PHARMACY PRIOR AUTHORIZATION
Clinical Guideline-Multiple Sclerosis Agents
Avonex®, Rebif® (Interferon Beta-1a), Betaseron®, Extavia® (Interferon Beta-1b), Copaxone® (Glatiramer), Tysabri® (natalizumab), Novantrone® (Mitoxantrone), Gilenya® (Fingolimod),

Indications: (use if necessary)

- For the treatment of
  - Avonex
    - For the treatment of Remitting-Relapsing Multiple Sclerosis (RRMS)
    - To prevent or slow the development of clinically definite MS in patients who have experienced a first clinical episode and have MRI features consistent with MS
  - Rebif
    - For the treatment of Remitting-Relapsing Multiple Sclerosis (RRMS)
  - Betaseron
    - For the treatment of Remitting-Relapsing Multiple Sclerosis (RRMS)
    - For the treatment of Secondary (Chronic) Progressive MS with relapses
  - Extavia
    - For the treatment of Remitting-Relapsing Multiple Sclerosis (RRMS)
    - For the treatment of Secondary (Chronic) Progressive MS with relapses
  - Copaxone
    - For the treatment of Remitting-Relapsing Multiple Sclerosis (RRMS)
    - To prevent or slow the development of clinically definite MS in patients who have experienced a first clinical episode and have MRI features consistent with MS
  - Tysabri
    - For the treatment of Remitting-Relapsing Multiple Sclerosis (RRMS)
  - Novantrone
    - For the treatment of Remitting-Relapsing Multiple Sclerosis (RRMS)
    - For the treatment of Secondary (Chronic) Progressive MS with relapses
    - For the treatment of Progressive Relapsing MS
  - Gilenya
    - For the treatment of Remitting-Relapsing Multiple Sclerosis (RRMS).

Authorization Guidelines:
For Patients who meet all of the following:
- Must be prescribed for an FDA approved indication
- Must be 18 years of age or older
Note: It is strongly recommended that these agents be prescribed by a neurologist, or in close consultation with a neurologist

In addition:
Tysabri:
- Baseline MRI to monitor for PML during treatment
- Patient is not immunocompromised (e.g., HIV or AIDS, leukemia or lymphoma, organ transplant)
- Patient is not taking immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, Rapamune® (sirolimus), Prograf® (tacrolimus))
- Will be used as monotherapy
- Failure of a compliant regimen of Avonex, Rebif, Betaseron, Extavia, or Copaxone

Novantrone:
- No hepatic impairment, pre-existing heart disease or heart failure (LVEF below the lower limit of normal)
- Cumulative dose is less than 140 mg/m² (if patient has received drug in the past)
- Cardiac assessment documented: symptoms, physical exam, ECG, baseline LVEF
- Failure of a compliant regimen of Avonex, Rebif, Betaseron, Extavia, or Copaxone
- Failure of a compliant regimen of Tysabri for 6 months

Gilenya:
- Baseline ophthalmologic evaluation (patients with a history of uveitis or diabetes are at higher risk for development of macular edema)
- Documentation of Baseline EKG (within the last 6 months)
- Documentation to support patient will be monitored for bradycardia for at least 6 hours after the first dose is given
- Documentation of recent (within the last 6 months) CBC with diff
- Documented positive antibody for VZV or has not received VZV vaccination in the previous 1 month
- Patient is not receiving antineoplastic, immunosuppressive or immune modulating therapies
- Failure of a compliant regimen of Avonex, Rebif, Betaseron, Extavia, or Copaxone

Initial Approval:
Avonex, Rebif, Betaseron, Extavia, Copaxone, and Gilenya:
Approve indefinitely
Tysabri:
Approve for 6 months
  • Provider, patient and infusion facility must be enrolled in the TOUCH prescribing program

Novantrone:
3 months

Gilenya:
6 months

Renewal
Tysabri
Approve for 6 months (the safety and efficacy of Tysabri beyond two years are unknown)
  • Supporting medical records
  • Review of Rx history

Novantrone:
Medical records to support that prior to each dose patient is:
  • Assessed for cardiac signs and symptoms by history, physical examination and ECG prior to each dose.
  • Quantitative reevaluation of LVEF prior to each dose using the same methodology that was used to
    assess baseline LVEF
  • Cumulative dose no greater than 140 mg/m2

Gilenya
Supporting medical records showing improvement or stabilization of MS
  • Documentation of recent ophthalmologic examination (within 3-4 months)

References:
   (an evidence-based review): Report of the Therapeutics and Technology Assessment Subcommittee of the American
5. American Academy of Neurology. Evidence Report: The efficacy and safety of mitoxantrone (Novantrone) in the
   treatment of multiple sclerosis: Report of the Therapeutics and Technology Assessment Subcommittee of the American