curative

Mavenclad Prior Authorization

Drug(s) Applied:	**Mavenclad** (cladribine)

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria
- **A. Relapsing Remitting Multiple Sclerosis (RRMS) or Active Secondary Progressive Disease (SPMS)** as indicated by chart notes within the past 90 days
  1. Patient has highly active MS disease activity & both of the following:
     a) Patient has greater than or equal to 2 relapses in the previous year **and**
     b) Patient has greater than or equal to 1 gadolinium enhancing lesion on MRI or significant increase in T2 lesion load compared with a previous MRI **and**
  2. A complete differential CBC has been performed, with results demonstrating lymphocyte count is within normal limits **and**
  3. Chart notes do not indicate that the patient has **any** of the following:
     a) Active malignancy
     b) Active chronic infections (e.g., hepatitis or tuberculosis)
     c) HIV infection
     d) Pregnancy status
     e) Breastfeeding while receiving Mavenclad treatment and for 10 days after the last dose **and**
  4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., neurology) **and**
  5. Patient has not exceeded 2 treatment courses or 4 cycles (2 cycles per year within the past 2 years) of treatment with Mavenclad

  Approval Duration: 8 weeks

II. Continued Therapy Criteria
- **A. Relapsing Remitting Multiple Sclerosis (RRMS) or Active secondary progressive disease (SPMS)** as indicated by chart notes within past 12 months
  1. Chart notes indicate patient has been on requested drug as a continuation of therapy and has documented clinical benefit (e.g., stabilization or improvement

in relapses and/or symptoms) with the requested drug **and**

2. A differential CBC has been performed, with results demonstrated a lymphocyte count of at least 800 cells/microliter **and**
3. Chart notes do not indicate that the patient has **any** of the following:
    a) Active malignancy
    b) Active chronic infections (e.g., hepatitis or tuberculosis)
    c) HIV infection
    d) Pregnancy status
    e) Breastfeeding while receiving Mavenclad treatment and for 10 days after the last dose **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., neurology) **and**
5. Patient has not exceeded 4 treatment cycles or 2 treatment courses (i.e., no more than 2 cycles per year over the past 2 years) and **one** of the following applies:
    a) If the request is for the second cycle of the same treatment course, at least 23-27 days have passed since the last dose of the first cycle, **or**
    b) If the request is for the first cycle of a new (second) treatment course, at least 43 weeks have passed since the last dose of the second cycle from the previous treatment course

Approval Duration: 4 weeks if request is per cycle, 8 weeks if request is per course
Lifetime limit: 2 courses (4 cycles)

Policy Owned by: Curative PBM team