ALASKA MEDICAID
Prior Authorization Criteria

Mavenclad® (cladribine)

FDA INDICATIONS AND USAGE[1]

Mavenclad® is a purine antimetabolite 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 alternate drug indicated for the treatment of MS.

APPROVAL CRITERIA[1,2]

1. Patient is 18 years of age or older **AND**;
2. Patient has a diagnosis of relapsing MS, including relapsing-remitting disease, and active secondary progressive disease **AND**;
3. Is being prescribed by or in consultation with a neurologist or a prescriber that specializes in MS **AND**;
4. The patient has had a complete blood cell count and liver function testing, showing results deemed appropriate for treatment **AND**;
5. The prescriber has counseled patients of reproductive potential to use effective contraception during and for 6 months after the last dose in each treatment course **AND;**
6. The patient has had an adequate trial and failure of at least one drug indicated for MS.

DENIAL CRITERIA[1,2]

1. Patient has the diagnosis of clinically isolated syndrome **OR**;
2. Patient has the presence of current malignancy **OR;**
3. The patient has HIV or an active chronic infection **OR**;
4. Mavenclad® is being administered with other disease modifying agents **OR**;
5. Patient is pregnant

CAUTIONS[1,2]

- Mavenclad® may increase the risk of malignancy.
- Mavenclad® may cause fetal harm if administered to pregnant women.
- A reduction in the body's immune defense, may increase the chances that an infection may occur.
- Immunizations should be administered at least 4-6 weeks before initiating treatment.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- Up to 10 tablets per cycle

REFERENCES / FOOTNOTES:

1. Mavenclad® (cladribine) [package insert]. Rockland, MA. EMD Serono, Inc.; April 2019. Available at: https://www.emdserono.com/content/dam/web/corporate/non-images/country-specifics/us/pi/mavenclad-pi.pdf Accessed July 5, 2019.
2. Olek, M., & Mowry, E. (June 2019) Disease-modifying treatment of relapsing-remitting multiple sclerosis in adults. In J. F. Dashe (Ed.), *UpToDate*. Retrieved July 7, 2019 from https://www.uptodate.com/contents/disease-modifying-treatment-of-relapsing-remitting-multiple-sclerosis-in-adults#H35