UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Mavenclad

Program	Prior Authorization
Medication	Mavenclad® (cladribine)
Markets in Scope	Colorado, Hawaii, Maryland, New Jersey, New York, New York EPP, Nevada, Rhode Island, California, Pennsylvania- CHIP, South Carolina
Issue Date	5/2019
Pharmacy and Therapeutics Approval Date	1/2021
Effective Date	2/2021

1. Background:

Mavenclad® (cladribine) is a purine antimetabolite 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, the use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS.[1]

According to the American Academy of Neurology, the benefit of initiating disease modifying therapy (DMT) has not been studied in currently untreated people with clinically isolated syndromes (CIS). It is unknown what the risk of harm is from initiating DMTs, including adverse events and burden of taking a long-term medication, relative to the benefit of reducing relapse rate.[2]

Mavenclad is not recommended for use in patients with CIS because of its safety profile.[1]

The recommended cumulative dosage of Mavenclad is divided into 2 yearly treatment courses. Each treatment course is divided into 2 treatment cycles with the 2nd cycle administered 23-27 days after the last dose of the 1st cycle. Additional cycles of Mavenclad are not to be administered after the completion of the 2nd treatment course. The safety and efficacy of reinitiating Mavenclad more than 2 years after completing 2 treatment courses has not been studied.

2. Coverage Criteria:

A. Relapsing Forms of Multiple Sclerosis (MS)

1. Initial Authorization

a. **Mavenclad** will be approved based on **all** of the following criteria:

(1) Diagnosis of relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary progressive MS with relapses)

-AND-

(2) Prescribed by or in consultation with a specialist in the treatment of MS (e.g., neurologist)

-AND-

(3) **One** of the following:

(a) Trial and failure (after trial of at least 4 weeks), contraindication, or intolerance to **two** of the following disease-modifying therapies for MS [document medication used, dose, and duration]:

- Interferon β-1a (Avonex®, Rebif®, Plegridy™)
- Interferon β-1b (Betaseron®, Extavia®)
- Glatiramer acetate products (e.g., Copaxone®, Glatopa®)
- A preferred dimethyl fumarate product (e.g.Tecfidera®)
- Aubagio® (teriflunomide)
- Gilenya® (fingolimod)
- Mayzent® (siponimod)
- Tysabri® (natalizumab)
- Ocrevus® (ocrelizumab)
- Lemtrada® (alemtuzumab)
- Zeposia® (ozanimod)
- Kesimpta® (ofatumumab)
- BafiertamTM (monomethyl fumarate)

NOTE: Avonex, Rebif, Betaseron, Bafiertam, Kesimpta, Zeposia and Extavia are non-preferred and should not be included in denial to provider.
NOTE: Tysabri, Ocrevus, and Lemtrada are medical benefit and should not be included in denial to provider.

-OR-

(b) Patient is currently on Mavenclad

-AND-

(4) Patient is **not** receiving Mavenclad in combination with another disease modifying therapy [e.g., interferon beta preparations, glatiramer acetate products, Tecfidera (dimethyl fumarate), Tysabri (natalizumab), Gilenya (fingolimod), Mayzent (siponimod), Ocrevus (ocrelizumab), Lemtrada (alemtuzumab), or Aubagio (teriflunomide)]

Authorization will be issued for 2 months.

2. Reauthorization

a. **Mavenclad** will be approved based on **both** the following criterion:

(1) Documentation of positive clinical response to Mavenclad treatment

-AND-

(2) Patient is **not** receiving Mavenclad in combination with another disease modifying therapy [e.g., interferon beta preparations, glatiramer acetate products, Tecfidera (dimethyl fumarate), Tysabri (natalizumab), Gilenya (fingolimod), Mayzent (siponimod), Ocrevus (ocrelizumab), Lemtrada (alemtuzumab), or Aubagio (teriflunomide)]

-AND-

(3) Patient has not exceeded the FDA-recommended limit of 2 treatment courses (4 treatment cycles) of Mavenclad

Authorization will be issued for 2 months.(Duration of coverage will be limited to 1 reauthorization to allow 2 cumulative treatment courses [4 treatment cycles] of Mavenclad therapy.)

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Mavenclad [package insert]. EMD Serono, Inc. Rockland, MA. April 2019.
2. 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. 2019; 92(2):112-112.

Program	Prior Authorization
Change Control	
Date	Change
5/2019	New program
10/2019	Changed number of step medication from three to two. Added Mayzent as a step medication to reflect PDL changes effective 1/1/20.
10/2020	Annual review. Changed Tecfidera to "a preferred dimethyl fumarate product: within preferred product criteria Added Additional Clinical Rules section.
1/2021	Changed authorization and reauthorization period to 2 months with allowance of only 1 reauthorization. Updated Background with information on authorization period duration information.