Clinical Policy: Ocrelizumab (Ocrevus)

Reference Number: PA.CP.PHAR.335
Effective Date: 01/18
Last Review Date: 04/19 Revision Log

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

FDA Approved Indication(s)
Ocrevus is indicated for the treatment of patients with relapsing or primary progressive forms of multiple sclerosis (MS).

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness® that ocrelizumab (Ocrevus) is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all):

1. Diagnosis of relapsing form of or primary-progressive multiple sclerosis (MS);
2. Age ≥ 18 years;
3. Prescribed by or in consultation with a neurologist;
4. If member has relapsing form of MS, failure of one of the following (a or b), at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects were experienced, unless the patient is currently stabilized on therapy:
   a. Tecfidera® or Gilenya™ and any of the following: an interferon-beta agent *(Avonex® and Plegridy® are preferred agents)* or glatiramer *(generic [including Glatopa®] is preferred);*
   b. Tecfidera and Gilenya;

   **Prior authorization is required for all disease modifying therapies for MS*
5. Member will not use other disease modifying therapies for MS concurrently(*see Appendix D*);
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

B. Other diagnoses/indications: Refer to PA.CP.PMN.53.

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Member is not using other disease modifying therapies for MS concurrently (*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 (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
   Approval duration: per request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

III. 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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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®, Extavia® (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
Tecfidera® (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® (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®), fingolimod

(Gilenya™), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), and ocreliuzmab (Ocrevus™).

IV. 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

V. Product Availability

Single-dose vial: 300 mg/10 mL

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: removed HBV screening requirement as a specialist is involved in care; references reviewed and updated.	01.05.18	
2Q 2019 annual review: specified that generic forms of glatiramer are preferred; approval duration updated; references reviewed and updated.	04.17.19	

References

1. Ocrevus Prescribing Information. South San Francisco, CA: Genentech, Inc; November 2018. Available at www.ocrevus.com. Accessed February 6, 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.