Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

I. Requirements for Prior Authorization of Natalizumab

A. Prescriptions That Require Prior Authorization

All prescriptions for a natalizumab product must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a natalizumab product, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the requested drug for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed the requested drug 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); **AND**

5. Does not have a contraindication to the requested drug; **AND**

6. Is not receiving chronic immunosuppressant or immunomodulator therapy; **AND**

7. For treatment of Crohn's disease, **both** of the following:

    a. **One** of the following:

        i. For a diagnosis of moderate to severe Crohn's disease, **one** of the following:

            a) Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids

            b) **One** of the following:

                (i) Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines[1]
                (ii) Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines,[1]

[1] e.g., American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], Canadian Association of Gastroenterology [CAG], European Crohn's and Colitis Organization [ECCO]

ii. Has a diagnosis of Crohn's disease that is associated with one or more high-risk or poor prognostic feature(s),[2]

iii. **Both** of the following:

a) Has achieved remission with the requested drug
b) Will be using the requested drug as maintenance therapy to maintain remission

b. **One** of the following:

i. **All** of the following:

a) **One** of the following:

(i) Has a history of therapeutic failure of at least one 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,

b) Has a history of therapeutic failure of or a contraindication or an intolerance to ustekinumab,

c) Has a history of therapeutic failure of or a contraindication or an intolerance to vedolizumab

ii. Has a current history (within the past 90 days) of being prescribed a natalizumab product;

AND

8. For a non-preferred natalizumab product, **one** of the following:

a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred natalizumab product(s) approved or medically accepted for the beneficiary's diagnosis
b. Has a current history (within the past 90 days) of being prescribed the same non-preferred natalizumab product (does not apply to non-preferred brands when the interchangeable biosimilar or unbranded biologic is preferred or to non-preferred interchangeable biosimilars or unbranded biologics when the therapeutically equivalent interchangeable brand or brand biologic is preferred).

See the Preferred Drug List (PDL) for the list of preferred natalizumab products at: https://papdl.com/preferred-drug-list;

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

[2] Examples of high-risk or poor prognostic features in patients with Crohn's disease include: initial diagnosis or clinical evidence supports the onset of symptoms at <30 years of age, extensive anatomic involvement, presence of fistula, perianal and/or severe rectal disease, large or deep mucosal lesions on endoscopy or imaging, prior surgical resection, stricturing and/or penetrating behavior, need for steroid therapy at initial diagnosis, extra-intestinal manifestations, and laboratory markers such as low hemoglobin, low albumin, high C-reactive protein, and high fecal calprotectin levels (AGA 2014; ECCO 2017; CAG 2019; AGA 2021).

FOR RENEWALS OF PRIOR AUTHORIZATION FOR A NATALIZUMAB PRODUCT: The determination of medical necessity of a request for renewal of a prior authorization for a natalizumab product that was previously approved will take into account whether the beneficiary:

1. For a diagnosis of multiple sclerosis, has documented improvement or stabilization of the multiple sclerosis disease course; **AND**

2. For a diagnosis of Crohn's disease, **both** of the following:

   a. **One** of the following:

      i. Has documentation of therapeutic benefit within three months of starting therapy
      ii. Was able to discontinue concomitant corticosteroid use within six months of starting therapy

   b. Did not require additional steroid use for disease control for more than three months in a calendar year;

   AND

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed the requested drug 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); **AND**

5. For a non-preferred natalizumab product with a therapeutically equivalent interchangeable biosimilar or brand or unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent interchangeable biosimilar or brand or unbranded biologic that would not be expected to occur with the requested drug.

   See the PDL for the list of preferred natalizumab products at: https://papdl.com/preferred-drug-list;

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a natalizumab product. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior

authorization will be approved when, in the professional judgment of the physician reviewer, the service is medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of a natalizumab product will be approved as follows:

1. For a diagnosis of multiple sclerosis:

    a. Initial requests will be approved for up to six months.
    b. Renewal requests will be approved for up to 12 months.

2. For a diagnosis of Crohn's disease:

    a. If the beneficiary is not taking chronic oral corticosteroids when starting the requested drug, initial requests will be approved for up to three months.
    b. If the beneficiary is taking chronic oral corticosteroids when starting the requested drug, initial requests will be approved for up to six months to allow tapering of the corticosteroids.
    c. Renewal requests will be approved for up to 12 months.

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NATALIZUMAB PRIOR AUTHORIZATION FORM *(form effective 1/8/2024)*

☐New request ☐Renewal request	total pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	Quantity: _____ vials	Refills:
Directions: ☐300 mg SQ every 4 weeks	☐other: _____		
Diagnosis *(submit documentation)*:		Dx code *(required)*:	
Is the beneficiary currently being treated with the requested medication?	☐Yes – date of last dose: _____ *Submit documentation.* ☐No		
Is natalizumab prescribed by or in consultation with a neurologist or gastroenterologist?	☐Yes ☐No	*Submit documentation of consultation if applicable.*	
Is the beneficiary receiving chronic immunosuppressive or immune modulating therapies?	☐Yes ☐No	*Submit complete medication list.*	

Complete all sections that apply to the beneficiary and this request. *Check all that apply and submit documentation for each item.*

INITIAL requests

1. For treatment of MULTIPLE SCLEROSIS (MS):
- ☐Has a relapsing form of MS

2. For treatment of CROHN'S DISEASE (CD):
- ☐Has moderate-to-severe CD AND:
  - ☐Tried and failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids
  - ☐Tried and failed to maintain remission with or has a contraindication or an intolerance to conventional immunomodulators (eg, AZA, 6-MP, MTX)
- ☐Has CD that is associated with high-risk or poor prognostic features
- ☐Has achieved remission with the requested medication AND:
  - ☐Will be using the requested medication as maintenance therapy to maintain remission
- ☐Tried and failed a TNF-inhibitor (e.g., Cimzia, Humira, Remicade) or has a contraindication or an intolerance to TNF-inhibitors
- ☐Tried and failed or has a contraindication or an intolerance to ustekinumab (Stelara)
- ☐Tried and failed or has a contraindication or intolerance to vedolizumab (Entyvio)

3. For a NON-PREFERRED natalizumab product:
- ☐Has a history of trial and failure of or a contraindication or an intolerance to the preferred natalizumab product(s) approved or medically accepted for the beneficiary's diagnosis

RENEWAL requests

1. For treatment of MULTIPLE SCLEROSIS (MS):
- ☐Experienced improvement or stabilization of the MS disease course since starting natalizumab

2. For treatment of CROHN'S DISEASE:
- ☐Experienced therapeutic benefit within 3 months of starting natalizumab
- ☐Was able to discontinue concomitant steroid use within 6 months of starting natalizumab (if applicable)
- ☐**Has been using natalizumab for at least 1 year AND:**
  - ☐Has not required additional steroid use for disease control for more than 3 months in the past 12 months

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	**Date**: