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. <u>Reauthorization Criteria:</u>

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) <u>or</u> (2)]:
    (1) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
    <u>Note</u>: 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

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
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*