Updated: 04/2019
PARP Approved: 04/2019

Gateway Health
Prior Authorization Criteria
**Tysabri (natalizumab)**

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
- Member must **NOT** have pre-existing hepatic disease or hepatic impairment defined as ALT or AST at least two times the upper limit of normal
- Provider, member, infusion site, and pharmacy must be enrolled in the TOUCH REMS prescribing program
- 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 multiple sclerosis (MS) and the following criteria are met:

- Documentation of a relapsing form of MS
- 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 currently receiving Tysabri
    - Member is initiating therapy and had therapeutic failure or an inadequate response to two or more formulary medications (prior authorization may be required) indicated for the treatment of MS
    - 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
- Coverage provided for situations in which there is functional status that can be preserved. Member must still either be able to walk at least a few steps or alternatively must have some functional arm/hand use consistent with performing activities of daily living
- **Initial Duration of Approval:** 6 months

- **Reauthorization criteria**
  - Documentation of a clinical response defined as:
    - Member continues to receive benefit from treatment by having the ability to walk at least a few steps or alternatively have some functional arm/hand use consistent with performing activities of daily living
    - No relapse rate increase or >1 relapse per year after at least 6 months of treatment
  - No evidence of liver impairment indicated by jaundice or ALT or AST at least two times the upper limit of normal
  - Continued enrollment and submission of requested patient data to TOUCH REMS Prescribing Program
- **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 have an inadequate response or intolerance/contraindication to at least 2 medications from each of the following classes:
  - Aminosalicylates
  - Immunomodulators
  - TNF-α inhibitors
- **Initial Duration of Approval:** 12 weeks
- **Reauthorization criteria**
  - Documentation of a clinical response (decrease in CDAI from baseline)
  - No evidence of liver impairment indicated by jaundice or ALT or AST at least two times the upper limit of normal
  - Continued enrollment and submission of requested patient data to TOUCH REMS Prescribing Program
- **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.

Gateway Health

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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 Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
**PHONE**: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

## PROVIDER INFORMATION

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

## MEMBER INFORMATION

| | |
|---|---|
| Member Name: | DOB: |
| Gateway ID: | Member weight: _____pounds or _____kg |

## REQUESTED DRUG INFORMATION

| | |
|---|---|
| Medication: | Strength: |
| Frequency: | Duration: |
| Is the member currently receiving requested medication? ☐ Yes ☐ No | Date Medication Initiated: |

## Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a 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:** _____
Is the prescriber, member, infusion center, and pharmacy enrolled in the TOUCH REMs program? ☐ Yes ☐ No

**For Multiple Sclerosis only**:
Is the member able to walk at least a few steps or have some functional arm/hand use consistent with performing activities of daily living? ☐ Yes ☐ No
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:**
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: _____

## LABORATORY VALUES

| Lab | Initial (Pre-Treatment) Level | Reference Range | Date | Post-Therapy Level (Reauthorization only) | Reference Range | Date |
|---|---|---|---|---|---|---|
| **Aspartate Transaminase (AST)** | | | | | | |
| **Alanine Transaminase (ALT)** | | | | | | |

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**TYSABRI (NATALIZUMAB)**
**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 Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
**PHONE**: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

**MEMBER INFORMATION**

| | |
|---|---|
| Member Name: | DOB: |
| Gateway ID: | Member weight: _____pounds or _____kg |

**CURRENT or PREVIOUS THERAPY**

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

**REAUTHORIZATION**

Has the member's current clinical information been submitted to the TOUCH REMs program? ☐ Yes ☐ No
Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe:_____

**For Multiple Sclerosis only**:
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**

| |
|---|
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| |
| |
| |

| Prescribing Provider Signature | Date |
|---|---|
| | |