| Market Applicability | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **GA** | **KY** | **MD** | **NJ** | **NY** | **WA** |
| **Applicable** | X | X | X | X | X | X | NA |

# Mavenclad (cladribine)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization | 1 year |

| Medications | Quantity Limit |
|---|---|
| Mavenclad (cladribine) tablets | May be subject to quantity limit |

## APPROVAL CRITERIA

Requests for Mavenclad (cladribine) may be approved if the following criteria is met:

I. Individual has a diagnosis of relapsing multiple sclerosis (RMS) including relapsing-remitting disease or active secondary progressive disease; **AND**
II. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to at least one alternative drug indicated for the treatment of multiple sclerosis;

**AND**

III. Individual has been on Mavenclad (cladribine); **OR**
IV. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one of the following:
    A. One preferred beta interferon agent:
        1. Avonex (interferon beta-1a); **OR**
        2. Rebif (interferon beta-1a); **OR**
        3. Betaseron (interferon beta-1b); **OR**
        4. Extavia (interferon beta1-1b);

    **OR**

    B. Tecfidera (dimethyl fumarate);

    **OR**

    C. Glatopa (glatiramer) or glatiramer.

Mavenclad (cladribine) may not be approved for the following:

| Market Applicability | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **GA** | **KY** | **MD** | **NJ** | **NY** | **WA** |
| **Applicable** | X | X | X | X | X | X | NA |

I. Concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, Mayzent, Tecfidera, Tysabri, Lemtrada, Ocrevus, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy, or Betaseron); **OR**
II. Individual with clinically isolated syndrome (CIS); **OR**
III. Individual with current malignancy; **OR**
IV. Individual with human immunodeficiency virus (HIV) infection; **OR**
V. Individual with an active chronic infection; **OR**
VI. Individual with moderate to severe renal impairment (creatinine clearance less than 60 mL/min); **OR**
VII. Individual with moderate to severe hepatic impairment (Child-Pugh class B or C); **OR**
VIII. Individual has completed two treatment courses (two years) of Mavenclad therapy; **OR**
IX. Individual is using to treat non-active secondary progressive multiple sclerosis.

**Note:**
Mavenclad has black box warnings for malignancy and risk of teratogenicity. Mavenclad may increase the risk of malignancy and is contraindicated in individuals with current malignancy. In individuals with prior malignancy or with increased risk of malignancy, evaluate the benefits and risks of Mavenclad therapy on an individual basis. Mavenclad is also contraindicated in pregnant women and in women and men of reproductive potential who do not plan to use effective contraception because of the risk of fetal harm. Exclude pregnancy before starting Mavenclad in females of reproductive potential. Advise females and males of reproductive potential to use effective contraception during Mavenclad dosing and for 6 months after the last dose in each treatment course. Stop Mavenclad if the individual becomes pregnant.

| State Specific Mandates | | |
|---|---|---|
| State name | Date effective | Mandate details (including specific bill if applicable) |
| N/A | N/A | N/A |

**Key References**:


1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 21, 2019.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
4. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: June 11, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 20, 2019.




This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
CRX-ALL-0463-19

| Market Applicability | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **GA** | **KY** | **MD** | **NJ** | **NY** | **WA** |
| **Applicable** | X | X | X | X | X | X | NA |

5. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018; 90: 777-788. Available from https://www.aan.com/Guidelines/home/GuidelineDetail/898. Accessed: July 20, 2019.