Mavenclad (cladribine)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Multiple sclerosis (MS) is a chronic, inflammatory, demyelinating disease of the central nervous system. It typically presents in young adults (generally diagnosed before 50 years of age) with symptoms such as

vision problems, muscle weakness, numbness, and difficulty with balance and coordination. The most common form is relapsing-remitting MS (occurring in about 85% of patients), characterized by acute attacks followed by periods of remission. Treatment goals include reducing relapses, slowing disability progression, and managing symptoms. Disease-modifying therapies (DMTs) are the primary treatment approach and include injectable medications (e.g., interferons, glatiramer acetate), oral medications (e.g, dimethyl fumarate, fingolimod, teriflunomide, etc.), and infusion therapies (e.g., natalizumab, ocrelizumab).

MS is a progressive disease, meaning that symptoms tend to worsen over time, and it can be classified into several types, including relapsing-remitting MS (RRMS), primary progressive MS (PPMS), and secondary progressive MS (SPMS).

Currently, there is no cure for MS, but various treatment options are available to manage symptoms, slow the progression of the disease, and improve quality of life.

- Disease-modifying therapies (DMTs) are a class of medications that target the immune system to reduce inflammation and slow down the progression of the disease. The type of DMT prescribed will depend on the type and severity of MS, as well as the individual's medical history and preferences. Some common DMTs include interferon beta, glatiramer acetate, dimethyl fumarate, and fingolimod.
- High dose corticosteroids, such as high dose intravenous methylprednisolone or oral prednisone can be prescribed to reduce inflammation during acute MS relapses.
- Symptomatic treatments are also available to manage specific symptoms of MS, such as muscle spasms, bladder problems, and depression. Physical therapy, occupational therapy, and speech therapy can help individuals with MS maintain mobility, independence, and communication skills.

Mavenclad (cladribine) is an oral DMT approved for relapsing forms of MS, including relapsing-remitting MS and active secondary progressive MS. It has a unique mechanism of action, selectively depleting lymphocytes, and is administered in two short annual oral treatment courses. However, due to significant potential risks, including increased chances of malignancy and harm to developing fetuses in pregnant women, it is typically prescribed only when individuals with MS have not responded adequately to, or cannot tolerate, other MS treatments. It's important to note that because of these safety concerns, Mavenclad (cladribine) is not recommended for use in those with clinically isolated syndrome, which is considered an early stage of MS.

Definitions

"Clinically isolated syndrome" refers to a first episode of neurologic symptoms lasting at least 24 hours caused by inflammation or demyelination in the central nervous system.

"Compendia" are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures. Examples include, but are not limited to:

1. American Hospital Formulary Service Drug Information
2. Clinical pharmacology
3. National Comprehensive Cancer Network Drugs and Biologics Compendium
4. Thomson Micromedex DrugDex
5. United States Pharmacopeia-National Formulary (USP-NF)

"Disease-modifying therapy" is a medication that modifies the course of MS by reducing relapses and slowing disability progression.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"MRI" or "Magnetic Resonance Imaging" refers to a medical imaging technique that creates detailed three-dimensional (3D) images of the organs and tissues in your body. A brain MRI can reveal areas of active MS disease called lesions within the central nervous system.

"Multiple sclerosis" is a chronic autoimmune disease of the central nervous system characterized by inflammation, demyelination, and neurodegeneration.
"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

"Primary progressive MS" refers to worsening neurologic function from the onset of symptoms, without early relapses or remissions.

"Relapse" is defined as the appearance of new symptoms or the worsening of existing symptoms lasting at least 24 hours in the absence of fever or infection.

"Relapsing-remitting MS" refers to a disease course characterized by clearly defined attacks of new or increasing neurologic symptoms followed by periods of partial or complete recovery.

"[s]" indicates state mandates may apply.

"Secondary progressive MS" is a disease course following relapsing-remitting MS that is characterized by a progressive worsening of neurologic function over time with or without relapses.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers Mavenclad (cladribine) medically necessary when ONE of the following criteria are met:

1. Authorization may be granted for pediatric members less than 18 years of age with multiple sclerosis when there is documentation that the benefits outweigh the risks*; OR*
   Note: If approved, the requested product will be authorized for up until the member reaches 18 years of age.
2. The member meets the applicable Medical Necessity Criteria for Initial Clinical Review or Subsequent Clinical Review listed below.

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Multiple Sclerosis - Adults

The Plan considers Mavenclad (cladribine) medically necessary when recent (within the last 3 months) clinical chart documentation provided indicates the member meets ALL of the following:

1. Prescribed by or in consultation with a neurologist or physician who specializes in the treatment of multiple sclerosis; *AND*
2. The member is 18 years of age or older; *AND*
3. The member has ONE (1) of the following forms of multiple sclerosis:
   a. Relapsing-remitting (RRMS)*; or*
   b. Active secondary progressive disease (SPMS); *AND*
4. The member is unable to use, or has tried and failed TWO (2) of the following:[s]
   a. An interferon beta product (e.g., Avonex, Betaseron, Plegridy, or Rebif)*; and/or*
   b. Dimethyl Fumarate (generic Tecfidera)*; and/or*
   c. Fingolimod (generic Gilenya)*; and/or*
   d. Glatiramer acetate (Copaxone)*; and/or*
   e. Teriflunomide (generic Aubagio); *AND*
5. The member meets ALL of the following criteria:
   a. No evidence of current malignancy*; or*
   b. No evidence of HIV infection*; or*
   c. No evidence of an active chronic infections (e.g., hepatitis, tuberculosis)*; or*
   d. No evidence of pregnancy; *or*

e. No evidence of breastfeeding (on the treatment day and for 10 days after the last dose)*; or*

f. No evidence of not using effective contraception during Mavenclad (cladribine) dosing and for at least 6 months after the last dose in women of childbearing potential or men of reproductive potential*; AND*

6. Mavenclad (cladribine) will be used as monotherapy for multiple sclerosis (i.e., member is not using and will not use other disease-modifying MS therapies while on Mavenclad [cladribine]); *AND*
7. Mavenclad (cladribine) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication. (see Appendix, Table 1)
    - *The recommended cumulative dose of Mavenclad is 3.5 mg/kg oral dose, administered as 1.75 mg/kg per treatment course (year). Each treatment course consists of 2 treatment cycles:*
        i. *First cycle: daily dosing for 4 or 5 consecutive days in the first month (to start at any time)*
        ii. *Second cycle: daily dosing for 4 or 5 consecutive days in the second month (between 23-27 days after the last dose of the first course/first cycle).*
    - *Maximum of 20 tablets per treatment course (maximum of 10 tablets per cycle).*

If the above prior authorization criteria are met, the requested medication will be authorized for one treatment course (maximum of 20 tablets over 2 cycles in 1 year).[5]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Multiple Sclerosis - Adults

The plan considers Mavenclad (clabridine) medically necessary when recent (within the last 6-months) clinical documentation provided indicates the member meets BOTH of the following:[1]

1. The requested medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; *AND*
2. The member has experienced at least ONE (1) of the following:
    a. Improvement in at least ONE (1) objective measure, such as:
        i. Reduced disease activity on MRI*; and/or*
        ii. Improved or stable disability scores*; and/or*
        iii. Reduced relapse rate*; and/or*
        iv. Improved fatigue or walking assessments; *AND/OR*

b. Member has shown stabilization or improvement in at least ONE (1) MS symptom, such as:
    i. Motor function*; and/or*
    ii. Fatigue*; and/or*
    iii. Vision*; and/or*
    iv. Bowel/bladder function*; and/or*
    v. Spasticity*; and/or*
    vi. Walking/gait*; and/or*
    vii. Pain/numbness/tingling; *AND*
3. At least 43 weeks have passed since the last dose of Mavenclad (cladribine); *AND*
4. Lymphocyte count is at least 800 cells/µL.
5. Mavenclad (cladribine) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication (see Appendix A, Table 1).
    a. *The recommended cumulative dose of Mavenclad is 3.5 mg/kg oral dose, administered as 1.75 mg/kg per treatment course (year). Each treatment course consists of 2 treatment cycles:*
        i. *First cycle: daily dosing for 4 or 5 consecutive days in the first month (to start at any time, at least 43 weeks after the last dose of the first course/second cycle).*
        ii. *Second cycle: daily dosing for 4 or 5 consecutive days in the second month (between 23-27 days after the last dose of the second course/first cycle).*
    b. *Maximum of 20 tablets per treatment course (maximum of 10 tablets per cycle).*
    c. *Maximum of 40 tablets over 2 years (four treatment cycles).*

⁂ ***NOTE:*** *The Plan does not consider treatment with Mavenclad (cladribine) beyond two courses (i.e., beyond a cumulative dose of 3.5 mg/kg annually for 2 years) to be medically necessary. The safety and efficacy of additional courses have not been established in clinical trials, and the FDA-approved labeling does not provide guidance for extended use. The drug's mechanism of action results in sustained efficacy beyond the administration period. Continued treatment may increase risks, particularly of malignancy, without clear evidence of additional clinical benefit. Given these factors and the availability of alternative MS therapies, the Plan will not authorize Mavenclad use beyond two treatment courses. Members experiencing disease activity after completing two courses should discuss alternative treatment options with their healthcare provider.*

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Experimental or Investigational / Not Medically Necessary[5]

Mavenclad (cladribine) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Treatment courses beyond two years. Administering Mavenclad (cladribine) beyond the first two years (first two courses), as this may increase the risk of malignancy. The safety and efficacy of reinitiating MAVENCLAD more than 2 years after completing 2 treatment courses has not been studied.
- Use for the treatment of clinically isolated syndrome (CIS). Mavenclad (cladribine) has not been studied and is not recommended for use in those with CIS, due to the safety profile of Mavenclad (cladribine).
- Use for the treatment of primary progressive multiple sclerosis (PPMS). The safety and efficacy of Mavenclad (cladribine) has not been established in those with PPMS. In a phase III study of those with CIS, exposure to Mavenclad (cladribine) has shown promise in delaying time to clinically definitive MS, and reduced requirement of wheelchairs or other assistive ambulatory devices.
- Use in combination with other disease-modifying therapies for MS. There is limited knowledge about the use of combining DMTs for MS.
- Use in members with current malignancy. Mavenclad (cladribine) is contraindicated in those with current malignancies.
- Use in members with HIV infection. Mavenclas (cladribine) is contraindicated in those with HIV infection.
- Use in pregnant or breastfeeding women. Mavenclad (cladribine) has been shown to increase the risk of teratogenicity. It is contraindicated in those who are pregnant, and in men and women of reproductive potential who do not plan to use effective contraception. Women intending to breastfeed on a MAVENCLAD treatment day and for 10 days after the last dose.
- Use for the treatment of myasthenia gravis, Mavenclad (cladribine) is currently being studied in a phase III study for the indication of myasthenia gravis and pending FDA approval.

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Appendix A

Table 1: Mavenclad (cladribine) Manufacturer Dose Recommendation Per Cycle by Patient Weight in Each Treatment Course

Weight Range	Dose in mg (Number of 10 mg Tablets) per Cycle	
Kilograms (kg)	First Cycle	Second Cycle
40* to less than 50	40 mg (4 tablets)	40 mg (4 tablets)
50 to less than 60	50 mg (5 tablets)	50 mg (5 tablets)
60 to less than 70	60 mg (6 tablets)	60 mg (6 tablets)
70 to less than 80	70 mg (7 tablets)	70 mg (7 tablets)
80 to less than 90	80 mg (8 tablets)	70 mg (87tablets)
90 to less than 100	90 mg (9 tablets)	80 mg (8 tablets)
100 to less than 110	100 mg (10 tablets)	90 mg (9 tablets)
110 and above	100 mg (10 tablets)	100 mg (10 tablets)
**The use of Mavenclad (cladribine) in those weighing less than 40 kg has not been investigated.*		

The recommended cumulative dosage of Mavenclad (cladribine) is 3.5 mg/kg body weight administered orally and divided into 2 yearly treatment courses (1.75 mg/kg per treatment course) (see Table 1 above). Each treatment course is divided into 2 treatment cycles:

Administration of First Treatment Course

- First Course/First Cycle: start any time.
- First Course/Second Cycle: administer 23 to 27 days after the last dose of First Course/First Cycle.
- Maximum of 10 tablets/cycle, or 20 tablets per course

Administration of Second Treatment Course

- Second Course/First Cycle: Administer at least 43 weeks after the last dose of First Course/Second Cycle.
- Second Course/Second Cycle: administer 23 to 27 days after the last dose of Second Course/First Cycle.
- Administer the cycle dosage as 1 or 2 tablets once daily over 4 or 5 consecutive days. Do not administer more than 2 tablets daily.
- Maximum of 10 tablets/cycle, or 20 tablets per course

Following the administration of 2 treatment courses, do not administer additional Mavenclad (cladribine) treatment during the next 2 years. Treatment during these 2 years may further increase the risk of malignancy]. The safety and efficacy of reinitiating Mavenclad (cladribine) more than 2 years after completing 2 treatment courses has not been studied.

Clinical Guideline Revision / History Information

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