**Tysabri® (natalizumab)**

| Pharmacy Benefit | N/A | Setting | Provider administered intravenous | Medical Benefit | Advantage, HMO, PPO/CDHP | Approval period | Initial approval: 3 months Continued approval: 6 months | CPT/HCPCS code | J2323 | Available through Tysabri Outreach Unified Commitment to Health (TOUCH™) registered providers and infusion centers |

Tysabri® (natalizumab) is approved as monotherapy for the treatment of relapsing forms of multiple sclerosis (MS) and for moderate to severely active Crohn’s disease. The specific mechanisms by which natalizumab exerts its effects in multiple sclerosis and Crohn’s disease have not been fully defined. Adverse effects include headache, fatigue, infusion related reactions, arthralgia, urinary tract infection, and upper and lower respiratory tract infections.

**Recommended authorization criteria**

Natalizumab should be prescribed by, or in conjunction with, a neurologist (for MS) or a gastroenterologist (for Crohn’s disease).

**FDA-Approved Indications**

1. **Adults with a relapsing form of MS.** Approve in patients who meet all of the following criteria (a AND b AND c):
   a. The patient is ≥ 18 years of age; AND
   b. The patient has a relapsing form of MS AND
   c. The patient has had an inadequate response to, or is unable to tolerate therapy with at least two of the following medications for MS: interferon beta-1a, interferon beta-1b, glatiramer, teriflunomide, fingolimod, OR dimethyl fumarate

2. **Adults with Crohn’s disease.** Approve in patients who meet the following criteria (a, b, c, AND d):
   a. The patient is ≥ 18 years of age; AND
   b. Patient has moderately to severely active Crohn’s disease with an elevated C-reactive protein AND
   c. Patient has failed or was intolerant to at least two of the following for Crohn’s disease: adalimumab, certolizumab pegol, or infliximab for at least 2 months each and had an inadequate response or was intolerant to the TNF antagonist

Continued approval requires evidence of clinical benefit (decrease in the number of relapses or flares or corticosteroids required).
Exclusions (Limitations)

1. Patients who have or have had progressive multifocal leukoencephalopathy.
2. Concurrent use with other disease-modifying agents used for MS.
3. Patients with primary progressive MS.
4. Concurrent use with immunosuppressant agents in those with Crohn’s disease.
5. Children with MS or Crohn’s disease.
6. Ulcerative colitis.
7. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Endorsed: 5/19/2010
Approved: 8/13/2013
Revised: 7/17/2013
Reviewed: 1/18/2012

References