ocrelizumab and hyaluronidase-ocsq (Ocrevus Zunovo)

Commercial Medical Benefit Drug Policy

Place of Service
Home Infusion
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: CENTRAL NERVOUS SYSTEM AGENTS
Mechanism of Action: CD20-directed cytolytic antibody
HCPCS:
J2351:Injection, ocrelizumab, 1 mg and hyaluronidase-ocsq
How Supplied:
920 mg ocrelizumab and 23,000 units hyaluronidase per 23 mL (40 mg and 1,000 units per mL) solution in a single-dose vial

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

- Multiple Sclerosis, Primary Progressive
- 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.

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 Zunovo (23 mL initial dose and a 23 mL second dose at 6 months] or is being re-initiated on Ocrevus Zunovo 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 Zunovo based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Ocrevus Zunovo 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

Meets medical necessity if all the following are met:

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

Covered Doses:

Up to 23 mL (920 mg ocrelizumab and 23,000 units hyaluronidase) given subcutaneously every 6 months

Coverage Period:

Initial: 1 year

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

Meets medical necessity if all the following are met:

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

Covered Doses:

Up to 23 mL (920 mg ocrelizumab and 23,000 units hyaluronidase) given subcutaneously every 6 months

Coverage Period:
Initial: 1 Year
Subsequent:

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

ICD-10:
G35

References

1. Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq). Prescribing Information. Genentech, Inc., South San Francisco, CA. 9/2024.

Review History

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

- HCPCS: Added J2351, effective 4/1/2025

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