SENTARA HEALTH PLANS

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 1-800-750-9692**. 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 Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

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

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

Weight: _____ **Date:** _____

NOTE: The Health Plan considers the use of concomitant therapy with more than one biologic immunomodulator (e.g., Dupixent, Entyvio, Humira, Rinvoq, Stelara, Zymfentra) 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.

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**. Provider please note: Renflexis® (infliximab-adbda) is the Health Plan's **PREFFERED** infliximab product, Q5104. NDC: 00006430501/02; 78206016201/99

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

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- 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

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.

❑ **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 is 18 years of age or older
- ❑ Member has **ONE** of the following diagnoses:
  - ❑ Moderate-to-severe **Crohn's disease**
  - ❑ Moderate-to-severe **ulcerative colitis**
- ❑ Prescribed by or in consultation with a **Gastroenterologist**
- ❑ Member meets **ONE** of the following:
  - ❑ Member has tried and failed budesonide or high dose steroids (40-60 mg prednisone)
  - ❑ Member has tried and failed at least **ONE** of the following **DMARD** therapies for at least **three (3) months**
    - ❑ 5-aminosalicylates (balsalazide, olsalazine, sulfasalazine)
    - ❑ oral mesalamine (Apriso, Asacol/HD, Delzicol, Lialda, Pentasa)
- ❑ Member meets **ONE** of the following:
  - ❑ Member tried and failed, has a contraindication, or intolerance to **BOTH** of the following **PREFERRED** biologics [***NOTE:** Humira NDC's starting with 83457 are not approved, NDC's starting with 00074 (MFG: Abbvie) are preferred; Hyrimoz NDC's starting with 83457 are not approved, NDC's starting with 61314 (MFG: Sandoz) are preferred]:
    - ❑ **ONE** of the following adalimumab products:
      - ❑ Humira®
      - ❑ Cyltezo®
      - ❑ Hyrimoz®
    - ❑ Stelara® SQ
  - ❑ Member has been established on Zymfentra or an infliximab IV product for at least 90 days **AND** claims history indicates **at least a 90-day supply was dispensed or administered within the past 130 days (verified by chart notes or pharmacy paid claims)**

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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.

- ❑ **Induction Dose for <u>PREFERED</u> Renflexis® 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**

<u>Authorization Criteria</u>: To be reviewed for one-time approval under the medical benefit

- ❑ Medication will be used as induction therapy
- ❑ Medication being provided by:
  - ❑ **Location/site of drug administration:**_____
  - ❑ **NPI or DEA # of administering location**:_____
- ❑ Member to receive FDA approved loading dose of Renflexis® 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.*

<u>*Previous therapies will be verified through pharmacy paid claims or submitted chart notes.</u>*