AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Zymfentra™ (infliximab-dyyb) (Pharmacy)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

ATTENTION: All patients must complete an intravenous induction regimen with an infliximab product before starting Zymfentra. IV induction (loading dose) for treatment of Crohn's disease & ulcerative colitis can only be billed under the **MEDICAL BENEFIT**. Renflexis® (infliximab-adba) and unbranded Infliximab are the Health Plan's **PREFFERED** infliximab products, Q5104/J1745.

Quantity Limits: 2 syringes/pens per 28 days

Adult Dosing:

- Zymfentra is indicated as maintenance treatment only, starting at Week 10 and thereafter.
  - All patients must complete an intravenous induction regimen with an infliximab product before starting Zymfentra. For induction dosing information, see the corresponding full prescribing information for the chosen infliximab product
- Zymfentra is for subcutaneous use only
- Maintenance dosage starting at Week 10 and thereafter: 120 mg subcutaneously once every two weeks.
- To switch patients who are responding to maintenance therapy with an infliximab product administered intravenously, administer the first subcutaneous dose of Zymfentra in place of the next scheduled intravenous infusion and every two weeks thereafter

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NOTE: The Health Plan considers the use of concomitant therapy with more than one biologic immunomodulator (e.g., Dupixent, Entyvio, Humira, Rinvoq, Stelara) prescribed for the same or different indications to be experimental and investigational. Safety and efficacy of these combinations has **NOT** been established and will **NOT** be permitted.

- ❑ Will the member be discontinuing a previously prescribed biologic if approved for requested medication?
  ❑ Yes **OR** ❑ No
- ❑ If yes, please list the medication that will be discontinued and the medication that will be initiated upon approval along with the corresponding effective date.

  Medication to be discontinued: _____ **Effective date:** _____

  Medication to be initiated: _____ **Effective date:** _____

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ **Diagnosis: Moderate-to-Severe Crohn's disease (CD)**

❑ **Maintenance Dose – 120 mg administered by subcutaneous injection starting at no sooner than Week 10, and then every 2 weeks thereafter**

Authorization Criteria: To be reviewed for approval under the pharmacy benefit

- ❑ Member has a diagnosis of moderate-to-severe **Crohn's disease**
- ❑ Prescribed by or in consultation with a **Gastroenterologist**
- ❑ Member meets **ONE** of the following unless member has a contraindication or intolerance:
  - ❑ Member has tried and failed corticosteroids
  - ❑ Member has tried and failed at least one conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine, or methotrexate)
  - ❑ Member has previously tried and failed another biologic medication other than the requested medication (e.g., adalimumab, Tremfya, ustekinumab)
  - ❑ Member has already started on or is currently undergoing an induction regimen with an infliximab IV product and is requesting continuation of therapy with Zymfentra
- ❑ According to the prescriber, the member will receive three induction doses with intravenous infliximab within 2 months of initiating maintenance therapy with Zymfentra subcutaneous

❑ **Diagnosis: Moderate-to-Severe Ulcerative Colitis (UC)**

❑ **Maintenance Dose – 120 mg administered by subcutaneous injection starting at no sooner than Week 10, and then every 2 weeks thereafter**

Authorization Criteria: To be reviewed for approval under the pharmacy benefit

- ❑ Member has a diagnosis of moderate-to-severe **ulcerative colitis**

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- ❑ Prescribed by or in consultation with a **Gastroenterologist**
- ❑ Member meets **ONE** of the following unless member has a contraindication or intolerance:
  - ❑ Member has tried and failed corticosteroids
  - ❑ Member has tried and failed at least **ONE** of the following **DMARD**:
    - ❑ 5-aminosalicylates (balsalazide, olsalazine, sulfasalazine)
    - ❑ oral mesalamine (Apriso, Asacol/HD, Delzicol, Lialda, Pentasa)
    - ❑ Other immunosuppressant drug: _____
  - ❑ Member has previously tried and failed another biologic medication other than the requested medication (e.g., adalimumab, Tremfya, ustekinumab)
  - ❑ Member has already started on or is currently undergoing an induction regimen with an infliximab IV product and is requesting continuation of therapy with Zymfentra
- ❑ According to the prescriber, the member will receive three induction doses with intravenous infliximab within 2 months of initiating maintenance therapy with Zymfentra subcutaneous

❑ **Induction Dose for PREFERED Renflexis® or unbranded Infliximab only (If required) – One time approval for duration of 2 months. Member to receive up to three (3) IV infusion doses, at a dose of 5 mg/kg at 0, 2 & 6 weeks**

Authorization Criteria: To be reviewed for one-time approval under the medical benefit

- ❑ Medication will be used as induction therapy
- ❑ Member must meet all maintenance dose authorization criteria above
- ❑ Medication being provided by:
  - ❑ **Location/site of drug administration:**_____
  - ❑ **NPI or DEA # of administering location**:_____
- ❑ Member to receive FDA approved loading dose of Renflexis® or unbranded Infliximab to be administered by intravenous infusion at a dose of 5 mg/kg at 0, 2 & 6 weeks

Medication being provided by Specialty Pharmacy – Proprium Rx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

***Approved by Pharmacy and Therapeutics Committee:** ~~5/23/2024;~~ ~~11/21/2024;~~ **3/26/2026**
REVISED/UPDATED/REFORMATTED: ~~6/6/2024; 12/11/2024; 12/22/2025;~~ **7/28/2026**