Policy Title:	Ocrevus (ocrelizumab) (Intravenous)		
		Department:	PHAPHA
Effective Date:	01/01/202001/01/2020		
Review Date:	05/20/2019, 09/18/2019, 12/20/2019, 01/22/2020, 06/10/2021, 3/17/2022, 7/13/2023, 12/07/2023, 01/10/2024		

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.

Summary of Evidence:

Ocrevus is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS) and primary progressive MS in adults. Clinical trials evaluating the efficacy and safety of Ocrevus in patients with multiple sclerosis (MS) have demonstrated significant reductions in disease activity, including the frequency of relapses, progression of disability, and accumulation of lesions on magnetic resonance imaging (MRI). Common adverse events include infusion-related reactions and upper respiratory tract infections. Serious adverse events, including infections and malignancies, have been reported with Ocrevus treatment.

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
- 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

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Ocrevus was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Ocrevus according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

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	Initial dose: 300 billable units (mg) on day 1 and day 15

	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	 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.

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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.; August 2023. Accessed November 2023.