Pharmacy Drug Policy & Procedure

Policy Name:	Mavenclad (cladribine)	Policy #:	2696P

Purpose of the Policy

The purpose of the policy is to establish the criteria for coverage of Mavenclad.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Mavenclad under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for Secondary Progressive Multiple Sclerosis (SPMS)

1.1 Age 18 years or older

1.2 Prescribed by a neurologist (nervous system doctor)

1.3 Diagnosis of active Secondary Progressive Multiple Sclerosis (SPMS) confirmed by progress notes which show a previous Relapsing and Remitting Multiple Sclerosis (RRMS) course with increasing disability over the last 6 months or longer

1.4 Documentation that lymphocyte and complete blood counts are being monitored before, during, and after treatment

2. Exclusions

2.1 Diagnosis of relapsing remitting multiple sclerosis (RRMS)

- Mavenclad is FDA-approved for RRMS in patients who have had inadequate response or are intolerant to other therapies. However, based on the availability of numerous formulary therapies used for treatment of RRMS and the side effect profile of Mavenclad coverage is limited to a diagnosis of SPMS

2.2 Current cancer diagnosis

2.3 History of cancer in members whom the provider feels the benefit of treatment for SPMS would not outweigh the increased risk of cancer.

2.4 Current pregnancy, breast-feeding, or men or women of reproductive potential who do not plan to use effective contraception during therapy and for 6 months after the last dose in each treatment course.

2.5 HIV infection

2.6 Active chronic infection (e.g., hepatitis or tuberculosis) 2.7 History of severe allergic reaction to cladribine

2.7 History of hypersensitivity to cladribine

3. Managed Dose Limitation

3.1 Quantity Limit: up to 10 tablets per five day cycle.

3.2 Maximum of one course per year, consisting of two 4 to 5 day treatment cycles separated by 23 to 27 days (from last day of first cycle to first day of second cycle).

3.3 Maximum of two treatment courses, with second course at least 43 weeks after the last dose of the previous year's course.

4. Approval Period

4.1 Initial: 12 months

4.2 Reapproval: 12 months with documentation of beneficial response.

4.3 Maximum approval time of 24 months. The Food and Drug Administration (FDA) states that treatment beyond two years may further increase the risk of cancer.

References

1. Mavenclad (cladribine) [prescribing information]. Rockland, MA: EMD Serono Inc; May 2024.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease- modifying therapies for adults with multiple sclerosis. Neurology. 2018 Apr 24;90(17):777-788.

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