Assessment: the use of natalizumab (Tysabri) for the treatment of multiple sclerosis (an evidence-based review) : report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology

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The clinical and radiologic impact of natalizumab (Tysabri) as therapy for multiple sclerosis (MS) is assessed. On the basis of Class I evidence, natalizumab has been demonstrated to reduce measures of disease activity and to improve measures of disease severity in patients with relapsing-remitting (RR) MS (Level A). The relative efficacy of natalizumab compared to current disease-modifying therapies cannot be defined accurately (Level U). Similarly, the value of natalizumab in the treatment of secondary progressive (SP) MS is unknown (Level U). The value of combination therapy using natalizumab and interferon in the treatment of RRMS is also unknown (Level U). There is an increased risk of developing progressive multifocal leukoencephalopathy (PML) in natalizumab-treated patients (Level A for combination therapy, Level C for monotherapy) and possibly an increased risk of other opportunistic infections (Level C). The PML risk in a pooled clinical trial cohort has been estimated to be 1 person for every 1,000 patients treated for an average of 17.9 months, although this figure could change in either direction with more experience with the drug.

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