The Medical Letter®
On Drugs and Therapeutics

Published by The Medical Letter, Inc. • 1000 Main Street, New Rochelle, NY 10801 • A Nonprofit Publication

Volume 48 (Issue 1243)
September 11, 2006

www.medicalletter.org

IN BRIEF

Natalizumab *(Tysabri)* Returns

Soon after The Medical Letter first reviewed use of natalizumab (*Tysabri* –- Biogen Idec and Elan) for treatment of relapsing forms of multiple sclerosis (MS) (Med Lett Drugs Ther 2005; 47:13), the drug was withdrawn from the market. The unpublished clinical trials that led to its approval by the FDA have since been published, and now the drug has been returned to the market with prescribing restrictions.

Natalizumab decreases the number of relapses and new brain lesions in patients with MS. It was withdrawn because progressive multifocal leukoencephalopathy (PML) occurred in 3 (of about 3000) patients being treated with the drug; two were taking the drug in combination with interferon beta for MS, and one was taking it with azathioprine for Crohn's disease. PML is an opportunistic infection of the brain, caused by reactivation of the JC virus in immunosuppressed patients, that often causes death or severe neurological disability. There is no treatment for PML.

The publication of the natalizumab clinical trials in MS provided information on the drug's effect on the progression of disability, which was not available when it was first reviewed here. In one study, combination therapy with natalizumab and interferon beta-1a for 2 years led to an estimated cumulative probability of progression of 23%, compared to 29% with interferon beta-1a alone (RA Rudick et al. N Engl J Med 2006; 354:911). In the second study, the estimated cumulative probability of progression over 2 years was 17% with natalizumab alone and 29% with placebo (CH Polman et al. N Engl J Med 2006; 354:899).