To begin the prescription process for MAVENCLAD, follow these steps:

MAVENCLAD®
(cladribine) tablets 10 mg

- Have your patient read the Patient Consent Information and request that the patient **sign the indicated area (2A)** on the Service Request Form.
    - Patient confidentiality is very important to EMD Serono. Signing the consent line (2A) will help to expedite your patient's enrollment in the MS LifeLines® Patient Support Program, which includes determining eligibility for financial assistance programs.
- **Complete the rest of the Service Request Form**.
    - Prescriber signatures are required to complete the prescription for each treatment month as well as for medical necessity.
    - Incomplete areas may delay the start of treatment.
- Fax to **MS LifeLines at 1-866-227-3243**.

The MAVENCLAD Prescriptions and Service Request Form can be found on MAVENCLAD.com/hcp or by requesting one from your Key Account Manager. If you have questions about the form, please call MS LifeLines at 1-877-447-3243.

INDICATION

MAVENCLAD® (cladribine) tablets 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 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.

Limitations of Use: MAVENCLAD is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

IMPORTANT SAFETY INFORMATION

WARNING: MALIGNANCIES and RISK OF TERATOGENICITY

- **Treatment with MAVENCLAD may increase the risk of malignancy. MAVENCLAD is contraindicated in patients with current malignancy. In patients with prior malignancy or with increased risk of malignancy, evaluate the benefits and risks of the use of MAVENCLAD on an individual patient basis. Follow standard cancer screening guidelines in patients treated with MAVENCLAD**
- **MAVENCLAD is contraindicated for use in pregnant women and in women and men of reproductive potential who do not plan to use effective contraception because of the potential for fetal harm. Malformations and embryolethality occurred in animals. Exclude pregnancy before the start of treatment with 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 patient becomes pregnant**

Please see **Full Important Safety Information** on back cover and the accompanying full **Prescribing Information**, including **boxed WARNING**, for additional information.

How to Complete the MAVENCLAD® (cladribine) tablets Prescription and Service Request Form

Questions filling out the form?
Call MS LifeLines at 1-877-447-3243

1 Complete patient demographics

3 Complete patient's insurance and pharmacy benefit information

Please fax copies of patient's insurance cards (front/back) along with this form. These copies can be supplied in lieu of written information

Add preferred pharmacy; If it is within network and allowed by insurance, MS LifeLines will forward prescription; if not, MS LifeLines will communicate an alternate pharmacy to process the prescription.

5 Complete prescription information

Enter patient weight in kilograms OR pounds (note the pounds are approximate)

Select whether this is the patient's first or second year of treatment

5A. Check box to choose appropriate weight range and corresponding first cycle (month 1) dose for your patient

5B. Check the appropriate box for second cycle (month 2). **Not completing this step will require additional follow-up that may delay the prescription fulfilling the second month.**

Prescriber to sign *either* "Dispense as written" or "Substitution permitted" for **BOTH** first and second cycle (month 1 and month 2)

MAVENCLAD® (cladribine) tablets PRESCRIPTIONS AND SERVICE REQUEST FORM

Fax this form to: 1-866-227-3243 | Call us toll free: 1-877-447-3243

MSLifeLines®

STEP 1: Complete Patient Information

Patient Name: _____
SS #: _____ DOB: _____
Home Address: _____
City: _____ State: _____ Zip: _____
Home Phone: _____ Work Phone: _____
Cell Phone: _____ Preferred Phone: ☐ Home ☐ Work ☐ Cell
Okay to leave a message at preferred number: ☐ Yes ☐ No
Email: _____
List Previous DMDs: _____
Last DMD: _____ Date of last dose: _____
List concurrent medications: _____
Allergies: _____

STEP 2A & 2B: Patient Authorization

2A I have read and understand the **Authorization to Use and Disclose Health and Other Personal Information** and agree to the terms on the following page.
PATIENT NAME (please print):
_____
PATIENT SIGNATURE (or personal representative):
_____
Date: _____
Authority/relationship of personal representative:
☐ Legal Guardian ☐ Power of Attorney

2B ☐ By checking this box, I agree that I have read and understand the **Opt-in for Marketing Text Messages** and agree to the terms on the following page.

STEP 3: Complete Insurance Information

Please fax front and back copies of insurance cards
☐ No Insurance ☐ Insurance change
☐ Insurance card/cards attached (front and back)
Primary Insurance: _____
Cardholder: _____
ID #: _____ Group #: _____
Phone #: _____
Preferred Pharmacy: _____
Does this patient have a separate pharmacy benefit card? ☐ Yes ☐ No
Name of Pharmacy Benefit Manager: _____
ID #: _____ Group #: _____

STEP 4: Complete Prescriber Information

Prescriber's Name: _____
Office Contact Name: _____
Office/Clinic/Institution: _____
Address: _____
City/State/Zip: _____
Phone: _____ Fax: _____
Tax ID #: _____
State Medical License #: _____
UPIN #: _____
NPI #: _____
Prescriber Email Address: _____

STEP 5A & 5B: MAVENCLAD® (cladribine) tablets Prescription Information

Patient Weight: _____kg **OR** _____lbs | **Treatment Course:** ☐ Year 1 ☐ Year 2

Check the row corresponding to the number of tablets to prescribe **in the first cycle (month 1) and again in the second cycle (month 2)**
The weight table below is provided for your reference.

Ready to start therapy? ☐ Yes ☐ No
if not ready, expected start date
_____

5A FIRST CYCLE (Month 1): Number of MAVENCLAD (cladribine) 10 mg tablets per cycle

Weight Range: kg (~lb)	Day 1	Day 2	Day 3	Day 4	Day 5	Total # of Tablets Authorized in 1st Cycle (Month 1)
☐ 40 to <50 (88 to <110 lb)	1	1	1	1	0	4
☐ 50 to <60 (110 to <132 lb)	1	1	1	1	1	5
☐ 60 to <70 (132 to <154 lb)	2	1	1	1	1	6
☐ 70 to <80 (154 to <176 lb)	2	2	1	1	1	7
☐ 80 to <90 (176 to <198 lb)	2	2	2	1	1	8
☐ 90 to <100 (198 to <220 lb)	2	2	2	2	1	9
☐ 100 to <110 (220 to <242 lb)	2	2	2	2	2	10
☐ 110 and above (≥242 lb)	2	2	2	2	2	10

No Refill. Instructions for Use: Take by mouth daily at intervals of 24 hours approximately the same time each day per product package instructions.

5B SECOND CYCLE (Month 2): Number of MAVENCLAD (cladribine) 10 mg tablets per cycle

Weight Range: kg (~lb)	Day 1	Day 2	Day 3	Day 4	Day 5	Total # of Tablets Authorized in 2nd Cycle (Month 2)
☐ 40 to <50 (88 to <110 lb)	1	1	1	1	0	4
☐ 50 to <60 (110 to <132 lb)	1	1	1	1	1	5
☐ 60 to <70 (132 to <154 lb)	2	1	1	1	1	6
☐ 70 to <80 (154 to <176 lb)	2	2	1	1	1	7
☐ 80 to <90 (176 to <198 lb)	2	2	1	1	1	7
☐ 90 to <100 (198 to <220 lb)	2	2	2	1	1	8
☐ 100 to <110 (220 to <242 lb)	2	2	2	2	1	9
☐ 110 and above (≥242 lb)	2	2	2	2	2	10

No Refill. Instructions for Use: Take by mouth daily at intervals of 24 hours approximately the same time each day per product package instructions.

SIGNATURE REQUIRED
Prescriber Signature (Dispense as written): _____
Prescriber Signature (Substitution permitted): _____
Date: _____ *Signature stamps not acceptable*

SIGNATURE REQUIRED
Prescriber Signature (Dispense as written): _____
Prescriber Signature (Substitution permitted): _____
Date: _____ *Signature stamps not acceptable*

STEP 6: Complete and Sign Statement of Medical Necessity

PRIMARY DIAGNOSIS: ICD-10 code G35

I certify the prescribed therapy is medically necessary for the treatment of relapsing forms of multiple sclerosis, and that this information is accurate to the best of my knowledge.

I authorize EMD Serono, Inc. to be my designated agent (1) to provide any information on this form to the insurer of the above-named patient and (2) forward the above prescription by fax or by other mode of delivery to the pharmacy chosen by the above-named patient.

SIGNATURE REQUIRED
Prescriber's Signature: _____ **Date:** _____

☐ **By checking this box, I hereby certify that my office has obtained HIPAA-compliant authorization from the above-named patient to disclose medical and other protected health information necessary for EMD Serono to provide the services described in the Authorization on the following page, including assisting the patient with obtaining insurance coverage for Mavenclad.**

Please see accompanying full **Prescribing Information** including **boxed WARNING** and **Medication Guide**. CONFIDENTIAL

2 Patient signature and acknowledgement for 2A & 2B

Have patient review the consent and authorization and then sign; Have patient read the Marketing Text Message consent and check the box if they agree.

To ensure a quick and efficient enrollment process (including benefits investigation and eligibility check for MS LifeLines Financial Assistance programs, etc), patient must sign 2A (consent and authorization)

2B: Patient opt-in for text communications from MS LifeLines and EMD Serono

4 Complete prescriber information

Ensure this information is complete to help expedite enrollment process - NPI # and Tax ID # are critical

6 Is the patient ready to start?

Check yes/no as to whether the patient is ready to start MAVENCLAD. If patient is not ready to start, fill in an approximate future start date

7 Complete and Sign Statement of Medical Necessity

Prescriber to sign statement of medical necessity and check box for HIPAA-compliant authorization (if applicable)

Total of 3 Prescriber Signatures required

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CONTRAINDICATIONS

- Patients with current malignancy.
- Pregnant women, and women and men of reproductive potential who do not plan to use effective contraception during and for 6 months after the last dose in each treatment course. May cause fetal harm.
- Patients with human immunodeficiency virus (HIV).
- Patients with active chronic infections (e.g., hepatitis or tuberculosis).
- Patients with a history of hypersensitivity to cladribine.
- Women intending to breastfeed while taking MAVENCLAD tablets and for 10 days after the last dose.

WARNINGS AND PRECAUTIONS

- **Malignancies:** Treatment with MAVENCLAD may increase the risk of malignancy. After the completion of 2 treatment courses, do not administer additional MAVENCLAD treatment during the next 2 years. The risk of malignancy with reinitiating MAVENCLAD more than 2 years after the completion of 2 treatment courses has not been studied. Follow standard cancer screening guidelines in patients treated with MAVENCLAD.
- **Risk of Teratogenicity:** MAVENCLAD may cause fetal harm when administered to pregnant women. In females of reproductive potential, exclude pregnancy before initiation of each treatment course of MAVENCLAD and prevent by the use of effective contraception during MAVENCLAD dosing and for at least 6 months after the last dose of each treatment course. Women who become pregnant during treatment with MAVENCLAD should discontinue treatment.
- **Lymphopenia:** MAVENCLAD causes a dose-dependent reduction in lymphocyte count. In clinical studies, 87% of MAVENCLAD-treated patients experienced lymphopenia. The lowest absolute lymphocyte counts occurred approximately 2 to 3 months after the start of each treatment course and were lower with each additional treatment course. Concomitant use of MAVENCLAD with hematotoxic drugs may increase the risk of adverse reactions because of the additive hematological effects. Monitor lymphocyte counts before and during treatment, periodically thereafter, and when clinically indicated.
- **Infections:** MAVENCLAD can reduce the body's immune defense and may increase the likelihood of infections. Infections occurred in 49% of MAVENCLAD-treated patients compared to 44% of patients treated with placebo in clinical studies. The most frequent serious infections included herpes zoster and pyelonephritis. Single fatal cases of tuberculosis and fulminant hepatitis B were reported in the clinical program. Administer live-attenuated or live vaccines at least 4 to 6 weeks prior to starting MAVENCLAD. Screen patients for latent infections; consider delaying treatment until infection is fully controlled. Vaccinate patients antibody-negative to varicella zoster virus prior to treatment. Administer anti-herpes prophylaxis in patients with lymphocyte counts less than 200 cells per microliter. Monitor for infections. In patients treated with parenteral cladribine for oncologic indications, cases of progressive multifocal leukoencephalopathy (PML) have been reported. No case of PML has been reported in clinical studies of cladribine in patients with MS.
- **Hematologic Toxicity:** In addition to lymphopenia, decreases in other blood cells and hematological parameters have been reported with MAVENCLAD in clinical studies. In general, mild to moderate decreases in neutrophil counts, hemoglobin levels, and platelet counts were observed. Severe decreases in neutrophil counts were observed in 3.6% of MAVENCLAD-treated patients, compared to 2.8% of placebo patients. Obtain complete blood count (CBC) with differential including lymphocyte count before and during treatment, periodically thereafter, and when clinically indicated.
- **Risk of Graft-versus-Host Disease With Blood Transfusions:** Transfusion-associated graft-versus-host disease has been observed rarely after transfusion of nonirradiated blood in patients treated with cladribine for non-MS treatment indications.
- **Liver Injury:** In clinical studies, 0.3% of MAVENCLAD-treated patients had liver injury (serious or causing treatment discontinuation) compared to 0 placebo patients. Obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels prior to treatment. Discontinue if clinically significant injury is suspected.
- **Hypersensitivity:** In clinical studies, 11% of MAVENCLAD-treated patients had hypersensitivity reactions, compared to 7% of placebo patients. Hypersensitivity reactions that were serious and/or led to discontinuation of MAVENCLAD, occurred in 0.5% of MAVENCLAD-treated patients, compared to 0.1% of placebo patients. If a hypersensitivity reaction is suspected, discontinue MAVENCLAD therapy. Do not use MAVENCLAD in patients with a history of hypersensitivity to cladribine.

Adverse Reactions: The most common adverse reactions with an incidence of >20% for MAVENCLAD are upper respiratory tract infection, headache, and lymphopenia.

Drug Interactions/Concomitant Medication: Concomitant use of MAVENCLAD with immunosuppressive or myelosuppressive drugs and some immunomodulatory drugs (e.g., interferon beta) is not recommended and may increase the risk of adverse reactions. Acute short-term therapy with corticosteroids can be administered.

Avoid concomitant use of certain antiviral and antiretroviral drugs. Avoid concomitant use of BCRP or ENT/CNT inhibitors as they may alter bioavailability of MAVENCLAD.

Use in Specific Populations: Studies have not been performed in pediatric or elderly patients, pregnant or breastfeeding women. Use in patients with moderate to severe renal or hepatic impairment is not recommended.

Please see the accompanying full **Prescribing Information**, including **boxed WARNING**, for additional information.

MAVENCLAD® (cladribine) tablets 10 mg | MSLifeLines®

EMD Serono

MS LifeLines is an educational patient support service for people living with MS and their families, and is sponsored by EMD Serono, Inc.

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