



Updated: 07/2024
Approved: 07/2024

Request for Prior Authorization for Natalizumab
Website Form – www.wv.highmarkhealthoptions.com
Submit request via: Fax - 1-833-547-2030.

All requests for Natalizumab require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Natalizumab Prior Authorization Criteria:

For all requests for 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
- Prescribed the requested medication by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of Crohn's disease)
- Does not have a contraindication to the requested medication
- Is not receiving chronic immunosuppressant or immunomodulator therapy

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
- 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
- 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:

- Documentation of C-reactive protein >2.87 mg/L (evidence of inflammation) and baseline Crohn's Disease Activity Index (CDAI) \geq 220 (moderate to severe disease)
- Must meet one of the following:
 - Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids OR
 - One of the following:
 - (i) Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines²

- (ii) Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines²
- Has a diagnosis of Crohn's disease that is associated with one or more high-risk or poor prognostic features³
- Must meet one of the following:
 - (i) Has a history of therapeutic failure of at least 1 tumor necrosis factor (TNF) inhibitor indicated or medically accepted for the treatment of Crohn's disease
 - (ii) Has a contraindication or an intolerance to the TNF inhibitors indicated or medically accepted for the treatment of Crohn's disease
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
 - Documentation of a clinical response such as a 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.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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: (833)-547-2030.**

If needed, you may call to speak to a Pharmacy Services Representative. **PHONE: 1-844-325-6251 Mon – Fri 8 am to 7 pm**

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? <input type="checkbox"/> Yes <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No		

Billing Information

This medication will be billed: <input type="checkbox"/> at a pharmacy OR <input type="checkbox"/> medically, JCODE:	
Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's office <input type="checkbox"/> Member's home <input type="checkbox"/> Other	

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:
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For relapsing forms of multiple sclerosis

Is the member receiving chronic immunosuppressant or immunomodulator therapy? Yes No

Will this be given as monotherapy? Yes No

Is the member initiating therapy for the first time? Yes No

Has the member had at least one clinical relapse? Yes No

What is the member's Expanded Disability Status Scale (EDSS) score? _____

For moderate to severe Crohn's disease

What is the members C-reactive protein level? _____

What is the member's baseline Crohn's Disease Activity Index? _____

Mark all that apply to the member:

- Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids
- Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines²
- Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines
- Has a diagnosis of Crohn's disease that is associated with one or more high-risk or poor prognostic features
- Has a history of therapeutic failure of at least 1 tumor necrosis factor (TNF) inhibitor indicated or medically accepted for the treatment of Crohn's disease
- Has a contraindication or an intolerance to the TNF inhibitors indicated or medically accepted for the treatment of Crohn's disease

CURRENT or PREVIOUS THERAPY

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

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PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

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MEMBER INFORMATION

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

REAUTHORIZATION

For relapsing forms of multiple sclerosis

Has the member experienced a clinical response since starting treatment such as no increase in their EDSS score or no relapse or less than 1 relapse per year? baseline Yes No (please provide documentation).

For moderate to severe Crohn’s disease

Has the member experienced a clinical response such as a decrease in CDAI from baseline Yes No (please provide documentation).

Prescribing Provider Signature

Date

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