TOUCH™ PRESCRIBING PROGRAM

TYSABRI Outreach: Unified Commitment to Health

# Getting Started With TYSABRI

## What you need to know

**Please see accompanying Medication Guide, including the section "What is the most important information I should know about TYSABRI?"**

TYSABRI® (natalizumab)

# *Frequently Asked Questions*

This brochure is designed to review the benefits and risks of TYSABRI. Biogen Idec and Elan Pharmaceuticals, Inc. believe it is important for you to understand important safety information before learning more about the benefits of TYSABRI.

This brochure does not take the place of talking to your doctor about your medical condition or your treatment. Ask your doctor or nurse if you have any questions.



## What is the most important information I should know about TYSABRI?

- **TYSABRI increases your chance of getting a rare brain infection that usually causes death or severe disability. This infection is called progressive multifocal leukoencephalopathy (PML).** PML usually happens in people with weakened immune systems
- No one can predict who will get PML
- There is no known treatment, prevention, or cure for PML
- Your chance of getting PML may be higher if you are also being treated with other medicines that can weaken your immune system, including other MS treatments

**Please see accompanying Medication Guide, including the section "What is the most important information I should know about TYSABRI?"**

- Even if you use TYSABRI alone to treat your MS, it is not known if your chance of getting PML will be lower. It is also not known if treatment for a long period of time with TYSABRI can increase your chance of getting PML
- TYSABRI is available only through a restricted distribution program called the TOUCH™ Prescribing Program. In order to receive TYSABRI, you must talk to your doctor and understand the benefits and risks of TYSABRI and agree to all of the instructions in the TOUCH Prescribing Program
- If you take TYSABRI, it is important that you call your doctor right away if you get any new or worsening medical problems (such as a new or sudden change in your thinking, eyesight, balance, or strength, or other problems) that have lasted over several days. Tell all of your doctors that you are getting treatment with TYSABRI



Also, see **"What are the possible side effects with TYSABRI?"** on pages 16-19 for other serious side effects with TYSABRI.

TYSABRI® (natalizumab)

# *Frequently Asked Questions*

## What is TYSABRI?

TYSABRI is a prescription medicine approved for patients with relapsing forms of MS to:

- Slow the worsening of disability that is common in patients with MS and,
- Decrease the number of flare-ups (relapses)

- Because of the chance of getting PML, TYSABRI is generally recommended for patients that have not been helped enough by, or cannot tolerate other treatments for MS
- TYSABRI does not cure MS
- TYSABRI has not been studied for use longer than 2 years. Also, TYSABRI has not been studied in patients with chronic progressive MS, or in children. It is not known if patients older than 65 years have a different response to TYSABRI



**Please see accompanying Medication Guide, including the section "What is the most important information I should know about TYSABRI?"**

## What makes TYSABRI different?

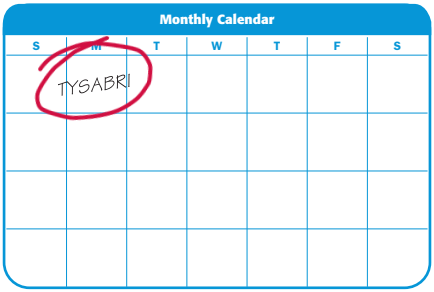
1) It works in a different way.

- TYSABRI is an antibody, not an interferon or glatiramer acetate
- TYSABRI inhibits white blood cells from getting into the brain and attacking nerves
- Keeping these cells from attacking nerves is believed to result in fewer brain lesions that cause MS symptoms
- It is important to note that while the way in which TYSABRI works has been studied, the exact way that TYSABRI works is not fully known



2) It is taken differently than other MS medicines.

- With TYSABRI, you don't need to self-inject
- TYSABRI is infused into a vein once every 4 weeks



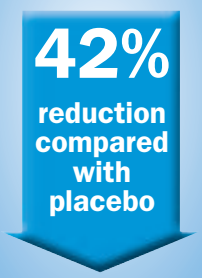

TYSABRI® (natalizumab)

## How much can TYSABRI help?

### WORSENING OF DISABILITY SLOWED

**At the end of a 2-year study, TYSABRI slowed the worsening of disability that is common in patients with MS**

- TYSABRI provided a 42% decrease in the chance that a person's disability would worsen compared with placebo (17% TYSABRI compared with 29% placebo)
- This means that patients who received TYSABRI had a much lower chance of progression of their disability than patients who received placebo



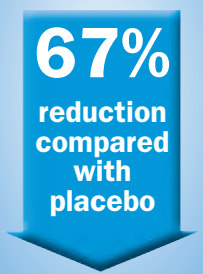



**Please see accompanying Medication Guide, including the section "What is the most important information I should know about TYSABRI?"**

## LOWER FREQUENCY OF FLARE-UPS

**At the end of a 2-year study, TYSABRI decreased the frequency of flare-ups (relapses)**

- TYSABRI provided a 67% decrease in the frequency of flare-ups compared with placebo (TYSABRI 0.22 compared with placebo 0.67)
- This means that patients who received TYSABRI had flare-ups much less often than patients who received placebo






## How does TYSABRI affect the brain lesions seen on MRI?

### FEWER MRI LESIONS

At the end of a 2-year study, patients who received TYSABRI had significantly fewer brain lesions than patients who received placebo

- It is not known exactly how well MRI findings relate to how your MS is progressing

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# *Frequently Asked Questions*

## How can I receive TYSABRI?

TYSABRI is only:

- Prescribed by doctors who are enrolled in the TOUCH Prescribing Program
- Infused at infusion centers that are enrolled in the TOUCH Prescribing Program
- Given to patients who are enrolled in the TOUCH Prescribing Program



## What is the TOUCH Prescribing Program?

TOUCH™ PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

Most MS medicines offer patients support programs. The TOUCH Prescribing Program is different because:

- You must be enrolled in the program in order to receive TYSABRI
- It was created to help manage the risk of PML
- It was developed by working with the FDA
- Your doctor will provide information about your health status to the TOUCH Prescribing Program every 6 months and will determine if you should continue to receive TYSABRI

## How do I enroll in the TOUCH Prescribing Program?

1) Read the Patient Medication Guide.
2) Discuss the benefits and risks of TYSABRI with your doctor.
3) Complete and sign the TOUCH Enrollment Form with your doctor.

## How can Biogen Idec help you?



After you enroll in the TOUCH Prescribing Program, you will be assigned a Biogen Idec Case Manager. Your Case Manager can help:

- Assure you are assigned to an authorized infusion site
- Answer questions related to TYSABRI and TYSABRI infusions
- Research your insurance options

TYSABRI® (natalizumab)

# *Frequently Asked Questions*

## What are my TOUCH™ Prescribing Program responsibilities?

By signing the TOUCH Enrollment Form, you acknowledge that you understand important information about TYSABRI.

**1 You should know what TYSABRI is and how it should be used:**

- Approved only to treat patients with relapsing forms of MS
- Generally recommended for patients that have not been helped enough by, or cannot tolerate other treatments for MS
- Understand benefits and risks as discussed with your doctor



**2 You should be aware that TYSABRI increases the risk of PML:**

- PML is a rare brain infection that usually causes death or severe disability
- PML usually happens in people with weakened immune systems, but no one can predict who will get it

**Please see accompanying Medication Guide, including the section "What is the most important information I should know about TYSABRI?"**

- There is no known treatment, prevention, or cure for PML
- The chance of getting PML may be higher if you take medicines that weaken your immune system
- Even if you use TYSABRI alone, your risk of getting PML may not be lower
- It is not known if treatment for a long period of time with TYSABRI can increase your risk of getting PML
- You must call your doctor if you get any new or worsening symptoms that last several days



**3 Additional important considerations:**

- You must notify the TOUCH Prescribing Program if you switch doctors or infusion sites
- You must receive, read, and understand the Patient Medication Guide
- You should bring a list of all medicines you've taken during the last month to each infusion
- **You should plan to see your doctor 3 months after the first infusion, 6 months after the first infusion, and at least as frequently as every 6 months thereafter**

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## Who should not receive TYSABRI?

Do **not receive** TYSABRI if you:

- Have PML
- Are allergic to TYSABRI or any of its ingredients

## TYSABRI is not recommended if you:

- Have a medical condition that can weaken your immune system such as HIV infection or AIDS, leukemia or lymphoma, or an organ transplant, and others
- Are taking medicines that can weaken your immune system. Talk with your doctor about all of the medicines you take or have taken



If you have questions about any of the above, talk to your doctor.

**Please see accompanying Medication Guide, including the section "What is the most important information I should know about TYSABRI?"**

## What should I tell my doctor and nurse before receiving each infusion of TYSABRI?

Tell your doctor and nurse about all of your medical conditions. Tell them if you:

- Have any new or worsening medical problems (such as a new or sudden change in your thinking, eyesight, balance, or strength, or other problems) that have lasted several days
- Have had hives, itching, or trouble breathing during or after an infusion of TYSABRI
- Have a fever or infection (including shingles or any unusually long-lasting infection)
- Are pregnant or plan to become pregnant
- Are breastfeeding



Tell your doctor and nurse about all of the medicines you are taking, including prescription and nonprescription medicines, vitamins, and herbal supplements.

- Know the medicines you take. Keep a list of them with you to show your doctor and nurse. The nurse may ask to see this list before every TYSABRI infusion

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# *Frequently Asked Questions*

## How do I receive TYSABRI?

- TYSABRI is given once every 4 weeks through a needle placed in a vein (IV infusion)
- You must follow all the instructions of the TOUCH™ Prescribing Program. Before you can begin to receive TYSABRI, your doctor or nurse will:
  - Explain the TOUCH Prescribing Program to you
  - Have you sign the TOUCH Prescriber/Patient Enrollment Form
- Call your doctor who prescribed TYSABRI right away to report any medical problems that keep getting worse and last several days



## Where will I receive my TYSABRI infusion?

You may get your TYSABRI infusion right in your doctor's office. If your doctor does not perform infusions, a TOUCH Prescribing Program Case Manager can help find an authorized infusion site that is convenient for you. This site could be in a hospital or a separate center that only gives infusions.

**Please see accompanying Medication Guide, including the section "What is the most important information I should know about TYSABRI?"**

## What can I expect at my TYSABRI infusion each month?

- You will receive a copy of the **Patient Medication Guide** to review
- Before every TYSABRI infusion you will be asked a series of questions to confirm that TYSABRI is still right for you
- Depending on your answers, the nurse will either give you your infusion or contact your doctor for further instructions. If the nurse cannot reach your doctor, you will not be able to receive your TYSABRI that day
- If you are able to receive the infusion, it will take about 1 hour
- After the infusion, you will be observed for another hour to make sure you are not having any reactions that may need medical help



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## What questions will I need to answer before my infusion?

At each infusion visit, you will need to answer questions about whether you:

1. Have any new or worsening medical problems.
2. Have a condition or are taking medicines that could weaken your immune system.
3. Have taken steroid medicines.



## What are the possible side effects of TYSABRI?

**TYSABRI increases your chance of getting a rare brain infection that usually causes death or severe disability. This infection is called progressive multifocal leukoencephalopathy (PML). PML usually happens in people with weakened immune systems.** (see **"What is the most important information I should know about TYSABRI?"** on pages 2-3)

## How many cases of PML were there in clinical trials?

PML occurred in 3 patients who received TYSABRI out of over 3,000 who participated in clinical studies. Two cases of PML were observed in 1,869 patients with MS. The third case occurred in 1 out of 1,043 patients with Crohn's disease.

## Other serious side effects with TYSABRI include:

### Allergic reactions

- Allergic reactions including serious allergic reactions. Symptoms can include:
  - hives
  - itching
  - trouble breathing
  - chest pain
  - dizziness
  - chills
  - rash
  - nausea
  - flushing of skin
  - low blood pressure



- Serious allergic reactions usually happen within 2 hours of the start of the infusion, but they can happen at any time after receiving TYSABRI
- Tell your doctor or nurse right away if you have any symptom of an allergic reaction, even if it happens after you leave the infusion center. You may need treatment if you are having an allergic reaction

### Infections

- TYSABRI may increase your chance of getting an unusual or serious infection because TYSABRI can affect your immune system

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## Other side effects with TYSABRI include:

- headache
- urinary tract infection
- lung infection
- pain in your arms and legs
- vaginitis
- feeling tired
- joint pain
- depression
- diarrhea
- rash
- stomach area pain



## What are persistently positive antibodies?

- Antibodies are proteins made by the body to help fight against foreign invaders like bacteria and viruses
- Sometimes the body recognizes a medicine as foreign and will make antibodies against it, which may prevent your medicine from working

## Can this happen with TYSABRI?

At the end of a 2-year study, about 6% of patients receiving TYSABRI had antibodies that didn't go away (persistently positive antibodies).

- TYSABRI did not work well in the patients who had persistently positive antibodies
- The patients who had persistently positive antibodies also had an increased chance of having an allergic reaction when they received their TYSABRI infusion

**Please see accompanying Medication Guide, including the section "What is the most important information I should know about TYSABRI?"**

- If your doctor decides you should be tested and you test positive for antibodies, you and your doctor should discuss whether TYSABRI is still right for you

Tell your doctor about any side effect that bothers you or does not go away.

These are not all the side effects with TYSABRI.

Ask your doctor for more information.

## General information about the safe and effective use of TYSABRI



This brochure provides a summary of the most important information about TYSABRI. If you would like more information or have any questions, talk with your doctor or nurse. You can ask your doctor or nurse for information about TYSABRI that is written for healthcare professionals. You can also call 1-800-456-2255 or visit **www.TYSABRI.com**.

## What are the ingredients in TYSABRI?

Each dose of TYSABRI contains natalizumab; sodium chloride; sodium phosphate, monobasic, monohydrate; sodium phosphate, dibasic, heptahydrate; polysorbate 80; and water for injection.

TYSABRI® (natalizumab)

INSIDE
POCKET

INSIDE
POCKET

REFERENCE
COPY

# *Learn more*

You and your doctor can call the toll-free customer support helpline at **1-800-456-2255** (Monday through Friday, 8:30 AM to 8:00 PM [ET]) to:

- Learn more about the TOUCH™ Prescribing Program
- Get answers to questions about TYSABRI
- Find out more about living with MS
- Sign up to participate in MS programs and teleconferences



Your healthcare provider is your best resource for information on staying well. Communication is an important part of your therapy. Talking with trusted friends and loved ones about how you're feeling can help them better support you.

**Please see accompanying Medication Guide, including the section "What is the most important information I should know about TYSABRI?"**

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TOUCH™ PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

# Prescriber/Patient Enrollment Form

Completion of all pages is required.

**Please fax this form to:**
Biogen Idec
Fax: 1-800-840-1278
Phone: 1-800-456-2255

## Patient Information

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

Name (first, middle initial, 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 ☐ Check if patient has Medicare

Policy holder's name (first, middle initial, 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.



This Authorization form applies to PHI created or obtained by my physician, my infusion center or other drug administration site, my pharmacy, and my health insurance company. I understand that by signing this Authorization, I authorize my physician, infusion center or other drug administration site, pharmacy, and/or health insurance company to disclose the PHI in my medical records to Biogen Idec Inc. and Elan Pharmaceuticals, Inc. and their representatives or agents (together, the "Companies"), including information related to my medical condition, treatment, and health insurance, as well as all information provided on any prescription. I also authorize the Companies to use this information to provide TYSABRI support services, such as investigating insurance coverage for TYSABRI, coordinating delivery of TYSABRI to the physician or site administering TYSABRI (which may include forwarding my health information to a pharmacy), and providing a referral to a physician or site willing to administer TYSABRI.

I understand that I may refuse to sign this Authorization and refusing to do so 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 agree to allow the Companies to contact me by mail, e-mail, and/or telephone to oversee these services. I understand that, once my PHI has been disclosed to the Companies, federal privacy laws may no longer protect the information. However, the Companies agree to protect my PHI by using it only for the purposes authorized in this Authorization or as permitted by law.

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, the Companies 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)*: _____

# Prescriber/Patient Enrollment Form

Completion of all pages is required.

**Please fax this form to:**
Biogen Idec
Fax: 1-800-840-1278
Phone: 1-800-456-2255

## Patient Acknowledgment

Biogen Idec and Elan Pharmaceuticals, Inc. consider 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 acknowledge that:**

**TYSABRI is a medicine approved only to treat patients with relapsing forms of multiple sclerosis (MS).**

- TYSABRI is generally recommended for patients who have not been helped enough by, or cannot tolerate, other treatments for MS
- I have talked to my doctor and understand the benefits and risks of TYSABRI treatment

Initials:_____

**TYSABRI increases your chance of getting a rare brain infection that usually causes death or severe disability.**

- This infection is called progressive multifocal leukoencephalopathy (PML). PML usually happens in people with weakened immune systems
- No one can predict who will get PML. 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, it is not known if my chance for getting PML will be lower. It is also not known if treatment for a long period of time with TYSABRI can increase my chance for PML
- I should call my doctor right away if I get any new or worsening symptoms that last several days, especially nervous system symptoms. 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 special program called the TOUCH Prescribing Program.**

- The TOUCH Prescribing Program is run by the company that makes TYSABRI. The company will 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 must notify the TOUCH Prescribing Program if I switch doctors 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, middle initial, last) (MM/DD/YYYY)

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

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

TOUCH™ PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

# Prescriber/Patient Enrollment Form

Completion of all pages is required.

**Please fax this form to:**
Biogen Idec
Fax: 1-800-840-1278
Phone: 1-800-456-2255

## Patient History

Patient name (first, middle initial, last) _____ DOB: ___/___/___ (MM/DD/YYYY)

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

Please indicate the patient's **most recent** therapy (if patient was most recently on combination therapy, check all that apply).

None ☐ Avonex® ☐ Betaseron® ☐ Copaxone® ☐ Rebif® ☐ Novantrone® ☐ TYSABRI® ☐

Azathioprine ☐ Methotrexate ☐ Mycophenolate ☐ Cyclophosphamide ☐ Other ☐

Please indicate the start and stop dates of most recent therapy: Start date ☐☐/☐☐☐☐ (M M / Y Y Y Y) Stop date ☐☐/☐☐☐☐ (M M / Y Y Y Y)

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

## 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 Idec 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 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



Name (first, last) _____ Office contact _____

Street address _____ Tax ID # _____

City _____ State _____ ZIP _____ DEA # _____

Telephone ☐☐☐-☐☐☐-☐☐☐☐

Fax ☐☐☐-☐☐☐-☐☐☐☐

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

## Administration Site Information*

1 **Prescriber will administer TYSABRI.** If YES, check here: ☐ and request services needed. If NO, go to 2 below.

☐ No services required ☐ Forward this prescription to a specialty pharmacy 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.** If YES, check here: ☐ and fill out the information below.

☐ I require assistance in locating an administration site. ☐ I am referring the patient to the following healthcare provider or administration site:

Name of administering healthcare provider (first, last) _____ Office contact _____

Site name _____ Telephone ☐☐☐-☐☐☐-☐☐☐☐

Street address _____ Fax ☐☐☐-☐☐☐-☐☐☐☐

City _____ State _____ ZIP _____

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

TOUCH™ PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

# Prescriber/Patient Enrollment Form

Completion of all pages is required.

**Please fax this form to:**
Biogen Idec
Fax: 1-800-840-1278
Phone: 1-800-456-2255

## Prescriber Acknowledgment

I acknowledge that:

- I have read and understand the full Prescribing Information for TYSABRI
- TYSABRI is indicated as monotherapy for relapsing forms of MS
- This patient has a relapsing form of MS based on clinical and radiological evidence
- TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. Although the cases of PML were limited to patients with recent or concomitant exposure to other immunomodulators or immunosuppressants, there were too few cases to rule out the possibility that PML may occur with TYSABRI monotherapy
- I am able to diagnose and manage opportunistic infections and PML, or am prepared to refer patients to specialists with these abilities
- Because TYSABRI increases the risk of PML, it is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, alternate MS therapies. I have discussed other MS treatments with this patient
- TYSABRI is not ordinarily recommended for patients who are receiving chronic immunosuppressant or immunomodulatory therapy, or who are significantly immunocompromised from any other cause
- This patient has no known contraindications to TYSABRI treatment, including PML
- I have instructed this patient to promptly report to me any continuously worsening symptoms that persist over several days
- This patient should be seen and evaluated 3 months after the first infusion, 6 months after the first infusion, at least every 6 months thereafter for as long as this patient receives TYSABRI, 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 every 6 months
- I should report, as soon as possible, cases of PML, hospitalizations due to opportunistic infection, or deaths to Biogen Idec
- Data concerning this patient and me will be entered into the mandatory TOUCH Prescribing Program. Biogen Idec 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 forfeiture 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, middle initial, last) (MM/DD/YYYY)

**Prescriber signature**: _____ Date: _____

**Please see accompanying full Prescribing Information.**



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DETACH HERE

TOUCH™ PRESCRIBING PROGRAM
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# Pre-infusion Patient Checklist

**Please fax this page to:**
Biogen Idec
Phone: 1-800-456-2255
Fax: 1-800-840-1278

**Patient name:**_____ **Patient Enrollment Number:** ☐☐☐☐☐☐☐☐☐☐
(Issued by Biogen Idec. Call 1-800-456-2255 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 faxed to Biogen Idec (1-800-840-1278) **within 1 day** of the patient's visit and a copy retained in the patient's medical record whether the patient has been infused or not.

## STEP 1: Ensure that the patient is currently authorized to receive TYSABRI.

You must refer to the patient's medical 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 that there is a current **Notice of Patient Authorization** on file
- ➤ Confirm that you have **not** received a **Notice of Patient Discontinuation**

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

**Yes** Continue to next question.

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

## 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** ☐

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



## STEP 3: Read aloud and record 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? | ☐ | ☐ |
| 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 reverse side with the patient.) | ☐ | ☐ |
| 4. In the past month, other than for the treatment of a recent relapse, have you taken any of the following medicines: Solu-Medrol®, methylprednisolone, Decadron®, dexamethasone, Depo-Medrol®, prednisone, or other steroid medicines? | ☐ | ☐ |

## STEP 4: IF AND ONLY IF the patient answered NO to ALL questions (1-4) can TYSABRI be infused.

**If the patient answered YES to any question,** do not infuse, contact the healthcare provider who prescribed TYSABRI to them, 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 reverse side for further instructions.) ☐

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

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

Note: If the patient tells you he or she is permanently discontinuing TYSABRI treatment, please contact the healthcare provider who prescribed TYSABRI.

Name and signature of staff completing checklist:_____
(Date)

## STEP 5: Fax the Pre-infusion Patient Checklist to Biogen Idec at 1-800-840-1278.

TOUCH™ PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

# Pre-infusion Patient Checklist

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

## Examples of Immunosuppressants, Antineoplastics, and Immunomodulators

**Approved MS Therapies:**
Glatiramer acetate (Copaxone®)
Interferon beta-1a (Rebif®, Avonex®)
Interferon beta-1b (Betaseron®)
Mitoxantrone (Novantrone®)

**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®)



**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 Idec and the TOUCH Prescribing Program, please contact us at 1-800-456-2255.

**Please see accompanying full Prescribing Information.**

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TYSABRI (natalizumab)



02/07 3-3025-02

TOUCH™ PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

# TYSABRI Patient Status Report and Reauthorization Questionnaire

**Please fax this form to:**
Biogen Idec
Fax: 1-800-840-1278
Phone: 1-800-456-2255

<Date>

<Prescriber Name>
<Prescriber Address>
<MD Number>

Re: <Patient Name>
Patient Enrollment Number: <Patient TOUCH ID>
Patient date of birth: <DOB>
Authorization expiration date: <MM/DD/YYYY>

Dear <MD Name>,

Our records indicate that <patient>'s authorization to receive TYSABRI will expire on <MM/DD/YYYY> and he/she will no longer be able to receive TYSABRI.

In order to prevent interruption of <patient>'s TYSABRI treatment, fax the completed form to Biogen Idec at 1-800-840-1278 by <expiration date> and place a copy in the patient's medical record.

**A** Is patient still under your care?

☐ Yes ☐ No

If **NO**, please provide contact information for new prescriber, if available.

Name and phone of new prescriber: _____

_____

**B** Is patient alive?

☐ Yes ☐ No

**C** Does patient have a diagnosis of progressive multifocal leukoencephalopathy (PML) that you have *not* already reported to Biogen Idec?

☐ Yes ☐ No ☐ Under investigation

**D** Has patient been hospitalized for an opportunistic infection that you have *not* already reported to Biogen Idec?

☐ Yes ☐ No ☐ Under investigation

**E** Is the patient currently receiving or has the patient received intermittent courses of steroids for the treatment of MS relapse in the previous 6 months?

☐ Yes ☐ No

If YES, please circle the number of courses received.

1 2 3 4 5 6 >6

**F** Is the patient currently receiving or has the patient received any immunomodulatory or immunosuppressant products in the previous 6 months?

☐ Yes ☐ No

If YES, circle the number of months received.

| | Use in Last 6 Months | | | | | |
|---|---|---|---|---|---|---|
| AVONEX® | 1 | 2 | 3 | 4 | 5 | 6 |
| Betaseron® | 1 | 2 | 3 | 4 | 5 | 6 |
| Copaxone® | 1 | 2 | 3 | 4 | 5 | 6 |
| Rebif® | 1 | 2 | 3 | 4 | 5 | 6 |
| Novantrone® | 1 | 2 | 3 | 4 | 5 | 6 |
| Azathioprine | 1 | 2 | 3 | 4 | 5 | 6 |
| Methotrexate | 1 | 2 | 3 | 4 | 5 | 6 |
| Mycophenolate | 1 | 2 | 3 | 4 | 5 | 6 |
| Cyclophosphamide | 1 | 2 | 3 | 4 | 5 | 6 |
| Chronic systemic steroids | 1 | 2 | 3 | 4 | 5 | 6 |
| Other immunomodulatory or immunosuppressant therapy | 1 | 2 | 3 | 4 | 5 | 6 |

**G** If patient is still under your care, do you authorize the continuation of TYSABRI treatment for the next 6 months for patient?

☐ Yes ☐ No

If you answer **NO**, Biogen Idec will contact the patient and the infusion site to stop TYSABRI treatment. The patient will not be eligible to receive TYSABRI treatment, and you will receive a final questionnaire for this patient in 6 months.



If any information on this form is incorrect, if you have questions, or if you need additional information, please call 1-800-456-2255 from 8:30 AM to 8:00 PM (ET).

Prescriber signature: _____ Date (MM/DD/YYYY): _____/_____/_____

**Please Note:** This questionnaire will be used consistent with the TOUCH Prescriber/Patient Enrollment Form signed by you and your patient and with HIPAA and applicable privacy rules.

**Please see accompanying full Prescribing Information.**

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TYSABRI (natalizumab)

TOUCH™ PRESCRIBING PROGRAM

TYSABRI Outreach: Unified Commitment to Health

# Infusion Site Enrollment Form

**Please fax this form to:**
Biogen Idec
Fax: 1-800-840-1278
Phone: 1-800-456-2255

The TOUCH Prescribing Program was developed as part of the Biogen Idec and Elan Pharmaceuticals, Inc. commitment to patient safety. Only authorized infusion sites may receive shipments of and infuse TYSABRI. An infusion site may become authorized only after it has taken part in compulsory training conducted by Biogen Idec or Elan Pharmaceuticals, Inc. and faxed a completed Enrollment Form to Biogen Idec. Upon receipt of this Enrollment Form, Biogen Idec will fax and mail an authorization confirmation letter to provide your Site Authorization Number and confirm your Shipping Address.

## Infusion Site Address (address where patient is infused)

Name of Infusion Site _____ Contact name _____

Address 1 _____ Telephone ☐☐☐-☐☐☐-☐☐☐☐

Address 2 _____ Fax ☐☐☐-☐☐☐-☐☐☐☐

City _____ State _____ ZIP _____

## Method of acquiring TYSABRI

1 **Infusion site will acquire TYSABRI directly.** If YES, check one of these boxes: ☐ Buy/Bill ☐ Assignment of Benefits/Specialty Pharmacy

**OR**

2 **Infusion site will acquire through a central pharmacy.*** ☐

*A central pharmacy is located within a hospital, group practice, or infusion site and is associated with an infusion site. Retail pharmacies and wholesalers are excluded from holding inventory and dispensing TYSABRI.

## Shipping Address (address to which drug will be shipped)



☐ Check here if address is same as above. **Please note that this is the ONLY address to which TYSABRI will be shipped.**

Name of Infusion Site _____ Contact name _____

Address 1 _____ Telephone ☐☐☐-☐☐☐-☐☐☐☐

Address 2 _____ Fax ☐☐☐-☐☐☐-☐☐☐☐

City _____ State _____ ZIP _____

## Infusion Site Acknowledgment

### The infusion site acknowledges that:

- A representative of Biogen Idec or Elan Pharmaceuticals, Inc. has provided training and educational materials on the TOUCH Prescribing Program
- TYSABRI will be administered only to patients who are enrolled in the TOUCH Prescribing Program
- Only currently authorized patients will receive TYSABRI. Authorization is confirmed by ensuring that there is a current Notice of Patient Authorization on file and that the site has not received a Notice of Patient Discontinuation
- Each patient will receive a copy of the TYSABRI Patient Medication Guide *prior to each infusion*
- A TYSABRI Pre-infusion Patient Checklist must be completed for *every patient scheduled to receive TYSABRI*. The Pre-infusion Patient Checklist must be faxed to Biogen Idec within 1 day of patient visit, and a copy placed in the patient's medical record
- I understand that, per the requirements of the TOUCH Prescribing Program, this infusion site may be audited by the Food and Drug Administration (FDA), Biogen Idec, Elan Pharmaceuticals, Inc., and/or a third party designated by the FDA, Biogen Idec, or Elan Pharmaceuticals, Inc.
- Noncompliance with the requirements of the TOUCH Prescribing Program will result in de-enrollment of the infusion site and forfeiture of the authorization to infuse TYSABRI

Responsible party acknowledgment: _____ Date: _____

Name: _____ Title: _____

**Please see accompanying full Prescribing Information.**

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TYSABRI® (natalizumab)