Medical Pharmacy Drug Prior Authorization Criteria

Drug Trade Name:	Ocrevus	**Drug Generic Name:**	Ocrelizumab
J Code:	J2350	**1 billable unit =**	1 mg
Original Date of Review:	12/7/2022	**Last Reviewed:**	9/11/2024
Revision Date History	12/7/2022, 3/15/2023, 8/30/2023, 12/13/2023		

Ocrelizumab binds to CD-20, a cell surface antigen present on pre-B and mature B lymphocytes, which results in antibody-dependent cellular cytolysis and complement-mediated lysis

Criteria:

- **Length of authorization:**
  - Initial authorizations will be provided for up to 6 months
  - Renewal authorizations will be provided for up to 12 months
- **Age:** see below for product specific requirements
- **Diagnoses:** Multiple Sclerosis (G35)
- **Quantity Limit:** 300mg single-dose vial: 2 vials in first 2 weeks, then 2 vials per 6 months
- **Maximum Units:**
  - **Initial dose:** 300 billable units (mg) D1 and D15
  - **Subsequent doses:** 600 billable units (mg) every 6 months

- **Initial Approval Criteria**
  - **Universal Criteria:**
    - Patient is 18 years or older (unless otherwise specified); AND
    - Patient has been screened for the presence of Hepatitis B virus (HBV) prior to initiating treatment AND does not have active disease (i.e., positive HBsAg and anti-HBV tests); AND
    - Patient has baseline serum immunoglobulins assessed; AND
    - Patient will not receive live vaccines concurrently with ocrelizumab; AND
    - Provider attests that the patient will be screened for active infection, including clinically important localized infections, prior to each administration of this medication; AND
  - **Indication Specific Criteria**
    - Multiple Sclerosis:
      - Patient must have a confirmed diagnosis* of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI); AND
      - Must be used as single agent therapy; AND
      - Patient has a diagnosis of a relapsing form of MS [i.e., relapsing-remitting MS (RRMS)*, active secondary progressive disease (SPMS)**, or clinically isolated syndrome (CIS)***]; OR
      - Patient has a diagnosis**** of primary progressive MS (PPMS); AND
        - Patient is less than 65 years; AND
        - Patient has an expanded disability status scale (EDSS) score of ≤ 6.5

**Active secondary progressive MS (SPMS) is defined as the following:
• Expanded Disability Status Scale (EDSS) score ≥ 3.0; AND

- Disease is progressive ≥ 3 months following an initial relapsing-remitting course (i.e., EDSS score increase by 1.0 in patients with EDSS ≤5.5 or increase by 0.5 in patients with EDSS ≥6); AND
  - ≥ 1 relapse within the previous 2 years; OR
  - Patient has gadolinium-enhancing activity or new and unequivocally enlarging T2 contrast- enhancing lesions as evidenced by MRI

***Definitive diagnosis of CIS is based upon ALL of the following:

- A monophasic clinical episode with patient-reported symptoms and objective findings reflecting a focal or multifocal inflammatory demyelinating event in the CNS
- Neurologic symptom duration of at least 24 hours, with or without recovery
- Absence of fever or infection
- Patient is not known to have multiple sclerosis

****Definitive diagnosis of MS with a primary progressive course is based upon the following:

- 1 year of disability progression independent of clinical relapse; AND
- TWO of the following:
  - ≥ 1 T2-hyperintense lesion characteristic of MS in one or more of the following regions of the CNS (periventricular, cortical or juxtacortical, or infratentorial)
  - ≥ 2 T2-hyperintense lesions in the spinal cord
  - Presence of CSF-specific oligoclonal bands

- **Renewal Criteria**
  - Patient continues to meet the universal and other indication-specific relevant criteria; AND
  - Patient has not received a dose of ocrelizumab within the past 5 months; AND
  - Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infusion reactions, severe infections, malignancy, hypogammaglobulinemia, etc.; AND
  - Continuous monitoring of response to therapy indicates a beneficial response [manifestations of MS disease activity include, but are not limited to, an increase in annualized relapse rate (ARR), development of new/worsening T2 hyperintensities or enhancing lesions on brain/spinal MRI, and progression of sustained impairment as evidenced by expanded disability status scale (EDSS), timed 25-foot walk (T25-FW), 9-hole peg test (9-HPT)]
    - Inadequate response, in those who have been adherent and receiving therapy for sufficient time to realize the full treatment effect, is defined as ≥ 1 relapse, ≥ 2 unequivocally new MRI-detected lesions, or increased disability on examination over a one-year period

Note: patients with primary progressive MS generally do not have clinical relapses and do not typicallydevelop new lesions on MRI

  - PPMS: Patient continues to be ambulatory, defined as EDSS score of <7.5

- **Dosage/Administration**

Ocrevus (ocrelizumab)	
Indication	**Dose**
Multiple Sclerosis	Initial dose: • 300 mg intravenous infusion, followed two weeks later by a second 300 mg IV infusion Subsequent doses: • 600 mg IV infusion every 6 months • Administer first subsequent dose 6 months after infusion of the initial dose

NDC: Ocrevus 300 mg/10 mL single-dose vial: 50242-0150-xx

References:

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4. Gawronski KM, Rainka MM, Patel MJ, Gengo FM. Treatment Options for Multiple Sclerosis: Current and Emerging Therapies. Pharmacotherapy. 2010; 30(9):916-927.
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12. Kappos L, Bar-Or A, Cree BAC, et al. Siponimod versus placebo in secondary progressive multiple sclerosis (EXPAND): a double-blind, randomised, phase 3 study. Lancet. 2018;391(10127):1263. Epub 2018 Mar 23.
13. Lorscheider J, Buzzard K, Jokubaitis V, et al, on behalf of the MSBase Study Group. Defining secondary progressive multiple sclerosis. Brain, Volume 139, Issue 9, September 2016, Pages 2395–2405, https://doi.org/10.1093/brain/aww173.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G35	Multiple Sclerosis