Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

I. Requirements for Prior Authorization of Tysabri (natalizumab)

A. Prescriptions That Require Prior Authorization

All prescriptions for Tysabri (natalizumab) must be prior authorized.

B. Review of Documentation for Medical Necessity

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

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

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

[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).

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

iii. **Both** of the following:
a) Has achieved remission with Tysabri (natalizumab)
b) Will be using Tysabri (natalizumab) 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 1 tumor necrosis factor (TNF) inhibitor indicated or medically accepted for the treatment of Crohn's disease
(ii) Has a history of 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 Tysabri (natalizumab);

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.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR TYSABRI (NATALIZUMAB): The determination of medical necessity of a request for renewal of a prior authorization for Tysabri (natalizumab) 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 3 months of starting therapy
ii. Was able to discontinue concomitant corticosteroid use within 6 months of starting therapy
b. Did not require additional steroid use for disease control for more than 3 months in a calendar year;

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.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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 Tysabri (natalizumab). 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 Tysabri (natalizumab) will be approved as follows:

1. For a diagnosis of multiple sclerosis:
   a. Initial requests will be approved for up to 6 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 Tysabri (natalizumab), initial requests will be approved for up to 3 months.
   b. If the beneficiary is taking chronic oral corticosteroids when starting Tysabri (natalizumab), initial requests will be approved for up to 6 months to allow tapering of the corticosteroids.
   c. Renewal requests will be approved for up to 12 months.

Gateway Health℠

It's Wholecare

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

TYSABRI (natalizumab) PRIOR AUTHORIZATION FORM

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

CLINICAL INFORMATION

Drug requested:	☐Tysabri (natalizumab) 300 mg/15 ml	Quantity: _____ vials	Refills:
Directions:	☐300 mg SQ every 4 weeks	☐other: _____	
Diagnosis *(submit documentation)*:			Dx code *(required)*:
Is the beneficiary currently being treated with Tysabri?	☐Yes – date of last dose: _____ *Submit documentation.* ☐No		
Is Tysabri being 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.*	

INITIAL requests

Check all of the following that apply to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐Is being treated for multiple sclerosis
- ☐Has a relapsing form of MS

☐Is being treated for Crohn's disease
- ☐Has moderate-to-severe disease
- ☐Has disease that is associated with high-risk or poor prognostic features
- ☐Failed to achieve remission with an induction course of corticosteroids
- ☐Has a contraindication or intolerance to an induction course of corticosteroids
- ☐Failed to maintain remission with an immunomodulator (e.g., AZA, 6-MP, MTX)
- ☐Has a contraindication or intolerance to immunomodulators (e.g., AZA, 6-MP, MTX)
- ☐Tried and failed or has a contraindication or intolerance to a TNF-inhibitor (e.g., Cimzia, Humira, Remicade)
- ☐Tried and failed or has a contraindication or intolerance to ustekinumab (Stelara)
- ☐Tried and failed or has a contraindication or intolerance to vedolizumab (Entyvio)

RENEWAL requests

Check all of the following that apply to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐For a diagnosis of multiple sclerosis, experienced improvement or stabilization of the MS disease course since starting Tysabri

☐For a diagnosis of Crohn's disease:
- ☐Experienced therapeutic benefit within 3 months of starting Tysabri
- ☐Was able to discontinue concomitant steroid use within 6 months of starting Tysabri (if applicable)
- ☐Has not required concomitant steroid use for disease control for more than 3 months in the past 12 months (if >1 year since starting Tysabri)

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date: