

## Algorithm for Tysabri (natalizumab) in Multiple Sclerosis

1. The patient **must** have a definitive diagnosis of **relapsing** Multiple Sclerosis. Relapsing MS is characterized by disease activity defined as one or more relapses in the 1 year prior to therapy, or gadolinium positive lesions on MRI, or new T2 lesions on MRI despite disease modifying therapy.

### AND

2. The patient has a documented inadequate response, during at least 4 weeks of therapy, or inability to tolerate an appropriate trial, with at least one of the following agents:

Avonex (interferon  $\beta$ -1a)

Betaseron (interferon  $\beta$ -1b)

Copaxone (glatiramer acetate)

Gilenya™ (fingolimod)

Rebif (interferon  $\beta$ -1a)

Aubagio (teriflunomide)

### OR

3. The patient fits into a **Poor Prognosis category** and therefore natalizumab may be used 1<sup>st</sup> line as prescribed by the treating neurologist. Poor prognosis category is defined as:

- Devastating relapse at onset
- Early high relapse rate
- High lesion activity/lesion load on brain MRI at first attack
- Rapid onset of disability (eg, cognitive, physical, activities of daily living)
- High-risk populations with historically more malignant forms of multiple sclerosis

### AND

4. The medication must be prescribed by a neurologist

### AND

5. Patient must be enrolled in the TOUCH Online program

### AND

6. Patient currently receiving immunosuppressants or antineoplastics (see list below\*) should generally have a washout period of at least 3-6 months prior to initiation of natalizumab.

\*adalimumab, alefacept, alemtuzumab, anakinra, azathioprine, cladribine, cyclophosphamide, cyclosporine, daclizumab, efalizumab, etanercept, fludarabine phosphate, infliximab, intravenous immunoglobulin, leflunomide, mercaptopurine, methotrexate, mycophenolate mofetil, mycophenolic acid, pemetrexed, rituximab, trastuzumab, mitoxantrone)

## References:

- Coyle PK. The role of natalizumab in the treatment of multiple sclerosis. *Am J Manag Care*. 2010; Jun;16(6 Suppl):S164-70.
- Coyle PK, Jeffrey DR, et al. Clinical efficacy and benefit of natalizumab. *Mult Scler*. 2009;15(4 suppl):S7-S15.
- Coyle PK, Foley J, et al. Best practice recommendations for the selection and management of patients with multiple sclerosis receiving natalizumab therapy. *Mult Scler*. 2009;15 (4 suppl): S26-36.

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