HIGHMARK HEALTH OPTIONS

Updated: 04/2025
Approved: 04/2025

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

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

Natalizumab and Natalizumab Biosimilar Prior Authorization Criteria:

For all requests for Natalizumab and Natalizumab biosimilar 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 natalizumab or natalizumab biosimilar 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 at least one of the following:
        - 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) ≥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 guidelines[2]
    - (ii) Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines[2]
    - Has a diagnosis of Crohn's disease that is associated with one or more high-risk or poor prognostic features[3]
- 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.

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NATALIZUMAB AND NATALIZUMAB BIOSIMILAR 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? ☐ 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:	ICD Code:

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 guidelines[2]
☐ 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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NATALIZUMAB AND NATALIZUMAB BIOSIMILAR
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

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.**
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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