HIGHMARK HEALTH OPTIONS

Updated: 06/2022
DMMA Approved: 07/2022

Request for Prior Authorization for Tysabri (natalizumab)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for **Tysabri (natalizumab)** require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Tysabri (natalizumab) Prior Authorization Criteria:

For all requests for Tysabri (natalizumab) all of the following criteria must be met:

- Member must be 18 years of age or older
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

Coverage may be provided with a diagnosis of relapsing forms of multiple sclerosis (e.g. relapsing-remitting, secondary-progressive, or clinically isolated syndrome) and the following criteria are met:

- The drug is given as monotherapy and not in combination with other therapies approved for the treatment of MS
- Must be prescribed by, or in consultation with, a neurologist or a physician that specializes in the treatment of MS
- Patients initiating therapy for the first time must have at least one clinical relapse documented (e.g., functional disability, hospitalization, acute steroid therapy, etc.) during the prior year
- Must meet one of the following:
    - Member is initiating therapy and has an aggressive initial course of disease defined as any of the following:
        - Member has ≥ 9 T2 lesions
        - Member has ≥ 2 relapses a year
        - Member has ≥ 1 Gd+ lesion
    - Therapeutic failure or an inadequate response to two or more preferred medications (prior authorization may be required) indicated for the treatment of MS
- Member must have documented Expanded Disability Status Scale (EDSS) score of 5.0 or lower
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Documentation of a clinical response defined as:
        - No increase in their Expanded Disability Status Scale (EDSS) score
        - No relapse rate increase or >1 relapse per year after at least 6 months of treatment
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided with a diagnosis of moderate to severe Crohn's disease and the following criteria are met:

- Must be prescribed by, or in consultation with, a gastroenterologist

- Documentation of C-reactive protein >2.87 mg/L (evidence of inflammation) and baseline Crohn's Disease Activity Index ≥220 (moderate to severe disease)
- Must meet one of the following:
    - Will also be used for concomitant multiple sclerosis
    - Must have an inadequate response or intolerance/contraindication to at least 2 medications from each of the following classes:
        - Corticosteroids
        - Immunomodulators
        - TNF-α inhibitors
- **Initial Duration of Approval:** 12 weeks
- **Reauthorization criteria**
    - Documentation of a clinical response (decrease in CDAI from baseline)
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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TYSABRI (NATALIZUMAB) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Mon-Fri 8:00am to 7:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No		

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____
Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: _____

For Multiple Sclerosis only:
Please provide the member's baseline Expanded Disability Status Scale (EDSS) score: _____ Date: _____
If this is the first time the member is initiating therapy, have they had at least one clinical relapse documented during the prior year? ☐ Yes ☐ No
If yes, please check any of the applicable boxes:
☐ Member has ≥ 9 T2 lesions ☐ Member has ≥ 2 relapses a year ☐ Member has ≥ 1 Gd+ lesion

For Crohn's disease only:
Will Tysabri also be used for concomitant multiple sclerosis? ☐ Yes ☐ No
Please provide the member's baseline C-reactive protein level: _____ Date: _____
Please provide the member's baseline Crohn's Disease Activity Index (CDAI) score: _____ Date: _____

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why / Current)

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TYSABRI (NATALIZUMAB)
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

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If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REAUTHORIZATION CRITERIA

For Multiple Sclerosis only:
Please provide the member's current Expanded Disability Status Scale (EDSS) score: _____ Date: _____
Has the member experienced an increase in relapse rate or had >1 relapse per year? ☐ Yes ☐ No

For Crohn's disease only:
Please provide the member's current C-reactive protein level: _____ Date: _____
Please provide the member's current Crohn's Disease Activity Index (CDAI) score: _____ Date: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date