Palmetto Infusion Services COMPLIANCE

MRN:_____

Phone: 1-800-809-1265 Fax: 1-866-872-8920

DOB:_____

STANDARD RENFLEXIS (infliximab-abda) PLAN OF TREATMENT FOR GASTROENTEROLOGY

(Re) Certification Period From_____to _____

NOTE: Patient ***may be ineligible*** to receive (infliximab-abda) 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: ☐ None ***OR*** ***Administered 30 minutes prior to infusion as selected:***

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

Acetaminophen:
- ☐ 650mgs PO
- ☐ 500mgs PO
- ☐ 325mgs PO

Diphenhydramine: ☐ 25 mgs PO, ☐ 50mgs PO, ☐ 25 mgs IVP, ☐ 50mgs IVP or

Alternate oral antihistamine to diphenhydramine:
- ☐ Cetirizine 10 mg, ☐ Loratadine 10 mg, Fexofenadine ☐ 60mgs or ☐ 180mgs

Methylprednisolone ☐ 40mgs IVP ☐ 125mgs IVP or other _____mgs IVP

Famotidine: ☐ 20mgs PO, ☐ 40mgs PO, ☐ 20mgs IVP, ☐ 40mgs IVP

Pre-medicate with other: _____

5. Dose: RENFLEXIS (infliximab-abda) infused via pump with 0.22 micron filter

_____ 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

6. Frequency:

_____ Induction orders to be completed at 0 week, 2 week, and 6 weeks, and then every 8 weeks.

_____ Orders every 8 weeks (maintenance).

Special orders: _____

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

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

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

Printed Physician's Name with Credentials: _____NPI: _____

8. Fax updated supporting clinical MD notes with each order renewal or change in orders

Infusion order forms and Adverse Drug Reaction Guidelines are available at www.palmettoinfusion.com

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Guidelines for Prescribing RENFLEXIS (infliximab-abda) for Gastroenterology

(Required documentation with all initial referrals)

Patient Name: _____ Referral Date:_____

___ Include signed and completed **Plan of Treatment**. ***(MD must complete sections 1-8)***
(Infusion order forms & Standard Adverse Reactions orders are available at www.palmettoinfusion.com under Agency/MD tab)

___ 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 biosimilar 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.**
- **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 RENFLEXIS as specified of _____ weeks. Last known biological therapy: _____ and last date received:_____. (Include copy of last infusion record if available and currently on therapy)

___ Other as requested: _____

Pre-Screening: **(TB and Hepatitis screening results must be available prior to start of therapy and within last 12 months.)**

___ **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 RENFLEXIS therapy in patients with moderate to severe Congestive Heart Failure. ***RENFLEXIS at doses of >5 mg/kg should not be administered 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. **Malignancies:** including lymphoma was greater in TNF blocker treated patients Due to the risk of HSTCL carefully assess the risk/benefits especially if the patient has Crohn's disease or ulcerative colitis, is male, and is receiving azathioprine or 6-mercaptopurine treatment. **Lupus-like syndrome:** stop if symptoms develop. Evaluation of immunizations should be completed prior to and live vaccines should not be given before or concurrently with RENFLEXIS. See full prescribing information.

Palmetto Infusion Services 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.

Please fax all information to 1-866-872-8920 or call 1-800-809-1265 for assistance.

Revised 5/25/18, ref PI 11/2017