



## **RX.PA.025.MPC Ocrevus® (Ocrelizumab)**

The purpose of this policy is to define the prior authorization process for Ocrevus® (ocrelizumab).

Ocrevus® (ocrelizumab) is indicated for relapsing or primary progressive forms of multiple sclerosis (MS).

The drug, Ocrevus® (ocrelizumab), is subject to the prior authorization process.

### **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 at least ONE of the following multiple sclerosis therapies: Avonex (interferon beta-1a), Copaxone (glatiramer acetate), Plegridy (peginterferon beta- 1a), or Tecfidera (dimethyl fumarate)
  - Previous trial of another multiple sclerosis therapy is not required in the following patients:
    - Patients with rapidly evolving severe relapsing remitting MS defined as 2 or more disabling relapses in 1 year AND with 1 or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI7 OR
    - Patients who have 3 or more predictive factors of poor prognosis:
      - Age of onset 40 years or older
      - Motor system involvement at onset including weakness of the extremities or ataxia
      - 4 or more T2-weighted lesions suggestive of MS seen on MRI
      - 2.5 years or less between the first 2 relapses
      - 2 or more relapses in the first year of disease
      - Poor recovery from the initial 2 relapses defined as an EDSS of 1.5 or higher sustained for at least 1 year
    - Members with a documented diagnosis of primary progressive MS

- 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

**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 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,

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interferon beta-1b, glatiramer acetate, dimethyl fumarate, or fingolimod) or have systemic medical conditions resulting in significant compromised immune system function

**Non-MPC Renewal:**

- Members who have previously been taking Ocrevus and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria)
- Member has not been receiving medication samples for Ocrevus; AND
- 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

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

**REFERENCES**

1. Ocrevus (ocrelizumab) [prescribing information]. San Francisco, CA: Genentech, Inc.; March 2017.

**REVIEW HISTORY**

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Selected Revision Removal of requiring chart documentation showing negative hepatitis B virus results from reauthorization criteria</i>	10/2023
<i>Selected Revision Diagnosis of primary progressive MS as an exception to trial and failure of preferred agents</i>	08/2023

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<i>Annual review</i>	<i>02/2023</i>
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<i>Selected Revision</i>	<i>07/2022</i>
<i>Addition of MPC vs Non-MPC Renewal Criteria</i>	
<i>Addition of clinical requirements to the reauthorization criteria</i>	<i>05/2022</i>
<i>Annual review</i>	<i>02/2022</i>
<i>Addition of dosing requirements and off-label restrictions</i>	<i>12/2021</i>
<i>P&amp;T Review</i>	<i>11/2020</i>