Palmetto INFUSION

MRN:_____

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

STANDARD Entyvio® (vedolizumab) PLAN OF TREATMENT FOR GASTROENTEROLOGY

Patient cannot receive Entyvio while receiving Tysabri® (Natalizumab) or other TNF

(Re) Certification Period From _____ to _____

NOTE: Patient ***may be ineligible*** to receive vedolizumab if receiving antibiotics for active infectious process, antifungal therapy, active fever and/or suspected infection, 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

☐ Other **ICD-10 Code**: _____**diagnosis description:**_____

4. Pre-medications: ☐ None ***OR*** ***Administered 30 minutes prior to infusion as selected:***

****Suggest caution with use of Diphenhydramine due to 30 minute infusion time and safety risks with driving.***

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: _____

_____

Orders: Obtain weight each visit. **Vital signs at baseline and after completion then may discharge when infusion is complete.** Instruct patient/caregiver on medications and signs/symptoms of adverse reaction. Assess patient for response to therapy. Utilize existing central line for administration or initiate a peripheral IV with each infusion as needed. Sodium Chloride 0.9% flush 3-10 ml before, after, and as needed during the infusion. Follow infusion with Heparin 100 units/ml 1 – 5 ml per line type or to peripheral IV as required for multiple day treatments. Pump, tubing, 0.22 micron filter, and supplies needed to complete prescribed therapy. Pharmacist to perform clinical drug monitoring. ***If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES.***

Dose: Entyvio (vedolizumab) 300mgs per 250ml of Sodium Chloride 0.9% IV to infuse over at least 30 minutes

5. Frequency:
- ☐ Induction orders to be completed at 0 week, 2 week, and 6 weeks, and then every 8 weeks thereafter
- ☐ Orders every 8 weeks (maintenance).
- ☐ Special Orders: _____

Lab orders with infusions: _____

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

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

Printed Physician's Name with Credentials: _____

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

Infusion order forms available at www.palmettoinfusion.com

Revised 4/20/17

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DOB:_____

Guidelines for Prescribing Entyvio® (vedolizumab) FOR GASTROENTEROLOGY

(Required documentation with all initial referrals)

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

☐ Include signed and completed **Plan of Treatment**. *(MD must complete sections 1-7)*
(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.**

- Entyvio® is indicated for adult patients with moderately to severely active Ulcerative Colitis or Crohn's Disease who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

☐ If patient is switching biological therapies, then MD must specify wash-out period prior to starting Entyvio® as specified of _____ weeks. Last known biological therapy: _____ and last date received:_____. (Include copy of last Entyvio® 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: **Infections:** Entyvio® is not recommended in patients with active, severe infections until the infections are controlled. Serious infections have also been reported in patients treated with ENTYVIO, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis and cytomegaloviral colitis. Patient should not have an active ongoing infection, signs or symptoms of malignancy, or invasive fungal infection. **Progressive Multifocal Leukoencephalopathy:** Although no cases have been observed in ENTYVIO® clinical trials, JCV infection resulting in progressive multifocal leukoencephalopathy (PML) and death has occurred in patients treated with another integrin receptor antagonist. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms. ENTYVIO® should be discontinued in patients with jaundice or other evidence of significant liver injury. Evaluation of immunizations should be completed prior to and live vaccines should not be given before or concurrently with Entyvio®. 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 4/20/17

Clear Form