

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

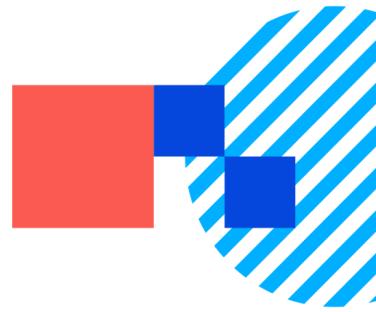
Approval Duration: 8 weeks

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

