

## Clinical Policy: Ocrelizumab (Ocrevus)

Reference Number: LA.PHAR.335

Effective Date:

Last Review Date: 01.21

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Ocrelizumab (Ocrevus™) is a CD20-directed cytolytic antibody.

### FDA Approved Indication(s)

Ocrevus is indicated for the treatment of:

- Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- Primary progressive MS, in adults

### Policy/Criteria

Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Ocrevus is medically necessary when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Multiple Sclerosis (must meet all):

1. Diagnosis of one of the following (a, b, c, or d):
  - a. Clinically isolated syndrome, and member is contraindicated to both or has experienced clinically significant adverse effects to one of the following at up to maximally indicated doses: an interferon-beta agent (Avonex®, Betaseron®, Rebif®, or Plegridy®), glatiramer (Copaxone®, Glatopa®);
  - b. Relapsing-remitting MS, and failure of two of the following at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated: Aubagio®, dimethyl fumarate (Tecfidera®), Gilenya™, an interferon-beta agent (Avonex, Betaseron, Rebif, or Plegridy), glatiramer (Copaxone®, Glatopa®);\*  
\*Prior authorization may be required for disease modifying therapies for MS
  - c. Secondary progressive MS
  - d. Primary progressive MS;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;
4. Ocrevus is not prescribed concurrently with other disease modifying therapies for MS (see Appendix D);

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5. Documentation of baseline number of relapses per year and expanded disability status scale (EDSS) score;
6. At the time of request, member does not have active hepatitis B infection (positive results for hepatitis B surface antigen and anti-hepatitis B virus tests);
7. Dose does not exceed the following:
  - a. Initial dose: 300 mg, followed by a second 300 mg dose 2 weeks later;
  - b. Maintenance dose: 600 mg every 6 months.

Approval duration:

Medicaid – 6 months

**B. Other diagnoses/indications**

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

## II. Continued Therapy

**A. Multiple Sclerosis (must meet all):**

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Member meets one of the following (a or b):
  - a. If member has received < 1 year of total treatment: Member is responding positively to therapy;
  - b. If member has received ≥ 1 year of total treatment: Member meets one of the following (i, ii, iii, or iv):
    - i. Member has not had an increase in the number of relapses per year compared to baseline;
    - ii. Member has not had ≥ 2 new MRI-detected lesions;
    - iii. Member has not had an increase in EDSS score from baseline;
    - iv. Medical justification supports that member is responding positively to therapy;
3. Ocrevus is not prescribed concurrently with other disease modifying therapies for MS (see Appendix D);
4. If request is for a dose increase, new dose does not exceed 600 mg every 6 months.

Approval duration:

Medicaid – first re-authorization: 6 months; second and subsequent re-authorizations: 12 months

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.  
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

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#### **III. Diagnoses/Indications for which coverage is NOT authorized:**

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid or evidence of coverage documents.

#### **IV. Appendices/General Information**

##### Appendix A: Abbreviation/Acronym Key

EDSS: expanded disability status scale

FDA: Food and Drug Administration

MS: multiple sclerosis

##### Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.

<u>Drug Name</u>	<u>Dosing Regimen</u>	<u>Dose Limit/ Maximum Dose</u>
<u>Aubagio® (teriflunomide)</u>	<u>7 mg or 14 mg PO QD</u>	<u>14 mg/day</u>
<u>Avonex®, Rebif® (interferon beta-1a)</u>	<u>Avonex: 30 mcg IM Q week Rebif: 22 mcg or 44 mcg SC TIW</u>	<u>Avonex: 30 mcg/week Rebif: 44 mcg TIW</u>
<u>Plegridy® (peginterferon beta-1a)</u>	<u>125 mcg SC Q2 weeks</u>	<u>125 mcg/2 weeks</u>
<u>Betaseron®(interferon beta-1b)</u>	<u>250 mcg SC QOD</u>	<u>250 mg QOD</u>
<u>glatiramer acetate (Copaxone®, Glatopa®)</u>	<u>20 mg SC QD or 40 mg SC TIW</u>	<u>20 mg/day or 40 mg TIW</u>
<u>Gilenya™ (fingolimod)</u>	<u>0.5 mg PO QD</u>	<u>0.5 mg/day</u>
<u>dimethyl fumarate (Tecfidera®)</u>	<u>120 mg PO BID for 7 days, followed by 240 mg PO BID</u>	<u>480 mg/day</u>

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

##### Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): active hepatitis B virus infection; history of life-threatening infusion reaction to Ocrevus
- Boxed warning(s): none reported

##### Appendix D: General Information

- Disease-modifying therapies for MS are: glatiramer acetate (Copaxone®, Glatopa®), interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®), dimethyl fumarate (Tecfidera®), diroximel fumarate (Vumerity™), monomethyl fumarate (Bafiertam™), fingolimod

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(Gilenya™), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), ocrelizumab (Ocrevus™), cladribine (Mavenclad®), siponimod (Mayzent®), and ozanimod (Zeposia®).

- Of the disease-modifying therapies for MS that are FDA-labeled for CIS, only the interferon products, glatiramer, and Aubagio have demonstrated any efficacy in decreasing the risk of conversion to MS compared to placebo. This is supported by the AAN 2018 MS guidelines.

#### V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
<u>Relapsing and primary progressive MS</u>	<u>Initial 300 mg IV infusion with a second 300 mg IV infusion two weeks later, followed by subsequent doses of 600 mg via IV infusion every 6 months</u>	<u>600 mg/6 months</u>

#### VI. Product Availability

Single-dose vial: 300 mg/10 mL

#### VII. References

1. Ocrevus Prescribing Information. South San Francisco, CA: Genentech, Inc; November 2019. Available at [www.ocrevus.com](http://www.ocrevus.com). Accessed January 27, 2020.
2. Costello K, Halper J, Kalb R, Skutnik L, Rapp R. The use of disease-modifying therapies in multiple sclerosis, principles and current evidence – a consensus paper by the Multiple Sclerosis Coalition. Updated June 2019. Accessed January 27, 2020.
3. 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(17): 777-788. Full guideline available at: <https://www.aan.com/Guidelines/home/GetGuidelineContent/904>.

Reviews, Revisions, and Approvals	Date
<u>Converted corporate to local policy</u>	<u>01.21</u>

#### Important Reminder

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This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

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The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results.

Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

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