St. Charles HEALTH SYSTEM	**St. Charles Health System** Adult Ambulatory Infusion Order Natalizumab (TYSABRI) Or Biosimilars	Patient Name: Date of Birth: *Patient Identification*

ALL ORDERS MUST BE MARKED IN INK WITH A CHECKMARK (✓) TO BE ACTIVE

Treatment Start Date: _____ Allergies: _____
Weight: _____kg Height: _____ cm

REQUIRED ITEMS for all orders – necessary for insurance approval, scheduling, and patient safety
1. FACE SHEET with complete INSURANCE information and patient CONTACT information
2. Recent VISIT NOTE to support treatment (if not available in Epic)
3. LAB RESULTS for any required prescreening (if not available in Epic)
4. DIAGNOSIS CODE _____
5. Patient NAME and DATE OF BIRTH on EVERY page faxed

GUIDELINES FOR ORDERING

1. **Send FACE SHEET and H&P or most recent chart note.**
2. Natalizumab is restricted to credentialed prescribers only through the product specific REMS Prescribing Program
    a. Prescribers MUST be enrolled in the REMS Prescribing Program
    b. Patients MUST be enrolled in the REMS Prescribing Program
    c. Contact the REMS Prescribing Program (e.g., TOUCH or TYRUKO REMS) by phone for details and enrollment
    d. Notify REMS Program Customer Service of any adverse reactions
3. If potential pregnancy risk, including female of child-bearing age not using effective contraceptive and sexually active, baseline hCG pregnancy test is completed no earlier than 2 weeks prior to first infusion.
4. Consider extending natalizumab 300 mg to every 5-8 WEEKS in stable patients on standard dose for at least 12 months.

PRE-SCREENING: (Results must be available prior to initiation of therapy and completed within 90 days of treatment initiation):

☐ Complete metabolic panel test results
☐ CBC with auto differential test results
☐ Stratify JC Virus Antibody with Reflex to Inhibition Assay test results
☐ HCG Qual, URINE test results

LABS:

☐ Complete Metabolic Panel, Routine, ONCE, every (visit)(days)(weeks)(months) – **Circle One**
☐ Complete Metabolic Panel, Routine, ONCE, every 3 months
☐ CBC with auto differential, Routine, ONCE, every (visit)(days)(weeks)(months) – **Circle One**
☐ CBC with auto differential, Routine, ONCE, every 6 months
☐ HCG Qual, URINE, Routine, ONCE, every (visit)(days)(weeks)(months) – **Circle One**
☐ Stratify JC Virus Antibody with Reflex to Inhibition Assay, SERUM, Routine, ONCE, every (visit)(days)(weeks)(months) – **Circle One**

☐ Stratify JC Virus Antibody with Reflex to Inhibition Assay, SERUM, Routine, ONCE, every 3 months

NURSING ORDERS:

1. Follow facility policies and/or protocols for vascular access maintenance with appropriate flush solution, declotting (alteplase), and/or dressing changes.
2. VITAL SIGNS – Obtain vital signs before start of natalizumab infusion and at end of infusion.
3. Do not need lab results of CBC + Diff and/or CMP to start natalizumab infusion. If HCG urine test is ordered, please verify that the urine test is negative before starting the natalizumab infusion.
4. Review and complete REMS Program on-line checklist with patient. Proceed according to guidelines. Fax to program within 1 business day of visit.
5. Patient's REMS Prescribing Authorization # is: _____
6. Encourage patient to continue follow-up with physician every 3 months.
7. Observe patient for infusion related reaction during and for 1 hour post infusion. For patients who have received 12 infusions without a hypersensitivity reaction, post infusion observation is not necessary. Discharge when stable.
8. Assess patient for signs of infection - notify provider if present.
9. Check most recently drawn JC antibody titer to make sure it is negative prior to proceeding with treatment. Hold treatment and contact patient's neurology provider if positive or if the JC virus was not drawn at last month's visit.
10. HYPERSENSITIVITY/INFUSION REACTION – If infusion reaction occurs:
    a. STOP INFUSION
    b. Infuse normal saline at 100 to 200 mL/hr when natalizumab is stopped for emergency or PRN medication
    c. DO NOT RESUME INFUSION. Notify provider and REMS Program of adverse reaction. Discontinue all future natalizumab infusions

PRE-MEDICATIONS:

☐ sodium chloride 0.9% solution, 250 mL, intravenous, infuse at rate necessary to keep vein open (KVO) until natalizumab is started and for 1 hour after infusion is complete, then discontinue.

MEDICATIONS:

☐ natalizumab (TYSABRI), 300 mg, intravenous, in sodium chloride 0.9% 100 mL, ONCE, over 60 minutes

Interval: (must check one)

☐ Once

☐ Every 4 weeks x ____ doses

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☐ Every 4 weeks until discontinued

INFUSION MONITORING/REACTION:

Infusion Reaction. Acute Infusion and Hypersensitivity Medication Protocol will be used unless the provider selects the option below. If opting out, alternative orders must be included.

1. diphenhydramine 25 mg IV, AS NEEDED x1 for hypersensitivity reaction
2. famotidine 20 mg IV, AS NEEDED x1 dose for hypersensitivity reaction
3. methylprednisolone 125 mg IV, AS NEEDED x1 dose for hypersensitivity reaction
4. epinephrine 0.3 mg IM, AS NEEDED x1 dose for hypersensitivity reaction
5. sodium chloride 0.9% 1000 mL IV, 200 mL/hr, AS NEEDED x 1 dose for alteration in hemodynamic status
6. albuterol 2.5 mg/3 mL nebule, AS NEEDED x1 dose for hypersensitivity reaction

☐ Opting out of standard protocol. Alternative orders are attached, or deviations are documented:

_____

Patient will be treated at the following infusion location:

☑ St. Charles Outpatient Infusion Center
2500 NE Neff Road, Bend, OR 97701
Phone: (541) 706-5820 Fax: (541) 706-5825

By signing below, I represent the following:

- I am responsible for the care of the patient identified on this form
- I hold an active, unrestricted license to practice medicine
- I am acting within my scope of practice and authorized by law to order the medication described above for the patient identified on this form

ALL ITEMS BELOW MUST BE COMPLETED TO BE A VALID PRESCRIPTION

Signature: _____ License #: _____ Date: _____

Print Name: _____ Phone: _____ Fax: _____

Plan will expire 1 year after signature date at which time a new order will need to be placed