JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP019
		Effective Date	01/01/2019
		Review Date	04/19/2023
	Subject **Ocrevus**	*Revision Date*	02/22/2023
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Ocrevus

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I. POLICY

Ocrevus (ocrelizumab) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

Ocrevus may be approved for patients who meet the following:

Treatment of Relapsing Multiple Sclerosis (MS)

- Patient is 18 years of age or older
- Documented diagnosis of a relapsing form of multiple sclerosis (relapsing-remitting MS [RRMS], secondary-progressive MS [SPMS] with relapses, progressive-relapsing MS [PRMS])
- Documentation that the patient is currently ambulatory, with minimal walking impairment
- Documentation of the timed 25-foot walk test
- Patient has had inadequate response, or intolerance with two or more formulary (oral or subcutaneous) products from different therapeutic classes indicated for treatment of MS (at least 1-month trial per medication)
- Prescriber is, or in consultation with, a neurologist

Treatment of Primary Progressive Multiple Sclerosis (PPMS)

- Patient is 18 years of age or older
- Documented diagnosis of primary progressive multiple sclerosis
- Documentation that the patient is currently ambulatory, with minimal walking impairment
- Documentation of the timed 25-foot walk test
- Prescriber is, or in consultation with, a neurologist

III. AUTHORIZATION PERIOD/LIMITATIONS

- Initial approval will be limited to a 6-month duration of therapy
- Continuation of therapy may be approved in 12-month intervals with documentation showing a beneficial response to treatment, evidence by:
  - Reduction in relapse rate, and disease progression

- Increase in patient functionality and activities of daily living

IV. EXCLUSIONS

Ocrevus will **not** be covered for the following:

- Patients who have an active hepatitis B virus infection
- Patients who are currently not ambulatory
- Patients who are less than 18 years of age
- Concomitant use with other disease-modifying agents
- Any indications that are not FDA-approved, or supported by clinical guidelines

V. RECOMMENDED DOSAGE

- Initial dose: 300 mg IV infusion, followed two weeks later by a second 300 mg IV infusion.
- Maintenance dose: single 600 mg IV infusion every 6 months.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Ocrevus 300 MG/10ML SOLN Injection, ocrelizumab, 1 mg	J2350

VII. REFERENCES

1. Ocrevus [Prescribing Information]. South San Francisco, CA; Genentech, Inc.; 2018 November
2. Hauser SL, Bar-Or A, Comi G, Giovannoni G, Hartung HP, Hemmer B, Lublin F, Montalban X, Rammohan KW, Selmaj K, Traboulsee A, Wolinsky JS, Arnold DL, Klingelschmitt G, Masterman D, Fontoura P, Belachew S, Chin P, Mairon N, Garren H, Kappos L; OPERA I and OPERA II Clinical Investigators.. Ocrelizumab versus Interferon Beta-1a in Relapsing Multiple Sclerosis. N Engl J Med. 2017 Jan 19;376(3):221-234. doi: 10.1056/NEJMoa1601277. Epub 2016 Dec 21.
3. Montalban X, Hauser SL, Kappos L, Arnold DL, Bar-Or A, Comi G, de Seze J, Giovannoni G, Hartung HP, Hemmer B, Lublin F, Rammohan KW, Selmaj K, Traboulsee A, Masterman D, Fontura P, Belachew S, Garren H, Mairon N, Chin P, Wolinsky JS; ORATORIO Clinical Investigators. Ocrelizumab versus Placebo in Primary Progressive Multiple Sclerosis. N Engl J Med. 2017 Jan 19;376(3):209-220. doi: 10.1056/NEJMoa1606468. Epub 2016 Dec

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
12/19/2018	Policy Creation
01/15/2020	No policy changes-presented policy for USFHP adoption effective 3/1/2020

11/10/2021	Removed Priority Partners as an applicable LOB
02/22/2023	Updated authorization guidance

Review Date: 12/19/18, 01/15/2020

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