Payment Policy | Natalizumab (Tysabri®) for Multiple Sclerosis and Crohn's Disease

EFFECTIVE DATE: 04/15/2008
POLICY LAST UPDATED: 04/15/2008

OVERVIEW

This payment policy documents the coverage determination for Natalizumab (Tysabri®) for Multiple Sclerosis and Crohn's Disease. Natalizumab (Tysabri®) is a genetically engineered monoclonal antibody that is indicated for use in the treatment of relapsing forms for multiple sclerosis (MS) to reduce the frequency of exacerbations.

PRIOR AUTHORIZATION

Prior authorization is not required.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial products

Natalizumab is a covered infusion therapy drug only available through the CD-TOUCH prescribing program, for relapsing forms of multiple sclerosis and for moderate-to-severe Crohn's disease.

MEDICAL CRITERIA

Not Applicable

BACKGROUND

Natalizumab (Tysabri®) is a genetically engineered monoclonal antibody that is indicated for use in the treatment of relapsing forms for multiple sclerosis (MS) to reduce the frequency of exacerbations. Natalizumab binds to white blood cells and inhibits their migration to the brain and spinal cord, thereby blocking damage to the brain/spinal cord in multiple sclerosis (MS) patients. Natalizumab is FDA approved for use in patients who have relapsing forms of MS. The safety and efficacy of Natalizumab in patients with chronic progressive MS has not been established.

Natalizumab is also FDA approved for treatment of moderate-to-severe Crohn's (inflammatory bowel) disease with evidence of inflammation who have had inadequate response to, or are unable to tolerate, conventional Crohn's disease therapies.

Per manufacturer dosage and administration instructions, 300 mg/15 mL of natalizumab should be administered as an intravenous infusion every 28 days. The infusion administration time is approximately one hour and patients should be observed for one hour after completion of the infusion. The safety and efficacy of natalizumab at doses higher than 300 mg every 28 days has not been adequately evaluated.

Approximately 10% of patients receiving natalizumab will develop anti-natalizumab antibodies; 6% of patients will experience persistent antibody positivity. A sustained anti-natalizumab antibody level is associated with a substantial decrease in the effectiveness of natalizumab. Anti-natalizumab antibodies usually develop by week 12 of treatment. Currently, there is no commercially available test for these antibodies.

Tysabri carries a boxed warning for progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection that affects the brain and can lead to death or severe disability when used in patients with recent or concomitant exposure to immuomodulators or immuosuppressants. Natalizumab must be prescribed by, or

in consultation with, a neurologist. Safety and efficacy of treatment with natalizumab beyond two years is not known.

Prescribing, Distribution, and Administration Program for Tysabri®
Treatment options for individuals with relapsing multiple sclerosis or moderate-to-severe Crohn's disease carry serious risks therefore; Natalizumab is available through a special restricted distribution program called the TOUCH Prescribing Program. Under the CD-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, natalizumab must be administered only to patients who are enrolled in and meet all the conditions of the CD-TOUCH Prescribing Program.[2]

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable Infusion Therapy benefits/coverage.

CODING
Blue CHiP for Medicare and Commercial

Code with appropriate diagnostic, prophylactic, and therapeutic codes

RELATED POLICIES
None

PUBLISHED

Provider Update	Oct 2008
Policy Update	Mar 2005
Policy Update	Jan 2005

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