

Effective Date: 12/2019
Reviewed: 9/2019, 6/2020, 3/2021, 3/2022, 7/2023, 6/2024, 6/2025, 4/2026
Scope: Medicaid

## Cladribine (generic Mavenclad)

### 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

Cladribine 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 Cladribine 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

*Cladribine 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 are not a covered benefit.

#### 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 the following criteria are met:

1. The medication must be prescribed by or in consultation with a neurologist.
2. Inadequate response or unable to tolerate two disease-modifying drugs indicated for the treatment of multiple sclerosis.
3. Member does not have clinically isolated syndrome (CIS).
4. Member has not received 2 courses (i.e., 4 cycles) of Cladribine.
5. Members will not use Cladribine concomitantly with other medications used for the treatment of multiple sclerosis, excluding Ampyra (dalfampridine).

###### 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. The medication must be prescribed by or in consultation with a neurologist.

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2. Member has not received 2 courses (i.e., 4 cycles) of Cladribine.
3. Members will not use Cladribine concomitantly with other medications used for the treatment of multiple sclerosis, excluding Ampyra(dalfampridine).
4. The member has not received Cladribine in the last 43 weeks.

### III. QUANTITY LIMIT

Cladribine 10mg tablets: 20 tablets per 270 days

### IV. REFERENCES

1. Mavenclad [package insert]. Rockland, MA: EMD Serono; September 2025. Accessed April 2026.
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.