Natalizumab (Tysabri®)

Tysabri is a disease modifying therapy administered as an IV infusion once every 28-42 days.

Mechanism of Action: Natalizumab is a monoclonal antibody against VLA4 that prevents immune cells from leaving the blood stream to enter the brain (causing inflammatory damage in the setting of MS).

Efficacy Data: Efficacy data is derived from the AFFIRM and SENTINEL trials, the long term follow up studies, and our own clinical experience using Natalizumab in our patients since 2004. Relapses: In the AFFIRM trial, Natalizumab (ARR 0.22) decreased relapse rates by 68% compared to placebo (ARR 0.67). Disability: Compared to placebo, NTZ lowered risk of 3 month confirmed disability progression by 42% and reduced gad+ enhancing lesions by 92%. NEDA: In post analysis of the AFFIRM trial, NEDA (no evidence of disease activity: no attacks, no 3 month confirmed disability progression on EDSS, no new / enlarged T2 lesions and no new gad+ enhancing lesions for 24 months) was achieved in 37% of Natalizumab treated patients, compared to 7% of placebo patients. In aggressive patients (2+ attacks and 1+ gad lesion in year prior to trial) 27% of Natalizumab treated patients vs. 3% of placebo patients achieved NEDA. Confirmed disability improvements (CDI): was seen in 30% with NTZ vs 19% with placebo.

Patient Education: **We will monitor for changes in the patient's MS and any evidence of early PML, a potentially fatal brain infection. MRIs will be monitored at least annually and JCV ab will be monitored about every 3 months. **Patient will be asked to alert the clinician if classic symptoms of PML manifest including sudden bilateral blindness, sudden weakness of one side of the body, or sudden significant confusion. Patient should alert clinician if new neurological deficits last for >24 hours.