

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



Objectives

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



Indications and Usage – Multiple Sclerosis

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



Indications and Usage - Crohn's Disease

- TYSABRI® is indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-α.
- TYSABRI should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF-α.



BOXED WARNING

- TYSABRI® increases the risk of PML, an opportunistic viral infection of the brain that usually leads to death or severe disability.
- Risk factors for the development of PML include presence of anti-JCV antibodies, duration of therapy, and prior use of immunosuppressants. These factors should be considered in the context of expected benefit when initiating and continuing treatment with TYSABRI.
- Healthcare professionals should monitor patients on TYSABRI® for any new sign or symptom that may be suggestive of PML.
- TYSABRI dosing should be withheld immediately at the first sign or symptom that may be suggestive of PML.



BOXED WARNING

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



Contraindications

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



- Three factors that are known to increase the risk of PML in TYSABRItreated 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).



- 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.



- 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.



- 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 antiviral 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 – Hematological Abnormalities

- 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 and 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% 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 ≥ 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

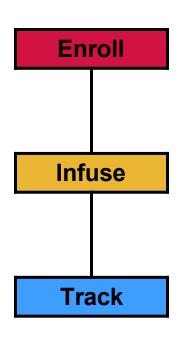


What are the program requirements?

Prescribers Prescribe TYSABRI® Must be registered in and meet all the **Infusion Sites** Infuse TYSABRI requirements of the TOUCH **Prescribing Pharmacies Program to** Dispense TYSABRI Must be enrolled in and meet all the requirements **Patients** Receive TYSABRI of the TOUCH **Prescribing Program to**

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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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?









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

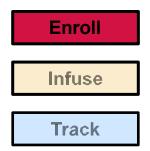


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Prescriber/Patient Enrollment





How do prescribers and patients enroll?

Education

Treatment Decision



Prescriber and Patient discuss TYSABRI® as a treatment option



and discusses the benefits and risks of TYSABRI with his/her prescriber.

Enrollment





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.





Authorization

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





<u>OR</u>



TOUCH Case
Manager sends a
Notice of Patient
Authorization

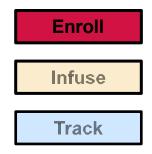
to the authorized Infusion Site.







Enrollment Tools





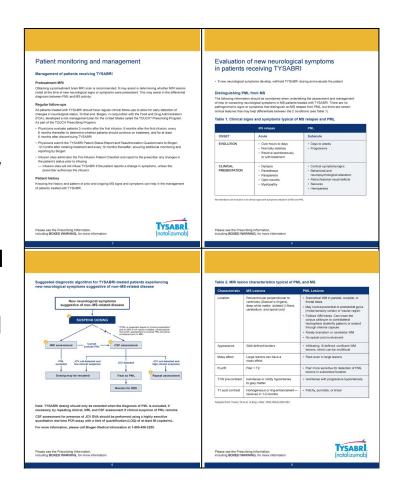
Helpful Information for Evaluation of New Neurological Symptoms in Patients Receiving TYSABRI®

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

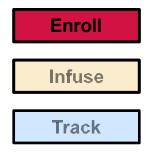


The information provided in this brochure is an educational resource and is not intended to be a substitute for consultation and review of relevant reference materials and medical literature. Treatment decisions should be made based on the context of the situation and clinical judgment.





Enrollment Tools





Understanding PML

Flashcard provided by Biogen

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

Key topics include:

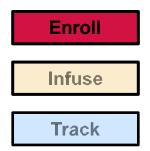
- Characteristics of PML
- Guidance on recognizing PML in context of Crohn's disease
- Action steps if PML is suspected



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?

Enroll

Infuse

Track

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



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

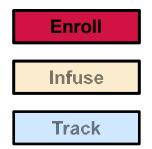


Infusion Site completes
and faxes the
Infusion Site
Enrollment Form to
TOUCH Prescribing
Program

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



Certified Pharmacy Enrollment





How does a Certified Pharmacy* enroll?

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







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.



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Infusion Overview

Enroll

Infuse

Track



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



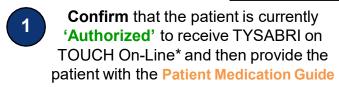


TYSABRI should <u>NOT</u> be prepared until the Pre-infusion Patient Checklist has been successfully completed

Prior to EVERY infusion of TYSABRI:









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.



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.



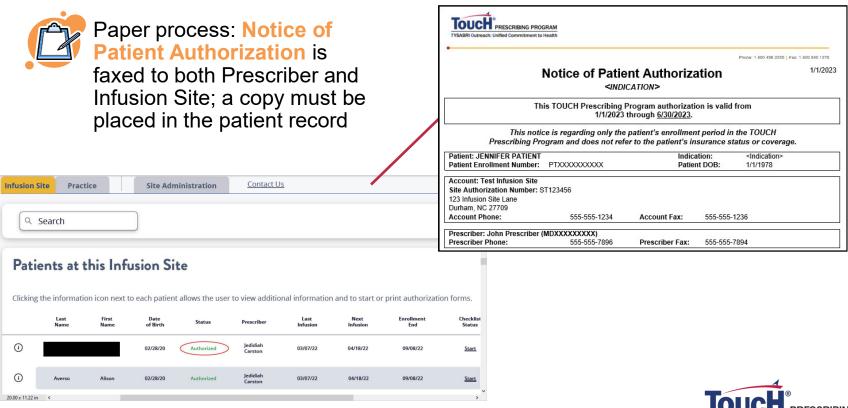
Checking Patient Authorization Status



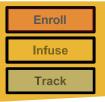
Only patients with a status 'Authorized' can receive TYSABRI®

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





Pre-infusion Patient Checklist



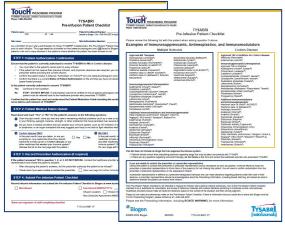


 All Infusion Sites must complete, sign, and submit the Pre-infusion Patient Checklist at every infusion visit

TYSABRI (natalizumab) Pre-infusion Pat STEP 1: Patient Authorization Confirmation Exercise the the patient country translation to sensin YTSABII for MS or Culvin to Value and retrieve the patient record prior to empiration. - If the patient of a rise receive their prioritation prioritation collection was required. The More priority the centre feature - Centre for the patient call and is finded in full centre of TOCHII On Child-planes. Such program Centre for the patient call and is finded in full centre of TOCHII On Child-planes. Such program.	ned e insat confirm authorization from the prescriber insat confirm authorization from the prescriber		0	it form ia TOU
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Read I and the Adhering operations: Ower the past control, the equip to led any ower or excessing method problemes (but), as a some strength, or order problemes (but have perceived over sense) depoil to the past of the pa	n or AIOS, leukemia or lymphomu, or an organ	infusion Patient Che	eklist	
After discoving the patient consume, confirm the precion weather but the patients in next page for further institution at incl. Precion withoms: BRANUM, LESLEE - Precion without (1657) 193-4009 STEP 3: Confirmation of Steps 1 & 2 Completion	TOM_PERNIO Password			
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Not infused	ulad Appairtment (men/ddlyyyy)			

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 <u>must</u> be completed and submitted whether or not the patient is infused.

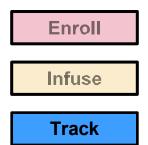


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Tracking Overview





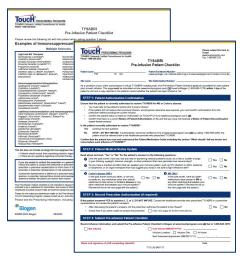
Tracking Overview



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®.

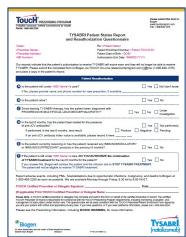
Infusion Site

Pre-Infusion Patient Checklist



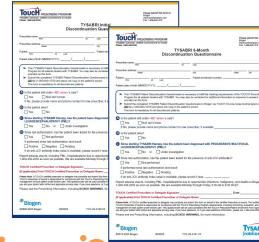
Prescriber

Patient Status Report and Reauthorization Questionnaire



Prescriber

Initial and 6-Month Discontinuation Questionnaire











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

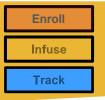


- A one-time enrollment in TOUCH is required to receive TYSABRI;
 Patients can return to TYSABRI from another natalizumab REMS without re-enrollment.
 - Call the TOUCH Prescribing Program if a patient enrolled in TOUCH will be switching to TYSABRI from another natalizumab product.
 - If a patient is discontinued from any natalizumab REMS by their prescriber, reenrollment 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.

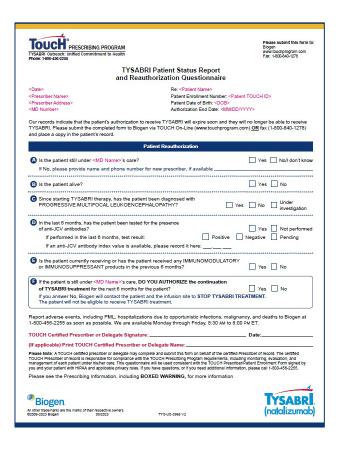




Prescriber Must Reauthorize the Use of TYSABRI® Every 6 Months



TYSABRI Patient Status Report and Reauthorization Questionnaire



- Prescriber will receive a Patient Status Report and Reauthorization Questionnaire every 6 months
- Completion of this form is required
 as it determines whether the prescriber
 authorizes the patient to receive
 TYSABRI for the next 6 months



OR





If a patient discontinues TYSABRI®, the prescriber is notified



FOUR PRESCRIBING PROGRAM VSABRI Outreach: Unified Commitment to Health none: 1400-456-2255			Please submit this form Blogen www.touchprogram.com Fax: 1-800-840-1278	to:
	TYSABRI In	itial		
rescriber name: First rescriber address: Otreet	TYSABRI Outreach: Unified Cor Phone: 1-800-456-2255	IBING PROGRAM		Please submit this form to: Blogen www.buschprogram.com Fax: 1-806-840-1278
atient: MI L		Disco	TYSABRI 6-Month ntinuation Question	naire
atient date of birth (MM/DD/YYYY):	Prescriber name:			
This TYSABRI Patient Discontinus Program for all patients treated will provided on this form. Submit the completed TYSABRI F QR fax (1-800-840-1278) and play This form is mandatory for all disc	Prescriber address: Street	MI Last	City Patient enrollmen	State ZIP tt number:
Is the patient still under <md alive?="" and="" don't="" i="" if="" is="" know="" nam="" name="" no="" no,="" no<="" p="" patient="" please="" provide="" td="" the="" yes=""><td>Program for all patier provided on this form Submit the complete QR fax (1-800-840-1:</td><td>its treated with TYSABF TYSABRI Patient Disc</td><td> You may also be contacted for ad ontinuation Questionnaire to Bioger in the patient's record. </td><td>acking requirements of the TOUCH® Prescribing difficial information in response to answers in via TOUCH On-Line (www.touchprogram.com)</td></md>	Program for all patier provided on this form Submit the complete QR fax (1-800-840-1:	its treated with TYSABF TYSABRI Patient Disc	 You may also be contacted for ad ontinuation Questionnaire to Bioger in the patient's record. 	acking requirements of the TOUCH® Prescribing difficial information in response to answers in via TOUCH On-Line (www.touchprogram.com)
Since starting TYSABRI therapy LEUKOENCEPHALOPATHY (PN Yes No or Since last authorization, has the p		don't know	er for new prescriber, if available	le
Yes Not performed If performed since last authorizati Positive Negative	Yes No Since starting TYSA	BRI therapy, has the	patient been diagnosed with i	PROGRESSIVE MULTIFOCAL
If an anti-JCV antibody index valu	LEUKOENCEPHALO	PATHY (PML)? or Under inw	estigation	
eport adverse events, including PMI 800-456-2255 as soon as possible.		n, has the patient bee	n tested for the presence of anti	-JCV antibodies?
OUCH Certified Prescriber or Delegapplicable) Print TOUCH Certified	If performed since last		sult:	
sase Note: A TOUCH certified prescriber or UCH Prescriber of record is responsible for nagement of each patient under his/her care u and your patient with HIPAA and applicable	Report adverse events, in	duding PML, hospital	ble, please record it here: zations due to opportunistic infe vailable Monday through Friday,	ctions, malignancy, and deaths to Biogen at 8:30 AM to 8:00 PM ET.
ease see the Prescribing Informatio	TOUCH Certified Prescrii (If applicable) Print TOUC			Date:
Biogen. 008-2023 Biogen 09/20	TOUCH Prescriber of record is n	esponsible for compliance i	with the TOUCH Prescribing Program re-	all of the certified Prescriber of record. The certified quirements, including monitoring, evaluation, and TOUCH Prescriber/Patient Enrolment Form signed by additional information, please call 1-800-456-2255.
	Please see the Prescribin	Information, including	g BOXED WARNING, for more	information.
	Biogen.			TYSABRI
	©2013-2023 Biogen	09/2023	TYS-US-4191 V2	(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



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 <u>only</u> to enrolled TOUCH participants
- TOUCH On-Line is accessed with secure username and password







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





