

## Clinical Policy: Ocrelizumab (Ocrevus)

Reference Number: CP.CPA.307

Effective Date: 04.11.17

Last Review Date: 05.19

Line of Business: Commercial

[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

*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 health plans affiliated with Centene Corporation® 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;
  - b. Relapsing-remitting MS, and failure of two of the following at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced: Aubagio®, Tecfidera®, Gilenya™, Avonex®, Betaseron®, Plegridy®, glatiramer, Copaxone®, Glatopa®, or Rebif®;  
*\*Prior authorization is required for all 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*);
5. 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);
6. 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: 6 months or to the member's renewal date, whichever is longer**

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

**II. Continued Therapy**

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. 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: 6 months or to the member’s renewal date, whichever is longer**

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

1. Currently receiving medication via Centene 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 for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

**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 – CP.CPA.09 for commercial or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

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 not be a formulary agent and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Avonex <sup>®</sup> , Rebif <sup>®</sup> (interferon beta-1a)	Avonex: 30 mcg IM Q week Rebif: 22 mcg or 44 mcg SC TIW	Avonex: 30 mcg/week Rebif: 44 mcg TIW
Plegridy <sup>®</sup> (peginterferon beta-1a)	125 mcg SC Q2 weeks	125 mcg/2 weeks
Betaseron <sup>®</sup> , Extavia <sup>®</sup> (interferon beta-1b)	250 mcg SC QOD	250 mg QOD

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
glatiramer acetate (Copaxone <sup>®</sup> , Glatopa <sup>®</sup> )	20 mg SC QD or 40 mg SC TIW	20 mg/day or 40 mg TIW
Aubagio <sup>®</sup> (teriflunomide)	7 mg or 14 mg PO QD	14 mg/day
Gilenya <sup>™</sup> (fingolimod)	0.5 mg PO QD	0.5 mg/day
Tecfidera <sup>®</sup> (dimethyl fumarate)	120 mg PO BID for 7 days, followed by 240 mg PO BID	480 mg/day

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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<sup>®</sup>, Glatopa<sup>®</sup>), interferon beta-1a (Avonex<sup>®</sup>, Rebif<sup>®</sup>), interferon beta-1b (Betaseron<sup>®</sup>, Extavia<sup>®</sup>), peginterferon beta-1a (Plegridy<sup>®</sup>), dimethyl fumarate (Tecfidera<sup>®</sup>), fingolimod (Gilenya<sup>™</sup>), teriflunomide (Aubagio<sup>®</sup>), alemtuzumab (Lemtrada<sup>®</sup>), mitoxantrone (Novantrone<sup>®</sup>), natalizumab (Tysabri<sup>®</sup>), ocrelizumab (Ocrevus<sup>™</sup>), cladribine (Mavenclad<sup>®</sup>), and siponimod (Mayzent<sup>®</sup>).

**V. Dosage and Administration**

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

**VI. Product Availability**

Single-dose vial: 300 mg/10 mL

**VII. References**

1. Ocrevus Prescribing Information. South San Francisco, CA: Genentech, Inc; July 2019. Available at [www.ocrevus.com](http://www.ocrevus.com). Accessed August 2, 2019.
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. March 2017. Accessed February 4, 2019.
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	P&T Approval Date
New policy.	04.17	04.17
Removed requirement of MRI to confirm diagnosis	10.18.17	
2Q 2018 annual review: added age; added redirection in line with clinical guidance; approval durations modified to 6 months or to the member’s renewal date; references reviewed and updated.	01.05.18	05.18
2Q 2019 annual review: no significant changes; added glatiramer as a step-through option; references reviewed and updated.	02.06.19	05.19
RT4: added coverage for CIS and SPMS per updated FDA labeling; references reviewed and updated.	08.02.19	

**Important Reminder**

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

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recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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