

## 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 that includes clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

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, based on continued response to therapy

#### **ICD-10:**

G35

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

**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, based on continued response to therapy

**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; August 2025.
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. [Guideline reaffirmed on October 19, 2024]

**Review History**

Date of Last Annual Review: 4Q2025

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*