MS TouCH PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health
Phone: 1-800-456-2255

Prescriber/Patient Enrollment Form—MS

Completion of all pages is required.

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

Patient Information

Date of birth: ____/____/____ (MM/DD/YYYY)

Patient name: _____ (First / MI / Last)

Street address: _____

City _____ State _____ ZIP _____

Work telephone ☐☐☐-☐☐☐-☐☐☐☐

Home telephone ☐☐☐-☐☐☐-☐☐☐☐

Patient may be contacted at ☐ Home ☐ Work Best time: _____

Female ☐ Male ☐

_____
E-mail address

Insurance Information

Patient SSN ☐☐☐-☐☐-☐☐☐☐

Please attach copies of both sides of patient's insurance and pharmacy card(s).

☐ Check if no insurance ☐ Medicare ☐ Medicaid _____
Medicaid Plan Type

Policyholder's name: _____ (First / MI / Last)

_____ _____
Primary insurance / Insurance company telephone

_____ _____
Policy number / Group number

_____
Pharmacy benefit manager

Patient Authorization to Use/Disclose Health Information

I understand that I have certain rights related to the collection, use, and disclosure of my medical and health information. This information is called "protected health information" (PHI) and includes demographic information (such as sex, race, date of birth, etc.), the results of physical examinations, clinical tests, blood tests, X-rays, and other diagnostic and medical procedures that may be included in my medical records.
Biogen will not use my PHI without my consent.

This Authorization form applies to PHI created or obtained by my prescriber, my infusion site, my pharmacy, and my health insurance company. I understand that by signing this Authorization, I authorize my prescriber, infusion site, pharmacy, and/or health insurance company to disclose the PHI in my medical records to Biogen and its representatives or agents, including information related to my medical condition, treatment, and health insurance, as well as all information provided on any prescription. I also authorize Biogen to use this information to provide TYSABRI support services, such as investigating insurance coverage for TYSABRI and coordinating delivery of TYSABRI to the prescriber or infusion site administering TYSABRI (which may include forwarding my health information to a pharmacy).

I agree to allow Biogen to ask me about and provide me with these support services, educational kits, and other information related to TYSABRI and/or my medical condition. I understand that, once my PHI has been disclosed to Biogen, federal privacy laws may no longer protect the information. However, Biogen agrees to protect my PHI by using it only for the purposes authorized in this Authorization or as required by law.

I understand that I may refuse to sign this Authorization, and refusing to do so will affect my eligibility to receive these additional services but will not affect my ability to receive TYSABRI. I understand that signing this Authorization will not change how my healthcare providers, health insurance plan, and pharmacies provide my medical treatment or payment for treatment or insurance benefits.

I understand that I may cancel all or a part of this Authorization at any time by mailing a letter requesting such cancellation to TYSABRI Support Services, 5000 Davis Drive, PO Box 13919, Research Triangle Park, NC 27709. If I cancel this Authorization, Biogen will end further use and disclosure of my PHI as soon as possible. This will not affect health information that has already been used or disclosed in reliance upon this Authorization.

I will receive a copy of this signed Authorization. This Authorization expires ten (10) years from the date this Authorization is signed.

Patient signature (or personal representative): _____ Date: _____

Authority of personal representative (*if applicable*): _____

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Patient Acknowledgment

Biogen considers patient safety a priority. Read each section below and **initial in the space** provided if you understand the information. **Do not sign this form if there is anything you do not understand about all the information you have received. Ask your doctor about anything you do not understand before you initial and sign this form.**

I understand that TYSABRI is a medicine approved to treat patients with relapsing forms of multiple sclerosis (MS).

- I have talked to my doctor and understand the benefits and risks of TYSABRI treatment
- TYSABRI increases the risk of PML. I understand that when starting and continuing treatment with TYSABRI, I should talk to my doctor about whether the expected benefit of TYSABRI is enough to outweigh this risk (see important information about PML below).

Initials:____

I understand that TYSABRI increases my chance of getting a rare brain infection that usually leads to death or severe disability.

- This infection is called progressive multifocal leukoencephalopathy (PML). PML usually happens in people with weakened immune systems
- There is no known treatment, prevention, or cure for PML
- My chance for getting PML may be higher if I am also being treated with other medicines that can weaken my immune system, including other MS treatments. Even if I use TYSABRI alone to treat my MS, I can still get PML
- My chance for getting PML increases if I:
  - Have received TYSABRI for a long time, especially longer than 2 years
  - Have received certain medicines that can weaken my immune system before I start receiving TYSABRI
  - Have been exposed to John Cunningham Virus (JCV). JCV is a common virus that is harmless in most people but can cause PML in people who have weakened immune systems, such as people taking TYSABRI. Most people who are exposed to JCV do not know it or have any symptoms. This exposure usually happens in childhood. My doctor may do a blood test to check if I have been exposed to JCV before I start receiving TYSABRI or during my treatment

  My risk of getting PML is greatest if I have all 3 risk factors listed above. There may be other risk factors for getting PML during TYSABRI treatment that we do not know about yet. My doctor should discuss the risks and benefits of TYSABRI treatment with me before I decide to receive TYSABRI
- I should call my doctor right away if I get any new or worsening symptoms that last several days, especially nervous system symptoms, while I am taking TYSABRI, and for at least 6 months after I stop taking TYSABRI. Some of these symptoms include a new or sudden change in my thinking, eyesight, balance, or strength, but I should also report other new or worsening symptoms

Initials:____

To receive TYSABRI, all patients must be enrolled in a restricted program called the TOUCH Prescribing Program.

- The TOUCH Prescribing Program is run by the company that makes TYSABRI. Under this program, the company is required to collect information about my health at regular time periods. **I cannot receive TYSABRI if I do not agree** to follow the requirements of the TOUCH Prescribing Program. I understand that the TOUCH Prescribing Program does not require me to sign the Authorization included on page 1 of this form
- The company may use my information to meet the requirements of the TOUCH Prescribing Program, including helping me locate an authorized infusion site
- I must notify the TOUCH Prescribing Program if I switch physicians or infusion sites
- I have received, read, and understand the Patient Medication Guide
- I will bring to each TYSABRI infusion a list of all medicines and treatments that I have taken during the last month

Initials:____

Patient name: _____ Date of birth: ____/____/____
First MI Last (MM/DD/YYYY)

Patient signature (or personal representative): _____ Date: _____

Authority of personal representative (*if applicable*): _____

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Patient name: _____ DOB: ___/___/___
First MI Last (MM/DD/YYYY)

Date of first MS symptoms: ___/___/___
(MM/DD/YYY)

Please indicate the patient's **MOST RECENT** therapy for MS (if patient was most recently on combination therapy, check all that apply). None ☐

AVONEX® ☐ PLEGRIDY® ☐ Betaseron® ☐ Copaxone® ☐ Rebif® ☐ TYSABRI® ☐ Extavia® ☐ Gilenya® ☐

TECFIDERA® ☐ Aubagio® ☐ LEMTRADA® ☐ Azathioprine ☐ Methotrexate ☐ Mitoxantrone ☐ Mycophenolate ☐

Cyclophosphamide ☐ ZINBRYTA™ ☐ Other ☐

Please indicate the start and stop dates of most recent therapy:

Start date: ☐☐/☐☐☐☐ (MM/YYYY) Stop date: ☐☐/☐☐☐☐ (MM/YYYY)

Has the patient ever received TYSABRI before? Yes ☐ No ☐

Has the patient **EVER** been prescribed an immunosuppressant or an antineoplastic therapy for any condition? Yes ☐ No ☐

If yes, please check all of the following that apply:

Azathioprine ☐ Cyclophosphamide ☐ Methotrexate ☐ Mitoxantrone ☐ Mycophenolate ☐ Other ☐

Has the patient **EVER** been tested for the presence of anti-JCV antibodies? Yes ☐ No ☐ Unknown ☐

If yes, has the patient **EVER** tested **POSITIVE** for the presence of anti-JCV antibodies? Yes ☐ No ☐ Pending ☐

Prescription for TYSABRI

Dose: TYSABRI® (natalizumab) 300 mg Dispense: 1 vial Refills: 12 Directions: IV infusion per Prescribing Information every 4 weeks

I authorize Biogen as my designated agent and on behalf of my patient to (1) use the information on this form to enroll the above-named patient in the TOUCH Prescribing Program, (2) furnish any information on this form to the insurer of the above-named patient, (3) forward the information on this form to the prescriber or infusion site administering TYSABRI, if applicable, (4) forward the above prescription by fax or by another mode of delivery to a pharmacy, if applicable, and (5) coordinate delivery of TYSABRI on behalf of the above-named patient.

Prescriber signature (Stamps not acceptable): _____ Date: _____

Prescriber

Prescriber name: _____
First MI Last

Office contact _____

Street address _____

Tax ID # _____

City _____ State _____ ZIP _____

DEA # _____

Telephone ☐☐☐-☐☐☐-☐☐☐☐

Fax ☐☐☐-☐☐☐-☐☐☐☐

NPI/UPIN/provider ID # with patient's insurer(s) _____

Continued on next page

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Prescriber Acknowledgment

- I have read and understand the full Prescribing Information for TYSABRI
- I understand that TYSABRI is indicated as monotherapy for relapsing forms of MS
- I understand that this patient has a relapsing form of MS based on clinical and radiological evidence
- I understand that TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. When initiating and continuing treatment with TYSABRI, I should consider whether the expected benefit of TYSABRI is sufficient to offset this risk
- I am aware that cases of PML have been reported in patients taking TYSABRI who were recently or concomitantly treated with immunomodulators or immunosuppresants, as well as in patients receiving TYSABRI monotherapy
- I understand that three risk factors identified thus far that increase the risk of PML in TYSABRI-treated patients are:
  -Longer treatment duration, especially beyond 2 years
  -Prior treatment with an immunosuppressant (e.g.,mitoxantrone, azathioprine, methotrexate, cyclophosphsmide, mycophenolate mofetil)
  -The presence of anti-JCV antibodies

  These factors should be considered in the context of expected benefit when initiating and continuing treatment with TYSABRI
- I understand that TYSABRI is not ordinarily recommended for patients who are receiving chronic immunosuppressant or immunomodulatory therapy, or who are significantly immunocompromised from any other cause
- To my knowledge, this patient has no known contraindications to TYSABRI treatment, including PML
- I understand that an MRI should be performed prior to initiating therapy with TYSABRI in MS patients
- I understand that MRI findings may be apparent before clinical signs or symptoms. Periodic monitoring for radiographic signs consistent with PML should be considered to allow for an early diagnosis of PML. Lower PML-related mortality and morbidity have been reported following TYSABRI discontinuation in patients with PML who were initially asymptomatic compared to patients with PML who had characteristic clinical signs and symptoms at diagnosis.
- I have instructed this patient to promptly report to me any continuously worsening symptoms that persist over several days, especially nervous system symptoms
- I understand that this patient should be seen and evaluated 3 months after the first infusion, 6 months after the first infusion, every 6 months thereafter, and for at least 6 months after TYSABRI has been discontinued
- I will determine every 6 months whether this patient should continue on TYSABRI and if so, authorize treatment for another 6 months. I understand that I am required to submit an "Initial Discontinuation Questionnaire" when TYSABRI is discontinued and a "6-Month Discontinuation Questionnaire" following discontinuation of TYSABRI
- I should report, as soon as possible, cases of PML, hospitalizations due to opportunistic infection, or deaths to Biogen
- I understand that data concerning this patient and me will be entered into the mandatory TOUCH Prescribing Program. Biogen requires my cooperation with periodic data collection. Failure to provide the requested information or otherwise comply with the requirements of the TOUCH Prescribing Program may result in discontinuation of TYSABRI treatment for this patient and termination of my authorization to prescribe TYSABRI
- I have received educational materials regarding the benefits and risks of TYSABRI treatment
- I have, or another healthcare provider under my direction has, educated this patient on the benefits and risks of treatment with TYSABRI, provided him or her with the Patient Medication Guide and Enrollment Form, instructed him or her to read these materials, and encouraged him or her to ask questions when considering TYSABRI

Patient name:_____ Date of birth: __/__/____
First MI Last (MM/DD/YYYY)

Prescriber signature:_____ Date:_____

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Date of birth: ____/____/____ (MM/DD/YYYY) Patient name: ____ First ____ MI ____ Last

In addition, I allow the sharing of my health information to the person or people I name below. Biogen may contact the people named below to discuss my enrollment in the TOUCH Program.

Designated Individual (print name): _____ Relationship: _____

Infusion Site Information*

1 Prescriber will administer TYSABRI and request the following services (check only one):

☐ No services required **OR** ☐ Forward this prescription to a specialty pharmacy **OR** provider to investigate pharmacy coverage and coordinate delivery to prescriber's office ☐ Please conduct insurance research and procurement options for TYSABRI

OR

2 Prescriber will refer TYSABRI treatment to another site (check only one):

☐ I require assistance in locating an infusion site **OR** ☐ I am referring the patient to the following infusion site or healthcare provider:

Name of administering healthcare provider (first, last)

Office contact

Site name

Telephone ☐☐☐-☐☐☐-☐☐☐☐

Street address or site Authorization Number

Fax ☐☐☐-☐☐☐-☐☐☐☐

City State ZIP

*Note: TYSABRI can only be infused at authorized infusion sites. Biogen will contact you if the infusion site you have indicated is not authorized to infuse TYSABRI.

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

Biogen

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TYSABRI® (natalizumab)