CLADRIBINE

Generic	Brand	HICL	GCN	Exception/Other
CLADRIBINE	MAVENCLAD		44338	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 48 weeks by GPID.**
   APPROVAL TEXT: Renewal requires 1) physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline, 2) the patient does not have lymphopenia, and 3) the patient has not received a total of two years of Mavenclad treatment (i.e., two treatment cycles divided into 2 yearly treatment courses).

   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **CLADRIBINE (Mavenclad)** requires a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.). In addition, the following criteria must be met:
   - The patient is 18 years of age or older

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g. relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient received a total of two years of Mavenclad treatment (i.e., two treatment cycles divided into 2 yearly treatment courses)?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #3.

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CLADRIBINE

RENEWAL CRITERIA (CONTINUED)

3. Does the patient meet **ALL** of the following criteria?
   - Physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline
   - The patient does not have lymphopenia

   If yes, **approve for 48 weeks by GPID.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **CLADRIBINE (Mavenclad)** requires a diagnosis of relapsing forms of multiple sclerosis (MS) (e.g. relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.) AND the patient has not received a total of two years of Mavenclad treatment. In addition, the following criteria must be met:
   - Physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline
   - The patient does not have lymphopenia

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Mavenclad.

REFERENCES

- Mavenclad [Prescribing Information]. Rockland, MA: EMD Serono, Inc., March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/20
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P&T Approval: 10/19