



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

Please see full Prescribing Information, including Boxed Warning, for important safety 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 patients with relapsing forms of multiple sclerosis.
- 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 Full 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 duration of therapy, prior use of immunosuppressants, and presence of anti-JCV antibodies. 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:
  - Longer treatment duration, especially beyond 2 years. There is limited experience in patients who have received more than 6 years of TYSABRI treatment
  - Prior treatment with an immunosuppressant (e.g., mitoxantrone, azathioprine, methotrexate, cyclophosphamide, mycophenolate mofetil)
  - The presence of anti-JCV antibodies. Patients who are anti-JCV antibody positive have a higher risk for developing PML
- These factors should be considered in the context of expected benefit when initiating and continuing treatment with TYSABRI.

# 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 exposure to the JC virus has 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.
- 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.
- Anti-JCV antibody testing should not be performed for at least two weeks following plasma exchange due to the removal of antibodies from the serum.

## Warnings and Precautions – 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 – 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.

# 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.

# Program Overview

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

# What is the TOUCH Prescribing Program?



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

# What is the TOUCH Prescribing Program designed to do?

- To inform prescribers, infusion center healthcare providers, and patients about the risk of progressive multifocal leukoencephalopathy (PML) associated with TYSABRI® including the increased risk of PML with longer treatment duration, prior immunosuppressant use, and the presence of anti-JCV antibodies
- 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

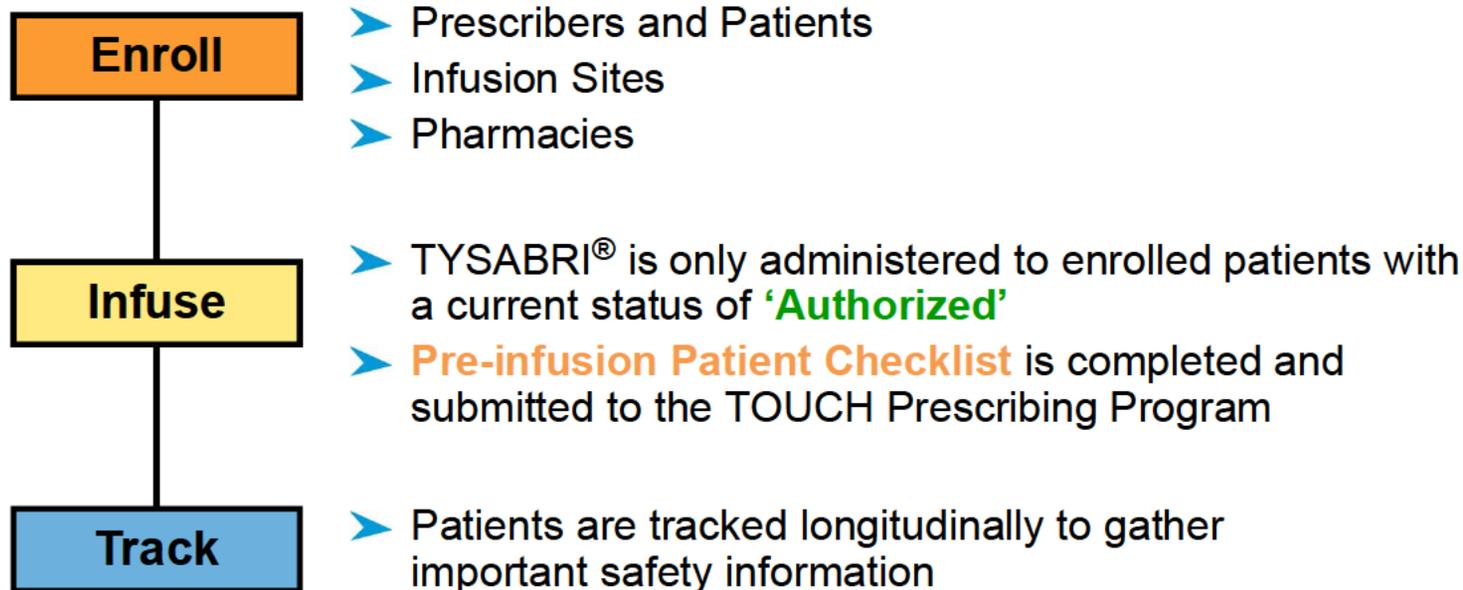
Dispense TYSABRI

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.

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# Tools to Support the TOUCH Prescribing Program – MS

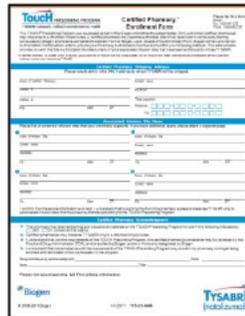
## Enrollment Forms



Prescriber/Patient



Infusion Site



Certified Pharmacy



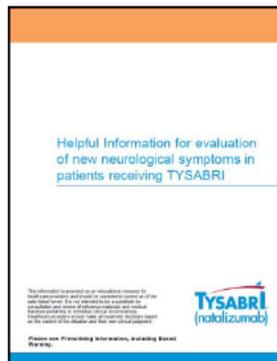
Patient Medication Guide



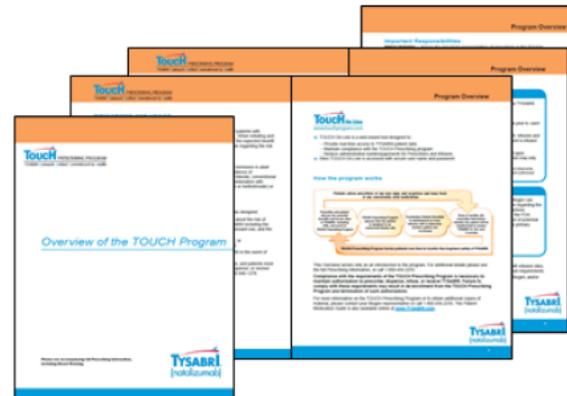
Notice of Patient Authorization



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

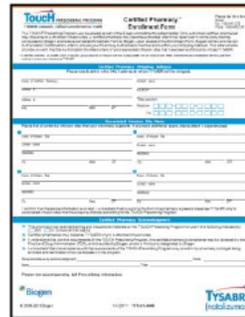
## Enrollment Forms



Prescriber/Patient



Infusion Site



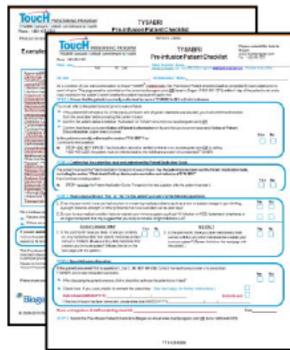
Certified Pharmacy



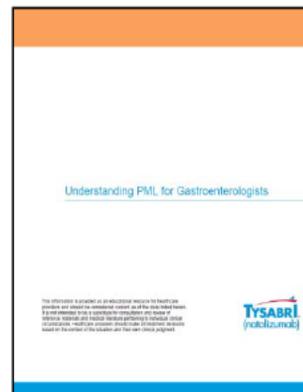
Patient Medication Guide



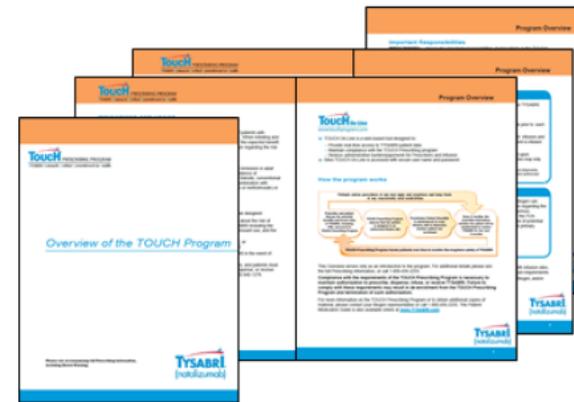
Notice of Patient Authorization



Pre-infusion Patient Checklist



Understanding PML for Gastroenterologists



TOUCH Prescribing Program Overview



# How Do I Communicate With TOUCH?



## WEB

**Touch** On-Line  
[www.touchprogram.com](http://www.touchprogram.com)



## PHONE

1-800-456-2255

Monday – Friday



## PAPER

Fax: 1-800-840-1278

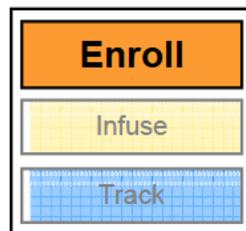
# Satisfying TOUCH Prescribing Program Requirements

- 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

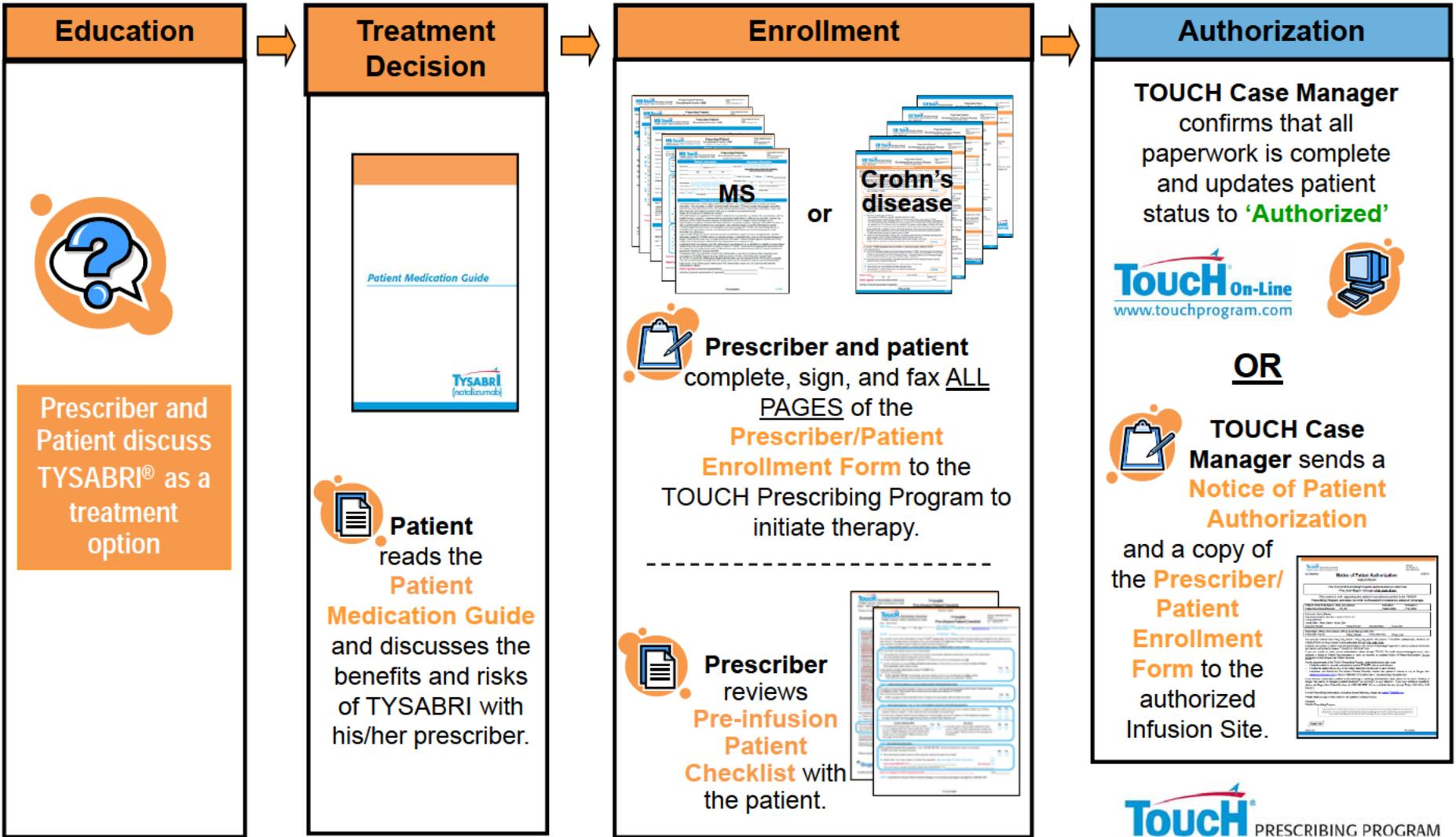
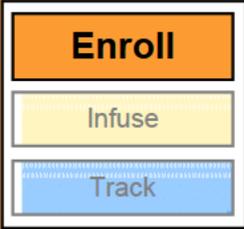
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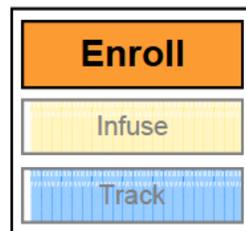
# Prescriber/Patient Enrollment



# How do prescribers and patients enroll?



# Enrollment Tools

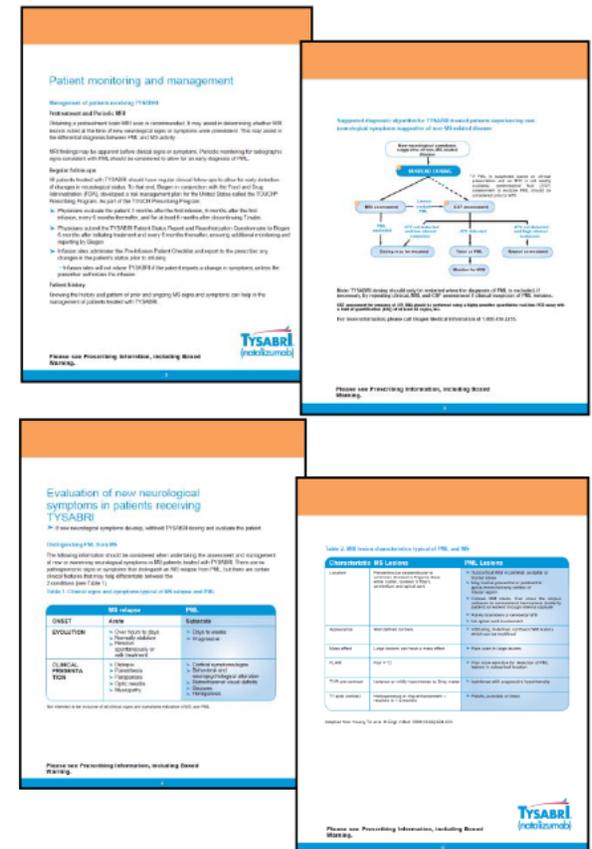


# Helpful Information for Evaluation of New Neurological Symptoms in Patients Receiving TYSABRI®

Brochure provided by Biogen  
Resource for: Neurology specialists

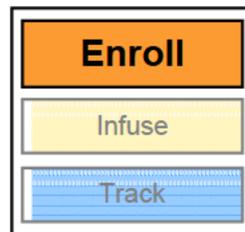
Key topics include:

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



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

## Enrollment Tools



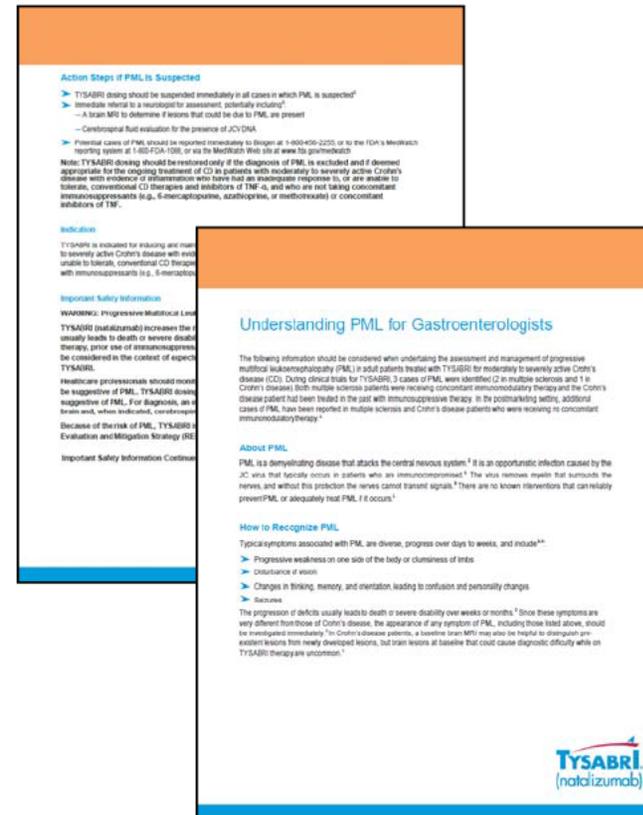
# Understanding PML

## Flashcard provided by Biogen

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

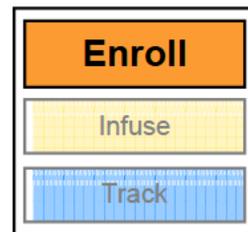
Key topics include:

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

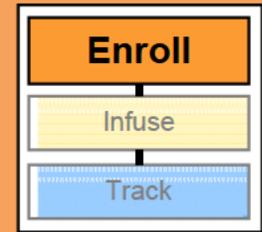


The information provided in this brochure is an educational resource and is not intended to be a substitute for consultation and review of relevant reference materials and medical literature. Treatment decisions should be made based on the context of the situation and clinical judgment.

# Infusion Site Enrollment



# How does an Infusion Site enroll?



A Bigen representative provides mandatory indication-specific TOUCH Prescribing Program training to Infusion Site\*



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 faxes and mails the **Site Authorization Confirmation** to the Infusion Site

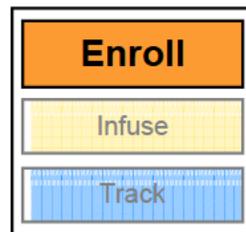


\* NOTE: Infusion Sites must select to receive training and education materials on MS TOUCH, CD TOUCH, or both.

A patient will be matched **ONLY** with Infusion Sites that have been trained on the program materials related to his/her indication.

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

# Certified Pharmacy Enrollment



# How does a Certified Pharmacy\* enroll?

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



The image shows a 'Certified Pharmacy Enrollment Form' from the TOUCH Prescribing Program. It includes fields for pharmacy name, address, phone, and fax, as well as checkboxes for 'Certified Pharmacy' and 'Site Authorization'. The form is branded with Biogen and TYSABRI logos.



The image shows a 'Certified Pharmacy Authorization Confirmation' form. It contains a table with columns for 'By Pharmacy' and 'By Patients', listing details like 'Current Date', 'Site ID', 'Site Name', 'Site Address', 'Site Phone', and 'Site Fax'. It also includes a section for 'Site Authorization' and a 'Notes' section.



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



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

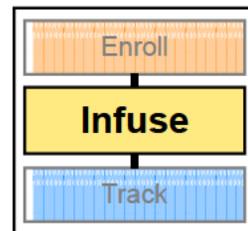


\*A Certified Pharmacy is located within a hospital, group practice, or infusion site and is associated with an infusion site.

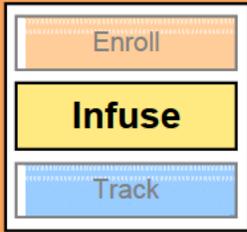
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# Infusion Overview



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



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

## Prior to EVERY infusion of TYSABRI:

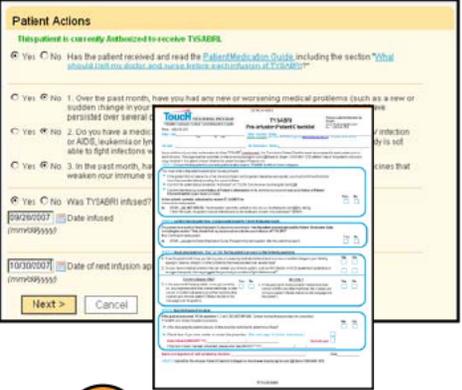
Patient arrives for TYSABRI infusion



**1** Confirm that the patient is currently **'Authorized'** to receive TYSABRI on TOUCH On-Line\*



**2** Provide the patient with the **Patient Medication Guide**



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

## Infusion

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

- Start an IV line
- Mix TYSABRI

↓

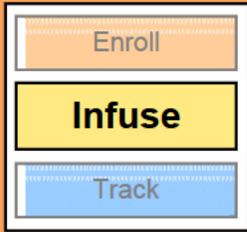
Infuse TYSABRI over 1 hour and observe patient for 1 hour post-infusion

↓

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

\*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

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

Phone: 1 800 458 2355 | Fax: 1 800 848 1278

By Facsimile **Notice of Patient Authorization** 9/19/2016  
<INDICATION>

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

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

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

Account: Test Infusion Site  
Site Authorization Number: ST123456  
123 Infusion Site Lane  
Durham, NC 27709  
Account Phone: 555-555-1234 Account Fax: 555-555-1236

Prescriber: John Prescriber (MDXXXXXXX)  
Prescriber Phone: 555-555-7896 Prescriber Fax: 555-555-7894

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

1 patient found.



# Pre-infusion Patient Checklist

Enroll

Infuse

Track



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

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



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

**Patient Actions**  
This patient is currently Authorized to receive TYSABRI.

Yes  No Has the patient received and read the Patient Medication Guide, including the section "What should I tell my doctor and nurse before each infusion of TYSABRI?"

Yes  No 1. Over the past month, have you had any new or worsening medical problems (such as a new or sudden change in your thinking, eyesight, balance, strength, or other problems) that have persisted over several days?

Yes  No 2. Do you have a medical condition that can weaken your immune system, such as HIV infection or AIDS, leukemia or lymphoma, or an organ transplant, that may suggest that your body is not able to fight infections well?

Yes  No 3. In the past month, have you taken medicines to treat cancer or MS or any other medicines that weaken your immune system? ([Click here to review the list with the patient.](#))

Yes  No Was TYSABRI infused?

09/26/2007 Date infused  
(mm/dd/yyyy)

10/03/2007 Date of next infusion appointment  
(mm/dd/yyyy)

Next > Cancel

## Verify and Sign the Pre-Infusion Patient Checklist

TOUCH On-Line username

Password



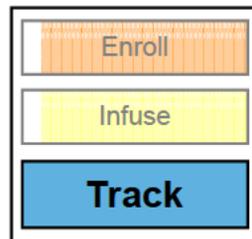
**NOTE:** Pre-infusion Patient Checklist **must** be completed and submitted whether or not the patient is infused.



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# Tracking Overview



# Tracking Overview

Enroll

Infuse

Track

MS

## Infusion Site

### Pre-infusion Patient Checklist



Crohn's  
disease

## Prescriber

### 12-Week Questionnaire

## Prescriber

### Patient Status Report and Reauthorization Questionnaire



## Prescriber

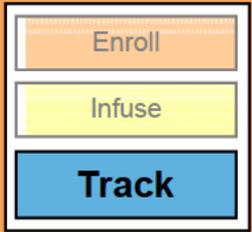
### Initial and 6-Month Discontinuation Questionnaire



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



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



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

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

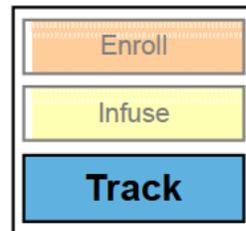
- Fax completed form to 1-800-840-1278 and place original in the patient's file



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

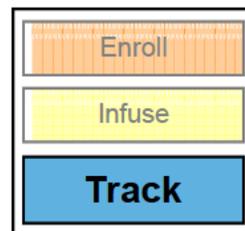


# Tracking Tools





# Tracking Tools



# Tracking Overview – Crohn's Disease

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

## Pre-infusion Patient Checklist (Every 28 days)

The form includes sections for patient information, a checklist of symptoms and side effects (e.g., fever, chills, nausea, diarrhea), and a section for the prescriber to complete. It is titled 'TYSABRI Pre-infusion Patient Checklist'.

## 12-Week Questionnaire (After initial 12 weeks)

This questionnaire asks about the patient's overall health, including questions like 'Has your patient experienced a flare up since their last 12 weeks after starting TYSABRI?' and 'Are you currently taking any other medications?' It is titled 'TYSABRI 12-Week Questionnaire for Crohn's Disease'.

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

This form includes a 'Patient Status Report' section with a table for recording symptoms and a 'Reauthorization Questionnaire' section. It is titled 'TYSABRI Patient Status Report and Reauthorization Questionnaire—Crohn's Disease'.

## Initial and 6-Month Discontinuation Questionnaire\*

This questionnaire is used when a patient's treatment is discontinued. It asks about the reasons for discontinuation and the patient's current status. It is titled 'TYSABRI 6-Month Discontinuation Questionnaire'.



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

# 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?**
- How is TYSABRI acquired?

# TOUCH On-Line Overview

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

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

# Summary Review

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



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**TYSABRI**<sup>®</sup>  
(natalizumab)