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, 7/13/2023		

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
- Ocrevus is prescribed by, or in consultation with, a neurologist; and
- Patient is diagnosed with primary progressive multiple sclerosis (PPMS), or a relapsing form of multiple sclerosis as documented by laboratory report (i.e., MRI); and
- Ocrevus 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
- 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:

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4. 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
5. 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.
6. 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.
7. 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.
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10. Ocrevus [package insert] South San Francisco, CA: Genentech, Inc.; November 2021