Reference number(s)
2975-A

Specialty Guideline Management Mavenclad

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Mavenclad	cladribine

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Mavenclad is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternative drug indicated for the treatment of MS.

Limitations of Use

Mavenclad is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

All other indications are considered experimental/investigational and not medically necessary.

Reference number(s)
2975-A

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist.

Coverage Criteria

Multiple Sclerosis[1,2]

Initial requests

Authorization of 45 days may be granted for treatment of relapsing forms of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapses) and when all of the following criteria are met:

- Inadequate response or unable to tolerate an alternative drug indicated for the treatment of multiple sclerosis.
- Member does not have clinically isolated syndrome (CIS).
- Member has not received 2 courses (i.e., 4 cycles) of Mavenclad.

Subsequent requests

Authorization of 45 days may be granted for treatment of relapsing forms of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapses) and when all of the following criteria are met:

- Member has not received 2 courses (i.e., 4 cycles) of Mavenclad.
- The member has not received Mavenclad in the last 43 weeks.

Other Criteria

- Members will not use Mavenclad concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).
- Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

References

1. Mavenclad [package insert]. Rockland, MA: EMD Serono, Inc.; May 2024.
2. Giovannoni, G., Comi, G., Cook, S., et al. A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis. N Engl J Med 2010;362:416-426.