such information solely to validate my income for the purposes of determining my eligibility for patient assistance. As a soft credit check, it will not impact my credit score.

☐ **I AGREE** to the terms above for electronic income verification using Experian Health.

☐ **I DO NOT AGREE** with the terms above and do not wish to have my income verified by using Experian Health. I understand that I will be asked to provide supporting documentation to authenticate my income and eligibility. If additional income documentation is required, the following documents are acceptable for income verification:

• Social Security/Disability benefit statement, monthly check, or 1099 • Previous year tax return or W-2 statement • Unemployment or disability determination letter

PATIENT INCOME VERIFICATION

Annual Gross Income (Including salary/wages, Social Security income, disability income, and any other income): _____ **Household Size** (Number of members including you): _____

☐ **By checking this box,** the patient agrees to income information specified here.

PRESCRIBER INFORMATION

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

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

Phone: (_____) _____ - _____ x: _____ Fax: (_____) _____ - _____ Email: _____

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

PRESCRIPTION INFORMATION ALL FIELDS REQUIRED, PRESCRIBER TO COMPLETE SECTION

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: _____

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. ZYMFENTRA is prescribed as an on-label diagnosis based on their professional judgment of medical necessity and that they will supervise the patient's medical treatment. The prescriber has also read and agrees to the terms, conditions, and authorizations and that all information provided in this application is complete and accurate to the best of their knowledge.

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, including BOXED WARNING ON SERIOUS infections on last page.**
Please see full Prescribing Information https://www.zymfentra.com/wp-content/uploads/2023/11/zymfentra_prescribing_information_final.pdf

PATIENTS ELIGIBLE FOR THE CELLTRION CONNECT® PATIENT ASSISTANCE PROGRAM

The Celltrion CONNECT® PAP is designed to provide free product to qualified individuals who are uninsured or are functionally uninsured, who have no applicable drug coverage, or who express financial hardship affording their medication. Celltrion CONNECT® will help activate PAP for eligible participants.

To receive PAP benefits, the patient must enroll in the program and meet the following eligibility requirements:

- Patient has no insurance or who is functionally uninsured:
  - Patients who do not have insurance (uninsured) or are insured, but product is not covered by their plan (Patient is responsible for 100% of product cost) (functionally uninsured).
    - Functionally uninsured includes all payor types:
      - For commercial patients who have exhausted their co-pay benefits through Celltrion CARES™ Co-pay Assistance Program.
    - In order to be considered functionally uninsured:
      - The patient has pharmacy benefits but the payor/pharmacy benefit manager (PBM) will not approve or pay for either the entirety or any portion of the medication.
        - The payor/PBM must deny one level of appeal of an initial coverage denial.
      - The patient is uninsured or their insurance plan excludes ZYMFENTRA™ (infliximab-dyyb) and its reference/generic/biosimilar.
  - This program excludes patients whose medication is reimbursed in whole or in part by any type of government insurance (e.g., Medicare, Medicaid, TRICARE, or any other federal or state program). Patients who have Medicare A&B only (no Medicare Part D) are still excluded.
- Patient must have a valid prescription from a licensed healthcare provider (HCP) for an on-label indication.
- Patient must have an adjusted annual household income of ≤500% of the federal poverty level (FPL).
- Income verification:
  - Electronic income verification (eIV) will be conducted by the program. No asset review will be required; however, patients will need to provide proof of income if eIV does not match what the patient has reported (proof of income could include one of the following: W-2s, tax returns (1040, 1099), 3 months of paystubs).
- Patient must show proof of residency by providing valid United States or the Commonwealth of Puerto Rico address and product must be administered and shipped to locations in the United States or the Commonwealth of Puerto Rico. Patient must have lived in the United States or the Commonwealth of Puerto Rico for at least 6 months.
- Diagnosis and dosing are consistent with FDA-approved indication for ZYMFENTRA.
- Patients with insurance plans or employers participating in an alternate funding program (also sometimes referred to as patient advocacy programs, specialty networks, SHARx, Paydhealth, or PayerMatrix, among other names) are not eligible for PAP.
  - These programs require patients to apply to a manufacturer's PAP or otherwise pursue specialty drug prescription coverage through an alternate funding vendor as a condition of, requirement for, or prerequisite to coverage of relevant products, or that otherwise denies, restricts, eliminates, delays, alters, or withholds any insurance benefits or coverage contingent upon application to, or denial of eligibility for, specialty drug prescription coverage through the alternate funding program.
  - Patients must promptly contact the Celltrion CONNECT® PAP if their financial status or insurance coverage changes.
- Electronic benefits verification (eBV) will be conducted by the program every 6 months to determine coverage changes.
- After the first fill, and upon subsequent refills, patients can receive a 3-month supply of PAP.
  - The pharmacy must contact the patient prior to each refill and the patient must be asked if they have had any changes in their coverage since their last fill. If the patient has indicated any changes in coverage, the pharmacy will notify the HUB to verify new information and determine continued eligibility in the program.
  - If the patient notifies the pharmacy, they are no longer taking ZYMFENTRA, the pharmacy will notify the HUB, and the HUB will follow up with the HCP/patient to confirm.
  - On first fill, the pharmacy is expected to explain cold chain delivery process and storage requirements for ZYMFENTRA.
- Program enrollment period is a rolling 12-month period from the date of eligibility in which they have been approved.
- Patients enrolled in START for a consecutive 10-month period who are not able to secure coverage, are eligible to convert to PAP if they meet criteria above and apply.

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.

For more information, see Full Prescribing Information including **BOXED WARNING**.

CELLTRION CONNECT
PATIENT SUPPORT PROGRAM