AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Mavenclad	Page:	1 of 2
Effective Date:	3/4/2024	Last Review Date:	01/12/2024

Applies to:	☒Illinois	☐Florida	☒Florida Kids
	☐New Jersey	☒Maryland	☐Michigan
	☒Pennsylvania Kids	☐Virginia	☐Texas

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Mavenclad under the patient's prescription drug benefit.

Description:

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
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.

Applicable Drug List:

Mavenclad

Policy/Guideline:

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

Criteria for Initial Approval:
Multiple Sclerosis

A. 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 the following criteria are met:

1. Inadequate response or unable to tolerate the required number of formulary alternative drugs (3) indicated for the treatment of multiple sclerosis.

2. Member does not have clinically isolated syndrome (CIS).
3. Member has not received 2 courses (i.e., 4 cycles) of Mavenclad.

B. 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 the following criteria are met:

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

Other Criteria:

A. Members will not use Mavenclad concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

B. Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

Approval Duration and Quantity Restrictions:

Approval: 45 days

Quantity Level Limit:

- Mavenclad tablets 10mg: 20 tablets per 301 days

References:

1. Mavenclad [package insert]. Rockland, MA: EMD Serono, Inc.; September 2022.
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.