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TouCH® PRESCRIBING PROGRAM

TYSABRI Outreach: Unified Commitment to Health

Phone: 1-800-456-2255

TYSABRI
Pre-infusion Patient Checklist

Please submit this form to:
Biogen
www.touchprogram.com
Fax: 1-800-840-1278

Patient name: _____ Patient Enrollment Number: _____
First MI Last (Issued by Biogen. Call 1-800-456-2255 or log on to www.touchprogram.com if number is not on file.)

Site name: _____ Site Authorization Number: _____

As a condition of your site's authorization to infuse TYSABRI® (natalizumab), this Pre-infusion Patient Checklist **must** be completed for each patient prior to each infusion. This page **must** be submitted on-line (www.touchprogram.com) **OR** faxed to Biogen (1-800-840-1278) **within 1 day** of the patient's visit and a copy retained in the patient's record whether the patient has been infused or not.

STEP 1: Ensure that the patient is currently authorized to receive TYSABRI for MS or Crohn's disease.

You must refer to the patient's record prior to every infusion.

- If the patient did not receive his or her previous infusion, and physician clearance was required, you must confirm authorization from the prescriber before providing the current infusion
- Confirm the patient status is listed as "Authorized" on TOUCH On-Line (www.touchprogram.com) **OR**
- Confirm that there is a current **Notice of Patient Authorization** on file and that you have not received a **Notice of Patient Discontinuation** (paper-based process)

Is the patient currently authorized to receive TYSABRI? Yes ☐ **No** ☐

Continue to next question.

No **STOP—DO NOT INFUSE**. If authorization cannot be verified on-line at www.touchprogram.com **OR** by calling 1-800-456-2255, the patient must be referred back to the healthcare provider who prescribed TYSABRI.

STEP 2: Confirm that the patient has read and understood the Patient Medication Guide.

The patient must read the Patient Medication Guide prior to every infusion. **Has the patient received and read the Patient Medication Guide, including the section "What should I tell my doctor and nurse before each infusion of TYSABRI?"**

Yes Continue to next question. ☐ **Yes**

No **STOP**—provide the Patient Medication Guide. Proceed to the next question after the patient has read it. ☐ **No**

STEP 3: Read aloud and mark "Yes" or "No" for the patient's answers to the following questions:

	Yes	No
1. Over the past month, have you had any new or worsening medical problems (such as a new or sudden change in your thinking, eyesight, balance, strength, or other problems) that have persisted over several days?	☐	☐
2. Do you have a medical condition that can weaken your immune system, such as HIV infection or AIDS, leukemia or lymphoma, or an organ transplant, that may suggest that your body is not able to fight infections well?	☐	☐

Crohn's disease ONLY

	Yes	No
3. In the past month have you taken, or are you currently on, any medicines other than steroid medicines, to treat cancer or **Crohn's disease** or any other medicines that weaken your immune system? (Review the list on the next page with the patient.)	☐	☐

MS ONLY

	Yes	No
3. In the past month, have you taken medicines to treat cancer or **MS** or any other medicines that weaken your immune system? (Review the list on the next page with the patient.)	☐	☐

STEP 4: Record infusion information.

If the patient answered YES to question 1, 2 or 3, DO NOT INFUSE. Contact the healthcare provider who prescribed TYSABRI and review the patient's answers.

- After discussing the patient's answers, did the prescriber authorize the patient to be infused? ☐ **Yes** ☐ **No**
- Check here if you were unable to contact the prescriber. (See next page for further instructions.) ☐

Date infused (MM/DD/YYYY): _____/_____/_____ **Not infused** ☐

If the next infusion has been scheduled, please enter date (MM/DD/YYYY): _____/_____/_____

Name and signature of staff completing checklist: _____ Date_____

STEP 5: Submit the Pre-infusion Patient Checklist to Biogen on-line at www.touchprogram.com OR fax to 1-800-840-1278.

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Please review the following list with the patient when asking question 3.

Examples of Immunosuppressants, Antineoplastics, and Immunomodulators

Multiple Sclerosis

Approved MS Therapies:
Daclizumab (ZINBRYTA™)
Dimethyl Fumerate(TECFIDERA®)
Glatiramer acetate (Copaxone®)
Interferon beta-1a (Rebif®,AVONEx®)
Interferon beta-1b (Betaseron®,Extavia®)
Fingolimod (Gilenya®)
Mitoxantrone (Novantrone®)
Peginterferon beta-1a (PLEGRIDY®)
Alemtuzumab (LEMTRADA®)
Teriflunomide (Aubagio®)

Immunosuppressants/Antineoplastics:
Azathioprine (Imuran®, Azasan®)
Cladribine (Leustatin®)
Cyclophosphamide (Cytoxan®, Neosar®)
Cyclosporine (Sandimmune®, Neoral®)
Fludarabine phosphate (Fludara®)
Leflunomide (Arava®)
Mercaptopurine (Purinethol®)
Methotrexate (Methotrex®, Rheumatrex®, Trexall®)
Mycophenolate mofetil (CellCept®)
Pemetrexed (Alimta®)

Additional Immunomodulators and Immunosuppressants:
Other interferons (Actimmune®, Infergen®, Intron® A, Pegasys®, PEG-Intron®, Rebetron®, Roferon®-A)
Adalimumab (Humira®)
Alefacept (Amevive®)
Alemtuzumab (Campath®)
Anakinra (Kineret®)
Daclizumab (Zenapax®)
Efalizumab (Raptiva®)
Etanercept (Enbrel®)
Infliximab (Remicade®)
Intravenous immunoglobulin (IVIG) Rituximab (Rituxan®)
Trastuzumab (Herceptin®)

Crohn's Disease

Approved TNF-α inhibitors for Crohn's disease:
Infliximab (Remicade®)
Adalimumab (Humira®)

Immunosuppressants/Antineoplastics:
Approved TNF-α inhibitors Azathioprine (Imuran®, Azasan®)
Chlorambucil (Leukeran®)
Cladribine (Leustatin®)
Cyclophosphamide (Cytoxan®, Neosar®)
Cyclosporine (Sandimmune®, Neoral®)
Fludarabine phosphate (Fludara®)
Leflunomide (Arava®)
Mercaptopurine (Purinethol®)
Methotrexate (Methotrex®, Rheumatrex®, Trexall®)
Mycophenolate mofetil (CellCept®)
Pemetrexed (Alimta®)
Thioguanine (Tabloid®)

Additional Immunomodulators and Immunosuppressants:
Interferon beta-1a (Rebif®, AVONEx®)
Interferon beta-1b (Betaseron®)
Alefacept (Amevive®)
Abatacept (Orencia®)
Anakinra (Kineret®)
Daclizumab (Zenapax®)
Efalizumab (Raptiva®)
Etanercept (Enbrel®)
Glatiramer acetate (Copaxone®)
Intravenous immunoglobulin (IVIG)
Mitoxantrone (Novantrone®)
Other interferons (Actimmune®, Infergen®, Intron® A, Pegasys®, PEG-Intron®, Rebetron®, Roferon®-A)
Rituximab (Rituxan®)
Trastuzumab (Herceptin®)
Vedolizumab (Entyvio®)

This list does not include all drugs that can suppress the immune system.

- Patients should consult their prescribing physician regarding drugs that may be taken concurrently with TYSABRI
- If there are any questions regarding concurrent therapy, **do not infuse** at this time and consult the healthcare provider who prescribed TYSABRI

If you are unable to contact the prescriber:

Instruct the patient to contact his/her prescriber and to reschedule an infusion as soon as possible. Continue efforts to reach the prescriber to inform him/her of the reason(s) for not infusing this patient. You will need to confirm authorization from the prescriber on the subsequent infusion.

This Pre-infusion Patient Checklist is not intended to replace the infusion site's general infusion protocol(s). Nor is this Pre-infusion Patient Checklist intended to be a substitute for consultation and review of reference materials and medical literature pertaining to individual clinical circumstances. Healthcare providers should make all treatment decisions based on the context of the situation and their clinical judgment.

Please do not make any extraneous marks on the Pre-infusion Patient Checklist. If there is information that you would like to share with Biogen and the TOUCH Prescribing Program, please contact us at 1-800-456-2255.

Please see accompanying full Prescribing Information, including Boxed Warning, for important safety information.

Biogen

TYSABRI (natalizumab)

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