TOUCH® PRESCRIBING PROGRAM

TYSABRI Outreach: Unified Commitment to Health

Overview of the TOUCH Program

Please see accompanying full Prescribing Information, including Boxed Warning.

TYSABRI® (natalizumab)

INDICATIONS AND USAGE

Multiple Sclerosis (MS)

- TYSABRI (natalizumab) is indicated as monotherapy for the treatment of patients with relapsing forms of multiple sclerosis. TYSABRI increases the risk of 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

Crohn's Disease (CD)

- TYSABRI is indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease (CD) 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

Why the program was developed

Biogen is committed to patient safety. The TOUCH® Prescribing Program was designed:

- 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

Prescribers, infusion sites, certified pharmacies associated with infusion sites, and patients must all enroll in the TOUCH Prescribing Program in order to prescribe, infuse, dispense, or receive TYSABRI. All completed Enrollment Forms must be faxed to Biogen at 1-800-840-1278.

TOUCH On-Line
www.touchprogram.com

- 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
  - Reduce administrative burden/paperwork for Prescribers and Infusion
- Sites TOUCH On-Line is accessed with secure user name and password

How the program works

This Overview serves only as an introduction to the program. For additional details please see the full Prescribing Information, or call 1-800-456-2255.

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.

For more information on the TOUCH Prescribing Program or to obtain additional copies of material, please contact your Biogen representative or call 1-800-456-2255. The Patient Medication Guide is also available online at www.TYSABRI.com.

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1 Enrollment

All participants must enroll in the TOUCH Prescribing Program by completing an Enrollment Form.

Prescribers and Patients

Prior to enrollment, prescribers must receive and review the full Prescribing Information and educational materials relating to the TOUCH Prescribing Program. Before completing and signing a Prescriber/Patient Enrollment Form, prescribers and patients are required to:

- Understand and discuss the benefits and risks of treatment with TYSABRI, including PML and other opportunistic infections
- Understand and acknowledge their respective program responsibilities as outlined in the Enrollment Kit

Patients should be fully counseled by either the enrolled prescriber or a healthcare provider under that prescriber's direction before an initial prescription is written. A copy of the completed Prescriber/Patient Enrollment Form should be retained in the patient's medical record. Upon receipt of a properly completed Enrollment Form:

- A Patient Enrollment Number will be assigned
- A Biogen Case Manager will be assigned to assure that the patient is assigned to an authorized infusion site

Infusion Sites and Certified Pharmacies*

Before completing and signing their respective Enrollment Forms, infusion sites and associated certified pharmacies must receive training from a Biogen representative.

*A certified pharmacy is a pharmacy that is part of a hospital, group practice, or infusion site, and is affiliated with one or more infusion sites. Retail pharmacies, wholesalers, and specialty distributors are excluded from holding inventory and dispensing TYSABRI.

Please see accompanying full Prescribing Information, including Boxed Warning.

2 Infusion

Only infusion sites authorized by the TOUCH Prescribing Program can infuse TYSABRI. They are required to:

- Confirm that the patient is currently authorized to receive TYSABRI
- Provide the patient with a copy of the TYSABRI Patient Medication Guide prior to each infusion
- Administer the Pre-Infusion Patient Checklist to every patient prior to each infusion and submit it to Biogen within 1 business day, regardless of whether the patient is infused or not

Authorized infusion sites must use the Authorization Number that is provided upon enrollment to order and receive shipments of TYSABRI.* Certified pharmacies may only dispense TYSABRI to authorized, associated infusion sites.

*The TOUCH Prescribing Program utilizes a closed distribution system that restricts all product shipments. This system includes a single distributor, specialty pharmacies under contract with Biogen and authorized certified pharmacies associated with authorized infusion sites.

3 Tracking

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. Prescribers are required to report any case of PML, serious opportunistic infection, or death in TYSABRI-treated patients to Biogen or the FDA. Furthermore, prescribers are also required to cooperate in the investigation of potential adverse events including providing relevant information upon request. The primary tracking tools include:

- Pre-infusion Patient Checklist
- Patient Status Report and Reauthorization Questionnaire
- Initial and 6-month Discontinuation Questionnaires

Missing or incomplete forms will prompt TOUCH Case Managers to follow up with infusion sites, patients, and/or prescribers to obtain such information in compliance with program requirements.

Prescribers, infusion sites, and certified pharmacies may be audited by the FDA, Biogen, and/or a third party authorized by Biogen.

TYSABRI® (natalizumab)

Important Responsibilities

PRESCRIBERS— Among the important responsibilities of prescribers in the TOUCH Prescribing Program are the following:

- Acknowledge that TYSABRI should only be prescribed in accordance with the FDA label
- Educate the patient on the benefits and risks of treatment with TYSABRI by using the Patient Medication Guide
- Evaluate the patient 3 and 6 months after the first infusion, and every 6 months thereafter, and for 6 months after TYSABRI has been discontinued
- Determine every 6 months whether the patient should continue on treatment, and if so, reauthorize treatment
- Submit to Biogen the TYSABRI Patient Status Report and Reauthorization Questionnaire 6 months after initiating treatment and every 6 months thereafter
- Report serious opportunistic infections and atypical infections with TYSABRI to Biogen at 1-800-456-2255 and to the Food and Drug Administration's MedWatch program at 1-800-FDA-1088

PATIENTS—Among the important responsibilities of patients in the TOUCH Prescribing Program are the following:

- Bring to each infusion a list of all medicines and treatments they have taken during the last
- month Read the Patient Medication Guide before starting TYSABRI and before each
- TYSABRI infusion Promptly report any continuously worsening symptoms that persist over several days to their prescriber Inform all of their physicians that they are receiving TYSABRI
- Plan to see their prescriber 3 and 6 months after the first infusion, and at least as frequently as every 6 months thereafter

INFUSION SITES—Among the important responsibilities of infusion sites in the TOUCH Prescribing Program are the following:

- Confirm that the patient is currently authorized to receive TYSABRI
- Provide the patient with a copy of the TYSABRI Patient Medication Guide *prior to each infusion*
- Administer the Pre-infusion Patient Checklist to every patient prior to each infusion and submit to Biogen within 1 business day, regardless of whether the patient is infused or not

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