Tysabri® (natalizumab)

Effective: 9/1/15

Clinical documentation and prior authorization required ✓ Type of review – case management

Not covered Type of review – clinical review
Fax: 617-673-0988 ✓

Pharmacy (RX) or medical (MED) benefit MED / RX Department to review RxUM

OVERVIEW

FDA-APPROVED INDICATIONS

Multiple Sclerosis
Tysabri (natalizumab) is indicated as monotherapy for the treatment of patients with relapsing forms of multiple sclerosis. Tysabri increases the risk of progressive multifocal leukoencephalopathy (PML). When initiating and continuing treatment with Tysabri, physicians should consider whether the expected benefit of Tysabri is sufficient to offset this risk.

Crohn’s Disease
Tysabri is indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn’s disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-α. Tysabri should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF-α.

Tysabri (natalizumab) is a recombinant humanized IgG4κ monoclonal antibody produced in murine myeloma cells. Tysabri binds to the α4β1 and α4β7 integrins expressed on the surface of all leukocytes except neutrophils, and inhibits the α4-mediated adhesion of leukocytes to their counter-receptor(s). The receptors for the α4 family of integrins include vascular cell adhesion molecule-1 (VCAM-1), which is expressed on activated vascular endothelium, and mucosal addressin cell adhesion molecule-1 (MadCAM-1) present on vascular endothelial cells of the gastrointestinal tract. Disruption of these molecular interactions prevents transmigration of leukocytes across the endothelium into inflamed parenchymal tissue. The clinical effect of natalizumab in multiple sclerosis may be secondary to blockade of the molecular interaction of α4β1-integrin expressed by inflammatory cells with VCAM-1 on vascular endothelial cells, and with CS-1 and/or osteopontin expressed by parenchymal cells in the brain.

Because of the risk of PML, Tysabri is available only through a special restricted distribution program called the TOUCH™ Prescribing Program. Under the TOUCH Prescribing Program, only prescribers, infusion centers, and pharmacies associated with infusion centers registered with the program are able to prescribe, distribute, or infuse the product. In addition, Tysabri must be administered only to patients who are enrolled in and meet all the conditions of the TOUCH Prescribing Program.

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan – Network Health may authorize coverage of Tysabri (natalizumab) for members when all the following criteria for a particular regimen are met and limitations do not apply:

For Multiple Sclerosis

1. The Member must have a definitive diagnosis of relapsing multiple sclerosis AND
2. The medication must be prescribed by a neurologist with expertise in treating Multiple Sclerosis AND
3. The Member has a documented inadequate response, contraindication, or inability to tolerate an appropriate trial with at least two of the following agents:
   • Aubagio® (teriflunomide)
   • Avonex® (interferon β-1a)
   • Betaseron® (interferon β-1b)
   • Copaxone® (glatiramer acetate)
   • Extavia® (interferon β-1b)
   • Gilenya® (fingolimod)
   • Lentrada™ (alemtuzumab)
   • Plegidyl® (peginterferon β-1a)
   • RebiS® (interferon β-1a)
   • Tecfidera® (dimethyl fumarate)
**For Crohn’s Disease**

1. The Member **must** have a definitive diagnosis of Crohn’s disease by a gastroenterologist AND
2. The Member has demonstrated an inadequate response or contraindication to an appropriate trial with two or more of the following agents:
   - Corticosteroids (e.g., prednisone, prednisolone, methylprednisolone).
   - 5-Aminosalicylates (e.g., sulfasalazine, Azulfidine®, Delzicol™, Pentasa®, Rowasa®, Dipentum®, Colazal®).
   - 6-mercaptopurine (6-MP, Purinethol*) and/or azathioprine (Imuran*).
   - Methotrexate (MTX) AND
3. The Member has demonstrated an inadequate response or contraindication to an appropriate trial with at least one of the following TNF-inhibitors:
   - Cimzia® (certolizumab pegol)
   - Humira® (adalimumab)
   - Remicade® (infliximab)

**LIMITATIONS**

1. Initial authorization will be limited to 6 months. Subsequent authorization may be given in 12-month intervals based on submission of current progress notes from the physician documenting efficacy and documentation of a negative John Cunningham (JC) virus test on subsequent requests at 12 months.
2. Tufts Health Plan – Network Health will not approve Tysabri when used in conjunction with other medications for the treatment of progressive multiple sclerosis.
3. Tufts Health Plan – Network Health will not approve Tysabri when used in conjunction with other medications (including immunosuppressants) for the treatment of Crohn’s disease.
4. Duration of coverage authorization is subject to the specific criteria stated within the Pharmacy Coverage Guidelines.

**CODES**

The following HCPCS/CPT code(s) are:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J2323</td>
<td>Injection, natalizumab, 1 mg</td>
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**REFERENCES**


**APPROVAL HISTORY**
- July 20, 2006: Reviewed by the Pharmacy and Therapeutics Committee.
- August 12, 2014: Reviewed by the Pharmacy and Therapeutics Committee.
- August 11, 2015: Added Lemtrada and Plegridy as prerequisite options for multiple sclerosis.

**BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION**
Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.