

Policy Title:	Ocrevus (ocrelizumab) (Intravenous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	05/20/2019, 09/18/2019, 12/20/2019, 01/22/2020, 06/10/2021, 3/17/2022		
Revision Date:	05/20/2019, 09/18/2019, 12/20/2019, 01/22/2020, 06/10/2021		

Purpose: To support safe, effective and appropriate use of Ocrevus (ocrelizumab) in the treatment of Multiple Sclerosis.

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:

Ocrevus (ocrelizumab) is covered under the medical benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Ocrevus (ocrelizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Patient is at least 18 years of age; and
- Patient is diagnosed with primary progressive multiple sclerosis (PPMS) or relapsing form of multiple sclerosis as documented by laboratory report (i.e. MRI); and
- Must be prescribed by a neurologist; and
- Will be used as single agent therapy; and
- For members with relapsing forms of multiple sclerosis, they will need to provide documentation of one of the following:
 - The member is newly diagnosed with relapsing multiple sclerosis
 - The member's current or previous disease modifying therapy does not adequately control the disease as evidenced by disease progression or the member is experiencing intolerable adverse events; and
- Initial dose does not exceed 300mg (300 billable units) initially followed two weeks later by a second dose of 300 mg (300 billable units); and
- Maintenance dose does not exceed 600mg (600 billable units) every 6 months;
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Continuation of therapy criteria:

- Patient diagnosed with PPMS:
 - Patient has not received a dose of ocrelizumab within the past 5 months
 - Patient is tolerating treatment with ocrelizumab
 - Patient has experienced a slowing of disease worsening (e.g., no decline in Expanded Disability Status Score [EDSS] or MRI findings) since initiating therapy
- Patient diagnosed with a relapsing form of MS:
 - Patient has not received a dose of ocrelizumab within the past 5 months
 - Patient is tolerating treatment with ocrelizumab
 - Patient has experienced disease improvement or slowing of disease worsening (e.g., no decline in Expanded Disability Status Score [EDSS] or MRI findings) since initiating therapy

Coverage durations:

- Initial coverage criteria = 6 months
- Continuation of therapy = 12 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = 1 mg)
Multiple Sclerosis	Initial dose: 300 mg intravenous infusion, followed two weeks later by a second 300 mg IV infusion Subsequent doses: 600 mg IV infusion every 6 months Administer first subsequent dose 6 months after infusion of the initial dose	Initial dose: 300 billable units (mg) on day 1 and day 15 Subsequent doses: 600 billable units (mg) every 6 months

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or



Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:

Below is a list of billing codes applicable to covered treatment options for multiple sclerosis. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria are provided in the procedure section.

Codes:

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J2350	Injection, ocrelizumab, 1mg

References:

Thomas RH, Wakefield RA. Oral disease-modifying therapies for relapsing-remitting multiple sclerosis. *Am J Health Syst Pharm.* 2015 Jan;72(1):25-38. [PubMed](#)

1. Fox RJ, Cutter G, Chan A, et al. Comparative Effectiveness Using A Matching-Adjusted Indirect Comparison Between Delayed-Release Dimethyl Fumarate and Fingolimod for The Treatment of Relapsing-Remitting Multiple Sclerosis. *Value Health.* 2015 Nov;18(7):A750. Epub 2015 Oct 20. [PubMed](#)
2. Metin H, Huppertz H. Adjusted Indirect Comparison of Oral Multiple Sclerosis Agents. *Value Health.* 2015 Nov;18(7):A750. Epub 2015 Oct 20. [PubMed](#)
3. Tramacere I, Del Giovane C, Salanti G, et al. Immunomodulators and immunosuppressants for relapsing-remitting multiple sclerosis: a network meta-analysis. *Cochrane Database Syst Rev.* 2015. [PubMed](#)
4. Tolley K, Hutchinson M, You X, et al. A Network Meta-Analysis of Efficacy and Evaluation of Safety of Subcutaneous Pegylated Interferon Beta-1a versus Other Injectable Therapies for the Treatment of Relapsing-Remitting Multiple Sclerosis. *PLoS One.* 2015;10(6):e0127960.
5. Bainbridge JL, Miravalle A, Corboy JR. Multiple Sclerosis. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L, eds. *Pharmacotherapy: A Pathophysiologic Approach.* 9th ed. New York, NY: McGraw-Hill; 2014. <http://accesspharmacy.mhmedical.com/content.aspx?bookid=689&Sectionid=45310489>. Accessed May 18, 2016.
6. Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. *Neurology.* 2002;58(2):169-178.
7. Hauser SL, Bar-Or A, Comi G, Giovannoni G, Hartung HP, Hemmer B, Lublin F, Montalban X, Rammohan KW, Selmaj K, et al. Ocrevus versus Interferon Beta-1a in Relapsing Multiple Sclerosis. *N Eng J Med.* 2016;376(3):221–234. doi: 10.1056/NEJMoa1601277.
8. Montalban X, et al. Ocrevus versus Placebo in Primary Progressive Multiple Sclerosis. *N Engl J Med.* 2017;376:209–220. doi: 10.1056/NEJMoa1606468
9. Ocrevus [package insert] South San Francisco, CA: Genentech, Inc.; November 2021