



**Touch**<sup>®</sup> PRESCRIBING PROGRAM

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TYSABRI Outreach: Unified Commitment to Health

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



**TYSABRI**<sup>®</sup>  
(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- $\alpha$ .
- TYSABRI should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF- $\alpha$ .

# 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.
- 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

# 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.
- 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  $\geq 10\%$  in the MS clinical studies 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 (22% vs 16%) and nausea (17% vs 15%).
  - In the induction studies for CD, patients experienced headache (32% vs 23%) and fatigue (10% vs 8%).
  - In the maintenance studies for CD, patients experienced headache (37% vs 31%), influenza (12% vs 5%), back pain (12% vs 8%), and influenza-like illness (11% vs 6%).
  - 11% of Tysabri-treated CD patients experienced infusion-related reactions versus 7% in the placebo-treated patients.
- 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 administer 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

NOTE: Some data concerning patients may be shared with REMS programs for other natalizumab products if patients switch to or from another natalizumab product. Enrollment in the TOUCH Prescribing Program is separate from enrollment in REMS programs for other natalizumab products.



# 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

# What are the program requirements?

Prescribers

Infusion Sites

Pharmacies

Patients

Must be registered in and meet all the requirements of the TOUCH Prescribing Program to

Prescribe TYSABRI®

Infuse TYSABRI

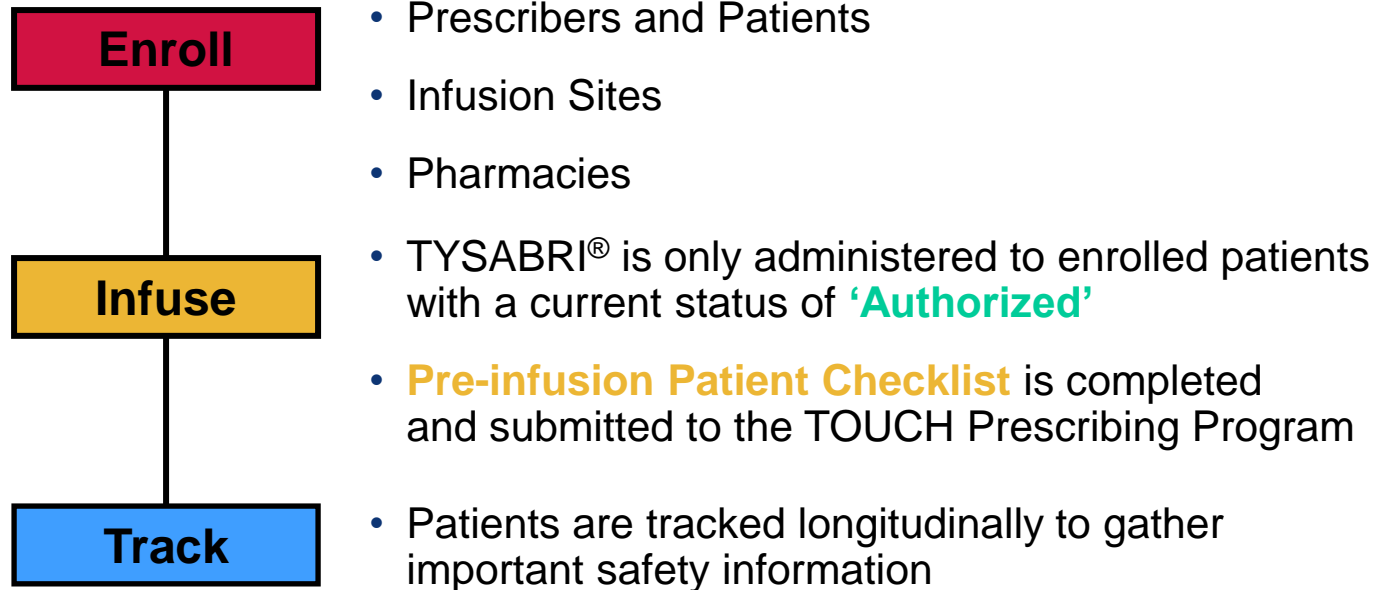
Dispense TYSABRI

Must be enrolled in and meet all the requirements of the TOUCH Prescribing Program to

Receive TYSABRI

# 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.



# Program Overview

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- What is TOUCH On-Line?

# 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

# 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

# How Do I Communicate With TOUCH?



**WEB**




**Touch<sup>®</sup> On-Line**  
[www.touchprogram.com](http://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

# 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?

# Prescriber/Patient Enrollment

Enroll

Infuse

Track

# How do prescribers and patients enroll?

Education

Treatment Decision

Enrollment

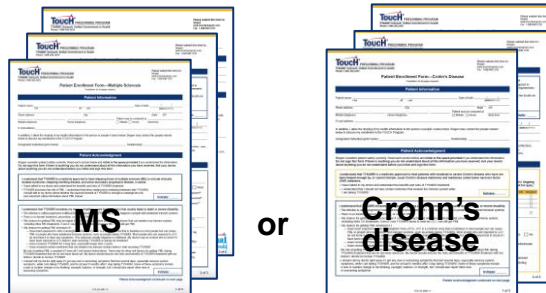
Authorization



Prescriber and Patient discuss TYSABRI® as a treatment option



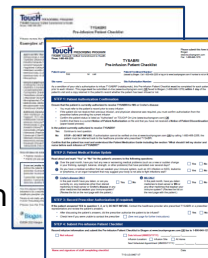
Patient reads the **Patient Medication Guide** and discusses the benefits and risks of TYSABRI with his/her prescriber.



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.



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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TYSABRI Outreach: Unified Commitment to Health





# Enrollment Tools

Enroll

Infuse

Track

# 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.

### Patient monitoring and management

**Management of patients receiving TYSABRI**


**Prevention 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-up 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.



### 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).

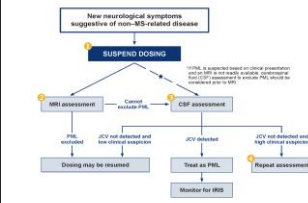
**Table 1. Clinical signs and symptoms typical of MS relapse and PML.**

| ONSET                 | MS relapse  |   |
|-----------------------|---|---|
|                       | Acute   | Subacute  |
| EVOLUTION             | <ul style="list-style-type: none"> <li>• Over hours to days</li> <li>• Normally stabilize</li> <li>• Resolve spontaneously or with treatment</li> </ul> | <ul style="list-style-type: none"> <li>• Days to weeks</li> <li>• Progressive</li> </ul>  |
| CLINICAL PRESENTATION | <ul style="list-style-type: none"> <li>• Fatigue</li> <li>• Parosmia</li> <li>• Parosmia</li> <li>• Otic neuritis</li> <li>• Hemiparesis</li> </ul>     | <ul style="list-style-type: none"> <li>• Cortical symptoms/signs</li> <li>• Behavioral and neuropsychological alteration</li> <li>• Pathognomonic visual deficits</li> <li>• Seizures</li> <li>• Hemiparesis</li> </ul> |

Not intended to be a review of all clinical signs and symptoms relative to MS and PML.

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

**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 of clinical suspicion of PML, remission, 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.

**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, subcortical, stem, cerebellum, and spinal cord | <ul style="list-style-type: none"> <li>• Subcortical WM in parietal, occipital, or frontal lobes</li> <li>• May involve periventricular or periaxonal gray matter (especially cortical or insular region)</li> <li>• Follows WM tracts. Can cross the corpus callosum to contralateral hemisphere (butterfly pattern) or extend through external capsule</li> <li>• Flairy transition or cerebellar WM</li> <li>• No spinal cord involvement</li> </ul> |
| Appearance       | Well-defined borders  | • Unfiring, 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 gray matter   | • Isointense with progressive hypointensity   |
| T1 post-contrast | Heterogeneous or ring-enhancement—resolves in 1-2 months  | • Patchy, punctate, or linear   |

Adapted from Nauta et al. in *PLoS Med* 2006;3(4):e1000433.

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





# Enrollment Tools

Enroll

Infuse

Track

# 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

The image shows two pages of a brochure. The top page is titled 'Action Steps if PML is Suspected' and contains several bullet points and a note. The bottom page is titled 'Understanding PML for Gastroenterologists' and contains a warning, a section on 'Important Safety Information', and a section on 'How to Recognize PML'. The brochure is from Biogen and includes the Touch Prescribing Program logo.

**Action Steps if PML is Suspected**

- TYSABRI dosing should be suspended immediately in all cases in which PML is suspected<sup>1</sup>
- Immediate referral to a neurologist for assessment, potentially including:
  - 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 1-800-456-2205. You are encouraged to report other adverse reactions to Biogen at 1-800-456-2205 or the FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**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- $\alpha$ , and who are not taking concomitant immunosuppressants (e.g., 6-mercaptopurine, azathioprine, or methotrexate) or concomitant inhibitors of TNF- $\alpha$ .

**Indication**

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

**Important Safety Information**

**WARNING: Progressive Multifocal Leukoencephalopathy (PML)** TYSABRI (natalizumab) increases the risk of PML, an opportunistic infection that can lead to death or severe disability. Risk factors for the development of PML include longer duration of therapy, and prior use of immunosuppressants. The expected benefits when initiating and continuing treatment with TYSABRI may outweigh the risks of PML in certain patients. Healthcare professionals should monitor patients on TYSABRI for signs and symptoms of PML. TYSABRI dosing should be withheld immediately at diagnosis, an evaluation including a gadolinium-enhanced MRI and analysis for JC viral DNA are recommended. Because of the risk of PML, TYSABRI is available only through Mitigation Strategy (MSMS) called the TOUCH Prescribing Program.

Important Safety Information continued on next page.

**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 gastroenterology setting, additional cases of PML have been reported in multiple sclerosis and Crohn's disease patients who were receiving no concomitant immunomodulatory therapy.<sup>1</sup>

**About PML**

PML is a demyelinating disease that attacks the central nervous system.<sup>1</sup> It is an opportunistic infection caused by the JC virus that typically occurs in patients who are immunocompromised.<sup>1</sup> The virus reactivates in the brain, and without this protection the nerves cannot transmit signals.<sup>1</sup> There are no known interventions that can reliably prevent PML, or adequately treat PML, if it occurs.<sup>1</sup>

**How to Recognize PML**

Typical symptoms associated with PML are diverse, progress over days to weeks, and include:<sup>1</sup>

- 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.<sup>1</sup> 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.<sup>1</sup> 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.<sup>1</sup>

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# Infusion Site Enrollment

Enroll

Infuse

Track

# How does an Infusion Site enroll?

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



**TOUCH PRESCRIBING PROGRAM**  
TOUCH Outreach: Unified Commitment to Health  
Phone: 1-800-445-2228

**Infusion Site Enrollment Form**

Please submit this form to:  
Biogen  
www.touchprogram.com  
Fax: 1-800-445-1212

The TOUCH Prescribing Program was developed as part of the program's 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 designated an authorized representative to carry out the enrollment process and to receive communications and shipments with the REMD program. An initial enrollment form and a signed Authorization Enrollment Form to Biogen, upon receipt of the 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 where hospital, group practice, or infusion site is associated with infusion site. Retail pharmacies and pharmacies are excluded from making inventory and shipping 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 must contact Biogen if my infusion site name, administration address, or shipping address changes. By signing below, I understand that I am the TOUCH Outreach Authorized 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.
- TYSABRI will be administered only to patients who are currently authorized in the TOUCH Prescribing Program. Patient administration must be reviewed prior to each infusion.
- For TOUCH On-line infusion sites, Patient status must be "Authorized" or "For patient-based infusion sites, receipt of current copies of Patient Administration and verification that no history of Patient Discontinuation is in the file.
- Each patient must receive a copy of the TYSABRI Patient Information Guide prior to each infusion.
- The 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 (or prior to the patient visit, for inpatient).
- For patient-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 name can now complete and submit the Pre-Infusion Patient Checklist directly to TOUCH On-line.
- Material reports of the infusion site, Site Authorization Confirmation.
- Understand full per the requirements of the TOUCH Prescribing Program. This infusion site's compliance may be reviewed by and/or audited by Biogen and/or a third party designated by Biogen.
- Understand that infusion site cannot administer Biogen products to another manufacturer's product.
- Understand that non-compliance 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.

Authorized Representative Acknowledgment: \_\_\_\_\_ Date: \_\_\_\_\_  
Name: \_\_\_\_\_ Title: \_\_\_\_\_  
Please see the Prescribing Information, including **BOXED WARNING**, for more information.

Biogen TYSABRI (natalizumab)

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



Infusion Site completes and faxes the **Infusion Site Enrollment Form** to TOUCH Prescribing Program

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

# Certified Pharmacy Enrollment

Enroll

Infuse

Track

# How does a Certified Pharmacy\* enroll?

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



The form is titled "TOUCH Prescribing Program Pharmacy Enrollment Form". It includes a header with the Biogen logo and the program name. The form is divided into several sections: "Certified Pharmacy Shipping Address", "Authorized Infusion Site Name", and "Certified Pharmacy Acknowledgment". Each section contains fields for name, address, city, state, and zip code. There are also checkboxes for "Yes/No" and "I confirm that the above information is correct." The form ends with a signature line for the Authorized Representative and a date field. Logos for Biogen and TYSABRI are at the bottom.



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



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



\*A pharmacy is defined as a certified pharmacy located within a hospital, group practice, or infusion site and is associated with an infusion site.



# 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?

# Infusion Overview

Enroll

Infuse

Track

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

- Enroll
- Infuse
- Track



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

## Prior to EVERY infusion of TYSABRI:

## Infusion

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

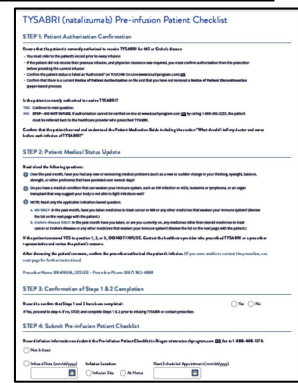
- Start an IV line
- Mix TYSABRI

↓

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



**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.



\*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

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

| Infusion Site  | Practice   | Site Administration | Contact Us    |            |                  |               |               |                |                       |               |               |                |                  |   |            |            |          |            |                  |          |          |          |                       |   |        |        |          |            |                  |          |          |          |                       |
|--|------------|---------------------|---------------|------------|------------------|---------------|---------------|----------------|-----------------------|---------------|---------------|----------------|------------------|---|------------|------------|----------|------------|------------------|----------|----------|----------|-----------------------|---|--------|--------|----------|------------|------------------|----------|----------|----------|-----------------------|
| <input type="text" value="Search"/>  |            |                     |               |            |                  |               |               |                |                       |               |               |                |                  |   |            |            |          |            |                  |          |          |          |                       |   |        |        |          |            |                  |          |          |          |                       |
| <h3>Patients at this Infusion Site</h3> <p>Clicking the information icon next to each patient allows the user to view additional information and to start or print authorization forms.</p> <table border="1"> <thead> <tr> <th></th> <th>Last Name</th> <th>First Name</th> <th>Date of Birth</th> <th>Status</th> <th>Prescriber</th> <th>Last Infusion</th> <th>Next Infusion</th> <th>Enrollment End</th> <th>Checklist Status</th> </tr> </thead> <tbody> <tr> <td>ⓘ</td> <td>[REDACTED]</td> <td>[REDACTED]</td> <td>02/28/20</td> <td>Authorized</td> <td>Jedidiah Carston</td> <td>03/07/22</td> <td>04/18/22</td> <td>09/08/22</td> <td><a href="#">Start</a></td> </tr> <tr> <td>ⓘ</td> <td>Averso</td> <td>Alison</td> <td>02/28/20</td> <td>Authorized</td> <td>Jedidiah Carston</td> <td>03/07/22</td> <td>04/18/22</td> <td>09/08/22</td> <td><a href="#">Start</a></td> </tr> </tbody> </table> |            |                     |               |            | Last Name        | First Name    | Date of Birth | Status         | Prescriber            | Last Infusion | Next Infusion | Enrollment End | Checklist Status | ⓘ | [REDACTED] | [REDACTED] | 02/28/20 | Authorized | Jedidiah Carston | 03/07/22 | 04/18/22 | 09/08/22 | <a href="#">Start</a> | ⓘ | Averso | Alison | 02/28/20 | Authorized | Jedidiah Carston | 03/07/22 | 04/18/22 | 09/08/22 | <a href="#">Start</a> |
|  | Last Name  | First Name          | Date of Birth | Status     | Prescriber       | Last Infusion | Next Infusion | Enrollment End | Checklist Status      |               |               |                |                  |   |            |            |          |            |                  |          |          |          |                       |   |        |        |          |            |                  |          |          |          |                       |
| ⓘ  | [REDACTED] | [REDACTED]          | 02/28/20      | Authorized | Jedidiah Carston | 03/07/22      | 04/18/22      | 09/08/22       | <a href="#">Start</a> |               |               |                |                  |   |            |            |          |            |                  |          |          |          |                       |   |        |        |          |            |                  |          |          |          |                       |
| ⓘ  | Averso     | Alison              | 02/28/20      | Authorized | Jedidiah Carston | 03/07/22      | 04/18/22      | 09/08/22       | <a href="#">Start</a> |               |               |                |                  |   |            |            |          |            |                  |          |          |          |                       |   |        |        |          |            |                  |          |          |          |                       |

**Touch** PRESCRIBING PROGRAM  
TYSABRI Outreach: Unified Commitment to Health

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

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**Notice of Patient Authorization**  
<INDICATION> 1/1/2023

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.*

|  |                                 |
|--|---------------------------------|
| <b>Patient:</b> JENNIFER PATIENT               | <b>Indication:</b> <Indication> |
| <b>Patient Enrollment Number:</b> PTXXXXXXXXXX | <b>Patient DOB:</b> 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

|   |                                       |                                     |
|---|---------------------------------------|-------------------------------------|
| <b>Prescriber:</b> John Prescriber (MDXXXXXXXXXX) | <b>Prescriber Phone:</b> 555-555-7896 | <b>Prescriber Fax:</b> 555-555-7894 |
|---|---------------------------------------|-------------------------------------|

# Pre-infusion Patient Checklist



• 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

• 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

Enroll

Infuse

Track

# 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

This form is used by infusion sites to verify patient information before administering TYSABRI. It includes sections for patient identification, consent, and verification of medical history. Key sections include:
 

- STEP 1: Patient Authorization Confirmation:** Verifies that the patient is currently authorized to receive TYSABRI and that the infusion site has received the necessary authorization from the prescriber.
- STEP 2: Patient Medical History Update:** Asks about recent changes in medical history, including other immunosuppressive treatments, infections, and pregnancy status.
- STEP 3: Record Prescriber Authorization (if required):** Verifies that the prescriber is authorized to prescribe TYSABRI and that the patient's medical history is up-to-date.
- STEP 4: Submit Pre-Infusion Patient Checklist:** Provides instructions on how to submit the completed form to Biogen.

## Prescriber

### Patient Status Report and Reauthorization Questionnaire

This questionnaire is used by prescribers to report on the patient's status and to request reauthorization for TYSABRI treatment. It includes sections for:
 

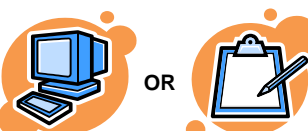
- Patient Identification:** Collects patient name, ID number, and contact information.
- Reauthorization Request:** Asks if the patient is still under the prescriber's care and if reauthorization is needed.
- Medical History Update:** Inquires about any new infections, immunosuppressive treatments, or changes in the patient's overall health since the last visit.
- STOP TYSABRI TREATMENT:** Provides a section for prescribers to indicate if they are stopping treatment and the reasons why.

## Prescriber

### Initial and 6-Month Discontinuation Questionnaire

This questionnaire is used by prescribers to report on the discontinuation of TYSABRI treatment. It includes sections for:
 

- Discontinuation Reason:** Asks why the patient is discontinuing treatment (e.g., side effects, loss of efficacy, patient preference).
- Follow-up Care:** Inquires about the patient's current status and any ongoing medical care.
- Additional Information:** Provides space for any other relevant details regarding the discontinuation.



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





# Tracking Overview –patients who switch from another natalizumab product

Enroll

Infuse

Track

- A one-time enrollment in TOUCH is required to receive TYSABRI; Patients can return to TYSABRI from another natalizumab REMS without re-enrollment.
  - Call the TOUCH Prescribing Program if a patient enrolled in TOUCH will be switching to TYSABRI from another natalizumab product.
  - If a patient is discontinued from any natalizumab REMS by their prescriber, re-enrollment in the TOUCH Prescribing Program is required to receive TYSABRI.
- For patients switching to TYSABRI from another Natalizumab REMS Program, cumulative REMS Data will be shared with the prescriber as soon as possible.
  - Data shared with the prescriber includes number of natalizumab infusions and date of last infusion, all available anti-JCV antibody results, prior treatment with immunosuppressants, and prior or current history of PML.



**PHONE**

**1-800-456-2255**

**Monday – Friday**

**Touch**<sup>®</sup> PRESCRIBING PROGRAM  
TYSABRI Outreach: Unified Commitment to Health

# Prescriber Must Reauthorize the Use of TYSABRI® Every 6 Months

Enroll

Infuse

Track

## 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: 1-800-640-1278

**TYSABRI Patient Status Report and Reauthorization Questionnaire**

Re: <Patient Name>  
Patient Enrollment Number: <Patient TOUCH ID>  
Patient Address: <Prescriber Address>  
Patient Date of Birth: <DOB>  
Authorization End Date: <MMDD/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**

1. Is the patient still under <MD Name>'s care?  Yes  No/If not know  
If No, please provide name and phone number for new prescriber, if available: \_\_\_\_\_

2. Is the patient alive?  Yes  No

3. Since starting TYSABRI therapy, has the patient been diagnosed with PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY?  Yes  No  Under Investigation

4. In the last 6 months, has the patient been tested for the presence of anti-JCV antibodies?  Yes  Not performed  
If performed in the last 6 months, test result:  Positive  Negative  Pending  
If an anti-JCV antibody index value is available, please record it here: \_\_\_\_\_

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

6. 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 FML, 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

Enroll

Infuse

Track

The image shows two forms from the TOUCH Prescribing Program. The top form is the 'TYSABRI Initial' form, which includes fields for prescriber and patient information, and a section for reporting adverse events. The bottom form is the 'TYSABRI 6-Month Discontinuation Questionnaire', which includes fields for prescriber and patient information, and a section for reporting adverse events. Both forms include instructions on how to submit them and a Biogen logo.

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 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

A screenshot of the TOUCH On-Line login interface. At the top, a small header reads: "TOUCH On-Line is a web-based tool designed to assist TOUCH Prescribing Program participants in fulfilling their TOUCH Prescribing Program Requirements." Below this, there are two input fields: "Username" and "Password", each with a small eye icon to its right. A yellow "Login" button is positioned below the fields. To the right of the fields, there is a section titled "Having trouble logging in?" with the text: "Check with your Site Administrator or call us toll free: 1-800-456-2255, Monday through Friday, 8:30 AM to 8:00 PM (ET)". At the bottom left of the form, there is a link: "My password is not working, please e-mail me my password - [click here](#)".

# 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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09/2023

TYS-US-0482 V8

