

Clinical Policy: Ocrelizumab (Ocrevus)

Reference Number: MDN.CP.PHAR.335

Effective Date: 04.01.22

Last Review Date: 3.2.23

Line of Business: Meridian IL 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

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, 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[®], or Rebif[®]), glatiramer (Copaxone[®], Glatopa[®]);
 - b. Relapsing-remitting MS, and failure of all of the following at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated (i, ii, iii, and iv):*
 - i. Dimethyl fumarate (Tecfidera[®] brand is preferred);
 - ii. Gilenya[®];
 - iii. An interferon-beta agent (Avonex, Betaseron, or Rebif,) or glatiramer (Copaxone[®] brand is preferred);
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;

**Prior authorization is required for all disease modifying therapies for MS*

4. Ocrevus is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);
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: 6 months

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.PMN.53 for Medicaid.

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 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: 12 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs in the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT in the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

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.PMN.53 for Medicaid or evidence of coverage documents.
- B. Rheumatoid arthritis
- C. Lupus nephritis/systemic lupus erythematosus.

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 not be a formulary agent for all relevant lines of business and may require prior authorization.

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

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

- 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 |
|--------------------------------------|--|-----------------|
| Relapsing and primary progressive MS | 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 | 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; December 2020. Available at www.ocrevus.com. Accessed February 8, 2021.
2. 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 |
|--|----------|-------------------|
| Policy created, adapted from CP.PHAR.335 | 04.01.22 | 04.22 |
| Corrected continuity errors; added rheumatoid arthritis and lupus nephritis/systemic lupus erythematosus as diagnoses not covered due to safety concerns resulting in termination of the respective clinical studies; template changes applied | 3.2.23 | |

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

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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