Natalizumab Removal Communication and Actions

VA Center for Medication Safety - A Patient Safety Center for Inquiry
VHA Pharmacy Benefits Management Strategic Healthcare Group
National Center for Patient Safety

OBJECTIVES:
To identify patients on natalizumab for discontinuation, follow-up, and monitoring.

METHODS:
Natalizumab Patient Evaluation Form was created to identify patients for discontinuation of natalizumab, follow-up, and monitoring. See Appendix I. Form was requested to be returned within 10 days. VISNs were requested to double check and report to MedSAFE and the PBM the number of unique patients on the agent per site. Directions for unused drug were forwarded. Most importantly, patient forms were to be filled out by sites to assure that patients that were identified to have a potential ADR from the agent received proper and timely follow-up.

Natalizumab Patient Evaluation

ID Number: Station Number: Facility Name: Clinician Initials
Date of Birth: Gender: ☐ Male ☐ Female

Race: ☐ Caucasian ☐ African-American ☐ Hispanic ☐ Asian ☐ Other:

Type of MS: ☐ Relapsing/Remitting ☐ Primary Progressive
☐ Secondary Progressive ☐ Progressive/Relapsing

1. Date of natalizumab initiation:
2. Dose: ☐ 300 mg IV every 4 weeks ☐ Other:
3. Duration of therapy (months):
4. Dual therapy with natalizumab initiated: ☐ Yes ☐ No
    a. If yes, date initiated:
    b. Dual therapy medication and dose:
        ☐ Interferon β-1A (Avonex) 30mcg IM once weekly
        ☐ Interferon β-1A (Rebif) (final dose)
            ☐ 8.8mcg SQ three times per week
            ☐ 22mcg SQ three times per week
            ☐ 44mcg SQ three times per week
        ☐ Interferon β-1B (Betaseron) (final dose)
            ☐ 0.0625mg SQ every other day
            ☐ 0.125mg SQ every other day
            ☐ 0.1875mg SQ every other day
            ☐ 0.25mg SQ every other day
    c. Duration of therapy (months):
5. MRI performed after initiation of natalizumab: ☐ Yes ☐ No
    a. If yes, date of MRI:
    b. Results of MRI:

☐ Presence of Gd lesions
☐ Presence of non-Gd lesions

6. Please check all of the complications that occurred after natalizumab initiation:
   ☐ Death Date:
   Cause of death associated with drug ☐ Yes ☐ No ☐ Unable to determine
   ☐ PML (progressive multifocal leukoencephalopathy) Date:
   ☐ Acute onset of slurred speech Date:
   ☐ Acute onset of unilateral weakness Date:
   ☐ Headache
   ☐ Fatigue
   ☐ Arthralgia
   ☐ Urinary Tract Infection
   ☐ Respiratory Tract Infection
   ☐ Viral Syndrome
   ☐ Depression
   ☐ Abdominal Discomfort/GI Distress
   ☐ Other complications requiring intervention:

FINDINGS/RESULTS:

17 patients were identified as using natalizumab nationally outside of study protocols at the time of removal. Eleven Patient Evaluation Forms were returned to VAMedSAFE and the PBM. VAMedSAFE contacted those sites where forms were not completed to encourage submission. Two patients were identified to have a possible ADR. VAMedSAFE worked with sites to further investigate. On February 28, 2005, a letter was sent out electronically to VISN Formulary Leaders, Chief Medical Officers, Chiefs of Pharmacy, CMOP Directors, and VHA Clinical pharmacists to notify of drug removal. Attachments containing the Warning and Provider Letter from the company were also provided. Reminder was sent via electronic communication on March 1, 2005, that agent should be discontinued and patients should have appropriate follow-up. VAMedSAFE's role was to assure proper follow-up for potential ADRs in patients