



Prior Authorization Approval Criteria *Tysabri (natalizumab)*

Generic name:	natalizumab
Brand name:	Tysabri
Medication class:	Monoclonal antibody that blocks alpha-4 integrin
FDA-approved uses:	Treatment of relapsing forms of multiple sclerosis Treatment of moderately to severely active Crohn's Disease with inadequate response to, or intolerant of, conventional Crohn's therapy and TNF- α inhibitors.
Available dosage forms:	300 mg, 15 ml, single-dose vial for dilution. Tysabri is only available through registered infusion centers participating in the TOUCH™ Prescribing Program
Usual dose:	300 mg by intravenous infusion over one hour once every 4 weeks for both MS and Crohn's
Approximate monthly cost: <i>(based on ASP+6% 1/1/08)</i>	\$2,253
Duration of therapy:	Indefinite

Criteria for use *(bullet points below are all inclusive unless otherwise noted):*

- Clinically diagnosed relapsing forms of multiple sclerosis.
Note: Safety and efficacy in patients with chronic progressive multiple sclerosis have not been established.
 - Must be 18 years of age or older.
 - Failed or intolerant to Copaxone (glatiramer).
 - Failed or intolerant to Avonex (IFN Beta-1a) or Betaseron (IFN Beta-1b).
 - Being used as monotherapy only.
- OR**
- Clinically diagnosed moderately to severely active Crohn's Disease.
 - Failed or intolerant to steroids.
 - Failed or intolerant to Humira.

Criteria for continuation of therapy:

- MS: continued response – decrease in number of, or no, relapses
- CD: continued response or continued remission

Cautions:

- Tysabri increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic virus that usually leads to death or severe disability.
- Tysabri is only available through a special restricted distribution program called the TOUCH™ Prescribing Program and must be administered only to patients enrolled in this program.

- There have been incidents of increased hepatotoxicity and clinically significant liver injury during treatment with Tysabri. Treatment should be discontinued in patients with jaundice or evidence of liver injury. Substantially elevated serum hepatic enzymes and elevated total bilirubin have occurred after multiple doses of Tysabri, but also as early as six days after the first dose.

Contraindications:

- Should not be administered to patients with known hypersensitivity to Tysabri or any of its components.
- Tysabri is contraindicated in patients who have or have had progressive multifocal leukoencephalopathy (PML).

Not approved if:

- Does not meet the above stated criteria.
- Patient has any contraindications to the use of Tysabri.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Revised: 03/12/08
03/14/12

Adopted: 11/12/04