SPECIALTY GUIDELINE MANAGEMENT

MAVENCLAD (cladribine)

POLICY

I. 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

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.

II. 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 of the following criteria are met:

- 1. Inadequate response or unable to tolerate an alternative drug 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 of 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.

III. OTHER CRITERIA

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

Mavenclad 2975-A SGM P2020.docx

© 2020 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.



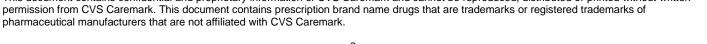
2975-A

IV. REFERENCES

- 1. Mavenclad [package insert]. Rockland, MA: EMD Serono; April 2019.
- 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.

Mavenclad 2975-A SGM P2020.docx

© 2020 CVS Caremark. All rights reserved.





This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written