



# **Part B Prior Authorization Guidelines**

# Immune Modulator Drugs Tysabri (natalizumab) J2323 Prior Authorization Request

Prior Authorization Request Medicare Part B Form

Instructions: \* Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

□ NEW START - Start Date:				Continuation (within 365 days):  Date of last treatment					
	Date Requested								
				Phone / Fax					
MEMBER INFORMATION									
*Name: *ID#: *DOB:									
PRESCRIBER INFORMATION									
*Name:									
*Address:				*Fax:					
DISPENSING PROVIDER / ADMINISTRATION INFORMATION									
*Name: Phone:									
*Address:				Fax:					
PROCEDURE / PRODUCT INFORMATION									
нс	PC Code	Name of Drug ☐ Self-administered	Dos	) (Wt:	kg Ht:	)	Frequency	End Date if known	
					_				
□Chart notes attached. Other important information:									
Diagnosis: ICD10:									
☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug									
CLINICAL INFORMATION									
<ul> <li>□ New Start or Initial Request: (Clinical documentation required for all requests)</li> <li>□ Provider has reviewed the attached "Criteria for Approval" and attests the member meets         ALL required PA criteria.     </li> <li>If not, please provide clinical rationale for formulary exception:</li> </ul>									
<ul> <li>□ Continuation Requests: (Clinical documentation required for all requests)</li> <li>□ Provider has reviewed the attached "Criteria for Continuation" and attests the member meets         ALL required PA Continuation criteria.</li> <li>□ Patient had an adequate response or significant improvement while on this medication.         If not, please provide clinical rationale for continuing this medication:</li> </ul>									
ACKNOWLEDGEMENT									
Request By (Signature Required):Date://									
Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.									



# **Prior Authorization Group – Immune Modulators PA**

## Drug Name(s):

TYSABRI NATALIZUMAB

# Criteria for approval of Prior Authorization Drug:

- 1. Prescribed for an approved FDA diagnosis (as listed below):
- 2. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
- 3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

#### **Exclusion Criteria:**

N/A

#### **Prescriber Restrictions:**

N/A

## **Coverage Duration:**

Approvals will be for 6 months

#### **FDA Indications:**

#### Tysabri

- Crohn's disease (Moderate to Severe)
- Multiple sclerosis, Relapsing forms

## Off-Label Uses:

N/A

#### Age Restrictions:

Safety and efficacy have not been established in pediatric patients

# **Other Clinical Considerations:**

CI: History of or active progressive multifocal leukoencephalopathy

#### Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/05156E/ND\_PR/evidencexpert/ND\_P/evidencexpert/DUPLICATIONSHIELDSYNC/9F2484/ND\_PG/evidencexpert/ND\_B/evidencexpert/ND\_AppProduct/evidencexpert/ND\_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Natalizumab&UserSearchTerm=Natalizumab&SearchFilter=filterNone&navitem=searchGlobal#

https://careweb.careguidelines.com/ed24/ac/ac04 085.htm