

Origination Date: 3/07	Revision Date(s): 3/08, 3/09
Developed By: Medical Criteria Committee	

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Approved: Csaba Mera, MD Date: 03/16/09

Description:

Tysabri® is a prescription intravenous (IV) medication that was approved by the FDA for patients with relapsing forms of multiple sclerosis (MS). Recently, approval was granted for patients with moderate to severe Crohn's disease who have had an inadequate response or intolerance to conventional Crohn's disease therapies. Tysabri is proposed to slow the worsening of disability and decrease the number of relapses in MS and aid in easing the symptoms of Crohn's disease. Because of the increased risk of progressive multifocal leukoencephalopathy (PML) with Tysabri® use, it is generally recommended for patients who have been refractory or intolerant to other MS or Crohn's treatments.

Tysabri® is only available through a 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

Criteria:

Tysabri® will be covered to plan limitations for one of the following indication when **all** of the criteria in section I or II are met:

- I. **Multiple Sclerosis**
 - A. The patient has a relapsing form of multiple sclerosis that is no longer responding to first line therapy (i.e. interferons); and
 - B. Tysabri® treatment is being used as monotherapy; and
 - C. The prescribing provider is a neurologist; and
 - D. The patient is enrolled in the TOUCH™ Prescribing Program (1-800-456-2255)

- II. **Crohn's Disease**
 - A. The patient has moderately to severely active Crohn's disease; and
 - B. There is evidence of inflammation; and
 - C. The patient has had an inadequate response or an inability to tolerate at least 2 of the following conventional Crohn's disease therapies:
 - 1. Corticosteroids (i.e. prednisone, prednisolone, methylprednisolone)
 - 2. 5-Aminosalicylates (i.e. Sulfasalazine, Azulfidine, Asacol, Pentasa, Rowasa, Dipentum, Colazal)
 - 3. 6-mercaptopurine (6-MP, Purinethol) and/or arazathioprine (Imuran)
 - 4. Methotrexate (MTX); and
 - D. The patient has had an inadequate response or inability to tolerate inhibitors of TNF-alpha (Humira or Remicade)
 - E. The patient is enrolled in the CD-TOUCH™ Prescribing Program (1-800-456-2255)

*If approved, Tysabri is administered IV every 4 weeks.

- III. **Limitations**
 - A. Tysabri should not be used in combination with immunosuppressants or inhibitors TNF-alpha
 - B. Tysabri is contraindicated for use in patients who have or have had PML

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C. Tysabri is contraindicated in patients who have had a hypersensitivity reaction to Tysabri

Information to be Submitted with Pre-Authorization Request:

1. Medical records from treating physician
2. Documentation showing previous MS or Crohn's therapy tried
3. Confirmation that Patient/Provider is enrolled in the TOUCH™ Prescribing Program; TOUCH™ Program phone number is 800-456-2255

Applicable CPT/HCPC:

Note: this list may not be all inclusive

J2323	Injection, natalizumab, 1 mg
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References:

- Tysabri product information, 06/2006. Biogen Inc. Elan Pharmaceuticals, Inc.
- MS drug back on market under restricted program. U.S. Food and Drug Administration. FDA Consumer Magazine. July-August 2006
- Virley D. Developing therapeutics for the treatment of multiple sclerosis. NeuroRX: The Journal of the American Society for Experimental NeuroTherapeutics. 2005 Oct. Vol 2,638-649.
- Rudick RA, Stuart WH, Calabresi PA, et al. Natalizumab plus interferon beta-1a for relapsing multiple sclerosis. N Engl J Med. 2006 Mar 2;354(9):911-23
- Yousry T, Habil M, Major E, et al. Evaluation of patients treated with natalizumab for progressive multifocal leukoencephalopathy. N Engl J Med. 2006 Mar 2;354(9):924-933
- FDA News: FDA approves Tysabri to treat moderate-to-severe crohn's disease. January 14, 2008. Available at URL address: <http://www.fda.gov/bbs/topics/news/2008/new01775.html>.
- Targan SR, Feagan BG, Fedorak RN, et al. Natalizumab for the treatment of active Crohn's disease: results of the ENCORE trial. Gastroenterology. 2007 May;132(5):1672-83. Epub 2007 Mar 21.
- Feagan BG, Sanborn WJ, Hass S, et al. Health-related quality of life during natalizumab maintenance therapy for Crohn's disease. Am J Gastroenterol. 2007 Dec;102(12):2737-46.
- MacDonald JK, McDonald JW. Natalizumab for induction of remission in Crohn's disease. Cochrane Database Syst Rev. 2007 Jan 24;(1):CD006097.
- Ghosh S, Goldin E, Gordon FH, et al. Natalizumab for active Crohn's disease. N Engl J Med. 2003 Jan 2;348(1):24-32.
- Facts about Crohn's disease. FDA Consumer Health Information January 15, 2008. Available at URL address: www.fda.gov/consumer/updates/crohnsdisease011508.html
- Physician Advisors