ocrelizumab (Ocrevus)

Commercial Medical Benefit Drug Policy

Place of Service

Home infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: CENTRAL NERVOUS SYSTEM AGENTS
Mechanism of Action: Humanized IgG1 anti-CD20 monoclonal antibody
HCPCS:
J2350:Injection, ocrelizumab, 1 mg
How Supplied:
300 mg (single-dose vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Multiple Sclerosis, primary progressive (PPMS)
- Multiple Sclerosis, relapsing forms

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** 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

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG 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.*

OR

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

2. Patient has experienced a previous severe adverse event on Ocrevus based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on 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.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Multiple Sclerosis, primary progressive (PPMS)

Meets medical necessity if all the following are met:

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

Covered Doses:

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

Coverage Period:

Initial: yearly

Reauthorization:

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

ICD-10:

G35

Multiple Sclerosis, relapsing forms

Meets medical necessity if all the following are met:

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

Covered Doses:

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

Coverage Period:
Initial: yearly
Reauthorization:

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

ICD-10:
G35

References

1. AHFS®. Available by subscription at http://www.lexi.com
2. DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Ocrevus (ocrelizumab) [prescribing information]. South San Francisco, CA: Genentech Inc; June 2024.
4. 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.

Review History

Date of Last Annual Review: 4Q2024
Changes from previous policy version:

- No clinical changes following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee