MRN:_____

DOB:_____

STANDARD INFLECTRA® (infliximab-dyyb) PLAN OF TREATMENT FOR GASTROENTEROLOGY

NOTE: Patient ***may be ineligible*** to receive (infliximab-dyyb) if receiving antibiotics for active infectious process, antifungal therapy, active fever and/or suspected infection, new or worsening symptoms of CHF, new-onset or deterioration neurological changes, and/or surgery.

1. Patient Name:_____Height (inches):_____Weight (lbs):_____

2. Allergies:_____

3. DIAGNOSIS: *** Please complete the 2nd and 3rd digits to complete the ICD-10 code for billing**

☐ **K50.0**_____Crohn's Disease (small intestine)
☐ **K50.1**_____Crohn's Disease (large intestine)
☐ **K50.8**_____Crohn's Disease (small & large intestine)
☐ **K50.9**_____Crohn's Disease, Unspecified
☐ **K51.8**_____Other Ulcerative (chronic) Colitis
☐ **K51.5**_____Left sided Ulcerative (chronic) Colitis
☐ **K51.0**_____Universal Ulcerative (chronic) Pancolitis
☐ **K51.9**_____Ulcerative Colitis, Unspecified
☐ **K60.3** Anal Fistula
☐ **K63.2** Fistula of Intestine ☐ Other ***ICD-10 Code*** (Diagnosis/Description):_____

4. Pre-medications: ***Administered 30 minutes prior to infusion as selected:***

****Product information suggests premedication of antihistamines, acetaminophen, and/or corticosteroids.***

a) Acetaminophen:
- □ 650mgs PO
- □ 500mgs PO
- □ 325mgs PO

b) Diphenhydramine: □ 25 mgs PO, □ 50mgs PO, □ 25 mgs IVP, □ 50mgs IVP or

c) Alternate oral antihistamine to diphenhydramine:
□ Cetirizine 10 mg, □ Loratadine 10 mg, Fexofenadine □ 60mgs or □ 180mgs

d) Other: Methylprednisolone □ 40mgs IVP □ 125mgs IVP or other_____mgs IVP
Famotidine: □ 20mgs PO, □ 40mgs PO, □ 20mgs IVP, □ 40mgs IVP

e) Pre-medicate with other: _____

If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES.

5. Order:

INFLECTRA® (infliximab-dyyb) 5 mg/kg per 250 ml Sodium Chloride 0.9% IV to infuse over at least 2 hours

OR

Other Dose:_____mg or_____mg/kg per 250 - 500 ml Sodium Chloride 0.9% IV

☐ Induction orders to be completed at 0 week, 2 week, and 6 weeks
☐ Maintenance Orders every 8 weeks

Special Orders: _____

Lab orders with infusions: _____

7. Physician's Signature:_____/_____Date: _____

No Stamp Signatures (Dispense as written) (Substitution permitted)

Printed Physician's Name with Credentials: _____

MRN:_____

DOB:_____

Guidelines for Prescribing INFLECTRA® (infliximab-dyyb) for Gastroenterology

(Required documentation with all initial referrals)

Patient Name: _____ **Referral Date:**_____

☐ Include signed and completed **Plan of Treatment**.

☐ Include patient demographic information and insurance information. (Copy of insurance cards if available)

☐ **Supporting clinical MD notes to include any past tried and/or failed therapies, intolerance, outcomes or contraindications to conventional therapy. Include any lab results and/or tests to support diagnosis. INFLECTRA® is a bilosimilar to Remicade® that is indications for:**

- **Adult Crohn's Disease:** reduces signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an **inadequate response to conventional therapy**. Reduces the number of draining enterocutaneous/rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease. **At a dose of 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response.**
- **Pediatric Crohn's Disease:** reduces signs/symptoms and inducing/maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an **inadequate response to conventional therapy**. **At a dose of 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Pediatric Use –INFLECTRA® has not been studied in children with Crohn's disease or ulcerative colitis**
- **Ulcerative Colitis:** reduces signs/symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an **inadequate response to conventional therapy. At a dose of 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.**

☐ If patient is switching biological therapies, then MD must specify wash-out period prior to starting INFLECTRA® as specified of_____weeks. Last known biological therapy:_____and last date received:_____. (Include copy of last INFLECTRA® infusion record if available and currently on therapy)

☐ Other as requested: _____

_____

Pre-Screening:

☐ **Required TB screening results: PPD or QuantiFERON Gold Test.**
(* If screening results are positive or indeterminate, then a negative CXR result is required.)

☐ **Required Hepatitis screening to include: Hepatitis B Surface Antigen results.**

** Warnings/Precautions: ***Product information suggests that patients who have stopped treatment for an extended period are at higher risk for hypersensitivity reactions. MD should evaluate premedication and consider antibody testing prior to restart of* **infliximab or biosimilar.** Patient should not have an active ongoing infection, signs or symptoms of malignancy, or invasive fungal infection. Do not initiate INFLECTRA® therapy in patients with moderate to severe Congestive Heart Failure. ***INFLECTRA ®at doses of >5 mg/kg should not be administer to patients with moderate to severe heart failure.*** Patient with mild CHF should be closely monitored. Therapy should be discontinued in patients who develop new or worsening symptoms of heart failure. **Hepatotoxicity:** Stop therapy in case of jaundice and/or marked liver enzyme elevations. Evaluation of immunizations should be completed prior to and live vaccines should not be given before or concurrently with INFLECTRA®. See full prescribing information.

Checklist for referrals to AccuRX Infusion Center:

Fax referral to 1-866-990-3192

- Patient demographics – address, phone number, SS#, etc.
- Insurance Information – copy of the card(s) if possible
- Plan of Treatment/Orders
- Most recent physician office notes to include tried and failed therapies – all insurance companies that require a pre-authorization require the note. This includes Medicare/Medicaid HMOs
- Any lab results or other diagnostic procedures to support the diagnosis

AccuRx Infusion Center will complete insurance verification and submit all required clinical documentation to the patient's insurance company for eligibility. Our office will notify you if any further information is required. We will review financial responsibility with the patient and refer them to any available Co-pay assistance as required. Thank you for the referral.