



Touch[®] PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

Please see the Prescribing Information, including **BOXED WARNING**, for more information



TYSABRI[®]
(natalizumab)

Objectives

- Provide an overview of important safety information
- Provide an overview of the TOUCH Prescribing Program for Multiple Sclerosis (MS) and Crohn's disease (CD)
- Review the process steps to complete TOUCH Prescribing Program components including use of TOUCH On-Line
- Review specific MS TOUCH and/or CD TOUCH Prescribing Program materials
- Review the responsibilities of each participant in the TOUCH Prescribing Program

Indications and Usage – Multiple Sclerosis

- TYSABRI® (natalizumab) is indicated as monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML).
- When initiating and continuing treatment with TYSABRI, physicians should consider whether the expected benefit of TYSABRI is sufficient to offset this risk.
- See Prescribing Information regarding the risk of PML with TYSABRI.

Indications and Usage – Crohn's Disease

- TYSABRI® is 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 .

BOXED WARNING

- TYSABRI® increases the risk of PML, an opportunistic viral infection of the brain that usually leads to death or severe disability.
- Risk factors for the development of PML include presence of anti-JCV antibodies, duration of therapy, and prior use of immunosuppressants. These factors should be considered in the context of expected benefit when initiating and continuing treatment with TYSABRI.
- 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 that may be suggestive of PML.

BOXED WARNING

- For diagnosis, an evaluation that includes a gadolinium-enhanced magnetic resonance imaging (MRI) scan of the brain and, when indicated, cerebrospinal fluid analysis for JC viral DNA are recommended.
- Because of the risk of PML, TYSABRI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the TOUCH Prescribing Program.

Contraindications

- TYSABRI is contraindicated in patients who have or have had PML.
- TYSABRI is contraindicated in patients who have had a hypersensitivity reaction to TYSABRI.

Warnings and Precautions - PML

- Three factors that are known to increase the risk of PML in TYSABRI-treated patients have been identified:
 - The presence of anti-JCV antibodies. Patients who are anti-JCV antibody positive have a higher risk for developing PML.
 - Longer treatment duration, especially beyond 2 years.
 - Prior treatment with an immunosuppressant (e.g., mitoxantrone, azathioprine, methotrexate, cyclophosphamide, mycophenolate mofetil)
- These factors should be considered in the context of expected benefit when initiating and continuing treatment with TYSABRI.
- Retrospective analyses of postmarketing data from various sources, including observational studies and spontaneous reports obtained worldwide, suggest that the risk of developing PML may be associated with relative levels of serum anti-JCV antibody compared to a calibrator as measured by ELISA (often described as an anti-JCV antibody index value).

Warnings and Precautions – PML

- Infection by the JC virus (JCV) is required for the development of PML.
- Anti-JCV antibody testing should not be used to diagnose PML.
- Anti-JCV antibody negative status indicates that antibodies to the JC virus have not been detected.
- Patients who are anti-JCV antibody negative have a lower risk of PML than those who are positive. Patients who are anti-JCV antibody negative are still at risk for the development of PML due to the potential for a new JCV infection, or a false negative test result.

Warnings and Precautions – PML

- MRI findings may be apparent before clinical signs or symptoms suggestive of PML.
- Periodic monitoring for radiographic signs consistent with PML should be considered to allow for an early diagnosis of PML.
- Consider monitoring patients at high risk for PML more frequently.
- 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.

Warnings and Precautions – PML

- The reported rate of seroconversion in patients with MS (changing from anti-JCV antibody negative to positive) is 3 to 8 percent annually. In addition, some patients' serostatus may change intermittently. Therefore, patients with a negative anti-JCV antibody test result should be retested periodically.
- For purposes of risk assessment, a patient with a positive anti-JCV antibody test at any time is considered anti-JCV antibody positive regardless of the results of any prior or subsequent anti-JCV antibody testing. When assessed, anti-JCV antibody status should be determined using an analytically and clinically validated immunoassay.
- After plasma exchange (PLEX), wait at least two weeks to test for anti-JCV antibodies to avoid false negative test results caused by the removal of serum antibodies.
- After infusion of intravenous immunoglobulin (IVIg), wait at least 6 months (5 half-lives) for the IVIg to clear in order to avoid false positive anti-JCV antibody test results

Warnings and Precautions – Herpes Infections

Herpes Encephalitis and Meningitis

- TYSABRI increases the risk of developing encephalitis and meningitis caused by herpes simplex and varicella zoster viruses.
- Serious, life-threatening, and sometimes fatal cases have been reported in the postmarketing setting in multiple sclerosis patients receiving TYSABRI.
- Monitor patients receiving TYSABRI for signs and symptoms of meningitis and encephalitis. If herpes encephalitis or meningitis occurs, TYSABRI should be discontinued, and appropriate treatment for herpes encephalitis/meningitis should be administered.

Warnings and Precautions – Herpes Infections

Acute Retinal Necrosis

- A higher risk of Acute Retinal Necrosis (ARN) has been observed in patients being administered TYSABRI.
- Some ARN cases occurred in patients with central nervous system (CNS) herpes infections (e.g., herpes meningitis or encephalitis).
- Serious cases of ARN led to blindness of one or both eyes in some patients.
- Following clinical diagnosis of ARN, consider discontinuation of TYSABRI. The treatment reported in ARN cases included anti-viral therapy and, in some cases, surgery.

Warnings and Precautions – Hepatotoxicity

- Clinically significant liver injury, including acute liver failure requiring transplant, has been reported in patients treated with TYSABRI® in a postmarketing setting.
- Signs of liver injury, including markedly elevated serum hepatic enzymes and elevated total bilirubin, occurred as early as 6 days after the first dose; and signs of liver injury have also been reported for the first time after multiple doses.
- In some patients, liver injury recurred upon rechallenge, providing evidence that TYSABRI caused the injury.
- The combination of transaminase elevations and elevated bilirubin without evidence of obstruction is generally recognized as an important predictor of severe liver injury that may lead to death or the need for a liver transplant in some patients.
- TYSABRI should be discontinued in patients with jaundice or other evidence of significant liver injury (e.g., laboratory evidence).

Warnings and Precautions – Hypersensitivity/Antibody Formation

- TYSABRI has been associated with hypersensitivity reactions, including serious systemic reactions (e.g., anaphylaxis), which occurred at an incidence of <1%.
- Patients who receive TYSABRI after an extended period without treatment may be at higher risk of hypersensitivity reactions.
- If a hypersensitivity reaction occurs, discontinue the use of TYSABRI, and initiate appropriate therapy.
- Do not re-treat with TYSABRI.
- Patients who receive TYSABRI for a short exposure (1 to 2 infusions) followed by an extended period without treatment are at higher risk of developing anti-natalizumab antibodies and/or hypersensitivity reactions on re-exposure, compared to patients who received regularly scheduled treatment.

Warnings and Precautions – Immunosuppression/Infections

- The immune system effects of TYSABRI® may increase the risk for infections.
- Concurrent use of antineoplastic, immunosuppressant, or immunomodulating agents may further increase the risk of infections, including PML and other opportunistic infections, over the risk observed with use of TYSABRI alone.
- The safety and efficacy of TYSABRI in combination with antineoplastic, immunosuppressant, or immunomodulating agents have not been established.
- For patients with Crohn's disease who start TYSABRI while on chronic corticosteroids, commence steroid withdrawal as soon as a therapeutic benefit has occurred. If the patient cannot discontinue systemic corticosteroids within 6 months, discontinue TYSABRI.

Warnings and Precautions – Thrombocytopenia

- Cases of thrombocytopenia, including immune thrombocytopenic purpura (ITP), have been reported with the use of TYSABRI in the postmarketing setting
- Symptoms of thrombocytopenia may include easy bruising, abnormal bleeding, and petechiae
- Delay in the diagnosis and treatment of thrombocytopenia may lead to serious and life-threatening sequelae. If thrombocytopenia is suspected, TYSABRI should be discontinued.

Adverse Reactions

- The most frequently reported serious adverse reactions in the Study MS1 were infections (3.2% vs 2.6% placebo), acute hypersensitivity reactions (1.1% vs 0.3%), depression (1.0% vs 1.0%), and cholelithiasis (1.0% vs 0.3%).
- The following serious adverse events in the induction Studies CD1 and CD2 were reported more commonly with TYSABRI than placebo and occurred at an incidence of at least 0.3%: intestinal obstruction or stenosis (2% vs. 1% in placebo), acute hypersensitivity reactions (0.5% vs. 0%), abdominal adhesions (0.3% vs. 0%), and cholelithiasis (0.3% vs. 0%).

Adverse Reactions (cont'd)

- The most common adverse reactions reported at an incidence of $\geq 10\%$ were headache (38% vs 33%), fatigue (27% vs 21%), infusion reactions (24% vs 18%), urinary tract infections (21% vs 17%), arthralgia (19% vs 14%), depression (19% vs 16%), lower respiratory tract infection (17% vs 16%), pain in extremity (16% vs 14%), rash (12% vs 9%), gastroenteritis (11% vs 9%), abdominal discomfort (11% vs 10%), vaginitis* (10% vs 6%), and diarrhea (10% vs 9%).

*Percentage based on female patients only.

- Other common adverse reactions (incidence $\geq 10\%$) in the CD population were upper respiratory tract infections and nausea.
- Based on animal data, TYSABRI may cause fetal harm. TYSABRI should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Program Overview

- **What is the TOUCH Prescribing Program?**
- What tools support the TOUCH Prescribing Program?
 - MS TOUCH Educational Materials
 - CD TOUCH Educational Materials
- What is the enrollment process?
- What is the process to infuse TYSABRI®?
- How are patients tracked?
- What is TOUCH On-Line?

What is the TOUCH Prescribing Program?

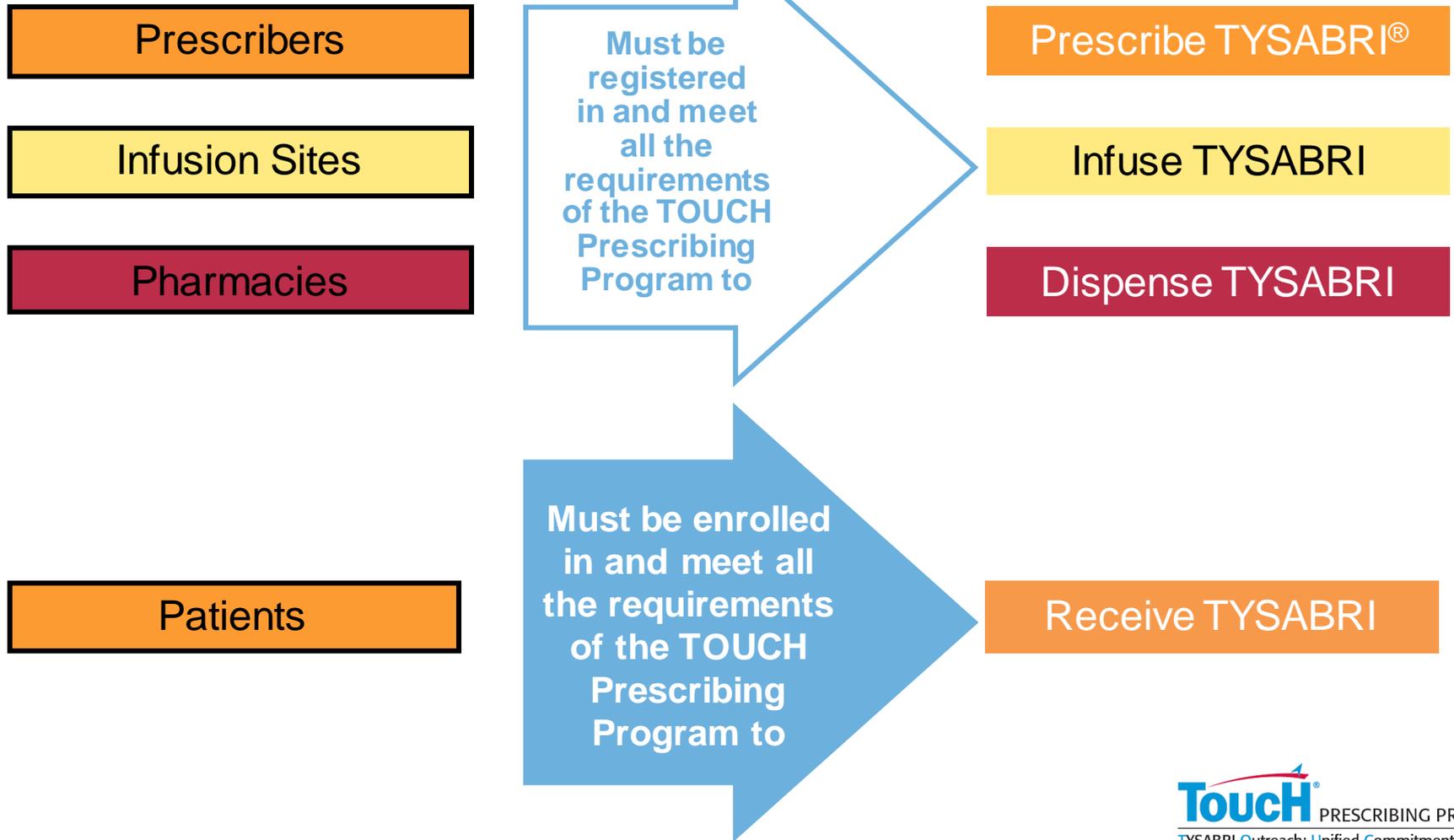


A program that makes TYSABRI® available only to prescribers, infusion centers, pharmacies associated with infusion centers, and patients who are enrolled in the program

What is the TOUCH Prescribing Program designed to do?

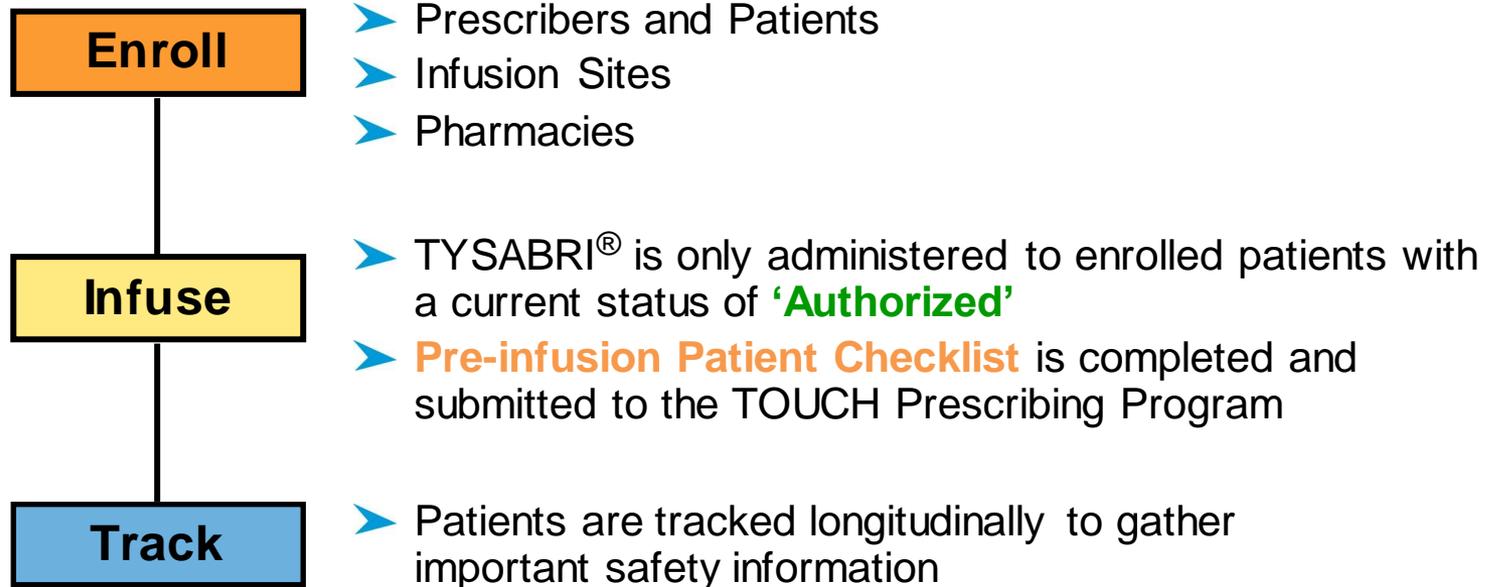
- To inform prescribers, infusion center healthcare providers, and patients about the risk of progressive multifocal leukoencephalopathy (PML) associated with TYSABRI® including the increased risk of PML with the presence of anti-JCV antibodies, longer treatment duration, and prior immunosuppressant use
- To warn against concurrent use with antineoplastic, immunosuppressant, or immunomodulating agents and in patients who are immunocompromised
- To promote early diagnosis of PML and timely discontinuation of TYSABRI in the event of suspected PML

What are the program requirements?



TOUCH Prescribing Program Components

There are 3 main components of the TOUCH Prescribing Program



NOTE: This overview of the TOUCH Prescribing Program components does not include a complete list of the program requirements.

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Tools to Support the TOUCH Prescribing Program – MS

Enrollment Forms

MS Touch Prescriber/Patient Enrollment Form

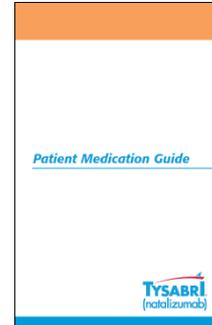
Prescriber/Patient

MS Touch Infusion Site Enrollment Form

Infusion Site

MS Touch Certified Pharmacy Enrollment Form

Certified Pharmacy



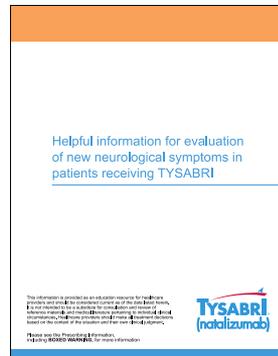
Patient Medication Guide

Notice of Patient Authorization

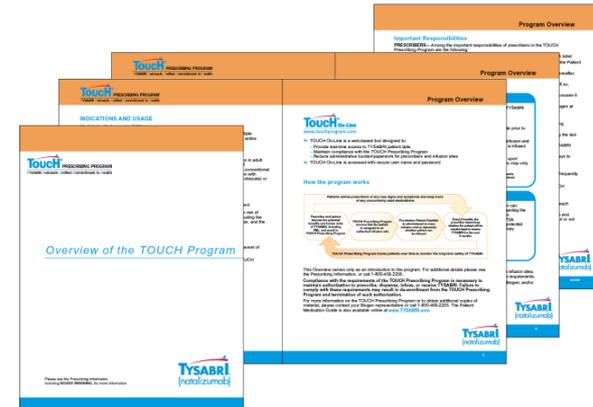
Notice of Patient Authorization

Pre-infusion Patient Checklist

Pre-infusion Patient Checklist



Helpful Information for Evaluation of New Neurological Symptoms in Patients Receiving TYSABRI®



TOUCH Prescribing Program Overview

Tools to Support the TOUCH Prescribing Program – Crohn's Disease

Enrollment Forms

Prescriber/Patient

Infusion Site

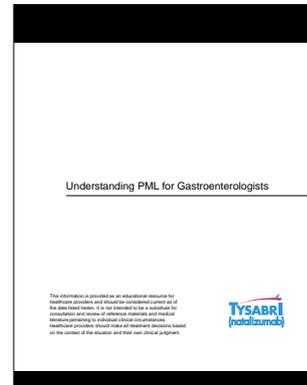
Certified Pharmacy



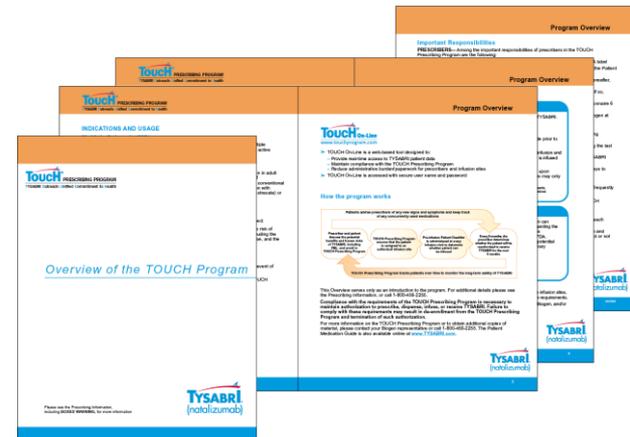
Patient Medication Guide

Notice of Patient Authorization

Pre-infusion Patient Checklist



Understanding PML for Gastroenterologists



TOUCH Prescribing Program Overview

How Do I Communicate With TOUCH?



WEB



Touch On-Line
www.touchprogram.com



PHONE

1-800-456-2255

Monday – Friday



PAPER

Fax: 1-800-840-1278

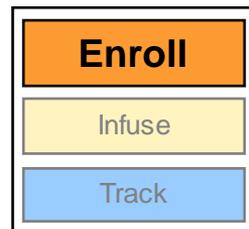
Satisfying TOUCH Prescribing Program Requirements

- The TOUCH Prescribing Program has been designed to facilitate appropriate use of TYSABRI®
- In order to assess if the Program is meeting its goals, registered sites and enrolled participant's compliance may be reviewed by the FDA, and/or audited by Biogen and/or a third party designated by Biogen
- Compliance with the requirements of the TOUCH Prescribing Program is necessary to maintain authorization to prescribe, dispense, infuse, or receive TYSABRI. Failure to comply with these requirements may result in de-enrollment from the TOUCH Prescribing Program and termination of such authorization

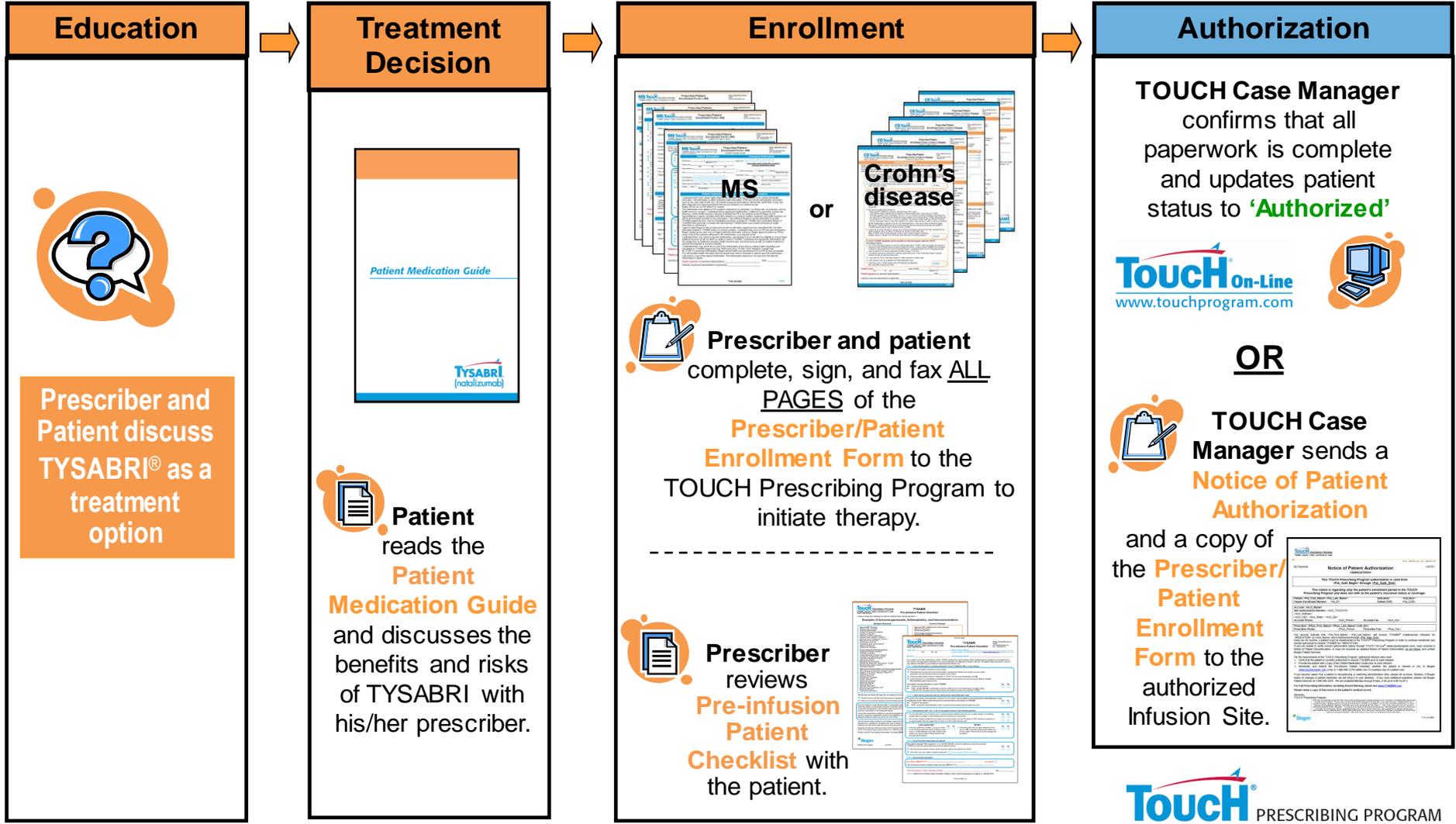
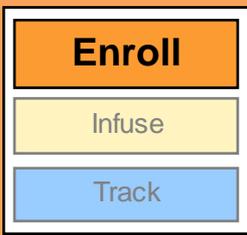
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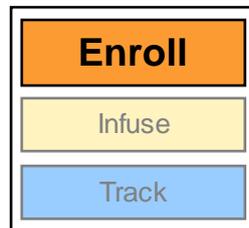
Prescriber/Patient Enrollment



How do prescribers and patients enroll?



Enrollment Tools



Helpful Information for Evaluation of New Neurological Symptoms in Patients Receiving TYSABRI®

Brochure provided by Biogen Resource for: Neurology specialists

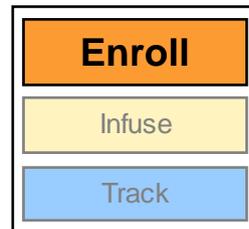
Key topics include:

- Importance of careful evaluation of any new or recurrent symptoms
- Differentiating between the signs, symptoms, and lesion characteristics typical of MS and PML
- PML diagnostic algorithm incorporating MRI and CSF assessment
- Action steps if PML is suspected
- Guidance on the treatment of relapse and other neurological symptoms

The information provided in this brochure is an educational resource and is not intended to be a substitute for consultation and review of relevant reference materials and medical literature. Treatment decisions should be made based on the context of the situation and clinical judgment.

The image displays four pages from a brochure. The top-left page is titled 'Patient monitoring and management' and discusses the management of patients receiving TYSABRI, including the importance of MRI scans and regular follow-up. The top-right page features a 'Suggested diagnostic algorithm for TYSABRI-treated patients experiencing new neurological symptoms' with a flowchart that starts with 'New neurological symptoms' and branches into 'MRI assessment' and 'CSF assessment', leading to 'Suspected PML' or 'Suspected MS' and subsequent actions like 'Report immediately' or 'Monitor as MS'. The bottom-left page is titled 'Evaluation of new neurological symptoms in patients receiving TYSABRI' and includes a table for 'Clinical signs and symptoms typical of MS, relapse and PML'. The bottom-right page contains 'Table 2. MS lesions characteristic typical of PML and MS' with a table comparing MS lesions and PML lesions.

Enrollment Tools



Understanding PML

Flashcard provided by Biogen

Resource for: Gastroenterologists, Internists, or other non-Neurology specialists

Key topics include:

- Characteristics of PML
- Guidance on recognizing PML in context of Crohn's disease
- Action steps if PML is suspected

Action Steps if PML is Suspected

- TYSABRI dosing should be suspended immediately in all cases in which PML is suspected¹
- Immediate referral to a neurologist for assessment, potentially including²
 - A brain MRI to determine if lesions that could be due to PML are present
 - Cerebrospinal fluid evaluation for the presence of JC DNA
- Potential cases of PML should be reported immediately to Biogen at 1-800-456-2255, or to the FDA's MedWatch reporting system at 1-800-FDA-1088, or via the MedWatch Web site at www.fda.gov/medwatch

Indication

TYSABRI is indicated for inducing and maintaining remission in adult patients with moderately to severely active Crohn's disease who are unable to tolerate, or have had an inadequate response to, or are unable to tolerate, conventional CD therapies and immunosuppressants (e.g., 6-mercaptopurine).

Important Safety Information

WARNING: Progressive Multifocal Leukoencephalopathy (PML) increases the risk of death or severe disability. Prior use of immunosuppressants should be considered in the context of PML risk.

Healthcare professionals should monitor for symptoms suggestive of PML. For diagnosis, an MRI of the brain and, when indicated, cerebrospinal fluid analysis should be performed.

Because of the risk of PML, TYSABRI is contraindicated in patients with PML. See the Evaluation and Mitigation Strategy (EMS) for TYSABRI.

Important Safety Information Continues

Understanding PML for Gastroenterologists

The following information should be considered when undertaking the assessment and management of progressive multifocal leukoencephalopathy (PML) in adult patients treated with TYSABRI for moderately to severely active Crohn's disease (CD). During clinical trials for TYSABRI, 3 cases of PML were identified (2 in multiple sclerosis and 1 in Crohn's disease). Both multiple sclerosis patients were receiving concomitant immunomodulatory therapy and the Crohn's disease patient had been treated in the past with immunosuppressive therapy. In the postmarketing setting, additional cases of PML have been reported in multiple sclerosis and Crohn's disease patients who were receiving no concomitant immunomodulatory therapy.¹

About PML

PML is a demyelinating disease that attacks the central nervous system.² It is an opportunistic infection caused by the JC virus that typically occurs in patients who are immunocompromised.³ The virus removes myelin that surrounds the nerves, and without this protection the nerves cannot transmit signals.³ There are no known interventions that can reliably prevent PML, or adequately treat PML, if it occurs.³

How to Recognize PML

Typical symptoms associated with PML are diverse, progress over days to weeks, and include^{4,5}:

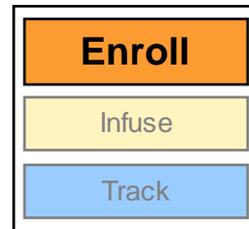
- Progressive weakness on one side of the body or clumsiness of limbs
- Disturbance of vision
- Changes in thinking, memory, and orientation, leading to confusion and personality changes
- Seizures

The progression of deficits usually leads to death or severe disability over weeks or months.⁶ Since these symptoms are very different from those of Crohn's disease, the appearance of any symptoms of PML, including those listed above, should be investigated immediately.⁷ In Crohn's disease patients, a baseline brain MRI may also be helpful to distinguish pre-existent lesions from newly developed lesions, but brain lesions at baseline that could cause diagnostic difficulty while on TYSABRI therapy are uncommon.⁸

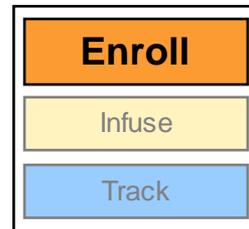
TYSABRI
(natalizumab)

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Infusion Site Enrollment



Certified Pharmacy Enrollment



How does a Certified Pharmacy* enroll?

A Biogen representative provides training to the Certified Pharmacy regarding the TOUCH Prescribing Program



TOUCH Prescribing Program
Enrollment Form

Infusion Site

Please attach this form to your enrollment request.

The TOUCH Prescribing Program uses a limited set of sites. All sites must be associated with an infusion site. All infusion sites must be associated with a pharmacy. All pharmacies must be associated with a pharmacy. All pharmacies must be associated with a pharmacy. All pharmacies must be associated with a pharmacy.

Infusion Site Address (Address where patient is infused)

Name of Infusion Site: Contact Name:
 Address 1: Address 2:
 City: State: Zip:

Method of Enrolling TYSABRI

Infusion site will enroll TYSABRI. YES, I will enroll site. NO Assignment of Biotechnology Pharmacy OR Infusion site will enroll through certified pharmacy. NO Assignment of Biotechnology Pharmacy

Shipping Address (Address where TYSABRI will be shipped)

Name of Infusion Site or Certified Pharmacy: Contact Name:
 Address 1: Address 2:
 City: State: Zip:

Infusion Site Address/Pharmacy

Infusion site address is same as above. Please note that this is the ONLY address where TYSABRI will be shipped.

Infusion site address is different. Please note that this is the ONLY address where TYSABRI will be shipped.

Response to any acknowledgment

Name: Title:
 Signature:
 Date:

*Please see the Prescribing Information, including **BOXED WARNING**, for more information.

Biogen TYSABRI (natalizumab)



Certified Pharmacy Authorization Confirmation
"IMPORTANT"
RETAIN FOR YOUR RECORDS

By Pharmacy

Date: Contact Name:
 Address:

Dear Pharmacist:

This letter confirms your enrollment in the TOUCH Prescribing Program. Your TOUCH Prescribing Program Site Authorization Number (TYSABRI ID is:) Please remember that as part of your responsibility in the TOUCH Program, you must confirm your TOUCH-associated infusion site is TOUCH-authorized before you dispense TYSABRI (natalizumab).

Your TYSABRI Shipping Address has been recorded as:

Account Name:
Address:

You may now begin shipping TYSABRI shipments, and patients will be assigned to your TOUCH-associated infusion site as appropriate. You will receive a copy of each Infusion Site Authorization Confirmation for each of your associated infusion sites as the process authorizes. This confirmation will include the Infusion Site Authorization Number.

TYSABRI is available only under a restricted distribution system. In general, you may order TYSABRI through your regular channels. Contact 1-800-485-2288 for information about other options for obtaining TYSABRI. If you choose to purchase your own TYSABRI inventory from Biogen/MSD at TYSABRISelect, please call 877-478-7418 or 877-801-1111, available 24 hours a day, 7 days a week, to set up your account and order process. Please remember to use your TYSABRI Site Authorization Number (TOUCH ID) when ordering TYSABRI.

Thank you for choosing to process TYSABRI. Please keep this fax on file. If you have any questions about this fax or the TOUCH Prescribing Program, please call 1-800-485-2288 to speak with a Biogen Support Coordinator. We are available Monday through Friday, 8:30 AM to 5:00 PM ET.

Sincerely,
 TOUCH Prescribing Program

For Full Prescribing Information including **Boxed Warning**, please see www.TYSABRI.com

This fax is intended only for the use of the addressee named herein and contains confidential patient health information. If you are not the intended recipient of this fax, you are hereby notified that any dissemination, distribution or copying of this fax is strictly prohibited. If you are not the intended recipient, please immediately call the number above to arrange for its return. You may choose not to receive this information from Biogen. To opt out of receiving promotional material from Biogen, please email optout@biogen.com. If you are not the intended recipient of this fax, you are hereby notified that any dissemination, distribution or copying of this fax is strictly prohibited. If you are not the intended recipient, please immediately call the number above to arrange for its return. You may choose not to receive this information from Biogen. To opt out of receiving promotional material from Biogen, please email optout@biogen.com.

Biogen TYSABRI (natalizumab) TYS-05-1173



Certified Pharmacy completes and faxes the **Certified Pharmacy Enrollment Form** to TOUCH Prescribing Program.



TOUCH Prescribing Program confirms that all paperwork is complete, assigns a **Site Authorization Number**, and provides **Site Authorization Confirmation** to the Certified Pharmacy.

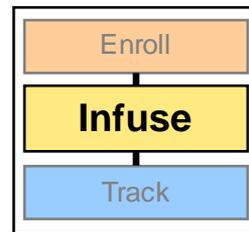


*A Certified Pharmacy is located within a hospital, group practice, or infusion site and is associated with an infusion site.

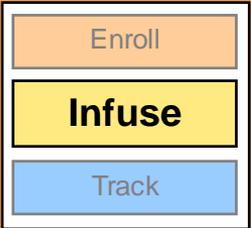
Program Overview

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- What tools support the TOUCH Prescribing Program?
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- **What is the process to infuse TYSABRI®?**
- How are patients tracked?
- What is TOUCH On-Line?

Infusion Overview



What process must be completed in order to infuse TYSABRI®?



TYSABRI should NOT be prepared until the **Pre-infusion Patient Checklist** has been successfully completed

Prior to EVERY infusion of TYSABRI:

- 1 **Confirm** that the patient is currently **'Authorized'** to receive TYSABRI on TOUCH On-Line*
- 2 **Provide** the patient with the **Patient Medication Guide**
- 3 **Complete** the **Pre-infusion Patient Checklist** on TOUCH On-Line*
- 4 If the patient answered **YES** to question 1, 2 or 3, in Step 3 of the Pre-infusion Patient Checklist, **DO NOT INFUSE**. Contact the healthcare provider who prescribed TYSABRI and review the patient's answers. Confirm authorization for infusion.

Infusion

ONLY upon successful completion of the **Pre-infusion Patient Checklist**:

- Start an IV line
- Mix TYSABRI

↓

Infuse TYSABRI over 1 hour and observe patient for 1 hour post-infusion

↓

Submit completed **Pre-infusion Patient Checklist** via TOUCH On-Line* within 1 business day

Patient arrives for TYSABRI infusion



*Paper process: Check patient record for current **Notice of Patient Authorization** and fax completed **Pre-infusion Patient Checklist** to 1-800-840-1278.

Checking Patient Authorization Status

- Enroll
- Infuse
- Track

Only patients with a status **'Authorized'** can receive TYSABRI®

➤ Check patient status as **'Authorized'** on TOUCH On-Line



Paper process: **Notice of Patient Authorization** is faxed to both Prescriber and Infusion Site; a copy must be placed in the patient record

Touch PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

Phone: 1 800 456 2255 | Fax: 1 800 840 1278

By Facsimile 9/19/2016

Notice of Patient Authorization
<INDICATION>

This TOUCH Prescribing Program authorization is valid from
1/01/2016 through 6/30/2016.

This notice is regarding only the patient's enrollment period in the TOUCH Prescribing Program and does not refer to the patient's insurance status or coverage.

Patient: Jennifer Patient		Indication: <Indication>	
Patient Enrollment Number: PTXXXXXXX		Patient DOB: 1/1/1978	

Account: Test Infusion Site
Site Authorization Number: ST123456
123 Infusion Site Lane
Durham, NC 27709

Account Phone: 555-555-1234	Account Fax: 555-555-1236
-----------------------------	---------------------------

Prescriber: John Prescriber (MDXXXXXXX)

Prescriber Phone: 555-555-7896	Prescriber Fax: 555-555-7894
--------------------------------	------------------------------

Today's Infusions							
(show the next 3 days)							
Patient Enrollment #	Last Name	First Name	Date of Birth	Status	Last Infusion Date	Next Infusion Date	Pre-Infusion Patient Checklist Status
[REDACTED]	PATIENT	JENNIFER	01/01/1978	Authorized	10/12/2007	09/28/2007	Start

1 patient found.



Pre-infusion Patient Checklist

Enroll

Infuse

Track



➤ All Infusion Sites must complete, sign, and submit the **Pre-infusion Patient Checklist** at every infusion visit

➤ Submit form within 1 business day of patient's visit via TOUCH On-Line



Paper process: Fax page one to 1-800-840-1278 and place original in the patient's record

Patient Actions

This patient is currently Authorized to receive TYSABRI.

Yes No 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 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?

Yes No 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?

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? ([Click here to review the list with the patient.](#))

Yes No Was TYSABRI infused?

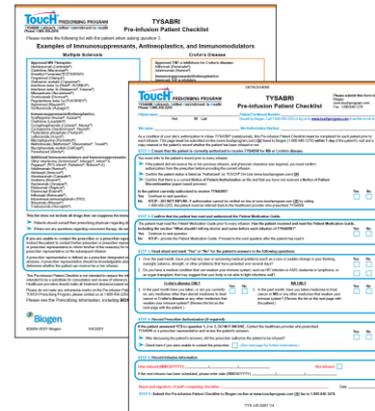
09/28/2007 Date infused
(mm/dd/yyyy)

10/30/2007 Date of next infusion appointment
(mm/dd/yyyy)

Verify and Sign the Pre-Infusion Patient Checklist

TOUCH On-Line username

Password



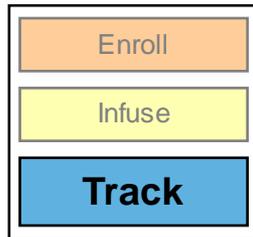
NOTE: Pre-infusion Patient Checklist **must** be completed and submitted whether or not the patient is infused.



Program Overview

- What is the TOUCH Prescribing Program?
- What tools support the TOUCH Prescribing Program?
 - MS TOUCH Educational Materials
 - CD TOUCH Educational Materials
- What is the enrollment process?
- What is the process to infuse TYSABRI®?
- **How are patients tracked?**
- What is TOUCH On-Line?

Tracking Overview



Tracking Overview

Enroll

Infuse

Track

MS

Infusion Site

Pre-infusion Patient Checklist



Crohn's
disease

Prescriber

Patient Status Report and Reauthorization Questionnaire



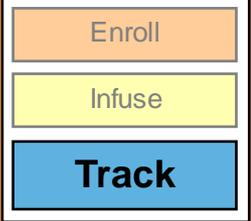
Prescriber

Initial and 6-Month Discontinuation Questionnaire



NOTE: Missing or incomplete TOUCH Prescribing Program forms will prompt continued follow-up by a TOUCH Compliance Manager.

Prescriber Must Reauthorize the Use of TYSABRI® Every 6 Months



TYSABRI Patient Status Report and Reauthorization Questionnaire

➤ Prescriber will receive a **Patient Status Report and Reauthorization Questionnaire** every 6 months

➤ Completion of this form is **required** as it determines whether the prescriber authorizes the patient to receive TYSABRI for the next 6 months

The image shows two versions of the TYSABRI Patient Status Report and Reauthorization Questionnaire form. The top form is for CD Touch, and the bottom form is for MS Touch. Both forms include fields for patient information, a reauthorization question, and a list of medical conditions. The MS Touch form includes a table of immunomodulatory and immunosuppressant therapies.

CD Touch TYSABRI Patient Status Report and Reauthorization Questionnaire—Crohn's Disease

MS Touch TYSABRI Patient Status Report and Reauthorization Questionnaire—MS

TOUCH Certified Prescriber or Delegate Name: _____ Date: _____

(If applicable) Print TOUCH Certified Prescriber or Delegate Name: _____



OR



If a patient discontinues TYSABRI®, important health information is collected and tracked over time

Enroll

Infuse

Track

CD Touch PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health
Phone: 1-800-456-2255

TYSABRI Initial Discontinuation Questionnaire-Crohn's Disease

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

Re: <Patient Name>
Patient Enrollment Number: <Patient TOUCH ID>

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

TYSABRI Initial Discontinuation Questionnaire-MS

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

Prescriber name: _____
Prescriber address: _____
Patient: _____
Patient date of birth (MM/DD/YYYY): _____

A Is the patient still under <MD name>'s care?
 Yes No/ don't know
If No, please provide name and phone number for new prescriber, if available: _____

B Is the patient alive?
 Yes No

C PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML)
 Yes No or Under investigation

D OPPORTUNISTIC INFECTION* for which they have been hospitalized
 Yes No or Under investigation

E MALIGNANCY
 Yes No or Under investigation

F Since <last authorization>, has the patient been tested for the presence of anti-JCV antibodies?
 Yes Not performed
If performed, since <last authorization> date, test result:
 Positive Negative Pending
If an anti-JCV antibody index value is available, please record it here: _____ Date: _____

TOUCH Certify Prescriber or Delegate Name: _____
(If applicable) Print TOUCH Certify Prescriber or Delegate Name: _____

Please see the Prescribing Information, including BOXED WARNING, for more information

Biogen TYSABRI (natalizumab)

The prescriber will be sent **Discontinuation Questionnaires**, which must be completed and submitted to the TOUCH Prescribing Program via TOUCH On-Line

Paper process: Upon notification of patient discontinuation, the **Discontinuation Questionnaire** will be faxed to the prescriber

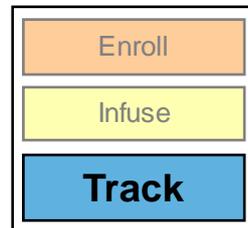
- Fax completed form to 1-800-840-1278 and place original in the patient's file



***NOTE: Discontinuation Questionnaires are ONLY sent upon notification of discontinuation and again six months following discontinuation of TYSABRI**



Tracking Tools



Tracking Overview – MS

The TOUCH Prescribing Program will track all patients over time, so that Biogen can inform the FDA, prescribers, and patients in a timely manner of information regarding the safety of TYSABRI®.

Pre-infusion Patient Checklist (Every 28 days)

This form is used to track patient safety before each TYSABRI infusion. It includes sections for:

- Examples of Immunosuppressants, Antineoplastic, and Immunomodulators:** Lists various medications like Azathioprine, Cyclophosphamide, and Rituximab.
- Additional immunosuppressants and immunomodulators:** A list for prescribers to check off.
- Medical History:** Questions about current and past conditions like infections, malignancies, and organ transplants.
- Current Medications:** A list for prescribers to check off.
- Other Health Information:** Questions about pregnancy, breastfeeding, and other health issues.

TYSABRI Patient Status Report and Reauthorization Questionnaire (Every 6 months)

This questionnaire is used to monitor patient safety and efficacy over a 6-month period. It includes:

- Demographic Information:** Patient name, address, and contact details.
- Authorization Status:** A section for the prescriber to confirm or deny the patient's authorization to receive TYSABRI.
- Current Health Status:** Questions about ongoing symptoms, infections, and other medical conditions.
- Medication History:** A list of other medications the patient is taking.
- Adverse Events:** A section to report any side effects or complications.
- Reauthorization Decision:** A final section for the prescriber to indicate if the patient's authorization should be renewed.

Initial and 6-Month Discontinuation Questionnaire*

This form is used to track patient safety and efficacy after discontinuation of TYSABRI. It includes:

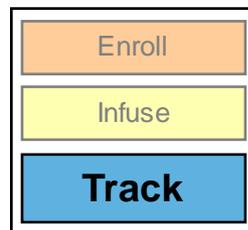
- Discontinuation Questionnaire (MS):** A section for the prescriber to report the reasons for discontinuation and any subsequent health issues.
- Initial Discontinuation Questionnaire (MS):** A section for the patient to report their experience with discontinuation.
- 6-Month Discontinuation Questionnaire (MS):** A section for the patient to report their health status 6 months after discontinuation.



*NOTE: Discontinuation Questionnaires are ONLY sent upon notification of discontinuation and again six months following discontinuation of TYSABRI



Tracking Tools



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- How are patients tracked?
- **What is TOUCH On-Line?**
- How is TYSABRI acquired?

TOUCH On-Line Overview

- TOUCH On-Line is a Web-based tool designed to:
 - Provide real-time access to TYSABRI® patient data
 - Maintain compliance with the TOUCH Prescribing Program
 - Streamline communication to/from Prescribers and Infusion Sites
- TOUCH On-Line is available only to enrolled TOUCH participants
- TOUCH On-Line is accessed with secure user name and password

A screenshot of the TOUCH On-Line login interface. At the top, a blue header bar contains the text "Please Login to TOUCH On-Line". Below this, there are two input fields: "TOUCH On-Line Username" and "Password". A blue link "Forgot your password?" is positioned below the password field. A blue "Login" button is centered below the input fields. At the bottom of the login area, there is a section titled "Having trouble logging in?" with the text: "Check with your Site Administrator or call us at 1-800-456-2255 Monday through Friday, 8:30 am to 8:00 pm EST."

Summary Review

- The TOUCH Prescribing Program makes TYSABRI® available only to prescribers, infusion sites, pharmacies associated with infusion sites, and patients who are enrolled in the program
- There are 3 main components of the program: Enroll – Infuse – Track
- TYSABRI must be administered only to patients who are enrolled in and meet all the conditions of the TOUCH Prescribing Program
- Indication-specific training and educational materials are required for a site to become authorized on MS TOUCH, CD TOUCH or both
- TOUCH On-Line is a web-based tool available only to authorized infusion sites and prescribers enrolled in TOUCH
- Only authorized infusion sites and their associated certified pharmacies may acquire TYSABRI



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TYS-US-0482 V5

