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

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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.

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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.

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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.

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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.

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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.
- Patients should continue to be monitored for any new signs or symptoms that may be suggestive of PML for at least six months following discontinuation of TYSABRI.
- 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

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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).

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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.

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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.
- Cases of neonatal thrombocytopenia, at times associated with anemia, have been reported in newborns with in utero exposure to TYSABRI. A CBC should be obtained in neonates with in utero exposure to TYSABRI.

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 ≥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 ≥ 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.

TOUCH® PRESCRIBING PROGRAM
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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 administer TYSABRI®?
- How are patients tracked?
- What is TOUCH On-Line?

TOUCH® PRESCRIBING PROGRAM
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What is the TOUCH Prescribing Program?

TOUCH® PRESCRIBING PROGRAM

TYSABRI Outreach: Unified Commitment to Health

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 site, 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

TOUCH® PRESCRIBING PROGRAM
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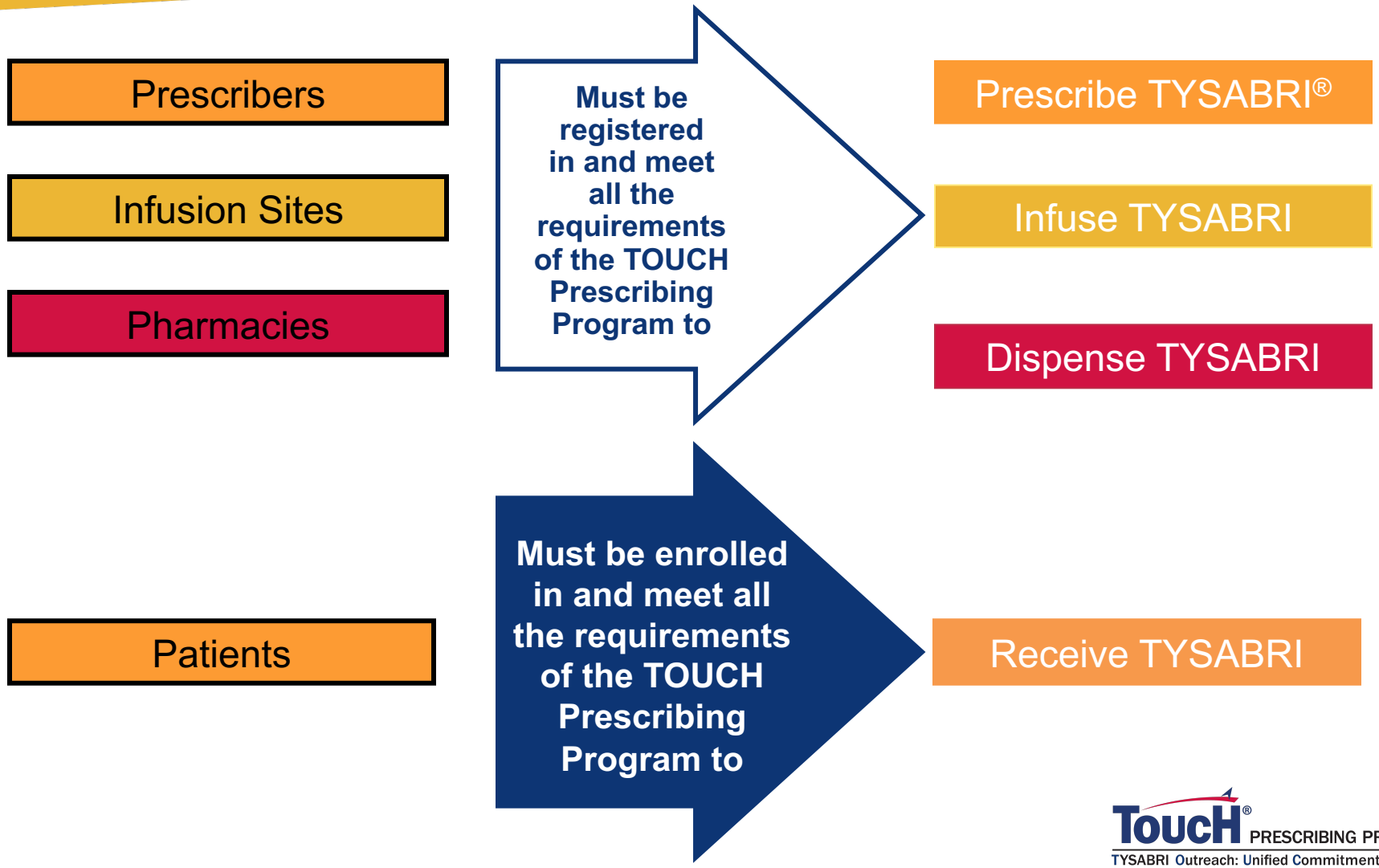
What are the program requirements?



TOUCH® PRESCRIBING PROGRAM
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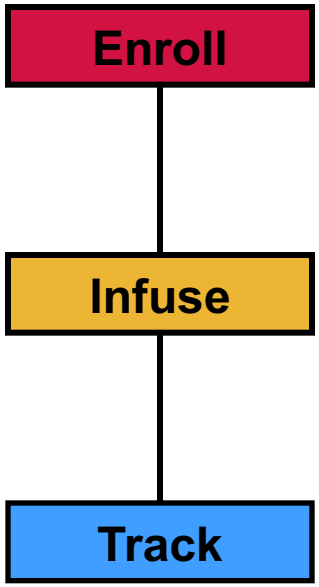
TOUCH Prescribing Program Components

There are 3 main components of the TOUCH Prescribing Program



- Prescribers and Patients
- Infusion Sites
- Pharmacies
- TYSABRI® is only administered to enrolled patients with a current status of **'Authorized'**
- **Pre-infusion Patient Checklist** is completed and submitted to the TOUCH Prescribing Program
- Patients are tracked longitudinally to gather important safety information

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

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TOUCH® PRESCRIBING PROGRAM
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Tools to Support the TOUCH Prescribing Program – MS

- Enrollment Forms
  - Patient
  - Prescriber
  - Infusion Site
  - Pharmacy
- Patient Medication Guide
- Notice of Patient Authorization
- Pre-infusion Patient Checklist
- Helpful Information for Evaluation of New Neurological Symptoms in Patients Receiving TYSABRI®
- TOUCH Prescribing Program Overview

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

- Enrollment Forms
  - Patient
  - Prescriber
  - Infusion Site
  - Pharmacy
- Patient Medication Guide
- Notice of Patient Authorization
- Pre-infusion Patient Checklist
- Understanding PML for Gastroenterologists
- TOUCH Prescribing Program Overview

TOUCH® PRESCRIBING PROGRAM
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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

TOUCH® PRESCRIBING PROGRAM
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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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TOUCH® PRESCRIBING PROGRAM
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Prescriber/Patient Enrollment

Enroll

Infuse

Track

TOUCH® PRESCRIBING PROGRAM
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How do prescribers and patients enroll?

Education

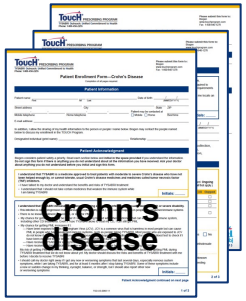
Prescriber and Patient discuss TYSABRI® as a treatment option

Treatment Decision

Patient reads the **Patient Medication Guide** and discusses the benefits and risks of TYSABRI with his/her prescriber.

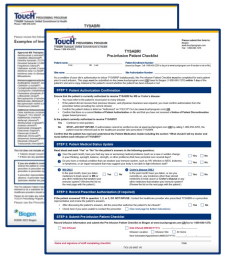
Enrollment

or



Prescriber and patient complete, sign, and fax ALL PAGES of the **Prescriber Enrollment Form** and **Patient Enrollment Form** to the TOUCH Prescribing Program to initiate therapy.

Prescriber reviews **Pre-infusion Patient Checklist** with the patient.



Authorization

TOUCH Case Manager confirms that all paperwork is complete and updates patient status to **'Authorized'**

TOUCH® On-Line
www.touchprogram.com

OR

TOUCH Case Manager sends a **Notice of Patient Authorization** to the authorized Infusion Site.

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Enrollment Tools

Enroll

Infuse

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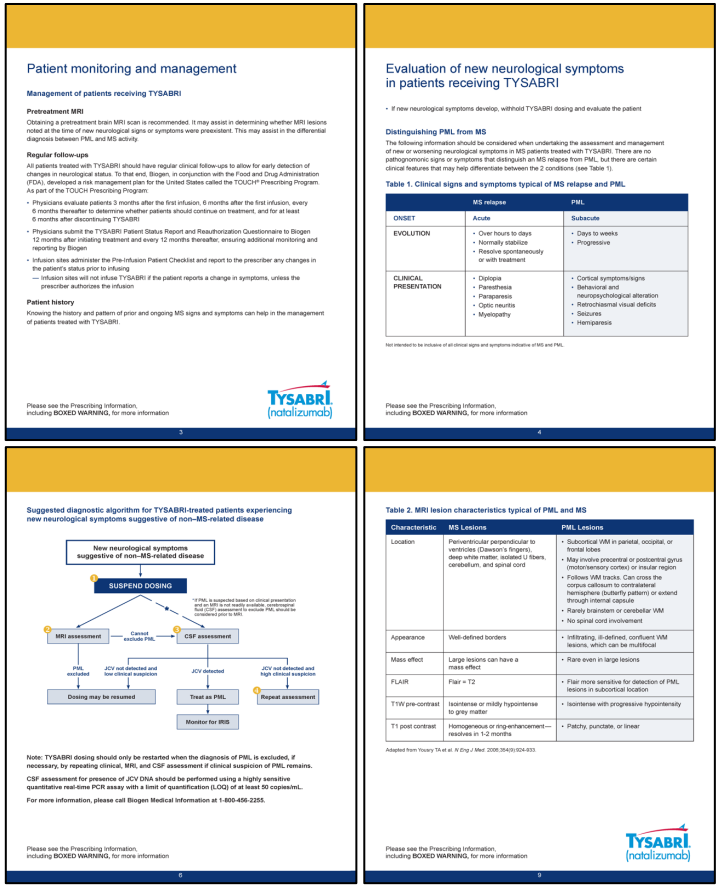
Helpful Information for Evaluation of New Neurological Symptoms in Patients Receiving TYSABRI®

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



Patient monitoring and management

Management of patients receiving TYSABRI

Pretreatment MRI

Obtaining a pretreatment brain MRI scan is recommended. It may assist in determining whether MRI lesions noted at the time of new neurological signs or symptoms were preexistent. This may assist in the differential diagnosis between PML and MS activity.

Regular follow-ups

All patients treated with TYSABRI should have regular clinical follow-ups to allow for early detection of changes in neurological status. To that end, Biogen, in conjunction with the Food and Drug Administration (FDA), developed a risk management plan for the United States called the TOUCH® Prescribing Program. As part of the TOUCH Prescribing Program:

- Physicians evaluate patients 3 months after the first infusion, 6 months after the first infusion, every 6 months thereafter to determine whether patients should continue on treatment, and for at least 6 months after discontinuing TYSABRI
- Physicians submit the TYSABRI Patient Status Report and Reauthorization Questionnaire to Biogen 12 months after initiating treatment and every 12 months thereafter, ensuring additional monitoring and reporting by Biogen
- Infusion sites administer the Pre-Infusion Patient Checklist and report to the prescriber any changes in the patient's status prior to infusing
  - Infusion sites will not infuse TYSABRI if the patient reports a change in symptoms, unless the prescriber authorizes the infusion

Patient history

Knowing the history and pattern of prior and ongoing MS signs and symptoms can help in the management of patients treated with TYSABRI.

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

TYSABRI (natalizumab)

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Evaluation of new neurological symptoms in patients receiving TYSABRI

- If new neurological symptoms develop, withhold TYSABRI dosing and evaluate the patient

Distinguishing PML from MS

The following information should be considered when undertaking the assessment and management of new or worsening neurological symptoms in MS patients treated with TYSABRI. There are no pathognomonic signs or symptoms that distinguish an MS relapse from PML, but there are certain clinical features that may help differentiate between the 2 conditions (see Table 1).

Table 1. Clinical signs and symptoms typical of MS relapse and PML

	MS relapse	PML
ONSET	Acute	Subacute
EVOLUTION	• Over hours to days • Normally stabilize • Resolve spontaneously or with treatment	• Days to weeks • Progressive
CLINICAL PRESENTATION	• Diplopia • Paresthesia • Paraparesis • Optic neuritis • Myelopathy	• Cortical symptoms/signs • Behavioral and neuropsychological alteration • Retrochiasmal visual deficits • Seizures • Hemiparesis

Not intended to be inclusive of all clinical signs and symptoms indicative of MS and PML.

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

4

Suggested diagnostic algorithm for TYSABRI-treated patients experiencing new neurological symptoms suggestive of non–MS-related disease

Note: TYSABRI dosing should only be restarted when the diagnosis of PML is excluded, if necessary, by repeating clinical, MRI, and CSF assessment if clinical suspicion of PML remains.

CSF assessment for presence of JCV DNA should be performed using a highly sensitive quantitative real-time PCR assay with a limit of quantification (LOQ) of at least 50 copies/mL.

For more information, please call Biogen Medical Information at 1-800-456-2255.

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

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Table 2. MRI lesion characteristics typical of PML and MS

Characteristic	MS Lesions	PML Lesions
Location	Periventricular perpendicular to ventricles (Dawson's fingers), deep white matter, isolated U fibers, cerebellum, and spinal cord	• Subcortical WM in parietal, occipital, or frontal lobes • May involve precentral or postcentral gyrus (motor/sensory cortex) or insular region • Follows WM tracks. Can cross the corpus callosum to contralateral hemisphere (butterfly pattern) or extend through internal capsule • Rarely brainstem or cerebellar WM • No spinal cord involvement
Appearance	Well-defined borders	• Infiltrating, ill-defined, confluent WM lesions, which can be multifocal
Mass effect	Large lesions can have a mass effect	• Rare even in large lesions
FLAIR	Flair = T2	• Flair more sensitive for detection of PML lesions in subcortical location
T1W pre-contrast	Isointense or mildly hypointense to grey matter	• Isointense with progressive hypointensity
T1 post contrast	Homogeneous or ring-enhancement—resolves in 1-2 months	• Patchy, punctate, or linear

Adapted from Yousry TA et al. *N Eng J Med.* 2006;354(9):924-933.

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

TYSABRI (natalizumab)

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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.

TOUCH® PRESCRIBING PROGRAM

TYSABRI Outreach: Unified Commitment to Health

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Enrollment Tools

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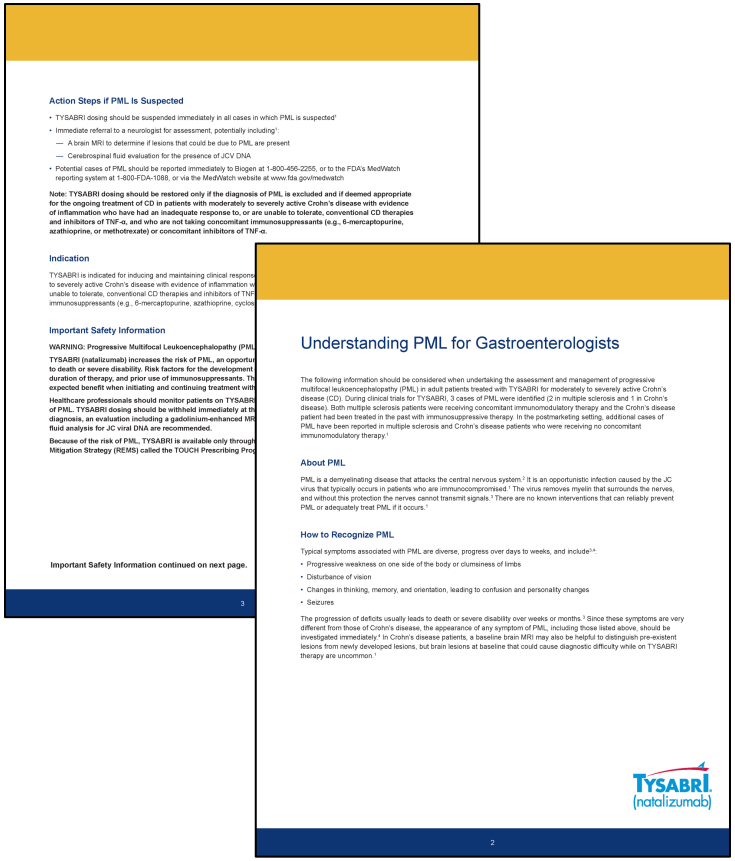
Understanding PML

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 suspected[1]
- Immediate referral to a neurologist for assessment, potentially including[1]:
  - A brain MRI to determine if lesions that could be due to PML are present
  - Cerebrospinal fluid evaluation for the presence of JCV 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 website at www.fda.gov/medwatch

Note: TYSABRI dosing should be restored only if the diagnosis of PML is excluded and if deemed appropriate for the ongoing treatment of CD in 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, and who are not taking concomitant immunosuppressants (e.g., 6-mercaptopurine, azathioprine, or methotrexate) or concomitant inhibitors of TNF-α.

Indication

TYSABRI is indicated for inducing and maintaining clinical respons
to severely active Crohn's disease with evidence of inflammation w
unable to tolerate, conventional CD therapies and inhibitors of TNF
immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclos

Important Safety Information

WARNING: Progressive Multifocal Leukoencephalopathy (PML)

**TYSABRI (natalizumab) increases the risk of PML, an opportur
to death or severe disability. Risk factors for the development
duration of therapy, and prior use of immunosuppressants. Th
expected benefit when initiating and continuing treatment with**

**Healthcare professionals should monitor patients on TYSABR
of PML. TYSABRI dosing should be withheld immediately at th
diagnosis, an evaluation including a gadolinium-enhanced MR
fluid analysis for JC viral DNA are recommended.**

**Because of the risk of PML, TYSABRI is available only through
Mitigation Strategy (REMS) called the TOUCH Prescribing Prog**

Important Safety Information continued on next page.

3

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.[1] The virus removes myelin that surrounds the nerves, and without this protection the nerves cannot transmit signals.[1] There are no known interventions that can reliably prevent PML or adequately treat PML if it occurs.[1]

How to Recognize PML

Typical symptoms associated with PML are diverse, progress over days to weeks, and include[3,4]:

- 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.[3] Since these symptoms are very different from those of Crohn's disease, the appearance of any symptom of PML, including those listed above, should be investigated immediately.[1] 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.[1]

TYSABRI (natalizumab)

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TOUCH® PRESCRIBING PROGRAM
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Infusion Site Enrollment

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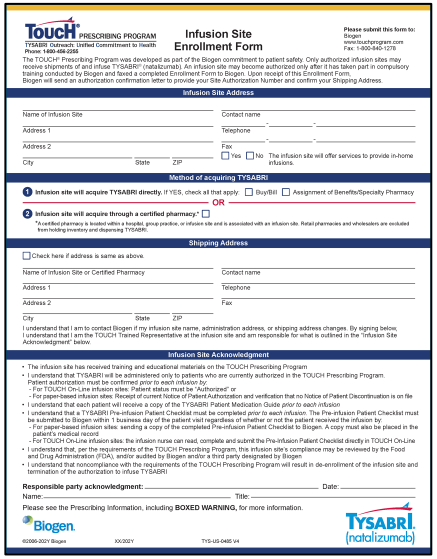
How does an Infusion Site enroll?

A Biogen representative provides mandatory TOUCH Prescribing Program training to Infusion Site*



TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health
Phone: 1-800-456-2255

Infusion Site Enrollment Form

Please submit this form to:
Biogen
www.touchprogram.com
Fax: 1-800-845-1278

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

Infusion Site Address

Name of Infusion Site | Contact name
Address 1 | Telephone
Address 2 | Fax
City | State | ZIP
☐ Yes ☐ No The infusion site will offer services to provide in-home infusions.

Method of acquiring TYSABRI

1 **Infusion site will acquire TYSABRI directly.** If YES, check all that apply: ☐ Buy/Bill ☐ Assignment of Benefits/Specialty Pharmacy

OR

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

*A certified 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

☐ Check here if address is same as above.

Name of Infusion Site or Certified Pharmacy | Contact name
Address 1 | Telephone
Address 2 | Fax
City | State | ZIP

I understand that I am to contact Biogen if my infusion site name, administration address, or shipping address changes. By signing below, I understand that I am the TOUCH Trained Representative at the infusion site and am responsible for what is outlined in the "Infusion Site Acknowledgment" below.

Infusion Site Acknowledgment

- The infusion site has received training and educational materials on the TOUCH Prescribing Program.
- I understand that TYSABRI will be administered only to patients who are currently authorized in the TOUCH Prescribing Program. Patient authorization must be confirmed *prior to each infusion* by:
  - For TOUCH On-Line infusion sites: Patient status must be "Authorized" or
  - For paper-based infusion sites: Receipt of current Notice of Patient Authorization and verification that no Notice of Patient Discontinuation is on file
- I understand that each patient will receive a copy of the TYSABRI Patient Medication Guide *prior to each infusion*.
- I understand that a TYSABRI Pre-infusion Patient Checklist must be completed *prior to each infusion*. The Pre-infusion Patient Checklist must be submitted to Biogen within 1 business day of the patient visit regardless of whether or not the patient received the infusion by:
  - For paper-based infusion sites: sending a copy of the completed Pre-infusion Patient Checklist to Biogen. A copy must also be placed in the patient's medical record
  - For TOUCH On-Line infusion sites: the infusion nurse can read, complete and submit the Pre-Infusion Patient Checklist directly in TOUCH On-Line
- I understand that, per the requirements of the TOUCH Prescribing Program, this infusion site's compliance may be reviewed by the Food and Drug Administration (FDA), and/or audited by Biogen and/or a third party designated by Biogen.
- I understand that noncompliance with the requirements of the TOUCH Prescribing Program will result in de-enrollment of the infusion site and termination of the authorization to infuse TYSABRI.

Responsible party acknowledgment: _____ Date: _____
Name: _____ Title: _____

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

Biogen.

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TYSABRI® (natalizumab)

Infusion Site completes and faxes the **Infusion Site 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 Infusion Site

*A patient will be matched **ONLY** with Infusion Sites that have been trained on the program materials.

TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

Certified Pharmacy Enrollment

Enroll

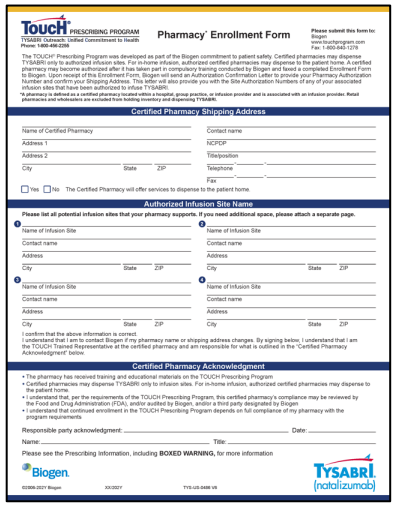
Infuse

Track

TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

How does a Certified Pharmacy* enroll?

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


TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health
Phone: 1-800-456-2255

Pharmacy* Enrollment Form

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

The TOUCH® Prescribing Program was developed as part of the Biogen commitment to patient safety. Certified pharmacies may dispense TYSABRI only to authorized infusion sites. For in-home infusion, authorized certified pharmacies may dispense to the patient home. A certified pharmacy may become authorized after it has taken part in compulsory training conducted by Biogen and faxed a completed Enrollment Form to Biogen. Upon receipt of this Enrollment Form, Biogen will send an Authorization Confirmation Letter to provide your Pharmacy Authorization Number and confirm your Shipping Address. This letter will also provide you with the Site Authorization Numbers of any of your associated infusion sites that have been authorized to infuse TYSABRI.

*A pharmacy is defined as a certified pharmacy located within a hospital, group practice, or infusion provider and is associated with an infusion provider. Retail pharmacies and wholesalers are excluded from holding pharmacy and dispensing TYSABRI.

Certified Pharmacy Shipping Address

Name of Certified Pharmacy
Address 1
Address 2
City State ZIP
Contact name
NCPDP
Title/position
Telephone
Fax
☐ Yes ☐ No The Certified Pharmacy will offer services to dispense to the patient home.

Authorized Infusion Site Name

Please list all potential infusion sites that your pharmacy supports. If you need additional space, please attach a separate page.

1. Name of Infusion Site
Contact name
Address
City State ZIP
2. Name of Infusion Site
Contact name
Address
City State ZIP
3. Name of Infusion Site
Contact name
Address
City State ZIP
4. Name of Infusion Site
Contact name
Address
City State ZIP

I confirm that the above information is correct.
I understand that I am to contact Biogen if my pharmacy name or shipping address changes. By signing below, I understand that I am the TOUCH Trained Representative at the certified pharmacy and am responsible for what is outlined in the "Certified Pharmacy Acknowledgment" below.

Certified Pharmacy Acknowledgment

- The pharmacy has received training and educational materials on the TOUCH Prescribing Program
- Certified pharmacies may dispense TYSABRI only to infusion sites. For in-home infusion, authorized certified pharmacies may dispense to the patient home.
- I understand that, per the requirements of the TOUCH Prescribing Program, this certified pharmacy's compliance may be reviewed by the Food and Drug Administration (FDA), and/or audited by Biogen, and/or a third party designated by Biogen
- I understand that continued enrollment in the TOUCH Prescribing Program depends on full compliance of my pharmacy with the program requirements

Responsible party acknowledgment: _____ Date: _____
Name: _____ Title: _____
Please see the Prescribing Information, including **BOXED WARNING**, for more information

Biogen.
TYSABRI® (natalizumab)
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Certified Pharmacy completes and faxes the **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 pharmacy is defined as a certified pharmacy located within a hospital, group practice, or infusion site and is associated with an infusion site.

TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

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?

TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

Infusion Overview

Enroll

Infuse

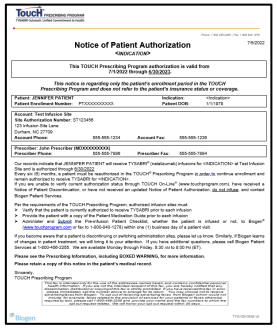
Track

TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

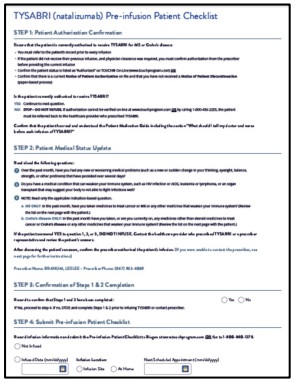
What process must be completed in order to infuse TYSABRI®?

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* and then provide the patient with the **Patient Medication Guide**



2 **Complete** the **Pre-infusion Patient Checklist** on TOUCH On-Line*

3 **If the patient answered YES to question 1, 2 or 3 in Step 2 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 patients during all infusions. Post-infusion, for the first 12 infusions, observe patients for 1 hour after the infusion is complete. For patients who have received 12 infusions without evidence of a hypersensitivity reaction, observe patients post-infusion for the 13th and subsequent infusions according to clinical judgment.

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

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

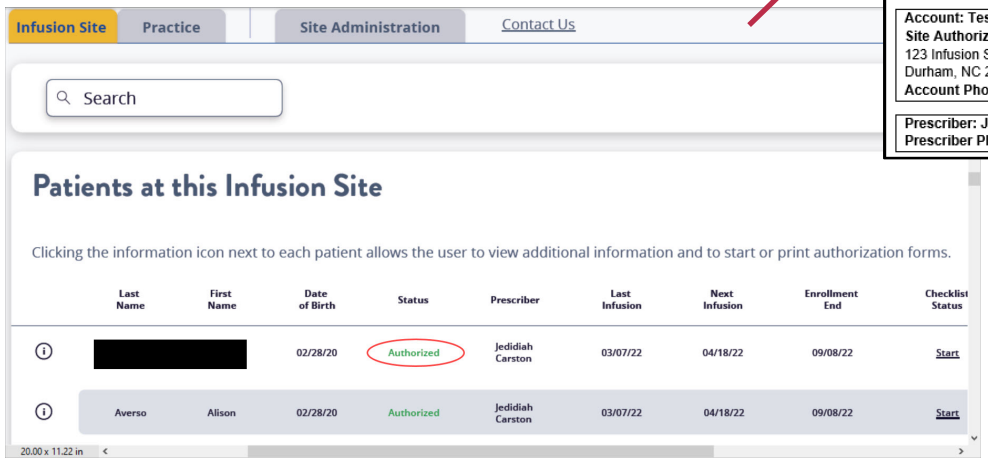
TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

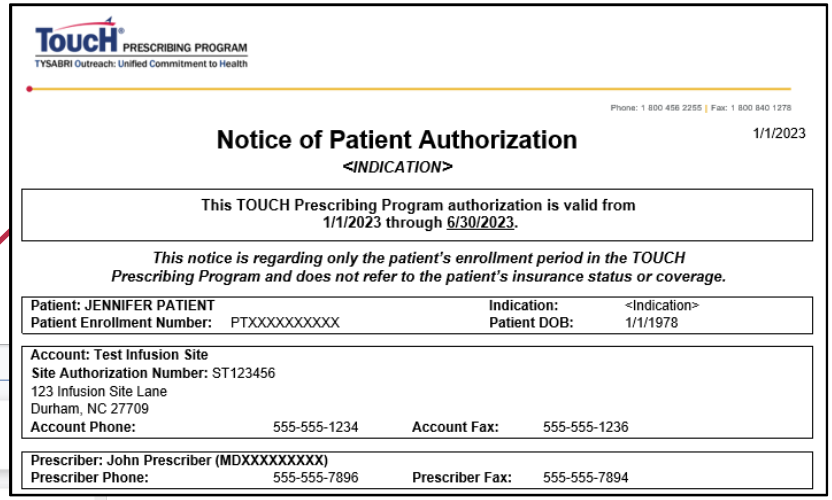
Checking Patient Authorization Status

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

Notice of Patient Authorization 1/1/2023

<INDICATION>

This TOUCH Prescribing Program authorization is valid from 1/1/2023 through 6/30/2023.

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: PTXXXXXXXXX **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

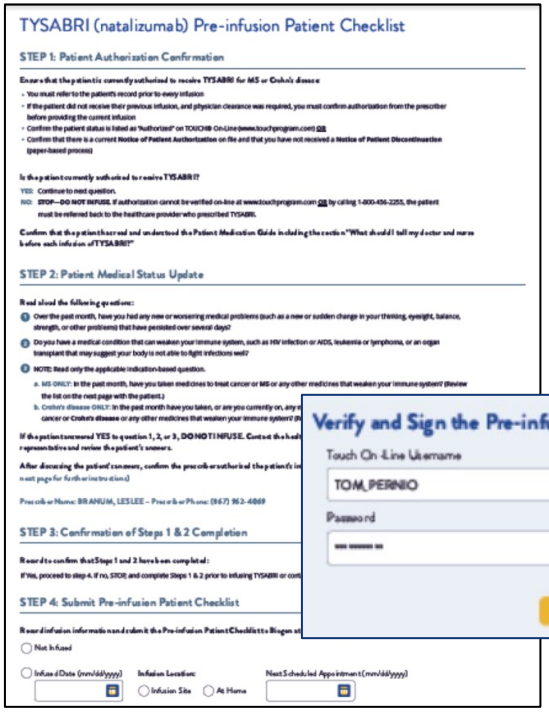
Prescriber: John Prescriber (MDXXXXXXXXX)
Prescriber Phone: 555-555-7896 **Prescriber Fax:** 555-555-7894

TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

Pre-infusion Patient Checklist

TOUCH® On-Line
www.touchprogram.com

- All Infusion Sites must complete, sign, and submit the **Pre-infusion Patient Checklist** at <u>every</u> infusion visit
- Submit form within 1 business day of patient's visit via TOUCH On-Line

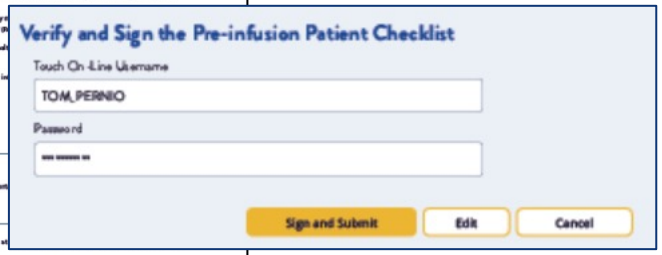

TYSABRI (natalizumab) Pre-infusion Patient Checklist

STEP 1: Patient Authorization Confirmation

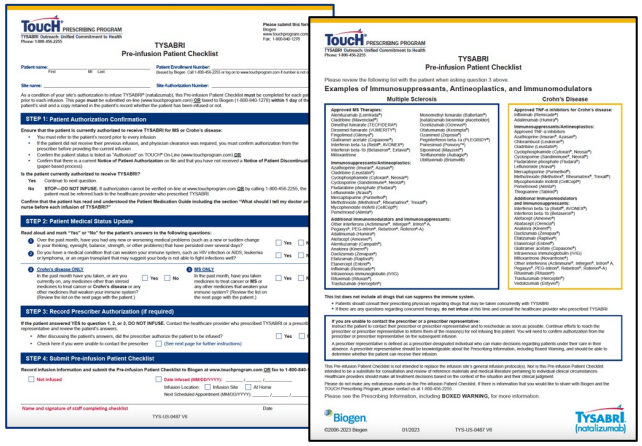
STEP 2: Patient Medical Status Update

STEP 3: Confirmation of Steps 1 & 2 Completion

STEP 4: Submit Pre-infusion Patient Checklist



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


TOUCH PRESCRIBING PROGRAM
TYSABRI
Pre-infusion Patient Checklist

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

TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

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?

TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

Tracking Overview

Enroll

Infuse

Track

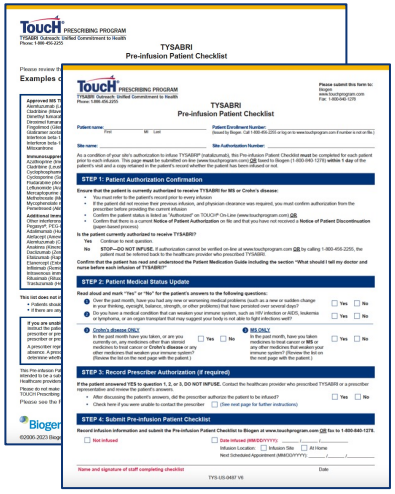
TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

Tracking Overview

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®.

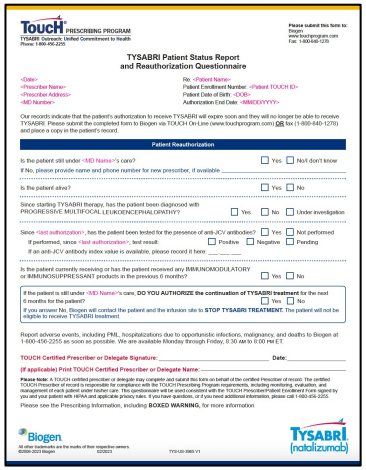
Infusion Site

Pre-Infusion Patient Checklist



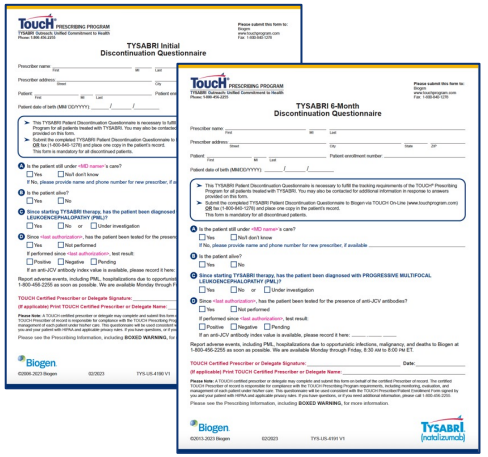
Prescriber

Patient Status Report and Reauthorization Questionnaire



Prescriber

Initial and 6-Month Discontinuation Questionnaire



OR

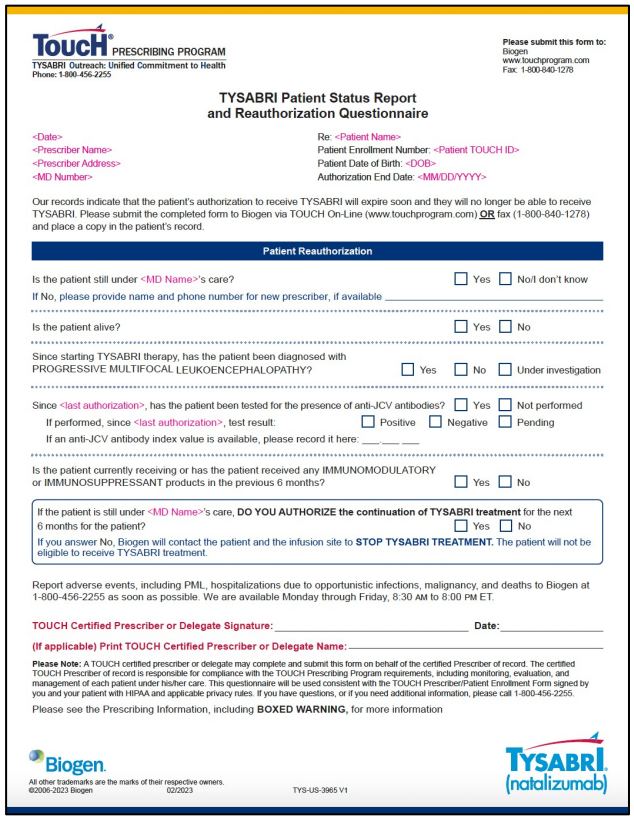
OR

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

TouCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

Prescriber Must Reauthorize the Use of TYSABRI® Every 6 Months

TYSABRI Patient Status Report and Reauthorization Questionnaire



TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health
Phone: 1-800-456-2255

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

TYSABRI Patient Status Report and Reauthorization Questionnaire

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

Re: <Patient Name>
Patient Enrollment Number: <Patient TOUCH ID>
Patient Date of Birth: <DOB>
Authorization End Date: <MM/DD/YYYY>

Our records indicate that the patient's authorization to receive TYSABRI will expire soon and they will no longer be able to receive TYSABRI. Please submit the completed form to Biogen via TOUCH On-Line (www.touchprogram.com) **OR** fax (1-800-840-1278) and place a copy in the patient's record.

Patient Reauthorization

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

Is the patient alive? ☐ Yes ☐ No

Since starting TYSABRI therapy, has the patient been diagnosed with PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY? ☐ Yes ☐ No ☐ Under investigation

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

Is the patient currently receiving or has the patient received any IMMUNOMODULATORY or IMMUNOSUPPRESSANT products in the previous 6 months? ☐ Yes ☐ No

If the patient is still under <MD Name>'s care, **DO YOU AUTHORIZE the continuation of TYSABRI treatment** for the next 6 months for the patient? ☐ Yes ☐ No
If you answer No, Biogen will contact the patient and the infusion site to **STOP TYSABRI TREATMENT.** The patient will not be eligible to receive TYSABRI treatment.

Report adverse events, including PML, hospitalizations due to opportunistic infections, malignancy, and deaths to Biogen at 1-800-456-2255 as soon as possible. We are available Monday through Friday, 8:30 AM to 8:00 PM ET.

TOUCH Certified Prescriber or Delegate Signature: _____ **Date:** _____

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

Please Note: A TOUCH certified prescriber or delegate may complete and submit this form on behalf of the certified Prescriber of record. The certified TOUCH Prescriber of record is responsible for compliance with the TOUCH Prescribing Program requirements, including monitoring, evaluation, and management of each patient under his/her care. This questionnaire will be used consistent with the TOUCH Prescriber/Patient Enrollment Form signed by you and your patient with HIPAA and applicable privacy rules. If you have questions, or if you need additional information, please call 1-800-456-2255.

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

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TYSABRI® (natalizumab)

- 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

OR

TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

If a patient discontinues TYSABRI®, the prescriber is notified

TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health
Phone: 1-800-456-2255

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

TYSABRI Initial Discontinuation Questionnaire

Prescriber name: First
Prescriber address: Street
Patient: First MI Last
Patient date of birth (MM/ DD/YYYY):

- This TYSABRI Patient Discontinuat Program for all patients treated with provided on this form.
- Submit the completed TYSABRI Pa OR fax (1-800-840-1278) and place This form is mandatory for all discon

A Is the patient still under <MD name
☐ Yes ☐ No/I don't know
If No, please provide name and ph

B Is the patient alive?
☐ Yes ☐ No

C Since starting TYSABRI therapy, LEUKOENCEPHALOPATHY (PML
☐ Yes ☐ No or ☐ U

D Since <last authorization>, has the
☐ Yes ☐ Not performed
If performed since <last authorizati
☐ Positive ☐ Negative ☐ P
If an anti-JCV antibody index value

Report adverse events, including PML, 1-800-456-2255 as soon as possible. W

TOUCH Certified Prescriber or Delega
(If applicable) Print TOUCH Certified

Please Note: A TOUCH certified prescriber or de TOUCH Prescriber of record is responsible for co management of each patient under his/her care. you and your patient with HIPAA and applicable p

Please see the Prescribing Information

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TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health
Phone: 1-800-456-2255

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

TYSABRI 6-Month Discontinuation Questionnaire

Prescriber name: First MI Last
Prescriber address: Street City State ZIP
Patient: First MI Last Patient enrollment number:
Patient date of birth (MM/DD/YYYY): ___/___/___

- This TYSABRI Patient Discontinuation Questionnaire is necessary to fulfill the tracking requirements of the TOUCH® Prescribing Program for all patients treated with TYSABRI. You may also be contacted for additional information in response to answers provided on this form.
- Submit the completed TYSABRI Patient Discontinuation Questionnaire to Biogen via TOUCH On-Line (www.touchprogram.com) OR fax (1-800-840-1278) and place one copy in the patient's record. This form is mandatory for all discontinued patients.

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

B Is the patient alive?
☐ Yes ☐ No

C Since starting TYSABRI therapy, has the patient been diagnosed with PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML)?
☐ Yes ☐ No or ☐ Under investigation

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

Report adverse events, including PML, hospitalizations due to opportunistic infections, malignancy, and deaths to Biogen at 1-800-456-2255 as soon as possible. We are available Monday through Friday, 8:30 AM to 8:00 PM ET.

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

Please Note: A TOUCH certified prescriber or delegate may complete and submit this form on behalf of the certified Prescriber of record. The certified TOUCH Prescriber of record is responsible for compliance with the TOUCH Prescribing Program requirements, including monitoring, evaluation, and management of each patient under his/her care. This questionnaire will be used consistent with the TOUCH Prescriber/Patient Enrollment Form signed by you and your patient with HIPAA and applicable privacy rules. If you have questions, or if you need additional information, please call 1-800-456-2255.

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

Biogen
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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**

TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

Program Overview

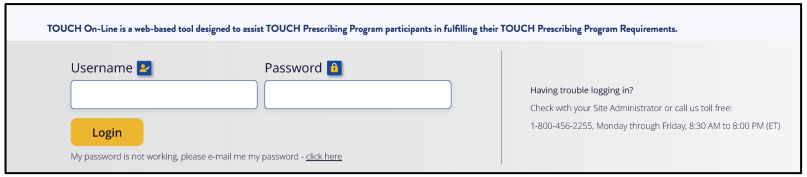
- What is the TOUCH Prescribing Program?
- What tools support the TOUCH Prescribing Program?
  - MS TOUCH Educational Materials
  - CD TOUCH Educational Materials
- What is the enrollment process?
- What is the process to infuse TYSABRI®?
- How are patients tracked?
- **What is TOUCH On-Line?**

TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

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 username and password

TOUCH® On-Line
www.touchprogram.com



TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health

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

TOUCH® PRESCRIBING PROGRAM
TYSABRI Outreach: Unified Commitment to Health