SUBJECT: Natalizumab (Tysabri)  
INDEX TITLE: Clinical Pharmacy Services  
ORIGINAL DATE: 12/29/2006

This policy applies to the following lines of business:  (Check those that apply.)

<table>
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<th>Commercial:</th>
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<td>Self-funded/ASO ( )</td>
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<td>Voluntary ( )</td>
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I. **POLICY**

It is the policy of UPMC Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Natalizumab (Tysabri) is subject to the prior authorization process.

II. **DEFINITIONS**

**TOUCH- Tysabri Outreach Unified: Commitment to Health.** TOUCH is a restricted distribution program focused on safety and developed with the help of the Food and Drug Administration (FDA). Only prescribers and patients enrolled in the TOUCH prescribing program can prescribe and receive Natalizumab (Tysabri) and only certain pharmacies and infusion sites authorized by the TOUCH prescribing program can dispense and infuse Natalizumab (Tysabri).

III. **PURPOSE**

The purpose of this policy is to define the Prior Authorization Process for Natalizumab (Tysabri).
IV. **SCOPE**

This policy applies to the Pharmacy Services Department.

V. **PROCEDURE**

Natalizumab is indicated as monotherapy for the treatment of members with relapsing forms of multiple sclerosis to delay the accumulation of physical disability and reduce frequency of clinical exacerbations and for inducing and maintaining clinical response and remission in patients with moderately to severely active Crohn’s disease (CD) with evidence of inflammation. Because natalizumab increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability, Natalizumab is recommended for members who have had an inadequate response to, or unable to tolerate, alternative multiple sclerosis therapies and conventional CD therapies including Tumor Necrosis Factor (TNF) alpha inhibitors. An MRI scan should be obtained prior to initiating therapy with Tysabri, as this will be helpful in differentiating subsequent multiple sclerosis symptoms from PML. Clinically significant liver injury has also been reported in patients treated with Natalizumab and should be discontinued in patients with jaundice or other evidence of significant liver injury (e.g., laboratory evidence).

**Initial Authorization Criteria:**

A. **Multiple Sclerosis**
   - Natalizumab must be prescribed by a neurologist who is registered with the TOUCH™ Prescribing program
   - Member must have a diagnosis of relapsing forms of multiple sclerosis
   - Member must be greater than 18 years of age
     - i. CHIP members eligible from age 18 to age 19.
   - Member must have previously had an inadequate response or intolerance to one of the other multiple sclerosis therapies, including interferon beta-1a, interferon beta-1b, and glatiramer acetate
   - Member must currently not have or have a history of progressive multifocal leukoencephalopathy (PML)
   - Member should not be receiving chronic immunosuppressant or immunomodulatory therapy (including interferon beta-1a, interferon beta-1b, or glatiramer acetate), or have systemic medical conditions resulting in significant compromised immune system function.
   - Dose: 300 mg IV infusion every four weeks

Initial Authorization
   - The medication will be approved based upon the above criteria for an initial period of one year
B. Crohn’s Disease

- Natalizumab must be prescribed by a gastroenterologist who is registered with the TOUCH™ Prescribing program
- Member must have a diagnosis of moderately to severely active Crohn’s disease with inflammation
- Member must be greater than 18 years of age
  - CHIP members eligible from age 18 to age 19.
- Member must have previously tried conventional therapies such as aminosalicylates (i.e., sulfasalazine, mesalamine), corticosteroids or immunomodulators (i.e., azathioprine, 6-mercaptopurine) for at least 3-6 months or had an inadequate response or intolerance to conventional therapies AND
- Member must have previously tried TNF-alpha inhibitors for at least 3-6 months or had an inadequate response or cannot tolerate TNF-alpha inhibitors
- Member must not currently have or have a history of progressive multifocal leukoencephalopathy (PML)
- Member should not be receiving chronic immunosuppressant or immunomodulatory therapy (including 6-mercaptopurine, azathioprine, cyclosporine, methotrexate, or inhibitors of TNF-alpha) or have systemic medical conditions resulting in significant compromised immune system function.
- Dose: 300 mg IV infusion every four weeks

Initial Authorization

- The medication will be approved based upon the above criteria for an initial period of 3 months if the patient is not on chronic oral corticosteroids while starting Natalizumab and 6 months if patient is on chronic oral corticosteroids while starting Natalizumab.

Reauthorization Criteria:

- **Multiple Sclerosis:** Authorization will be extended at one-year intervals based upon chart documentation from the provider that the member’s disease has improved based upon the prescriber’s assessment while on therapy.
- **Crohn’s Disease:** For patients with CD that start Natalizumab while not on chronic oral corticosteroids, authorization will be extended at one-year intervals based upon chart documentation from the provider that the member’s disease has improved based upon the prescriber’s assessment while on therapy. For patients with CD that start Natalizumab while on chronic oral corticosteroids, authorization will be extended at one-year intervals if the patient is tapered off oral corticosteroids within six months of starting Natalizumab.
Limitation:
If the established criteria are not met, the prior authorization request will be referred to the UPMC Health Plan Medical Director.

VI. BIBLIOGRAPHY