RX.PA.025.MPC Ocrevus® (Ocrelizumab) & Ocrevus Zunovo® (Ocrelizumab and hyaluronidase-ocsq)

The purpose of this policy is to define the prior authorization process for Ocrevus® (ocrelizumab) and Ocrevus Zunovo® (Ocrelizumab and hyaluronidase-ocsq)

Site of Service
Medication(s) included in this criteria are subject to review under policy RX.PA.070.MPC: Site of Service – Outpatient Infusion/Injection Services

Ocrelizumab is indicated for relapsing or primary progressive forms of multiple sclerosis (MS).

PROCEDURE

A. Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a neurologist
- Must have a diagnosis of relapsing form of MS or primary progressive MS
- Must be age 18 years or older
- Must have chart documentation showing negative result for hepatitis B virus
- Must have previously had an inadequate response (trial and failure for at least 3 months) or intolerance to the following multiple sclerosis therapies: Fingolimod (Gilenya) and Dimethyl Fumarate (Tecfidera)
- For relapsing form of MS: Must have previously had an inadequate response (trial and failure for at least 3 months) or intolerance to Natalizumab (Tyruko)
- Must not have an active infection
- Must not be receiving concurrent disease modifying antirheumatic drugs (DMARDS)

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Ocrevus & Ocrevus Zunovo will be considered investigational or experimental for any other use and will not be covered.

D. Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

MPC Renewal:

- Chart documentation from the prescriber that the member's condition has improved or stabilized based upon the prescriber's assessment while on therapy
  - **a)** Patient meets one of the following [(1) or (2)]:
    (1) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
    Note: Examples include stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging (MRI) [absence or a decrease in gadolinium enhancing lesions, decrease in the number of new or enlarging T2 lesions]; stabilization or reduced worsening on the Expanded Disability State Scale (EDSS) score; achievement in criteria for No Evidence of Disease Activity-3 (NEDA-3) or NEDA-4; improvement on the fatigue symptom and impact questionnaire-relapsing multiple sclerosis (FSIQ-RMS) scale; reduction or absence of relapses; improvement or maintenance on the six-minute walk test or 12-Item Multiple Sclerosis Walking Scale; improvement on the Multiple Sclerosis Functional Composite (MSFC) score; and/or attenuation of brain volume loss; OR
    (2) Patient experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation
- Member must have a recent MRI (within 6 months) with no new asymptomatic lesions
- Must be prescribed by a neurologist
- Must have a diagnosis of relapsing form of MS or primary progressive MS
- Must be age 18 years or older
- Must have chart documentation of annual testing and monitoring for hepatitis B virus
- Must not have an active infection
- Must not be receiving concurrent disease modifying therapy (interferon beta-1a, interferon beta-1b, glatiramer acetate, dimethyl fumarate, or fingolimod) or have systemic medical conditions resulting in significant compromised immune system function

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples should be considered under criterion A (Initial Authorization Criteria)
- Provider has a documented clinical response of the member's condition which

has stabilized or improved based upon the prescriber's assessment

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	6 months
Reauthorization	1 year
Quantity Level Limit	
300 mg/10ml	20 ml per 6 months for Ocrevus
920mg/23ml	23ml per 6 months for Ocrevus Zunovo

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

HCPCS Code(s):

Code	Description
J2350	Injection, ocrelizumab, 1 mg
J2351	Injection, ocrelizumab, 1 mg and hyaluronidase-ocsq

REFERENCES

1. Ocrevus (ocrelizumab) [prescribing information]. San Francisco, CA: Genentech, Inc.; March 2017.
2. Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) [prescribing information]. San Francisco, CA: Genentech, Inc.; Aug 2025.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Selected Revision *Addition of Ocrevus Zunovo*	*04/2026*
Annual Review	*02/2026*
Annual Review	*02/2025*
Annual Review *Change in Non-MPC renewal to renewal from previous insurer*	*02/2024*
Selected Revision *Removal of requiring chart documentation showing negative hepatitis B virus results from reauthorization criteria*	*10/2023*

Selected Revision *Diagnosis of primary progressive MS as an exception to trial and failure of preferred agents*	*08/2023*
Annual review	*02/2023*
Selected Revision *Addition of MPC vs Non-MPC Renewal Criteria*	*07/2022*
Addition of clinical requirements to the reauthorization criteria	*05/2022*
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2020*