Mavenclad (cladribine)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	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 and inadequate response or intolerance to at least one alternative drug indicated for the treatment of multiple sclerosis. Medication samples/coupons/discount cards are excluded from consideration as a trial.

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

I. Use in combination with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Kesimpta, Lemtrada, Mayzent, Ocrevus, Ocrevus Zunovo, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Tyruko, Tysabri, Vumerity and Zeposia); **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 at the initiation of therapy; **OR**
VI. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC)-recommended equivalent to evaluate for latent tuberculosis if initiating therapy; **OR**
VII. Individual with moderate to severe renal impairment (creatinine clearance less than 60 mL/min); **OR**
VIII. Individual with moderate to severe hepatic impairment (Child-Pugh class B or C); **OR**
IX. Individual has completed two treatment courses (two years) of Mavenclad therapy; **OR**
X. 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.

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: October 27, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Feuerstein JD, Issacs KL, Schneider Y, et al. American Gastroenterological Association Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020; 158:1450-1461.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
5. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: April 26, 2024. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 27, 2024.
6. 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: October 27, 2024.