TYSABRI® (natalizumab) ACCESS AND REIMBURSEMENT GUIDE

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

Indication

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 PML. When initiating and continuing treatment with TYSABRI, physicians should consider whether the expected benefit of TYSABRI is sufficient to offset this risk.

IMPORTANT SAFETY INFORMATION

WARNING: Progressive Multifocal Leukoencephalopathy (PML)

TYSABRI® (natalizumab) 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 the 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 suggestive of PML. For diagnosis, an evaluation including a gadolinium-enhanced 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.

Please see pages 50-53 for additional Important Safety Information.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

ABOUT THIS GUIDE

Biogen is committed to providing coverage and reimbursement support to patients, HCPs, and sites that administer TYSABRI® (natalizumab). As part of this commitment, we have developed this guide to provide information to help you understand the administrative aspects of the TYSABRI access and reimbursement process: the TOUCH® Prescribing Program; BI; navigating payer restrictions; ordering; billing and claims filing; the appeals process; and patient support.

- The TYSABRI Access and Reimbursement Guide is intended for informational purposes only and does not represent legal or billing advice
- Consult a legal/billing advisor or billing/coding specialist for specific guidance in this area; it is the responsibility of the office to ensure the accuracy of all claims that are submitted for reimbursement
- The content in the TYSABRI Access and Reimbursement Guide is based on information current as of August 2024
- Providers who have patients enrolled in the Free Drug Program may seek reimbursement for the drug administration but not for the drug itself. Payers may require the drug to be entered on the claim form with a zero dollar or nominal charge in order to provide payment for the drug administration

BIOGEN SUPPORT SERVICES
FOR PEOPLE WITH RELAPSING MS

Biogen

Biogen Support Services is here to help support your patients. Biogen Support Services is a support program that provides a variety of financial and insurance assistance options.

These resources can help your patients start and continue on TYSABRI.

- Benefits Investigation to help determine the best coverage options for patients
- Coverage and reimbursement support
- Free STRATIFY™ JCV Antibody testing
- Insurance counseling for the uninsured and underinsured
- A variety of financial and insurance support services
- Phone assistance from Nurse Educators Monday-Friday from 8:30 AM to 8 PM ET. Support is available in Spanish
- Information about Biogen's RMS treatment options
- Disease-state education

Biogen Support Services
www.BiogenSupportServices.com
1-800-456-2255
Monday through Friday, 8:30 AM to 8 PM ET

www.TYSABRIHCP.com

BI=benefits investigation; HCP=healthcare providers; JCV=John Cunningham virus; MS=multiple sclerosis; RMS=relapsing multiple sclerosis.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

STEPS TO HELP YOUR PATIENTS ACCESS TYSABRI® (natalizumab)

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

STEPS TO HELP YOUR PATIENTS ACCESS TYSABRI® (natalizumab)

ONCE HCP & PATIENT CHOOSE TYSABRI

1

Enroll the patient in the TOUCH® Prescribing Program and complete the Start Form

Details on the TOUCH Prescribing Program are provided on pages 7-9

BEFORE INFUSION

2

Complete a BI to determine if a Prior Authorization (PA) is required

Details on the BI and PA are provided on pages 11-14 and pages 17-24, respectively

BEFORE INFUSION

3

Determine if the patient is eligible for financial assistance programs and confirm the out-of-pocket (OOP) costs

Details on the financial assistance programs are provided on pages 43-48

4

Schedule the patient's appointment

5

Acquire TYSABRI via Buy-and-Bill or specialty pharmacy (SP)

Determine the patient's payer requirements and determine whether to purchase through Buy-and-Bill or specialty pharmacy. Details on ordering TYSABRI are provided on pages 26-29

AFTER INFUSION

6

Submit a claim for reimbursement and track progress

Track payer remittance and evaluate responsiveness in addressing reimbursement issues; if claim is denied, start appeal process. Details on claims and reimbursement are provided on pages 31-41

7

Schedule the patient's next appointment

Review patient's benefits before scheduling, and coordinate the next appointment between the patient and administration site (if applicable)

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

TOUCH® PRESCRIBING PROGRAM

TYSABRI Outreach: Unified Commitment to Health

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

TOUCH® PRESCRIBING PROGRAM

As part of Biogen's commitment to patient safety, TYSABRI® (natalizumab) is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the TYSABRI Outreach: Unified Commitment to Health (TOUCH) Prescribing Program.

Designed with the help of the US Food and Drug Administration (FDA), the TOUCH Prescribing Program facilitates appropriate use of TYSABRI due to the risk of progressive multifocal leukoencephalopathy (PML).

- Only prescribers and patients enrolled in the TOUCH Prescribing Program can prescribe and receive TYSABRI, respectively
- Only certain pharmacies and infusion centers authorized by the TOUCH Prescribing Program can dispense and infuse TYSABRI

The TOUCH Prescribing Program is designed to

Inform

prescribers, administration site healthcare providers, and patients about the risk of PML associated with TYSABRI, including the increased risk of PML with the presence of anti-JCV antibodies (JCV+), longer treatment duration, and prior immunosuppression

Warn

against concurrent use with antineoplastic, immunosuppressant, or immunomodulating agents, and in patients who are immunocompromised

Promote

early diagnosis of PML and timely discontinuation of TYSABRI in the event of suspected PML

Report cases of PML, hospitalizations due to opportunistic infections, and deaths to Biogen at 1-800-456-2255 as soon as possible.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

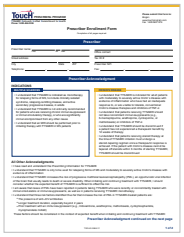
EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

TOUCH® PRESCRIBING PROGRAM FORMS

1 PRESCRIBER/PATIENT

The prescriber must:

- Review the TOUCH® Prescribing Program prescriber educational materials, including the full Prescribing Information
- Review, complete, and sign the Prescriber Enrollment Form for new HCPs
- Educate patients on the benefits and risks of treatment with TYSABRI® (natalizumab), ensure that patients receive the Medication Guide, and encourage them to ask questions
  - Review, complete, and sign the Patient Enrollment Form



Prescriber Enrollment Form
(TYS-US-3966)

Patient Enrollment Form
(TYS-US-3967)

2 BIOGEN

The TOUCH Prescribing Program assigns patient to an authorized administration site, changes patient status to "Authorized" in TOUCH On-Line, and provides a **Notice of Patient Authorization**

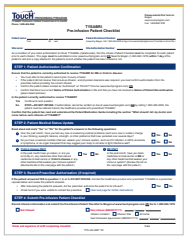
TYSABRI Notice of Patient Authorization
(TYS-US-0495)

3 ADMINISTRATION SITE

The administration site confirms that patient is currently authorized to receive TYSABRI

The patient receives TYSABRI based on answers to the **Pre-infusion Patient Checklist**

The Pre-infusion Patient Checklist is submitted by the administration site via TOUCH On-Line or faxed within 1 day of the patient's dose



TYSABRI Pre-infusion Patient Checklist
(TYS-US-0487)

4 BIOGEN

Tracking begins for the 6-month authorization period and **Pre-infusion Patient Checklist**

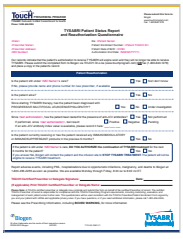
5 PRESCRIBER/PATIENT

The prescriber evaluates patient at 3 and 6 months after the first infusion and every 6 months thereafter

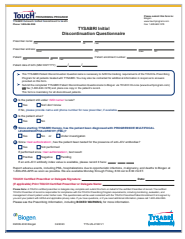
The prescriber determines if patient should continue on treatment and completes the **Patient Status Report and Reauthorization Questionnaire** every 6 months

The prescriber completes an **Initial Discontinuation Questionnaire** when TYSABRI is discontinued

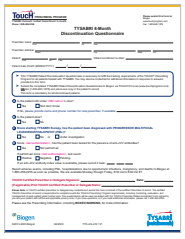
Six months after discontinuation, the prescriber completes the **TYSABRI 6-Month Discontinuation Questionnaire**



TYSABRI Patient Status Report and Reauthorization Questionnaire
(TYS-US-3965)



TYSABRI Initial Discontinuation Questionnaire
(TYS-US-4190)



TYSABRI 6-Month Discontinuation Questionnaire
(TYS-US-4191)

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

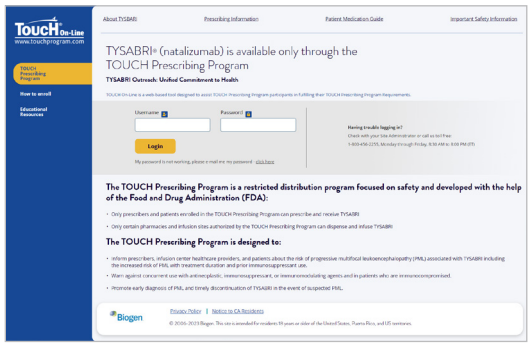
Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

TOUCH® ON-LINE

TOUCH On-Line is a web-based tool designed to assist TOUCH Prescribing Program participants in fulfilling their TOUCH Prescribing Program requirements. TOUCH On-Line enables your office to:

- Receive notifications for missing information, action items, and updates
- Verify a patient's authorization status (Notice of Patient Reauthorization) and authorization dates
- View a patient's Summary of Benefits and financial assistance information
- Access and print TOUCH Prescribing Program information, including the most current Medication Guide
- Export a full list of patients to Microsoft Excel® to view patients who are scheduled for an infusion, those without a scheduled infusion, overdue for an infusion, or enrolled in **Biogen Support Services** and receiving financial assistance
- Save data to a patient's electronic medical records
- Receive Notice of Patient Reauthorization and/or Notice of Discontinuation
- Review STRATIFY™ JCV antibody test results after obtaining patient consent
- Obtain electronic patient consent to release their historical STRATIFY™ JCV test results into TOUCH On-Line

If you do not have a TOUCH On-Line user name and password, your **Biogen Access and Reimbursement Manager** can help, as well as provide training materials and support. If you forget your TOUCH On-Line user name or password, **Biogen Support Services** can get you back online.



- Provides real-time access to TYSABRI® (natalizumab) patient data
- Helps maintain compliance with the TOUCH Prescribing Program
- Streamlines communication to and from prescribers and infusion centers

If you are interested in more information about the TOUCH Prescribing Program or TOUCH On-Line, please reach out to your center's administrator (if TOUCH On-Line is already within your site), your **Biogen Access and Reimbursement Manager**, or **Biogen Support Services.**

Biogen Support Services
www.BiogenSupportServices.com
1-800-456-2255
Monday through Friday, 8:30 AM to 8 PM ET

www.TYSABRIHCP.com

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

COMPLETING A BENEFITS INVESTIGATION

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

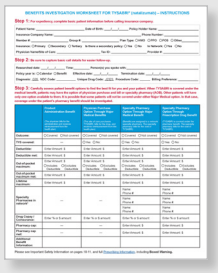
CONSIDERATIONS WHEN CONDUCTING A BENEFITS INVESTIGATION

Payers have different requirements for coverage, so it is important to complete a BI to determine the key clinical and coverage criteria that apply to each patient. A **Biogen Case Manager** can help conduct a BI to help determine what coverage is available for your patient.

Potential items to research and questions to consider when conducting a BI:

PA and required documentation	• Does the patient need prior authorization from the payer before receiving TYSABRI® (natalizumab) in order for it to be covered? • Does the payer require specific documentation—for example, a Letter of Medical Necessity, package insert, FDA approval letter, pricing sheet, and/or clinical reprint—before approving?
Step edits	• Does the payer require prior use of one or more RMS therapies before TYSABRI can be prescribed? • How does each payer define "failure" of an MS drug; for example, 6 months on therapy?
Site-of-care (SOC)	• Does the payer have an SOC policy that mandates where its members can receive infusions? • Is the patient being transitioned to a different SOC, such as office to home infusion, and needing a separate benefits investigation?
Appeals process	• What is the payer's specific process for appealing a denied PA or medical exception?
Acquisition requirements	• Does the payer require your office to acquire TYSABRI through Buy-and-Bill or from a specific SP?
Coding and claims submission details	• Does the payer require any specific information to accompany claims submissions; for example, chart notes? • Have you determined the appropriate billing codes, NDC number, and confirmed the payer's mailing address for claims processing?
Patient financial responsibility	• Does the patient have a separate copay or coinsurance responsibility for the drug and for the administration of TYSABRI? • What are the patient's copay and deductible amounts? • Does the patient have an OOP maximum, lifetime maximum, or annual benefit cap?

Biogen offers helpful resources that you can use when conducting a BI. The Benefits Investigation Worksheet allows you to populate patient-specific payer information, such as claims addresses, referral requirements, policy effective dates, deductible, copay, patient financial notification, and explanation of primary and secondary coverage. Visit the Coverage & Reimbursement section of www.TysabriHCP.com or ask your **Biogen Access and Reimbursement Manager** for more information.



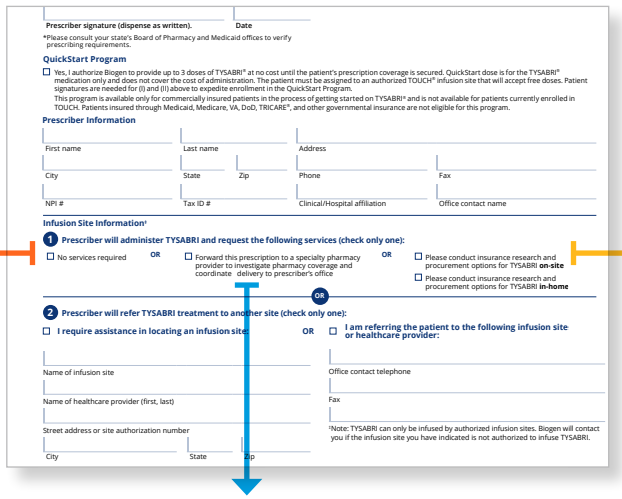
TYSABRI Benefits Investigation Worksheet (TYS-US-0549)

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

BENEFITS INVESTIGATION PROCESS FOR TYSABRI® (natalizumab)

For patients who will be administered a TYSABRI infusion, select 1 of 3 options on the Start Form.



Prescriber signature (dispense as written). Date

*Please consult your state's Board of Pharmacy and Medicaid offices to verify prescribing requirements.

QuickStart Program

☐ Yes, I authorize Biogen to provide up to 3 doses of TYSABRI® at no cost until the patient's prescription coverage is secured. QuickStart dose is for the TYSABRI® medication only and does not cover the cost of administration. The patient must be assigned to an authorized TOUCH® infusion site that will accept free doses. Patient signatures are needed for (I) and (II) above to expedite enrollment in the QuickStart Program.
This program is available only for commercially insured patients in the process of getting started on TYSABRI® and is not available for patients currently enrolled in TOUCH. Patients insured through Medicaid, Medicare, VA, DoD, TRICARE®, and other governmental insurance are not eligible for this program.

Prescriber Information

First name | Last name | Address
City | State | Zip | Phone | Fax
NPI # | Tax ID # | Clinical/Hospital affiliation | Office contact name

Infusion Site Information[1]

1 Prescriber will administer TYSABRI and request the following services (check only one):

☐ No services required OR ☐ Forward this prescription to a specialty pharmacy provider to investigate pharmacy coverage and coordinate delivery to prescriber's office OR ☐ Please conduct insurance research and procurement options for TYSABRI **on-site** ☐ Please conduct insurance research and procurement options for TYSABRI **in-home**

OR

2 Prescriber will refer TYSABRI treatment to another site (check only one):

☐ I require assistance in locating an infusion site OR ☐ I am referring the patient to the following infusion site or healthcare provider:

Name of infusion site | Office contact telephone
Name of healthcare provider (first, last) | Fax
Street address or site authorization number
City | State | Zip

[1]Note: TYSABRI can only be infused by authorized infusion sites. Biogen will contact you if the infusion site you have indicated is not authorized to infuse TYSABRI.

1 "No services required"

Biogen Support Services will provide no further services. Select this if there are no questions regarding patient coverage or if you prefer to do the BI yourself.

2 "Forward this prescription to a specialty pharmacy to investigate pharmacy coverage and coordinate delivery to prescriber's office"

Biogen Support Services will forward the prescription to an SP and will not conduct a BI. The SP will conduct a BI and will generally communicate benefits directly to the patient.

3 "Please conduct insurance research and procurement options for TYSABRI on-site or in-home"

Biogen Support Services will conduct a BI upon receiving the Start Form and send a completed Summary of Benefits to your office.

If you select Option 3, on the Start Form, your office must provide the following information to Biogen Support Services to determine if the patient's benefits will be considered in or out of network:

- **Your payer-specific provider ID #**
- **Your Tax ID #**
- **Whether you use the CMS-1500 Form for Physician Office Billing or the CMS-1450/UB-04 Form for Hospital Outpatient Billing**

If the required information is not on file, a **Biogen Case Manager** will contact your office to obtain the information. When this information is on file, a **Biogen Case Manager** may check in periodically to ensure that the information has not changed.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

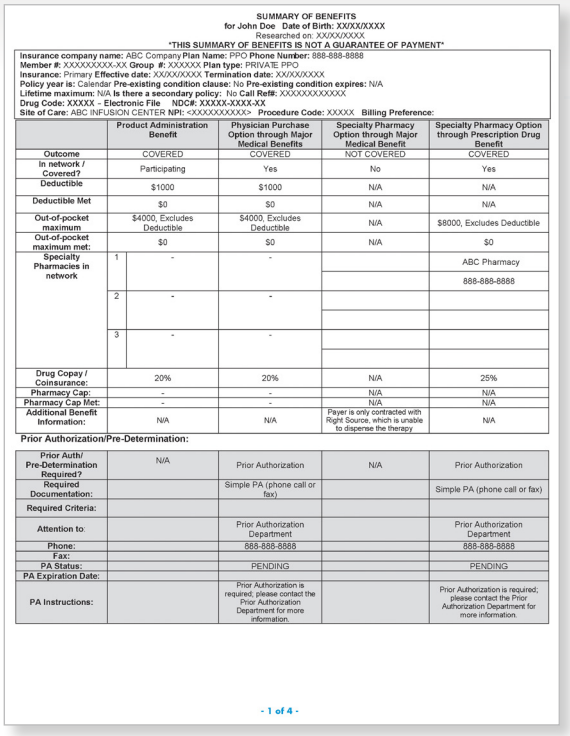
EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

BENEFITS INVESTIGATION PROCESS FOR TYSABRI® (natalizumab) (cont'd)

For patients who you are referring to a nonaffiliated administration site

- Your office will not conduct a BI
- A **Biogen Case Manager** will contact the patient's administration site to find out if it would like **Biogen Support Services** to assist with the BI
- If the administration site requests that **Biogen Support Services** conduct a BI, a **Biogen Case Manager** will research the patient's insurance benefits and send a patient-specific Summary of Benefits to your office and the administration site. This Summary of Benefits can also be viewed at TOUCH® On-Line
- If your office requests a BI on the Start Form, a **Biogen Case Manager** will conduct the BI. You will receive a patient-specific Summary of Benefits for your records

Sample Summary of Benefits



SUMMARY OF BENEFITS
for John Doe Date of Birth: XX/XX/XXXX
Researched on: XX/XX/XXXX
THIS SUMMARY OF BENEFITS IS NOT A GUARANTEE OF PAYMENT

Insurance company name: ABC Company **Plan Name:** PPO **Phone Number:** 888-888-8888
Member #: XXXXXXXXX-XX **Group #:** XXXXXX **Plan type:** PRIVATE PPO
Insurance: Primary **Effective date:** XX/XX/XXXX **Termination date:** XX/XX/XXXX
Policy year is: Calendar **Pre-existing condition clause:** No **Pre-existing condition expires:** N/A
Lifetime maximum: N/A **Is there a secondary policy:** No **Call Ref#:** XXXXXXXXXXX
Drug Code: XXXXX - **Electronic File** **NDC#:** XXXXX-XXXX-XX
Site of Care: ABC INFUSION CENTER **NPI:** <XXXXXXXXXX> **Procedure Code:** XXXXX **Billing Preference:**

	Product Administration Benefit	Physician Purchase Option through Major Medical Benefits	Specialty Pharmacy Option through Major Medical Benefit	Specialty Pharmacy Option through Prescription Drug Benefit
Outcome	COVERED	COVERED	NOT COVERED	COVERED
In network / Covered?	Participating	Yes	No	Yes
Deductible	$1000	$1000	N/A	N/A
Deductible Met	$0	$0	N/A	N/A
Out-of-pocket maximum	$4000, Excludes Deductible	$4000, Excludes Deductible	N/A	$8000, Excludes Deductible
Out-of-pocket maximum met:	$0	$0	N/A	$0
Specialty Pharmacies in network	1 -	-		ABC Pharmacy 888-888-8888
	2 -	-		
	3 -	-		
Drug Copay / Coinsurance:	20%	20%	N/A	25%
Pharmacy Cap:	-	-	N/A	N/A
Pharmacy Cap Met:	-	-	N/A	N/A
Additional Benefit Information:	N/A	N/A	Payer is only contracted with Right Source, which is unable to dispense the therapy	N/A

Prior Authorization/Pre-Determination:

Prior Auth/ Pre-Determination Required?	N/A	Prior Authorization	N/A	Prior Authorization
Required Documentation:		Simple PA (phone call or fax)		Simple PA (phone call or fax)
Required Criteria:				
Attention to:		Prior Authorization Department		Prior Authorization Department
Phone:		888-888-8888		888-888-8888
Fax:				
PA Status:		PENDING		PENDING
PA Expiration Date:				
PA Instructions:		Prior Authorization is required; please contact the Prior Authorization Department for more information.		Prior Authorization is required; please contact the Prior Authorization Department for more information.

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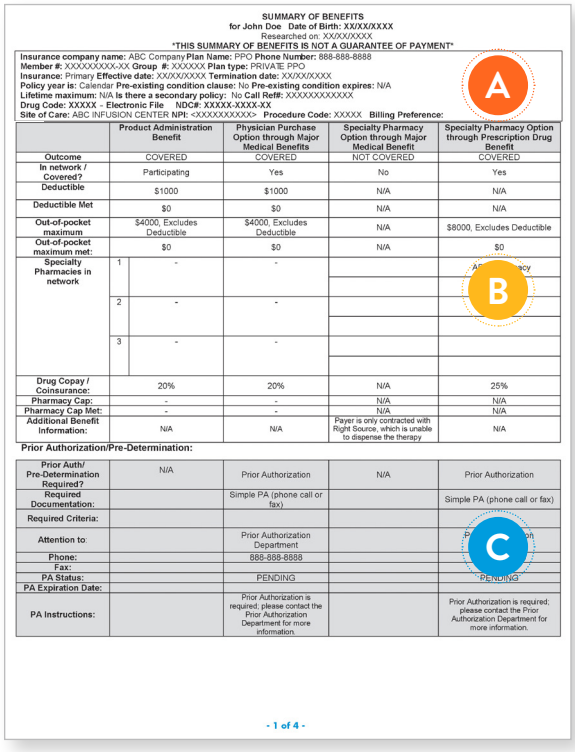
Biogen Support Services
www.BiogenSupportServices.com
1-800-456-2255
Monday through Friday, 8:30 AM to 8 PM ET

www.TYSABRIHCP.com

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

SAMPLE SUMMARY OF BENEFITS



SUMMARY OF BENEFITS
for John Doe Date of Birth: XX/XX/XXXX
Researched on: XX/XX/XXXX
THIS SUMMARY OF BENEFITS IS NOT A GUARANTEE OF PAYMENT

Insurance company name: ABC Company **Plan Name:** PPO **Phone Number:** 888-888-8888
Member #: XXXXXXXXX-XX **Group #:** XXXXXX **Plan type:** PRIVATE PPO
Insurance: Primary **Effective date:** XX/XX/XXXX **Termination date:** XX/XX/XXXX
Policy year is: Calendar **Pre-existing condition clause:** No **Pre-existing condition expires:** N/A
Lifetime maximum: N/A **Is there a secondary policy:** No **Call Ref#:** XXXXXXXXXXX
Drug Code: XXXXX - **Electronic File** **NDC#:** XXXXX-XXXX-XX
Site of Care: ABC INFUSION CENTER **NPI:** <XXXXXXXXXX> **Procedure Code:** XXXXX **Billing Preference:**

		Product Administration Benefit	Physician Purchase Option through Major Medical Benefits	Specialty Pharmacy Option through Major Medical Benefit	Specialty Pharmacy Option through Prescription Drug Benefit
Outcome		COVERED	COVERED	NOT COVERED	COVERED
In network / Covered?		Participating	Yes	No	Yes
Deductible		$1000	$1000	N/A	N/A
Deductible Met		$0	$0	N/A	N/A
Out-of-pocket maximum		$4000, Excludes Deductible	$4000, Excludes Deductible	N/A	$8000, Excludes Deductible
Out-of-pocket maximum met:		$0	$0	N/A	$0
Specialty Pharmacies in network	1	-	-		
	2	-	-		
	3	-	-		
Drug Copay / Coinsurance:		20%	20%	N/A	25%
Pharmacy Cap:		-	-	N/A	N/A
Pharmacy Cap Met:		-	-	N/A	N/A
Additional Benefit Information:		N/A	N/A	Payer is only contracted with Right Source, which is unable to dispense the therapy	N/A

Prior Authorization/Pre-Determination:

Prior Auth/ Pre-Determination Required?	N/A	Prior Authorization	N/A	Prior Authorization
Required Documentation:		Simple PA (phone call or fax)		Simple PA (phone call or fax)
Required Criteria:				
Attention to:		Prior Authorization Department		
Phone:		888-888-8888		
Fax:				
PA Status:		PENDING		PENDING
PA Expiration Date:				
PA Instructions:		Prior Authorization is required; please contact the Prior Authorization Department for more information.		Prior Authorization is required; please contact the Prior Authorization Department for more information.

- 1 of 4 -

A

B

C

Patient Insurance Overview

The patient's information, including insurance and infusion administration benefit

Determine Access Restrictions and Purchasing Options

Product Administration Benefit: The coverage that a patient has for the administration of TYSABRI® (natalizumab)

Buy-and-Bill Option: The purchasing option that the payer will cover through the medical benefit if a provider purchases TYSABRI and submits a claim to the payer for reimbursement

Specialty Pharmacy Assignment of Benefits Option: The purchasing option that the payer will cover through the medical benefit with the drug shipped to the provider through an authorized TYSABRI Specialty Pharmacy

Specialty Pharmacy Prescription Drug Benefits Option: The purchasing option that the payer will cover through the prescription drug benefit with the drug shipped from the SP to the provider

Determine PA and Documentation Requirements

Any PA or step therapy requirements that a provider or administration site must complete to help a patient gain access to therapy

The Summary of Benefits is not a guarantee of coverage or payment. It is the responsibility of the administration site to confirm eligibility and that coverage requirements are met prior to each infusion.

Having a completed BI Worksheet or Summary of Benefits on file may help avoid delays in obtaining TYSABRI.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

NAVIGATING PAYER RESTRICTIONS

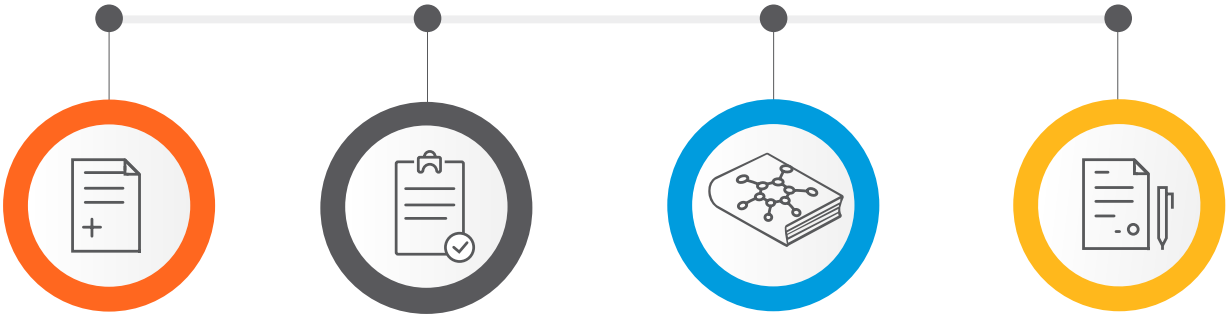
Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

MEDICAL POLICY COVERAGE FOR TYSABRI® (natalizumab)

TYSABRI is administered as an infusion; therefore, payers typically manage TYSABRI under the medical benefit.

For drugs like TYSABRI that are typically managed under the medical benefit, a payer will create a medical policy to provide guidelines that outline specific coverage requirements that must be met before it will pay for the drug. An example of this would be defining appropriate use in accordance with the TYSABRI Prescribing Information. If you need a copy of a specific medical policy, you may find it published on the payer's website; you may also contact the payer directly.

Medical policy coverage criteria for TYSABRI may be based on the following:



- TYSABRI Prescribing Information
- Criteria developed by professional associations
- Data reported in peer-reviewed scientific literature
- Guidelines adopted by other healthcare organizations

Medical policy coverage criteria for TYSABRI may vary and some policies may not be aligned with the latest evidence regarding the product's approved labeling by the FDA.[1]

Biogen Support Services
www.BiogenSupportServices.com
1-800-456-2255
Monday through Friday, 8:30 AM to 8 PM ET

www.TYSABRIHCP.com

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

OBTAINING PRIOR AUTHORIZATION

Depending on the type of insurance and a patient's specific plan or benefits, a PA, a precertification, or a referral may be required before a payer agrees to cover the cost of TYSABRI® (natalizumab) and its administration. Otherwise, the treatment and its administration may not be covered by the patient's insurance.

PA vs precertification

A PA (also known as preauthorization) means that a payer requires approval of the coverage of a drug and/or treatment before the treatment is administered. Depending on drug procurement, TYSABRI may be covered under the medical or pharmacy benefit, which will dictate whether the Payer or PBM oversees the PA.

A precertification (also known as predetermination) helps determine which services or treatment are medically necessary and identifies any plan restrictions that must be addressed before services are provided. If a medical policy is unclear, you may conduct a predetermination to determine if your patient is eligible for treatment.

A precertification is optional, whereas a PA is required by a plan.

Identify specific documentation that must be submitted with the request. Some types of documentation that a health plan may request are:

- Letter of Medical Necessity
- Chart notes
- Specific payer PA form
- Relevant literature
- Magnetic resonance imaging (MRI) and other clinical data related to disease level
- Lab tests (STRATIFY JCV)
- Documented failure of another product

Your office will also need to determine the PA coverage parameters, which can include:

- Number of visits or infusions
- Time limits of authorization
- Diagnosis limitations
- Required use of specific SP
- Submission requirements
- Definition of failure on previous therapies
- Specific site of administration

Not all services will require preapproval. When in doubt, it is best to contact the payer before providing any type of drug or medical service.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

CHECKLIST: OBTAINING PRIOR AUTHORIZATION

- **Identify a TOUCH®-certified administration site.** Investigate for any payer requirements on the administration site. Consider submitting medical exception if a physician disagrees with the payer's SOC policy.
- **Obtain the proper form and fill it out completely.** Some payers require MS-specific forms. PAs can be denied simply because the form has incorrect or incomplete information.
  - A payer may require you to provide a patient's medical record (eg, lab results or MRI report) with appropriate notes, a Letter of Medical Necessity, and/or other documents
  - When utilizing a SP for TYSABRI acquisition, the SP may initiate the PA process to collect additional information. Please respond promptly to help minimize delays
- **Determine a payer's preference on submitting PAs.** Find out if a payer prefers to receive PAs and related documents via phone, fax, or email, or through its website.
  - Keep copies of all documentation that your office submits with the PA
- **Inquire how much time it will take for a decision.** Once a payer receives the necessary forms and documentation, it is important to ask for a time frame, to monitor the progress, and to confirm the PA's approval.
  - Follow up with a payer if your office does not receive notification of the decision in a timely manner
- **Log any calls your office makes about a PA request.** Log the date and time of the call, the person you spoke with, and their direct telephone extension or email address.
  - Record the approval code and date once a PA is approved
- **Maintain a summary sheet of the requirements** that are unique to common payers in your area to help expedite the PA submission process.

Biogen Support Services can help your office understand the PA requirements for most individual payers in your area. If you are having difficulty obtaining approval for TYSABRI® (natalizumab) and need further assistance, contact a **Biogen Case Manager** at 1-800-456-2255, Monday through Friday, 8:30 AM to 8 PM ET.

Biogen Support Services
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EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

SITE-OF-CARE POLICY OPTIONS

In an effort to contain costs, payers have been implementing restrictive SOC policies that may require your patients with RMS to travel to a different location[2] for their TYSABRI® (natalizumab) infusion. This could create difficulty for patients to receive the TYSABRI you prescribed if they have physical or cognitive impairment[3] or geographic issues. Maintaining continuity of care (including the same SOC) may help reduce your patient's overall burden and healthcare costs and improve quality of care.[3,4] Some health plans may request a letter of medical necessity when considering SOC policy restrictions.

In-home administration of TYSABRI is now available to support patient optionality. Not all patients may be appropriate for this based on their circumstances. It is up to the prescriber and patient to determine if home infusion is an appropriate option.

Be sure to confirm coverage with a patient's Payer prior to administration.

The patient experience with TYSABRI: potential benefits of using a consistent administration site

TYSABRI Administration Site Locator

A large number of TOUCH-authorized centers across the country administer TYSABRI infusions. These include administration sites, specially equipped physicians' offices, and specialized infusion clinics within hospitals. This easy-to-use search tool can be found at TYSABRIHCP.com and can help you find the location closest to and most convenient for each patient.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

REQUESTING A MEDICAL EXCEPTION

There are occasions when a physician may wish to prescribe a medication outside of a payer's standard coverage policy. A medical exception communicates a physician's request to use medication that is nonpreferred or not covered due to the patient's individual circumstances.

A request for medical exception may require specific documentation, including a Letter of Medical Necessity detailing considerations specific to a patient's medical history.

A prescriber may request a medical exception when coverage:

- Is nonpreferred (not covered by a payer)
- Requires step therapy
- Limits options for site of administration

Additional documentation may include medical history such as:

- Expanded Disability Status Scale (EDSS) scores, MRI data, and relapse history
- Comorbidities and medication history, including contraindications
- Evidence of inadequate response, adverse events, or side effects

Other documentation

- Letters from medical professionals that provide insights into treatment choice
- Clinical information regarding your treatment choice, such as the TYSABRI Prescribing Information

Payers may change coverage guidelines, which could impact a patient's ability to access therapy through their insurance plan. This is most common at the start of a new benefit year. It is the responsibility of the administration site to ensure eligibility and coverage prior to each infusion. If your office needs information on payer changes or the medical exception process, contact **Biogen Support Services** at 1-800-456-2255, Monday through Friday, 8:30 AM to 8 PM ET.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

CHECKLIST: REQUESTING A MEDICAL EXCEPTION

Determine the need for a medical exception. If a PA for TYSABRI® (natalizumab) has been denied and a physician still believes that TYSABRI is appropriate for the patient, your office may choose to submit a medical exception.

- If an SP completes a BI on your behalf, you may be notified that a medical exception is required based on a payer's formulary or coverage policies

Complete the medical exception request with a Letter of Medical Necessity. Confirm if the payer requires a specific medical exception or a separate letter from your office.

- Remember to carefully and accurately complete the medical exception request form. Medical exception requests may be denied because the form has inaccurate or incomplete information

Completing a Letter of Medical Necessity

In a Letter of Medical Necessity, be clear about your patient's individual circumstances. Include whether you are initiating or changing treatment, or that you want to continue your patient's therapy after their health insurance benefits have changed.

- Provide background on your patient's RMS. Summarize your patient's disease measures (eg, MRI data, EDSS score, relapse history, comorbidities, or contraindications). List any failed medications and provide clinical evidence about the patient's inadequate response
- Provide a clinical justification supporting the treatment you have chosen for your patient and state any patient-specific reasons, such as efficacy, tolerability issues, route of administration, or comorbidities, that preclude the payer's preferred medication
- Explain why the payer's preferred treatments are not appropriate for your patient. Include information about side effects or adverse events that your patient has experienced, compliance concerns, the patient's experience on similar treatments and why they are not suitable, and patient considerations that impact treatment choice. Be sure to note if the prescribing physician is an MS specialist, as many health plans value this information in the Letter of Medical Necessity

Properly submit the medical exception. Determine whether a payer requires a medical exception to be submitted via phone, fax, email, or a specific website. Also inquire about the appropriate contact for the medical exception request.

- Medical exception requests for TYSABRI can also be submitted through the CoverMyMeds® portal
- Record the date, time, and method of submission

Track the status of the medical exception request. Some states have legislation that requires insurance carriers to respond to medical exception requests within a certain time frame.

- Follow up with a payer if your office does not receive notification of the decision in a timely manner

APPEALING PRIOR AUTHORIZATION AND MEDICAL EXCEPTION DENIALS

There are many reasons why a PA or an medical exception request may be denied by a payer. One of the main reasons PA or medical exception requests are denied is **incomplete or inaccurate information on the form**. Check to ensure all information is accurately completed and resubmit the form, if necessary.

In the event that a PA or medical exception request has been denied, the prescribing physician can appeal the decision by contacting the payer directly to discuss the patient, the clinical issues, and the reasons for requesting TYSABRI® (natalizumab). This peer-to-peer dialogue may help the payer understand your patient's concerns with the preferred formulary drugs and why TYSABRI may be the most appropriate treatment option.

Once you submit your appeal, here's how a standard appeals process may go*:

Contract Review

Components of the appeals process are designated in

- The physician's contract with a payer
- The patient's insurance policy

Specialist Review

A neurologist or other specialist familiar with RMS therapies may review the claim for medical necessity

Medical Director Review

Direct physician-to-medical director communication is recommended

Third-Party Review

If the health plan denies the appeal, state insurance department resources may be used as a final means of arbitration

Biogen Support Services helps patients gain access to their prescribed Biogen medication for RMS. A **Biogen Case Manager** can follow up with a patient's payer to ensure that any PA or step edit requirements are approved before treatment is initiated.

You and your patients can call a **Biogen Case Manager** at 1-800-456-2255, Monday through Friday, 8:30 AM to 8 PM ET.

*Please see page 41 to review the Standard Appeals Process for Medicare.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

CHECKLIST: APPEALING A DENIED PRIOR AUTHORIZATION OR MEDICAL EXCEPTION

- **Review the reason for the PA or medical exception denial.** Identify any incorrect or incomplete information in the PA or medical exception, as these are the most common reasons for a denied claim.

- **Verify the appeal process with the payer.** It is important to determine the right course of action in the appeal process. Probe for the following:
  - Does the payer require use of a specific form?
  - Can the appeal be conducted over the phone?
  - If the appeal must be submitted in writing, to whom should it be directed?
  - What information must be included in the appeal (eg, a copy of the original claim, Summary of Benefits, Letter of Medical Necessity)?
  - How long does the appeal process usually take?
  - How will the payer communicate the appeal decision?

- **Review the appeal request for accuracy and completeness.** Be sure to review patient ID numbers, codes, and additional requested information.

- **File the appeal promptly and within filing time limits.**

- **Record the appeal decision.** If the appeal is approved, document the PA number to include on the claim form.

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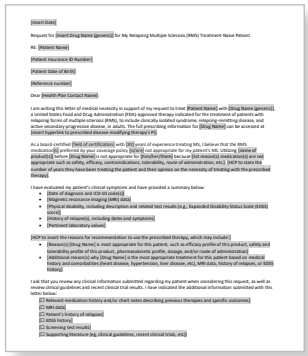
EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

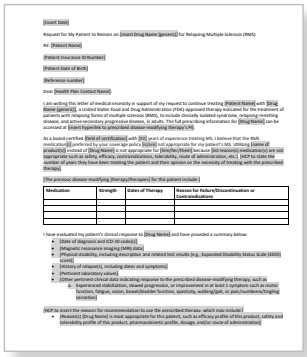
SAMPLE LETTERS OF MEDICAL NECESSITY

Based on common payer restriction scenarios that you may encounter, you may need to fill out a Letter of Medical Necessity to include in your medical exception request. You can access the Sample Letter of Medical Necessity templates listed below at TYSABRIHCP.com. It is important to be as comprehensive as possible in your Letter of Medical Necessity; include why the physician is requesting the specific treatment, reasons other treatments may not be appropriate, the patient's medical history, and previous testing results and disease-modifying therapies, if needed.

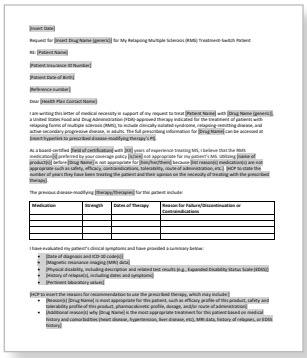
Letter of Medical Necessity for a Treatment-Naive Patient



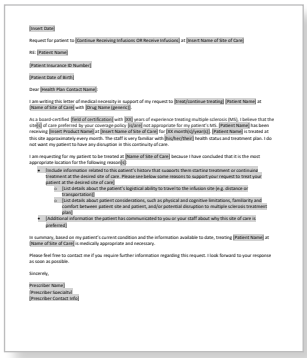
Letter of Medical Necessity for a Patient Currently on Therapy



Letter of Medical Necessity — Change of Coverage



Letter of Medical Necessity for Site-of-Care Exceptions



Payers usually respond to medical exception requests within a few days. Some payers will do an expedited review when a physician believes that a treatment needs to begin without delay due to a patient's circumstances.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

ORDERING TYSABRI® (natalizumab)

Please see Important Safety Information on pages 50-53 and full **Prescribing Information**, including **Boxed Warning**.

ORDERING REQUIREMENTS BY TYPE OF COVERAGE

Ordering requirements, which can be determined during the BI, may differ based on the patient's payer coverage. Regardless of how TYSABRI® (natalizumab) is ordered, only orders from infusion centers and certified pharmacies enrolled in and authorized by the TOUCH® Prescribing Program will be processed. SP orders must be placed through the TOUCH Prescribing Program.

Commercial Payers

Many private payers (including some Medicare Advantage and Managed Medicaid plans) use an SP to deliver TYSABRI. It is important to determine procurement options before treatment with TYSABRI.

Medicaid

Some Medicaid plans use an SP; some require Buy-and-Bill.

Medicare

Traditional Fee-for-Service Medicare is Buy-and-Bill only.

The way in which TYSABRI is purchased may influence the financial responsibility of the patient. Your office may want to discuss these options and requirements with the patient before determining how TYSABRI will be ordered.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

ORDERING TYSABRI® (natalizumab)

Biogen provides 3 options for acquiring TYSABRI to provide flexibility based on the services your office provides and your patients' needs.

1. Purchase from a **wholesaler**

2. Purchase **direct**

   If your office would like to purchase TYSABRI directly, please reach out to your Biogen Access and Reimbursement Manager

3. Procure TYSABRI through an **SP** that is authorized to dispense TYSABRI and is covered by the patient's insurance company. Online ordering for SP is available for infusion centers through TOUCH On-Line

Note: If you request a BI from **Biogen Support Services**, your office will be notified if the patient's payer requires TYSABRI to be purchased from a specific SP. The TOUCH® Prescribing Program can also help identify this information and get your patient's TYSABRI prescription to the right SP.

Some payers may require you to use a specific acquisition method. When conducting a BI, research all of the options that are available in order to identify the one that is best for your office and your patient.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

THE TYSABRI® (natalizumab) SPECIALTY PHARMACY NETWORK

The TYSABRI Specialty Pharmacy Network provides you and your patients with the services you need.

Six SPs have been authorized by Biogen to supply TYSABRI under the special distribution requirements of the TOUCH® Prescribing Program. In some cases, you may be mandated to order TYSABRI from a specific SP. In cases where an SP is the sole acquisition option offered by the payer, but you prefer Buy-and-Bill, this can sometimes be negotiated.

The TYSABRI Specialty Pharmacy Network

Specialty Pharmacy Name	Phone Number	Fax Number
AcariaHealth	1-877-928-5120	1-877-928-5121
Accredo	1-866-898-0034	1-877-201-4499
AllianceRx Walgreens/Prime	1-888-884-8714	1-866-889-1510
Birdi, Inc.	1-877-437-9012	1-877-309-0687
CenterWell	1-800-486-2668	1-877-405-7940
CVS Caremark	1-800-237-2767	1-800-323-2445
Optum	1-855-312-9074	1-866-876-8966

If you need to check on the status of your TYSABRI shipments or follow up on TYSABRI reorders, you can call the SP directly and ask to speak to SP staff who are familiar with TYSABRI or check the status on TOUCH On-Line.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

SPECIALTY PHARMACY ORDERING PROCESS FOR TYSABRI® (natalizumab)

Step 1
Patient/Prescriber

A prescriber or administration site enrolled in the TOUCH Prescribing Program can use a TOUCH-authorized SP to acquire TYSABRI. The completed and signed Patient Enrollment Form and TYSABRI Start Form (contains the prescription) are needed to begin an order.

A prescriber can enroll in the TOUCH Prescribing Program by completing a (1-time) Prescriber Enrollment Form.

Step 2
TOUCH® Prescribing Program

The TOUCH Prescribing Program faxes a TYSABRI order referral form to the TOUCH-authorized SP (this fax includes a prescription and patient enrollment number). Some SPs require that the prescription be sent directly from the prescriber's office.

Step 3
SP

The TOUCH-authorized specialty pharmacy places an order with TysabriDirect®, and TYSABRI is shipped to the SP.

Step 4
Administration Site

The TOUCH-authorized SP ships to your office or nonaffiliated, TOUCH-authorized administration site, which in turn bills the payer directly for administration costs only.

On average, it can take 1 to 3 weeks to receive TYSABRI after you place an order through an SP. Due to payer order limits, TYSABRI will only be dispensed by the SP within a week prior to infusion.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

REIMBURSEMENT AND CLAIMS FOR TYSABRI® (natalizumab)

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

PAYER COVERAGE AND PAYMENT FOR DRUGS AND SERVICES

Medicare, commercial (private) payers, and Medicaid each have different reimbursement policies. Being familiar with these differences will enable your office to avoid potential challenges when seeking reimbursement.

Medicare Part B

Medicare Part B reimburses physician services, including drug administration services, based on the Medicare Physician Fee Schedule (MPFS) at the Average Sales Price (ASP) plus 6%,[5]* as published quarterly by the Centers for Medicare & Medicaid Services (CMS).[6]

Medicare Part B pays for 80% of the allowed charges for TYSABRI® (natalizumab) and its administration, with the beneficiary (or supplemental insurance) responsible for the remaining 20% coinsurance.[7] Medicare Part B patients could have a secondary plan, (eg, Medigap), to help cover the Part B 20% coinsurance.

Medicaid and Private Payers

Some payers may require PA for TYSABRI or they may have other requirements.

Medicaid: Reimbursement for TYSABRI and its administration services varies by state.[8] Medicaid rates may be updated quarterly and can be found on the Medicaid.gov website.[9]

Private Payers: Reimbursement for TYSABRI and its administration services will vary by payer, depending on the specific provisions outlined in your contract.

*Medicare Part B reimbursement is subject to sequestration, which reduces the portion of the payment paid by Medicare by 2%. As a result, the payment rate is effectively ASP + 4.3%.

CLAIMS INFORMATION FOR TYSABRI® (natalizumab)

When the patient has received the TYSABRI infusion, your office may submit a claim to the patient's insurance plan. Depending on the patient's benefits, your office may submit a claim for the drug, for the administration services, or for both. The information within this section reviews some of the codes commonly associated with the administration of TYSABRI. However, your office should check directly with the patient's insurance plan to verify coding recommendations.

DIAGNOSIS AND PRODUCT CODES FOR TYSABRI® (natalizumab)

Patient Diagnosis – RMS

Coding System	Code (Description)	Location on CMS-1500 Payer Form (Electronic Equivalent)[11]	Location on CMS-1450/ UB-04 Form (Electronic Equivalent)[12]
ICD-10-CM[10]	G35 (Multiple Sclerosis)	Field 21 (Loop: 2300; Segment: HI01-2)	Field 67 (Loop: 2300; Segment: HI01-2)

Product Coding

Diagnosis Code	Code and Description	Location on CMS-1500 Payer Form (Electronic Equivalent)[11]	Location on CMS-1450/ UB-04 Form (Electronic Equivalent)[12]
HCPCS[13,14]	J2323 (Injection, natalizumab, 1 mg)	Field 24D (Loop: 2400; Segment: SV101)	Field 44 (Loop: 2400; Segment: SV202-2)
	Units: 300* (1 mg=1 unit)	Field 24G (Loop: 2400; Segment: SV104)	Field 46 (Loop: 2400; Segment: SV205)
NDC[15]	11-digit: 64406-0008-01 10-digit: 64406-008-01	Per payer requirements	Per payer requirements

*The recommended dose for TYSABRI is 300 mg.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

DIAGNOSIS AND PRODUCT CODES FOR TYSABRI® (natalizumab)

5010 Electronic Transaction Codes for TYSABRI NDC[14]

How Supplied	NDC	NDC Qualifier	Unit Basis[a]	Sample 5010 Format[b]
One 300 mg/15 mL (20 mg/mL) single-dose vial per carton	64406-0008-01	N4	ML	N464406000801ML15[c]

[a]Unit basis, or quantity qualifier, includes UN (units), F2 (international units), GR (gram), or ML (milliliter).
[b]Please refer to specific payer requirements for required reporting format.
[c]Quantity will differ based on actual quantity administered.

Accurate coding is key to receiving timely reimbursement for TYSABRI and services administered.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

ADMINISTRATION CODES FOR TYSABRI® (natalizumab)

Product Administration

Coding System	Code and Description	Location on CMS-1500 Claims Form (Electronic Equivalent)[11]	Location on CMS-1450/ UB-04 Claims Form (Electronic Equivalent)[12]
CPT®	**96413** (Chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug; also applies to certain monoclonal antibody agents and biologic response modifiers)[16] **OR** **96365** (IV infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]; initial, up to 1 hour)[16] **OR** **99601** (Home infusion/specialty drug administration, per visit, up to 2 hours)[16]	Field 24D (Loop: 2400; Segment: SV101)	Field 44 (Loop: 2400; Segment: SV202-2)
	Units: 1	Field 24G (Loop: 2400; Segment: SV104)	Field 46 (Loop: 2400; Segment: V205)
HCPCS	**S9379** (Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment [drugs and nursing visits coded separately], per diem)[17] **S9329** (Home infusion therapy, chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment [drugs and nursing visits coded separately], per diem [do not use this code with S9330 or S9331])[18]	Field 24D (Loop: 2400; Segment: SV101)	Field 44 (Loop: 2400; Segment: SV202-2)
	Units: 1	Field 24G (Loop: 2400; Segment: SV104)	Field 46 (Loop: 2400; Segment: V205)
Place of Service	**11 - Office** (Location, other than a hospital, skilled nursing facility [SNF], military treatment facility, community health center, State or local public health clinic, or intermediate care facility [ICF], where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis)[19] **12 - Home** (Location, other than a hospital or other facility, where the patient receives care in a private residence) **19 - Off Campus-Outpatient Hospital** (A portion of an off-campus hospital provider based department which provides diagnostic, therapeutic [both surgical and nonsurgical], and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization)[19] **22 - On Campus-Outpatient Hospital** (A portion of a hospital's main campus which provides diagnostic, therapeutic [both surgical and nonsurgical], and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization)[19]	Field 24B (Loop 2300; CLM05-1–Facility Type Code) (Loop: 2400; Segment: SV105–POS code if different than on claim level)	Field not required
Modifiers	**JZ** (to indicate zero drug wasted/not administered to any patient) **JW** (to indicate drug wastage)[20] **JG** (340B acquired drug)[21] **TB** (340B drug: select entities)[21]	Field 24D (Loop: 2400; Segment: SV104)	Field 46 (Loop: 2400; Segment: V205)

Typically, administration of TYSABRI requires approximately 1 hour of infusion. The total number of hours (from when the medication starts dripping until it stops) is reported in Field 24G (Electronic equivalent—Loop: 2400; Segment: SV104).[14] In-home administration of TYSABRI requires approximately 1 hour of infusion. Therefore, 1 unit must be reported in Field 24G (Electronic equivalent—Loop: 2400; Segment: SV104).[14]

If you order TYSABRI through an SP or a Patient Assistance Program, you should not seek reimbursement for the product; however, your patient's health plan may still require that you include the J-code on the claim with a zero or nominal charge in order for them to reimburse the drug administration procedure.

Remember to submit a claim for reimbursement for services associated with TYSABRI.

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System.

These codes are presented for informational purposes only and do not guarantee reimbursement. Home infusion may be available for eligible patients. All coding and documentation requirements should be confirmed with each payer before submitting a claim for reimbursement.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVALUATION AND MANAGEMENT (E/M) CODES

In some instances, you may provide an E/M service in addition to the infusion within the physician office (office visit) or hospital outpatient (clinic visit). A separate and identifiable procedure must be performed in order to bill for an E/M service in addition to the drug infusion. To bill for both services, the additional service must be clearly documented in the patient's medical record. Some payers will also require the use of the -25 modifier, which tells the payer that the additional services were performed within the same visit.[16]

If the payer allows you to bill for an E/M code in addition to the drug infusion, there are many factors that you should consider in determining which E/M code to use:

- Patient status (new or established)
- Level of decision-making required
- Complexity of the case
- Time spent with the patient

The level of clinic visit billed is based on the level of service documented in the patient's medical record and on the 2021-2023 E/M guidelines used by your facility to select the appropriate E/M code for clinic visits.[16,22] The table below provides a summary of some of the E/M codes that providers may use for established patients.

Coding System	Code and Description
CPT®[16]	**99211**[a] - E/M of an established patient that may not require the presence of a physician or other qualified healthcare professional • Usually, the presenting problem(s) are minimal **99212** - E/M of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision-making • When using time for code selection, 10-19 minutes of total time is spent on the date of the encounter **99213** - E/M of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision-making • When using time for code selection, 20-29 minutes of total time is spent on the date of the encounter **99214** - E/M of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision-making • When using time for code selection, 30-39 minutes of total time is spent on the date of the encounter **99215** - E/M of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision-making • When using time for code selection, 40-54 minutes of total time is spent on the date of the encounter

[a]Medicare does not pay for 99211 separately when reported on the same day as a drug-infusion service.

ADMINISTRATION CODES FOR TYSABRI® (natalizumab)

Use of the JZ Modifier for Zero Drug/Biosmiliar Amount Discarded

- The JZ modifier is available for use as of January 1, 2023[23]
- Starting July 1, 2023, HCPs are required to report the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts[23]

JZ Modifier Example: Use is applicable for both CMS-1500 (clinic) and CMS-1450 (HOPD) settings.

- A provider infuses 300 mg from a 300 mg vial of TYSABRI
- There is no discarded amount; therefore, the provider must use the JZ modifier

K.	L.				
D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	
J2323	JZ			300	

- The provider lists the drug with a J-code on a single line to represent 300 mg of drug administered to the patient, an appends the J-code with the JZ modifier (indicating no discarded units)
  - 1 mg of TYSABRI = 1 unit

Use of the JW Modifier for Drug/Biosimilar Amount Discarded or Not Administered

- Healthcare providers are required to report the JW modifier on Part B drug claims to indicate the amount of discarded product[23]
- The discarded amount is defined as what remains from a single-use vial or other single-use packaging after administering a dose or quantity of the drug to a Medicare patient[23]

JW Modifier Example: The following is for sites other than hospital outpatient departments that use the CMS-1500 form.

- A provider unexpectedly discontinues the procedure and infuses only 100 mg from a 300 mg vial, so the provider discards 200 mg
- The provider lists the product on 2 lines of the claim; both lines start with the J-code
- The first line shows 100 mg of drug administered to the patient

K.	L.				
D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	
J2323				100	
J2323	JW			200	

- The second line shows 200 mg of discarded drug so the JW modifier is appended to the J-code

HOPD=hospital outpatient department.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

HOSPITAL OUTPATIENT BILLING – REVENUE CODES

Relevant Revenue Codes for TYSABRI® (natalizumab)

Revenue codes are required for hospital outpatient billing and will vary depending on the revenue center to which your hospital maps TYSABRI and its associated infusion. Typically, TYSABRI will be reported using the revenue codes listed below.

Coding System	Code and Description	Location on CMS-1450/UB-04 Claims Form (Electronic Equivalent)[15]
AHA[24]	**0258** (IV solutions) **0260** (General) **0262** (Pharmacy services) **0264** (Supplies) **0510** (General clinic) **0636**[a] (Drugs requiring detailed coding)	Field 42[b] (Loop: 2400; Segment: SV201)

AHA=American Hospital Association; IV=intravenous.

[a]For Medicare, claims with HCPCS codes for drugs and biologics billed under the revenue code 0636 should be billed in conjunction with a CPT code for the drug administration. Private payers may also have this requirement.

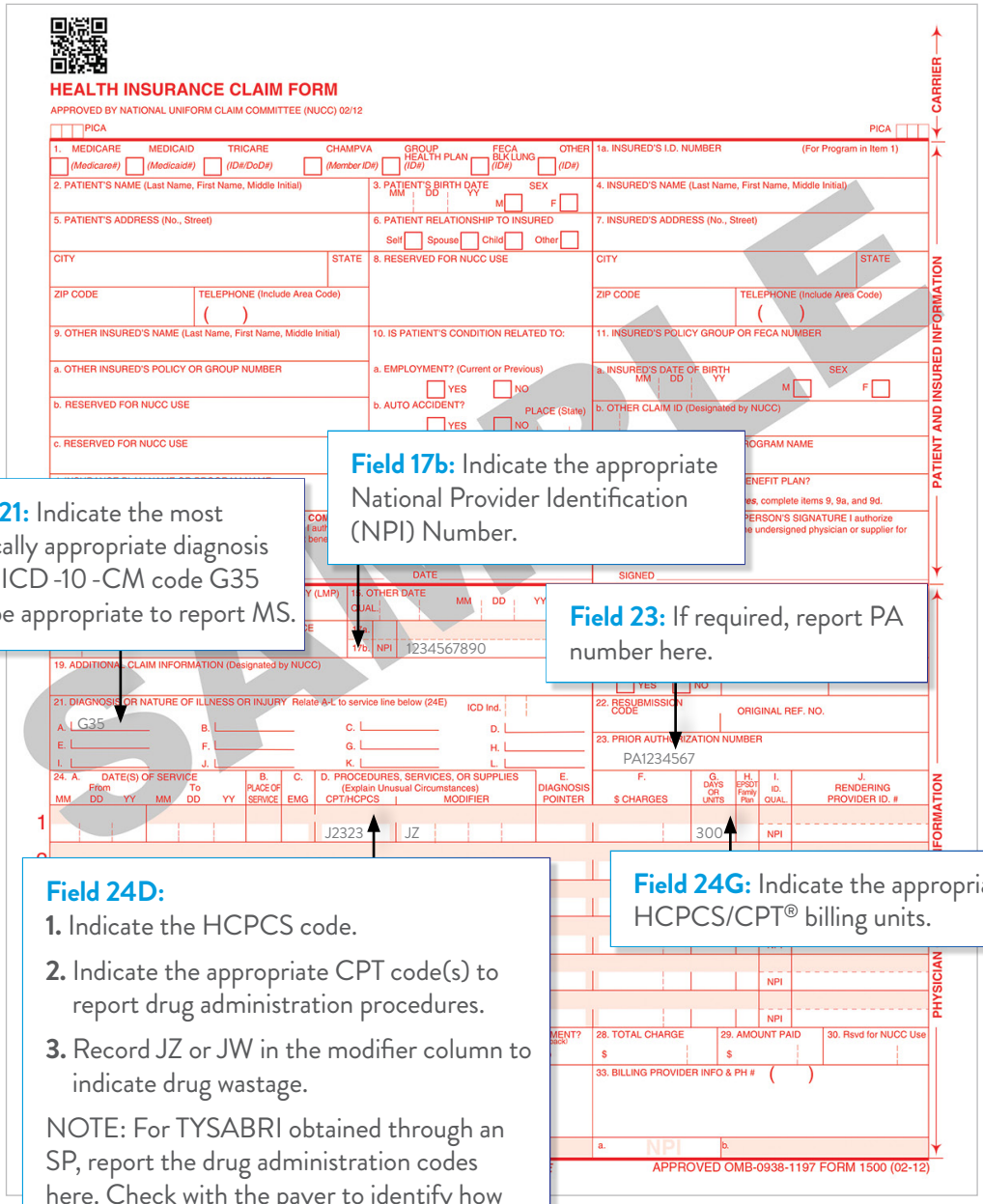
[b]The appropriate revenue code should be entered into Field 42 of the CMS-1450/UB-04 claim form. Revenue Code 11 Description Location on CMS-1450/UB-04.

These codes are presented for informational purposes only and do not guarantee reimbursement. All coding and documentation requirements for drugs should be confirmed with each payer before submitting a claim for reimbursement.

Providers are responsible for the accuracy of the claims they submit.

SAMPLE CMS-1500 CLAIM FORM – PHYSICIAN OFFICE OR HOME ADMINISTRATION SETTING

Sample CMS-1500 Claim Form: Private Payer and Medicare



Field 21: Indicate the most medically appropriate diagnosis code. ICD-10-CM code G35 may be appropriate to report MS.

Field 17b: Indicate the appropriate National Provider Identification (NPI) Number.

Field 23: If required, report PA number here.

Field 24D:

1. Indicate the HCPCS code.
2. Indicate the appropriate CPT code(s) to report drug administration procedures.
3. Record JZ or JW in the modifier column to indicate drug wastage.

NOTE: For TYSABRI obtained through an SP, report the drug administration codes here. Check with the payer to identify how to report the drug that was administered if needed.

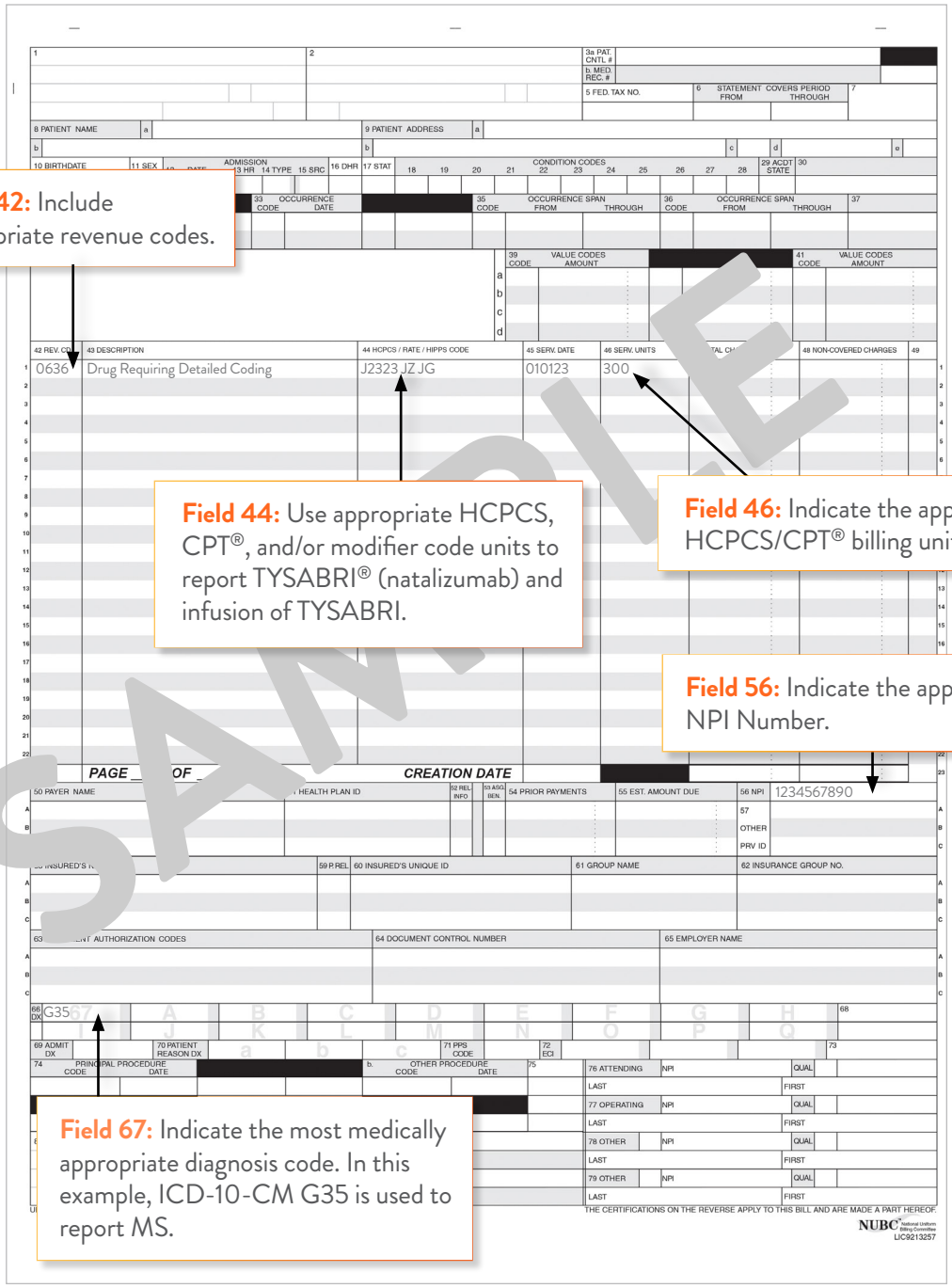
Field 24G: Indicate the appropriate HCPCS/CPT® billing units.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

SAMPLE CMS-1450/UB-04 CLAIM FORM – HOSPITAL OUTPATIENT DEPARTMENTS

Sample CMS-1450/UB-04 Claim Form: Private Payer and Medicare



Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

APPEALING DENIED CLAIMS

If a claim for TYSABRI® (natalizumab) is denied or is improperly reimbursed, your office may consider submitting an appeal. Review the payer's documentation for the denial reason(s) and contact the payer to obtain its claims appeals process.

The most common reasons for claims denials include:

- **Use of incorrect CPT®/HCPCS code(s)**
- **Incorrect number of units billed**
- **Transposed, missing, or abbreviated policy numbers**
- **No PA on file**
- **PA number is missing from claim**
- **Patient's payer mandates the use of an SP**
- **Missing NDC number**

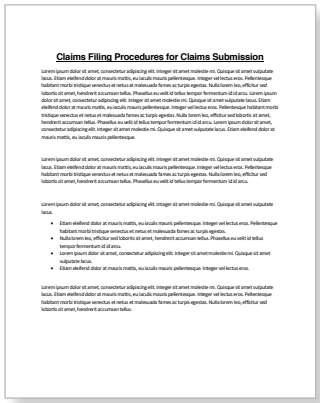
Contact the payer to check on the status of your request. Notify the patient of instances in which your office may need their involvement. Often, the patient, too, can appeal a denied claim with the payer.

It is important that you understand the appeals process for each payer and the time frame in which it must respond. Many states have specific time frames within which payers must respond to appeals (eg, 30 days). A **Biogen Access and Reimbursement Manager** is available to assist with education on billing, coding, reimbursement, and navigating challenges.

RESOURCES TO HELP YOU SUPPORT PATIENTS THROUGHOUT THE APPEALS PROCESS

Biogen Access and Reimbursement Managers are available to provide information during the appeals process.

Payer Support Materials



Claims Filing Procedures for Claims Submission

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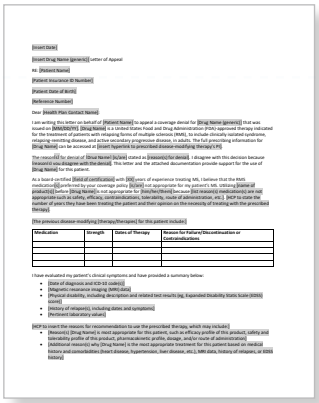
Claim Filing Procedures for Claims Submission (available on Payer's website)



[Insert Date]

[Insert Drug Name (generic)] Letter of Appeal

RE: [Patient Name]

[Patient Insurance ID Number]

[Patient Date of Birth]

Reference Number

Dear [Health Plan Contact Name]:

I am writing this letter on behalf of [Patient Name] to appeal a coverage denial for [Drug Name (generic)] that was issued on [MM/DD/YY]. [Drug Name] is a United States Food and Drug Administration (FDA)-approved therapy indicated for the treatment of patients with relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. The full prescribing information for [Drug Name] can be accessed at [insert hyperlink to prescribed disease-modifying therapy's PI].

The reason(s) for denial of [Drug Name (styles)] stated as [reason(s) for denial]. I disagree with this decision because [reason(s) you disagree with the denial]. This letter and the attached documentation provide support for the use of [Drug Name] for this patient.

As a board-certified [field of certification] with [XX] years of experience treating MS, I believe that the RMS medication(s) prescribed by your coverage policy [is/are] not appropriate for my patient's MS. Utilizing [name of product(s)] before [Drug Name] is not appropriate for [him/her/them] because [list reason(s) medication(s) are not appropriate such as safety, efficacy, contraindications, tolerability, route of administration, etc.]. [HCP to state the number of years they have been treating the patient and their opinion on the necessity of treating with the prescribed therapy].

[My previous disease-modifying [therapy/therapies] for this patient include:]

Medication	Strength	Dates of Therapy	Reason for Failure/Discontinuation or Contraindications

I have evaluated my patient's clinical symptoms and have provided a summary below:

- [Date of diagnosis and ICD-10 code(s)]
- [Magnetic resonance imaging (MRI) data]
- [Physical disability, including description and related test results (eg, Expanded Disability Status Scale (EDSS) score)]
- [History of relapse(s), including dates and symptoms]
- [Pertinent laboratory values]

[HCP to insert the reasons for recommendation to use the prescribed therapy, which may include:]

- [Reason(s) [Drug Name] is most appropriate for this patient, such as efficacy profile of this product, safety and tolerability profile of this product, pharmacokinetic profile, dosage, and/or route of administration]
- [Additional reason(s) why [Drug Name] is the most appropriate treatment for this patient based on medical history and comorbidities (insert disease, hypertension, liver disease, etc.), MRI data, history of relapses, or EDSS history]

Sample Letter of Appeal, (if the Payer does not have a specific appeals format)

Standard Appeals Processes for Original Medicare (Parts A & B) and Medicare Advantage (Part C) Plans

ORIGINAL MEDICARE

A,B

Please click here or visit the Center for Medicare & Medicaid Services (CMS) website for the full **Original Medicare (Parts A & B)** Appeals Process

MEDICARE ADVANTAGE

C

Please click here or visit the CMS website for the full **Medicare Advantage Plan (Part C)** Appeals Process

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

PATIENT SUPPORT AND FINANCIAL ASSISTANCE PROGRAMS

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

UNDERSTANDING PATIENT FINANCIAL RESPONSIBILITY

Biogen Support Services is a support program that provides a variety of financial and insurance assistance options. These resources can help your patients start and continue on TYSABRI® (natalizumab).

In addition to providing assistance with BIs and PA requirements, **Biogen Support Services** can help with patients' concerns related to cost or insurance. Most patients will have either a separate copay or coinsurance responsibilities for the drug and the administration of TYSABRI, in addition to deductible or maximum OOP costs.

At Biogen, our goal is for everyone to get the support they need so they can afford their treatment. We can work with patients to help them understand their insurance coverage and medication cost, and explore financial assistance options for TYSABRI.

Your patients can contact a **Biogen Case Manager** by calling 1-800-456-2255.

Common Patient Financial Responsibility Terms[25]

Copayment	A fixed amount a patient will pay for a healthcare service covered by their insurance
Coinsurance	The percentage of the costs of medical services the patient is required to pay
Deductible	The fixed amount of money a patient is required to pay according to their insurer before benefits become payable
OOP Maximum Limit	An annual limitation on all cost-sharing for which patients are responsible under a health insurance plan. This limit does not apply to premiums, balance-billed charges from out-of-network healthcare providers, or services that are not covered by the plan
OOP Costs	The portion of costs for covered health services the patient is required to pay, including copayments, coinsurance, and deductibles
Premium	A set amount paid to a health plan for providing healthcare coverage under a contract

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

BIOGEN IS COMMITTED TO HELPING MAKE TYSABRI® (natalizumab) AFFORDABLE FOR PATIENTS

Biogen is committed to helping people living with relapsing MS. We can provide assistance once your patients are prescribed TYSABRI. **Biogen Support Services** provides a variety of financial and insurance assistance options to help your patients start and continue on TYSABRI. We're here to be a resource for your patients. And we're just a phone call away.

Insurance and Financial Assistance Process

BENEFITS INVESTIGATION

Review insurance coverage

Assistance with PAs and denied claims

COPAY ASSISTANCE

Biogen Copay Program[a] and Administration Copay Assistance Program for privately insured eligible patients, regardless of income[b]

INSURANCE COUNSELING

Insurance BI and research on financial assistance options

FREE DRUG PROGRAM

Free drug to eligible patients

QUICKSTART PROGRAM

Eligible commercially insured patients to start on TYSABRI without extended delay by providing up to three doses at no drug cost while seeking to secure insurance coverage[c,d]

Biogen Support Services
www.BiogenSupportServices.com
1-800-456-2255
Monday through Friday, 8:30 AM to 8 PM ET

www.TYSABRIHCP.com

[a]There is an annual cap on the amount of assistance that patients can receive over a 1-year period. Federal and state laws and other factors may prevent or otherwise restrict eligibility. People covered by Medicare, Medicaid, the VA/DoD, or any other federal plans are not eligible to enroll. Patients are eligible to enroll in the **Biogen Copay Program** for as long as it is offered and they are treated with TYSABRI.
[b]The **Biogen Copay Program and Administration Copay Assistance Program** are separately managed and eligibility criteria are different for each.
[c]Patients insured through Medicaid, Medicare, VA, DoD, TRICARE®, or other governmental insurance are not eligible for this program.
[d]For eligible patients, TYSABRI is shipped to a TOUCH®-authorized administration site within approximately 1 week of receipt of the TYSABRI Start Form and QuickStart Form. Please see the TYSABRI QuickStart enrollment program form for full terms and conditions.

DoD=United States Department of Defense; FDA=US Food and Drug Administration; VA=United States Department of Veterans Affairs.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

INITIATING THE BIOGEN COPAY PROGRAM AND ADMINISTRATION COPAY ASSISTANCE PROGRAM

Biogen created the Biogen Copay Program and Administration Copay Assistance Program to provide financial assistance for eligible commercially insured patients who have been prescribed TYSABRI® (natalizumab).

Biogen Copay Program
No income requirements and no enrollment time limit for eligible patients receiving TYSABRI.[a]

Administration Copay Assistance Program
Up to $250 for the cost of infusion administration for eligible patients receiving TYSABRI.[b]

Please have your patients contact **Biogen Support Services** at **1-800-456-2255**, Monday through Friday, 8:30 AM to 8 PM ET, to learn more and determine if they are eligible.[c]

Financial and Insurance Assistance
When cost may be a concern for your patients, Biogen may be able to help them start and continue on a Biogen therapy. **Biogen Support Services** offers a variety of different financial and insurance resources.

[a]There is an annual cap on the amount of assistance that patients can receive over a 1-year period. Federal and state laws and other factors may prevent or otherwise restrict eligibility. People covered by Medicare, Medicaid, the VA/DoD, or any other federal plans are not eligible to enroll. Patients are eligible to enroll in the Biogen Copay Program for as long as it is offered and they are treated with TYSABRI.

[b]Patients will be responsible for any costs associated with infusion administration above the $250 per infusion assistance provided by the program. In order to participate in the program and get assistance, patients must meet the following requirements:

- They have a financial responsibility or copay for their infusion
- They are not a resident of Massachusetts or Rhode Island
- They are not covered by any federal healthcare program, like Medicare, Medicaid, the VA/DoD, or TRICARE®, and/or state medical or pharmaceutical assistance programs. They agree to tell Biogen immediately if they obtain coverage through programs listed above
- They are using TYSABRI as described in the FDA-approved label

[c]The Biogen Copay Program and Administration Copay Assistance Program are separately managed and eligibility criteria are different for each.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

SUBMITTING CLAIMS THROUGH BIOGEN COPAY PROGRAMS

Commercially Insured Patients

TYSABRI is obtained through **physician purchase or Buy-and-Bill**

Seek reimbursement from the patient's insurance for **both TYSABRI (J2323) and administration costs**

TYSABRI is obtained through a **specialty pharmacy**

Seek reimbursement from the patient's insurance for the drug **administration costs only**

Obtain EOB or remittance advice **AND** Complete Claim Form CMS-1450 (UB-04) or CMS-1500

Uninsured Patients

TYSABRI is obtained through the **Free Drug Program**

SOC administers to the patient and generates detailed statement that includes billing codes for **both TYSABRI (J2323) and administration charges**[a]

Complete Claim Form CMS-1450 (UB-04) or CMS-1500

Fax documents to Biogen Support Services at 1-866-291-6114 after each administration

or

Submit documents to our new Biogen Copay Portal at https://copay.mybiogen.com/login

or

Email documents to copayprogram@biogen.com

NOTE: Include the patient's name, date of birth, and TOUCH® ID number. If you have questions about implementation or have process questions about the **Biogen Copay Program**, call 1-866-293-1756

Upon receipt of the **Biogen Copay Program and Administration Copay Assistance Program AUTHORIZATION FAXES** from Biogen, charge the cost of the patient's copay to the authorized credit card account and the cost of administration up to $250 to the Mastercard account provided

Upon receipt of the **Administration Copay Assistance Program AUTHORIZATION FAX** from Biogen, charge the cost of administration up to $250 to the Mastercard account provided

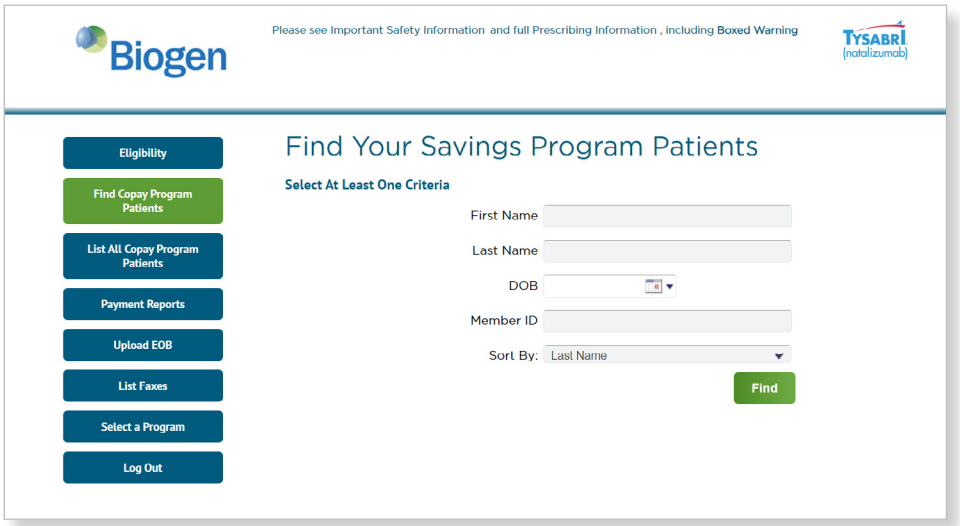
[a]Other applicable codes include 99601, S9379, S9329, and more. These codes are presented for informational purposes only and do not guarantee reimbursement.

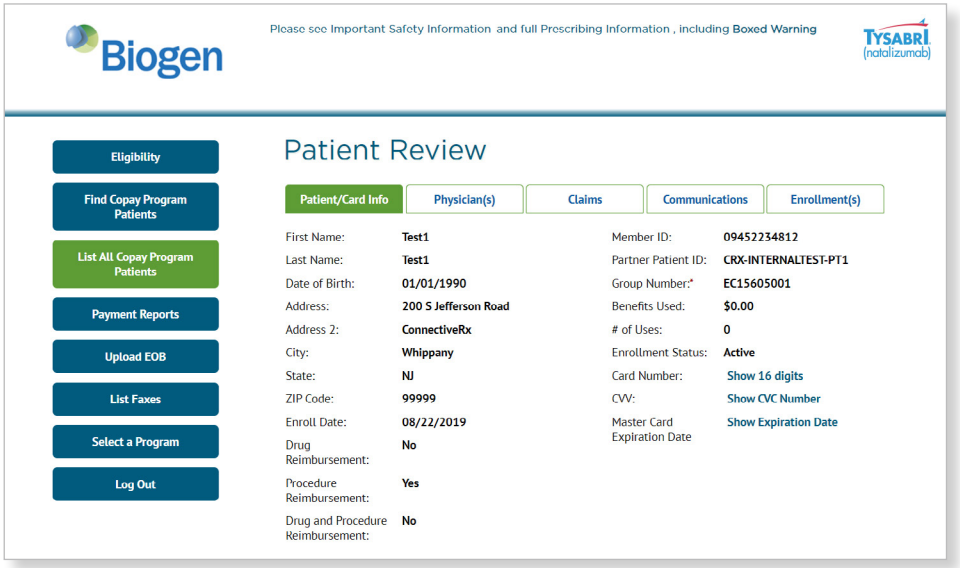
Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

BIOGEN COPAY PORTAL

- Enables sites with patients enrolled in Biogen Copay Programs for TYSABRI to manage and submit Copay Program claims, monitor claim status, and select their preferred reimbursement or payment methods
- The Biogen Copay Portal provides:
  - Enhanced visibility to Buy-and-Bill and procedure copay claims
  - Ability to upload claims
  - Visibility of credit card numbers for payment
  - Patient-level reporting
  - Visibility of all communications between the site and ConnectiveRx
  - Ability to receive Automated Clearing House and Electronic Funds Transfer payments via direct deposit
  - Ability to monitor the amount of copay assistance a patient received year-to-date





Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI (natalizumab)

BIOGEN
SUPPORT SERVICES
FOR PEOPLE WITH RELAPSING MS

Biogen

Biogen will work with your patients based on their individual needs

Biogen Support Services offers a variety of different financial and insurance resources, including

Nurse Educators

- Help patients understand what to expect during treatment
- Give information about common side effects of TYSABRI® (natalizumab)
- Provide education about available resources

Biogen Case Managers

- Help your patients start and continue on their Biogen therapy
- Educate your patients on financial assistance options
- Connect patients to free STRATIFY JCV Antibody testing and administration site information

Financial and Insurance Assistance

- Communicating with insurance companies to clarify and confirm coverage, including assistance with the PA process and denied claims
- Insurance counseling that educates uninsured and underinsured patients on government insurance programs
- Financial assistance options

Patients can call 1-800-456-2255 to speak with a **Biogen Case Manager** Monday through Friday from 8:30 AM until 8 PM ET. Patients may also visit www.BiogenOptions.com.

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

IMPORTANT SAFETY INFORMATION

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

INDICATION AND IMPORTANT SAFETY INFORMATION

Indication

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 PML. When initiating and continuing treatment with TYSABRI, physicians should consider whether the expected benefit of TYSABRI is sufficient to offset this risk.

IMPORTANT SAFETY INFORMATION

WARNING: Progressive Multifocal Leukoencephalopathy (PML)

TYSABRI® (natalizumab) 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 the 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 suggestive of PML. For diagnosis, an evaluation including a gadolinium-enhanced 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.

- Infection by the JC Virus (JCV) is required for the development of PML
- There are no known interventions that can reliably prevent PML or that can adequately treat PML if it occurs
- Postmarketing data 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)
- MRI findings may be apparent before clinical signs or symptoms suggestive of PML. Monitoring with MRI for signs that may be consistent with PML may be useful, and any suspicious findings should lead to further investigation to allow for an early diagnosis of PML, if present. Consider monitoring patients at high risk for PML more frequently. 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
- PML has been reported after discontinuation of TYSABRI in patients who did not have findings suggestive of PML at the time of discontinuation. Patients should continue to be monitored for any new signs or symptoms that may be suggestive of PML for at least 6 months after discontinuation of TYSABRI
- Adverse events that may occur during plasma exchange (PLEX) include clearance of other medications and volume shifts, which have the potential to lead to hypotension or pulmonary edema. Although PLEX has not been prospectively studied in TYSABRI-treated patients with PML, it has been used in such patients in the postmarketing setting to remove TYSABRI more quickly from the circulation. There is no evidence that PLEX has any benefit in the treatment of opportunistic infections such as PML

Please see Important Safety Information continued on the next page and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

IMPORTANT SAFETY INFORMATION (cont'd)

WARNING: Progressive Multifocal Leukoencephalopathy (PML) (cont'd)

- JCV infection of granule cell neurons in the cerebellum, i.e., JCV granule cell neuronopathy (GCN), with symptoms similar to PML, has been reported in patients treated with TYSABRI. JCV GCN can occur with or without concomitant PML and can cause cerebellar dysfunction. Diagnosis and management of JCV GCN should follow guidance provided for PML
- Immune reconstitution inflammatory syndrome (IRIS) has been reported in the majority of TYSABRI-treated patients who developed PML and subsequently discontinued TYSABRI. In almost all cases, IRIS occurred after PLEX was used to eliminate circulating TYSABRI. It presents as a clinical decline in the patient's condition after TYSABRI removal (and, in some cases, after apparent clinical improvement) that may be rapid, can lead to serious neurological complications or death, and is often associated with characteristic changes in the MRI. TYSABRI has not been associated with IRIS in patients discontinuing treatment with TYSABRI for reasons unrelated to PML. In TYSABRI-treated patients with PML, IRIS has been reported within days to several weeks after PLEX. Monitoring for development of IRIS and appropriate treatment of the associated inflammation should be undertaken

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

TYSABRI TOUCH Prescribing Program

- Because of the risk of PML, TYSABRI is available only through a restricted distribution program under a REMS called the TOUCH® Prescribing Program
- Patients must be enrolled in the TOUCH Prescribing Program, read the Medication Guide, understand the risks associated with TYSABRI, and complete and sign the Patient Enrollment Form

Herpes Infections – Encephalitis, Meningitis and Acute Retinal Necrosis

- 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
- The duration of treatment with TYSABRI prior to onset ranged from a few months to several years
- 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
- Patients being administered TYSABRI are at a higher risk of acute retinal necrosis (ARN), a fulminant viral infection of the retina caused by the family of herpes viruses. Patients with eye symptoms such as decreased visual acuity, redness or eye pain should be referred for retinal screening as serious cases of ARN can lead to blindness of one or both eyes
- Following clinical diagnosis of ARN, consider discontinuation of TYSABRI

Please see Important Safety Information continued on the next page and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

IMPORTANT SAFETY INFORMATION (cont'd)

Hepatotoxicity

- Clinically significant liver injury, including acute liver failure requiring transplant, has been reported in patients treated with TYSABRI in the postmarketing setting
- Signs of liver injury, including markedly elevated serum hepatic enzymes and elevated total bilirubin, occurred as early as six days after the first dose; signs of liver injury have also been reported for the first time after multiple doses
- TYSABRI should be discontinued in patients with jaundice or other evidence of significant liver injury (e.g., laboratory evidence)

Hypersensitivity/Antibody Formation

- Hypersensitivity reactions have occurred in patients receiving TYSABRI, including serious systemic reactions (e.g., anaphylaxis) which occurred at an incidence of <1%
- Reactions usually occur within 2 hours of the start of the infusion. Symptoms associated with these reactions can include urticaria, dizziness, fever, rash, rigors, pruritus, nausea, flushing, hypotension, dyspnea, and chest pain
- If a hypersensitivity reaction occurs, discontinue administration of TYSABRI and initiate appropriate therapy. Patients who experience a hypersensitivity reaction should not be re-treated with TYSABRI
- Hypersensitivity reactions were more frequent in patients with antibodies to TYSABRI compared with patients who did not develop antibodies to TYSABRI in both MS and CD studies
- 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

Immunosuppression/Infections

- The immune system effects of TYSABRI may increase the risk for infections
- In Study MS1, certain types of infections—including pneumonias and urinary tract infections (including serious cases), gastroenteritis, vaginal infections, tooth infections, tonsillitis, and herpes infections—occurred more often in TYSABRI-treated patients than in placebo-treated patients. One opportunistic infection, a cryptosporidial gastroenteritis with a prolonged course, was observed in a patient who received TYSABRI in Study MS1
- In Studies MS1 and MS2, an increase in infections was seen in patients concurrently receiving short courses of corticosteroids. However, the increase in infections in TYSABRI-treated patients who received steroids was similar to the increase in placebo-treated patients who received steroids
- In a long-term safety study of patients, opportunistic infections (pulmonary mycobacterium avium intracellulare, aspergilloma, cryptococcal fungemia and meningitis, and Candida pneumonia) have been observed in <1% of TYSABRI-treated patients
- Concurrent use of antineoplastic, immunosuppressant, or immunomodulating agents may further increase the risk of infections over the risk observed with use of TYSABRI alone

Please see Important Safety Information continued on the next page and full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

IMPORTANT SAFETY INFORMATION (cont'd)

Immunosuppression/Infections (cont'd)

- In Studies MS1 and MS2, the rate of any type of infection was approximately 1.5 per patient-year in both TYSABRI-treated patients and placebo-treated patients
- In Study MS1, the incidence of serious infections was approximately 3% in TYSABRI-treated patients and in placebo-treated patients. Most patients did not interrupt treatment with TYSABRI during infections

Laboratory Test Abnormalities

- In clinical trials, TYSABRI was observed to induce increases in circulating lymphocytes, monocytes, eosinophils, basophils, and nucleated red blood cells. Observed changes persisted during TYSABRI exposure, but were reversible, returning to baseline levels usually within 16 weeks after the last dose. Elevations of neutrophils were not observed. TYSABRI induces mild decreases in hemoglobin levels (mean decrease of 0.6 g/dL) that are frequently transient

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 common adverse reactions reported at an incidence of ≥10% with TYSABRI and ≥2% difference with placebo 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%), pain in extremity (16% vs 14%), rash (12% vs 9%), gastroenteritis (11% vs 9%), and vaginitis (10% vs 6%)
- The most frequently reported serious adverse reactions in Study MS1 were infections (3.2% vs 2.6% placebo), including urinary tract infection (0.8% vs 0.3%) and pneumonia (0.6% vs 0%), acute hypersensitivity reactions (1.1% vs 0.3%, including anaphylaxis/anaphylactoid reaction [0.8% vs 0%]), depression (1.0% vs 1.0%, including suicidal ideation or attempt [0.6% vs 0.3%]), and cholelithiasis (1.0% vs 0.3%)
- 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

Please see full Prescribing Information, including **Boxed Warning**.

EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

FREQUENTLY ASKED QUESTIONS (FAQs) AND GLOSSARY OF COMMON HEALTH INSURANCE TERMS

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

FREQUENTLY ASKED QUESTIONS

How do I submit a claim for an infusion of TYSABRI® (natalizumab) when I did not purchase the drug?

If you have received TYSABRI at no cost (for example, either through an SP or through the Free Drug Program), you may not bill third-party payers for it. Although you may not bill for the drug, you may be able to bill for the administration service. Some payers may require you to enter the J-code (J2323) on the claim form with a zero charge to identify which drug was administered. To verify if there are special billing guidelines for a drug obtained at no charge, it is important to check with the specific payer.

Does the patient authorization from the TOUCH® Prescribing Program have anything to do with the patient's insurance coverage?

No. It means that the patient has been authorized to receive TYSABRI. It is **not** an authorization from the insurance company and it does not address any reimbursement-related issue.

How frequently will payers allow an infusion of TYSABRI to be given?

This varies according to the guidance published by specific payers. It is important to check with the payer regarding its policy. The recommended dose of TYSABRI is 300 mg administered intravenously once every 4 weeks.

What should I do if I drop or damage a TYSABRI vial?

- If you purchased TYSABRI through a distributor, contact your **Biogen Access and Reimbursement Manager** to get more information on replacement vials
- If you purchased TYSABRI through an SP, contact your SP and a **Biogen Case Manager** to get more information on replacement vials

I received a denial because we infused the drug when the PA was "pending." Now what do we do?

For more information on appealing claims and options for patient assistance, contact a **Biogen Case Manager** or your **Biogen Access and Reimbursement Manager**.

What can I do if the PA is denied?

- For help in determining the reason(s) for denial and to explore possible options for patient assistance, contact a **Biogen Case Manager** or your **Biogen Access and Reimbursement Manager**
- Please see pages 40-41 for assistance with handling denials and appeals

Biogen Support Services
www.BiogenSupportServices.com
1-800-456-2255
Monday through Friday, 8:30 AM to 8 PM ET

www.TYSABRIHCP.com

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EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)

GLOSSARY OF COMMON HEALTH INSURANCE TERMS

Ancillary Services: Supplemental services, such as physical therapy or diagnostic service, used to support a patient during the diagnosis and treatment of their condition.[25]

Appeal: A request on behalf of a patient or their provider to reconsider a decision, such as a benefit payment or administrative action.[25]

Benefits Investigation: The process of verifying a patient's insurance coverage and helping to secure Prior Authorizations when necessary.[26]

Buy-and-Bill: When a provider purchases a drug directly from a manufacturer or wholesaler and bills the payer for an amount that is established in a fee schedule, not based on the actual cost to the provider to acquire the drug.[27]

Claim: A request by a patient or their provider that is sent to the patient's insurance company to pay for the costs incurred while receiving services from a healthcare professional.[25]

Coinsurance: The percentage of the costs of medical services the patient is required to pay, which on average is 20% of the total costs.[25]

Commercial (Private) Insurance: Health insurance coverage that is offered to groups or individuals through private insurers. Commercial insurance policies may be purchased through an employer, a broker, or a public health insurance marketplace (also known as an insurance exchange).[28]

Copayment: A fixed amount a patient will pay for a healthcare service covered by their insurance.[25]

Cost Sharing: Payment method in which the patient is required to pay for some of their healthcare costs, including deductibles, coinsurance, and copayments.[25]

Current Procedural Technology® (CPT®): A code set maintained by the American Medical Association that describes medical, surgical, and diagnostic services; it ensures the information communicated about these services is aligned among all medical professionals.[25]

Deductible: The fixed amount of money a patient is required to pay according to their insurer before benefits become payable.[25]

Denial: When your health insurance company notifies you that it will not cover the cost of your medication or treatment.[29]

Fee-for-Service: When the physician is paid the full rate of charge for the service performed for a patient without any insurance arrangement.[25]

Government-Funded Health Insurance: Health insurance benefits provided through programs funded by each state or the federal government, such as Medicare, Medicaid, TRICARE®, or the DoD/VA.[30]

CMS-1500: The claim form developed by the Centers for Medicare & Medicaid for use by healthcare professionals and suppliers.[31]

HCPCS: The Health Care Financing Administration Procedural Coding System, which uses 5-digit codes to list services, procedures, and supplies ordered by physicians and other providers.[25]

ICD-10-CM: The *International Classification of Diseases, Tenth Revision, Clinical Modification* is a standardized system used to code diseases and medical conditions.[32]

Please see Important Safety Information on pages 50-53 and full Prescribing Information, including **Boxed Warning**.

GLOSSARY OF COMMON HEALTH INSURANCE TERMS (cont'd)

In-Network: Providers or healthcare facilities that have negotiated a discount within a health plan's network. Patients who are insured will pay less when using a provider or facility under their plan's network.[33]

Medicaid: State programs that assist people whose income is insufficient to pay for healthcare, regardless of age.[25]

Medical Exception: A request to use a drug even though the drug is not covered by the health plan.[34]

Medical Policy: Determines whether a procedure, drug, or device is considered experimental/investigational, cosmetic, or medically necessary.[35]

Medically Necessary: Services or supplies used to identify and treat a patient's condition, which have been determined to be consistent with the symptoms, diagnosis, and treatment of that condition and are considered standard practice.[25]

Medicare: A national health insurance program operated by the Centers for Medicare & Medicaid Services that provides health insurance primarily to patients aged 65 years and older.[25]

Modifier: Additional information given during CPT® coding that describes more details about a procedure and may be critical to a claim with the patient's insurance.[36]

OOP Maximum Limit: An annual limitation on all cost-sharing for which patients are responsible under a health insurance plan. This limit does not apply to premiums, balance-billed charges from out-of-network healthcare providers, or services that are not covered by the plan.[25]

Out-of-Pocket Costs: The portion of costs for covered health services that the patient is required to pay, including copayments, coinsurance, and deductibles.[25]

Out-of-Network: A healthcare provider that is not contracted with a patient's insurer. If a patient uses an out-of-network provider, he or she may be responsible for all of the costs and/or their cost-sharing requirements will increase.[25]

Payer: An entity that reimburses or pays for the cost of healthcare services. Examples of payers include commercial or government-funded health plans, self-insured employers, and uninsured patients.[37]

Precertification: Process of reviewing claims for hospital admission before the patient arrives in order to eliminate unnecessary costs due to a denial.[25]

Premium: A set amount paid to a health plan for providing healthcare coverage under a contract.[25]

Prior Authorization: A process used by health plans that requires prescribers to receive preapproval before a patient can qualify for drug coverage or request an exception.[25]

Referral: When a patient is sent from one healthcare provider to another for additional services. Health plans may require a referral for specialty services.[25]

Specialty Pharmacy: A pharmacy for drugs that cannot be stocked in retail pharmacies, most often injections and infusions, due to storage and shipping requirements, or the need for additional support required by healthcare professionals.[25]

Step Therapy: When a patient is required to start treatment for their condition using the most cost-effective and safe drug before they can continue stepping up though a sequence of alternative therapies.[25]

Summary of Benefits (or Explanation of Benefits): A document that allows patients to compare the costs and coverage between different health plans.[38]

UB-04: Also known as CMS-1450, the standard claim form used to bill Medicare Administrative Contractors, as well as various government and private insurers.[39]

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