



Guidelines for Medication Use:

Natalizumab (Tysabri®)

Background:

Tysabri is an α_4 -integrin antagonist indicated for the management of relapsing forms of multiple sclerosis. α_4 -integrin is thought to regulate cell and adhesion and migration. By blocking the effects of α_4 -integrin, Tysabri is thought to interfere with the movement of damaging immune cells across the blood-brain barrier.

After initial FDA approval in November 2004, Tysabri marketing was voluntarily suspended in February 2005 after three reports of progressive multifocal leukoencephalopathy (PML), a progressive and potentially fatal demyelinating neurological disease, were discovered. Tysabri re-entered the market in June 2006 after the manufacturer developed a strict monitoring and follow-up program for patients prescribed Tysabri. This program, called the TOUCH program, requires all physicians, pharmacists, and infusion centers that prescribe and dispense Tysabri to be registered in the program. The program provides for required MRI imaging before and for the duration of Tysabri therapy to identify potential cases of PML. Although Tysabri was initially approved for both monotherapy and as an add-on to existing immunomodulating therapies, it is now indicated only as monotherapy.

Administration:

Natalizumab is administered by intravenous infusion over 60 minutes. The recommended dose is 300mg, administered every four weeks.

Criteria for Coverage:

- 1) Tysabri must be prescribed by a neurologist enrolled in the TOUCH program; **AND**
- 2) The candidate for Tysabri must have a diagnosis of relapsing multiple sclerosis and be enrolled in the TOUCH program; **AND**
- 3) The candidate for Tysabri must have a documented treatment failure to a trial of at least six months in duration of glatiramer or a beta interferon product or have a documented intolerance or documentation to these therapies; **AND**
- 4) Tysabri must be used as monotherapy and is not to be used concurrently with other immunomodulating therapies for MS

Duration of Authorization: 6 months.

Prescribers shall be asked to confirm ongoing enrollment in the TOUCH program before coverage is continued.

Special Instructions:

- Tysabri is administered by intravenous infusion. Coverage is under the SummaCare medical benefit when provided in a physician office or ambulatory infusion setting. Tysabri must be administered in an ambulatory infusion that is enrolled in the TOUCH program.
- At the point of Tysabri coverage authorization, any previous coverage authorizations for glatiramer (Copaxone®) or interferon beta (Betaseron®, Avonex®, or Rebif®) should be terminated. Contact the Pharmacy Administration department to confirm termination of any authorizations for these agents.

Approved: January 4, 2007

Medical Director

Pharmacy Director

References:

Biogen Idec Inc. Tysabri Prescribing Information. Cambridge MA: June 5, 2007

Natalizumab (Tysabri) for Relapsing Multiple Sclerosis. Med Lett Drugs Ther. 2005; 1202 (Feb 14):13-14

Natalizumab (Tysabri) Returns. Med Lett Drugs Ther. 2006; 1243 (Sept 11): 76.