Louisiana Medicaid
Multiple Sclerosis Agents

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for preferred and non-preferred multiple sclerosis agents.

Additional Point-of-Sale edits may apply.

*Some medications in this therapeutic class have **Black Box Warnings**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. Please refer to individual prescribing information for details.*

~~Cladribine (Mavenclad®)~~

~~Approval Criteria~~

- ~~The recipient is 18 years of age or older on the date of the request; **AND**~~
- ~~Cladribine (Mavenclad®) is being prescribed by, or the request states cladribine (Mavenclad®) is being prescribed in consultation with, a neurologist; **AND**~~
- ~~The recipient has been diagnosed with a relapsing form of multiple sclerosis (ICD-10 code G35), to include relapsing-remitting disease or active secondary progressive disease; **AND**~~
- ~~**ONE** of the following applies:~~
  - ~~The recipient has had a *treatment failure* with at least **TWO** multiple sclerosis agents [at least **ONE** must be preferred] (See Multiple Sclerosis – Immunomodulatory Agents on PDL); **OR**~~
  - ~~The recipient has had an *intolerable side effect* with at least **TWO** multiple sclerosis agents [at least **ONE** must be preferred] (See Multiple Sclerosis – Immunomodulatory Agents on PDL); **OR**~~
  - ~~The recipient has *documented contraindication(s)* to **ALL** multiple sclerosis agents that are appropriate to use for the condition being treated (See Multiple Sclerosis – Immunomodulatory Agents on PDL); **OR**~~
  - ~~There are *no multiple sclerosis agents that are appropriate for the condition* being treated (See Multiple Sclerosis – Immunomodulatory Agents on PDL); **AND**~~
- ~~By submitting the authorization request, the prescriber attests to the following:~~
  - ~~The prescriber has advised all patients of reproductive potential to use effective contraception during cladribine dosing and for 6 months after the last dose in each treatment course; **AND**~~
  - ~~The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**~~
  - ~~All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**~~

- The recipient has no concomitant drug therapies or disease states that limit the use of cladribine (Mavenclad®).

Reauthorization Criteria

- The recipient continues to meet all initial approval criteria; **AND**
- By submitting the reauthorization request, the prescriber attests that:
  - At least 43 weeks have passed since the last dose of the second cycle of the first course of cladribine (Mavenclad®) treatment; **AND**
  - At least 2 years have passed since the last dose of the second cycle of the second course of cladribine (Mavenclad®) treatment.

Duration of initial and reauthorization approval: 40 days

Siponimod (Mayzent®)

Approval Criteria

- Recipient has a diagnosis of a multiple sclerosis; **AND**
- Siponimod (Mayzent®) is prescribed by, or the request states that the medication is being prescribed in consultation with, a neurologist; **AND**
- **ONE** of the following applies:
  - The prescriber **states on the request** that the recipient is currently using the medication *(current use of the requested medication is not established through use of medication samples, coupons or discount cards)*; **OR**
  - The recipient has had a *treatment failure* with at least one preferred product that is indicated for treatment of multiple sclerosis [see Multiple Sclerosis Agents – Immunomodulatory Agents on the preferred drug list (PDL)]; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product that is indicated for treatment of multiple sclerosis [see Multiple Sclerosis Agents – Immunomodulatory Agents on the PDL]; **OR**
  - The recipient has a *documented contraindication(s)* to all the preferred products that are appropriate to use for the condition being treated [see Multiple Sclerosis Agents – Immunomodulatory Agents on the PDL]; **OR**
  - There is *no preferred product that is appropriate to use for the condition* being treated [see Multiple Sclerosis Agents – Immunomodulatory Agents on the PDL]; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**

- ~~The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.~~

~~**Reauthorization Criteria**~~

- ~~Recipient continues to meet all initial approval criteria; **AND**~~
- ~~The prescriber **states on the request** that the recipient is responding positively to therapy.~~

~~**Duration of initial and reauthorization approval: 12 months**~~

~~**For ALL Other Multiple Sclerosis Agents Except Mavenclad® and Mayzent®**~~

Approval Criteria for Specific Diagnoses

Multiple Sclerosis

- The recipient has a diagnosis of multiple sclerosis; **AND**
- For Glatopa® or Glatiramer Acetate 20mg/ml (generic for Copaxone®) – there has been a treatment failure or intolerable side effect with or contraindication to brand Copaxone® 20mg/ml; **AND**
- For Mavenclad® or Vumerity®, the recipient is 18 years of age or older on the date of the request; **AND**
- The medication is being prescribed by or in consultation with a neurologist; **AND**
- **ONE** of the following applies:
  - The request is for a preferred medication; **OR**
  - The request is for Mavenclad®, and **ONE** of the following applies:
    - The recipient has had a *treatment failure* with at least **TWO** multiple sclerosis agents (at least **ONE** must be preferred); **OR**
    - The recipient has had an *intolerable side effect* with at least **TWO** multiple sclerosis agents (at least **ONE** must be preferred); **OR**
    - The recipient has *documented contraindication(s)* to **ALL** multiple sclerosis agents that are appropriate to use for the condition being treated; **OR**
    - There are *no multiple sclerosis agents that are appropriate for the condition* being treated; **OR**
  - The request is for any other non-preferred medication (**EXCEPT** Mavenclad®); **AND**
    - **ONE** of the following applies:
      - There is no preferred product that is the exact same chemical entity, formulation, strength, etc.; **OR**
      - The following is true and is **stated on the request** – The recipient is unable to use the chemically equivalent preferred product for reasons such as a contraindication or clinically significant adverse effect(s) to an inactive ingredient that it contains; **AND**
    - **ONE** of the following applies:

        - The prescriber **states on the request** that the recipient is currently using the medication *(current use of the requested medication is not established through use of medication samples, coupons or discount cards)*; **OR**
        - The recipient has had a *treatment failure* with at least one preferred product that is indicated for treatment of multiple sclerosis; **OR**
        - The recipient has had an *intolerable side effect* to at least one preferred product that is indicated for treatment of multiple sclerosis; **OR**
        - The recipient has a *documented contraindication(s)* to all the preferred products that are appropriate to use for the condition being treated; **OR**
        - There is *no preferred product that is appropriate to use for the condition* being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - For Mavenclad®, the prescriber has advised patients of reproductive potential to use effective contraception during cladribine dosing and for 6 months after the last dose in each treatment course; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Crohn's Disease

- The request is for natalizumab (Tysabri®); **AND**
- The medication is being prescribed by or in consultation with a gastroenterologist; **AND**
- **ONE** of the following applies:
    - The prescriber **states on the request** that the recipient is currently using the medication *(current use of the requested medication is not established through use of medication samples, coupons or discount cards)*; **OR**
    - The recipient has had a *treatment failure* with at least one preferred product that is indicated for treatment of Crohn's disease (see Pain Management – Cytokine and CAM Antagonists on PDL); **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product that is indicated for treatment of Crohn's disease (see Pain Management – Cytokine and CAM Antagonists on PDL); **OR**
    - The recipient has a *documented contraindication(s)* to all the preferred products that are indicated for treatment of Crohn's disease (see Pain Management – Cytokine and CAM Antagonists on PDL); **OR**
    - There is *no preferred product that is appropriate to use for the condition* being treated (see Pain Management – Cytokine and CAM Antagonists on PDL); **AND**

- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria for BOTH Multiple Sclerosis and Crohn's Disease

- The recipient continues to meet all initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is responding positively to therapy; **AND**
- If the renewal request is for Ampyra®, the patient's walking has improved with Ampyra® therapy, and this is **stated on the request**; **OR**
- If the renewal request is for Lemtrada®:
    - It has been at least 12 months since completion of the most recent treatment course; **AND**
    - The duration of treatment for the renewal is 3 consecutive days**; OR**~~.~~
- If the renewal request is for Mavenclad®:
    - At least 43 weeks have passed since the last dose of the second cycle of the first course of cladribine (Mavenclad®) treatment; **AND**
    - At least 2 years have passed since the last dose of the second cycle of the second course of cladribine (Mavenclad®) treatment.

Duration of initial approval: 12 months (or a 5-day treatment course for Lemtrada®, or a 40-day treatment course for Mavenclad®)

Duration of renewal approval: 12 months (or a 3-day treatment course for Lemtrada®, or a 40-day treatment course for Mavenclad®)

References

Ampyra (dalfampridine) [package insert]. Ardsley, NY: Acorda Therapeutics, Inc; December 2019. https://ampyra.com/prescribing-information.pdf

Aubagio (teriflunomide) [package insert]. Cambridge, MA: Genzyme Corporation, A Sanofi Company; February 2020. http://products.sanofi.us/Aubagio/ aubagio.html

Avonex (interferon beta-1a) [package insert]. Cambridge, MA: Biogen Inc; March 2020. https://www.avonex.com/content/dam/commercial/multiple-sclerosis/avonex/pat/en_us/pdf/Avonex_US_Prescribing_Information.pdf

Betaseron (interferon beta-1b) [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; August 2019. https://labeling.bayerhealthcare.com/html/products/pi/Betaseron_PI.pdf

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Copaxone (glatiramer acetate) [package insert]. Overland Park, KS: Teva Pharmaceuticals USA, Inc; December 2019. https://www.copaxone.com/globalassets/copaxone/prescribing-information.pdf

Extavia (interferon beta-1b) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2019. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/extavia.pdf

Gilenya (fingolimod) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2019. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/gilenya.pdf

Glatopa (glatiramer acetate) [package insert]. Princeton, NJ: Sandoz Inc; January 2020. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=5f01e40a-b6f6-40fb-b37c-3d06f1428e86&type=display

Lemtrada (alemtuzumab) [package insert]. Cambridge, MA: Genzyme Corporation; October 2019. http://products.sanofi.us/lemtrada/lemtrada.html

Mavenclad (cladribine) [package insert]. Rockland, MA: EMD Serono, Inc; April 2019. https://www.emdserono.com/us-en/pi/mavenclad-pi.pdf

Mayzent (siponimod) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/mayzent.pdf

Ocrevus (ocrelizumab) [package insert]. South San Francisco, CA: Genentech, Inc; November 2019. https://www.gene.com/download/pdf/ocrevus_prescribing.pdf

Plegridy (peginterferon beta-1a) [package insert]. Cambridge, MA: Biogen Inc; March 2020. https://www.plegridyhcp.com/content/dam/commercial/multiple-sclerosis/plegridy/hcp/en_us/home/pdf/prescribing-information.pdf

Rebif (interferon beta-1a) [package insert]. Rockland, MA: EMD Serono, Inc; July 2019. https://www.emdserono.com/content/dam/web/corporate/non-images/country-specifics/us/pi/rebif-pi.pdf

Tecfidera (dimethyl fumarate) [package insert]. Cambridge, MA: Biogen Inc; February 2020. https://www.tecfiderahcp.com/content/dam/commercial/multiple-sclerosis/tecfidera/hcp/en_us/pdf/Tecfidera_PI.pdf

Tysabri (natalizumab) [package insert]. Cambridge, MA: Biogen Inc; August 2019. https://www.tysabrihcp.com/content/dam/commercial/multiple-sclerosis/tysabri/hcp/en_us/PDFs/tysabri_prescribing_information.pdf

Vumerity (diroximel fumarate) [package insert]. Cambridge, MA: Biogen Inc.; March 2020. https://www.vumerityhcp.com/content/dam/commercial/vumerity/hcp/en_us/pdf/vumerity-prescribing-information.pdf

Revision	Date
Single PDL Implementation	May 2019
Removed medication list, added wording to allow diagnosis of Crohn's for Tysabri®	August 2019
Added specific wording for use of Copaxone® 20mg/ml	November 2019
Added clinical criteria for Tysabri®	December 2019

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Combined Mavenclad® and Mayzent® criteria with Multiple Sclerosis criteria, modified formatting, updated references	June 2020
Added wording for Vumerity® and incorporated individual criteria into one criteria	June 2020

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