Palmetto Infusion Services COMPLIANCE

MRN:_____

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

DOB:_____

STANDARD Tysabri® (natalizumab) PLAN OF TREATMENT for Crohn's Disease

(Re) Certification Period From_____to _____

NOTE: Patient ***may be ineligible*** to receive natalizumab 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
□ Other **ICD-10 Code:** _____**Diagnosis description:** _____

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

****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 therapy.***

Acetaminophen: □ 650 mg PO □ 500 mg PO □ 325 mg PO	Diphenhydramine: □ 25 mg PO, □ 50 mg PO, □ 25 mg IVP, □ 50 mg IVP or Fexofenadine □ 60 mg or □ 180 mg, □ Cetirizine 10 mg, □ Loratadine 10 mg Methylprednisolone □ 40 mg IVP □ 125 mg IVP or other _____mg IVP Famotidine: □ 20 mg PO, □ 40 mg PO, □ 20 mg IVP, □ 40 mg IVP

Pre-medicate with other: _____

Dose:

Tysabri® (natalizumab) 300 mg per 100 ml Sodium Chloride 0.9% IV to infuse over at least 1- hour with no filter required. Follow each infusion with 1-hour post infusion monitoring.

Frequency: Dosing every 4 weeks, no less than every 28 days.

***Prior to each infusion: ensure that the patient has a current Notice of Patient Authorization on file to receive Tysabri® (natalizumab) for Crohn's disease and complete/submit Pre-infusion Patient Checklist within 24 hours to Biogen Idec.**

Special orders: _____

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

5. Physician's Signature: _____/ _____Date: _____
No Stamp Signatures (Dispense as written) (Substitution permitted)

Printed Physician's Name with Credentials: _____NPI: _____

6. 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

Revised 6/4/18

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DOB:_____

Guidelines for Prescribing Tysabri® (natalizumab) for Crohn's Disease

(Required documentation with all initial referrals)

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

___ Tysabri® (natalizumab) is restricted to credentialed prescribers and patients enrolled in the TOUCH® Prescribing Program. Contact TOUCH® Prescribing Program at 1-800-456-2255 for details and enrollment. TOUCH® Authorization form must be received prior to scheduling.

___ Include signed and completed **Plan of Treatment**. *(MD must complete sections 1-6)*
(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.**

- TYSABRI® (natalizumab) is an integrin receptor antagonist indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-α. TYSABRI should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF-α.
- If the patient with Crohn's disease has not experienced therapeutic benefit by 12 weeks of induction therapy, discontinue TYSABRI. For patients with Crohn's disease who start TYSABRI while on chronic oral corticosteroids, commence steroid tapering as soon as a therapeutic benefit of TYSABRI has occurred; if the patient with Crohn's disease cannot be tapered off of oral corticosteroids within six months of starting TYSABRI, discontinue TYSABRI. Other than the initial six-month taper, prescribers should consider discontinuing TYSABRI for patients who require additional steroid use that exceeds three months in a calendar year to control their Crohn's disease.

___ **Include the following:**
Past tried and/or failed therapies:_____
Last known therapy: _____ and last date received:_____.
MD must specify wash-out period prior to starting Tysabri® as specified of _____ weeks.

___ Other as requested: _____

Pre-Screening:

___ **anti-JCV antibodies test results within last 6 months.** (Patients who are anti-JCV antibody positive, will require documentation from referring MD that risks and benefits have been discussed

** Warnings/Precautions: TYSABRI® increases the risk of **progressive multifocal leukoencephalopathy (PML):** an opportunistic viral infection of the brain that usually leads to death or severe disability • Risk factors for the development of PML include duration of therapy, prior use of immunosuppressants, and presence of anti-JCV antibodies. • Healthcare professionals should monitor patients on TYSABRI® for any new sign or symptom that may be suggestive of PML. TYSABRI® dosing should be withheld immediately at the first sign or symptom suggestive of PML. • **Herpes encephalitis and meningitis**: Life-threatening and fatal cases have occurred, discontinue TYSABRI® if this occurs • **Hepatotoxicity**: Significant liver injury, including liver failure requiring transplant, has occurred. Discontinue TYSABRI® in patients with evidence of liver injury. • **Immunosuppression/Infections**: TYSABRI® may increase the risk for certain infections including: pneumonias, urinary tract infections (including serious cases), gastroenteritis, vaginal infections, tooth infections, tonsillitis, and herpes infections. • **Hypersensitivity reactions:** Serious hypersensitivity reactions (e.g., anaphylaxis) have occurred. **Permanently discontinue TYSABRI® if such a reaction occurs**. •***Pregnancy Category C.*** 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 6/4/18