

Ocrelizumab (Ocrevus®)

Place of Service

Home infusion Administration

Infusion Center Administration

Office Administration

Outpatient Facility Infusion Administration

HCPCS: J2350 per 1 mg

Condition listed in policy (see criteria for details)

- [Multiple sclerosis - primary progressive \(PPMS\)](#)
- [Multiple sclerosis - relapsing forms that includes clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease](#)

AHFS therapeutic class: Immunomodulatory agent

Mechanism of action: Humanized IgG1 anti-CD20 monoclonal antibody

(I) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO/Shared Advantage/HMO (non-direct contract)**, may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

ADMINISTRATION OF OCREVUS IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted*)

1. Patient is initiating therapy with Ocrevus (300mg initial dose, 300 mg 2 weeks later, then one 600 mg maintenance dose) or is being re-initiated on Ocrevus after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event to Ocrevus based on documentation submitted.

3. Patient continues to experience moderate to severe adverse events to Ocrevus based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Ocrevus® (ocrelizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Multiple sclerosis - primary progressive (PPMS)

1. Not used in combination with other immunomodulators for multiple sclerosis

Covered Dose

Up to 600 mg IV every 6 months [*for first infusion: 2 infusions of 300mg, given 2 weeks apart*]

Coverage Period

Initial: Yearly

Subsequent:

- Yearly if administered at a hospital outpatient facility
- Indefinite if administered in a preferred site of service

ICD-10:

G35

Multiple sclerosis - relapsing forms that includes clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

1. Not used in combination with other immunomodulators for multiple sclerosis

Covered Dose

Up to 600 mg IV every 6 months [*for first infusion: 2 infusions of 300mg, given 2 weeks apart*]

Coverage Period

Initial: Yearly

Subsequent:

- Yearly if administered at a hospital outpatient facility
- Indefinite if administered in a preferred site of service

ICD-10:

G35

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Ocrevus® (ocrelizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Commercial

Ocrelizumab (Ocrevus®)

Effective: 04/03/2024

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Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:

300 mg (single-dose vial)

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Ocrevus® (ocrelizumab) [Prescribing information]. South San Francisco, CA: Genentech, Inc.; 8/2023.
- 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.

(7) Policy Update

Date of last review: 4Q2023

Date of next review: 4Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*