

Medical Pharmacy Drug Prior Authorization Criteria

Drug Trade Name:	Ocrevus® (IV) Ocrevus Zunovo® (SQ)	Drug Generic Name:	Ocrelizumab Ocrelizumab and hyaluronidase-ocsq
J Code:	J2350, J2351	1 billable unit =	1 mg
Original Date of Review:	12/7/2022	Last Reviewed:	3/11/2026
Revision Date History	12/7/2022, 3/15/2023, 8/30/2023, 12/13/2023, 9/10/2025, 3/11/2026		

Ocrelizumab binds to CD-20, a cell surface antigen present on pre-B and mature B lymphocytes, which results in antibody-dependent cellular cytotoxicity 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:** 18 years and older
- **Diagnoses:**
- **Quantity Limit:**
 - **Ocrevus** 300mg single-dose vial: 2 vials in first 2 weeks, then 2 vials per 6 months
 - **Ocrevus Zunovo 920mg single-dose vial every 6 months**
- **Maximum Units:**
 - **Initial dose:**
 - **Ocrevus** 300 billable units (mg) D1 and D15
 - **Ocrevus Zunovo 920 billable units (mg) every 6 months**
 - **Subsequent doses:**
 - **Orevus** 600 billable units (mg) every 6 months
 - **Ocrevus Zunovo 920 billable units (mg) every 6 months**
- **Initial Approval Criteria**
 - **Universal Criteria:**
 - Patient is 18 years or older (unless otherwise specified); AND
 - Clinical documentation 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
 - Clinical documentation patient had baseline serum immunoglobulins assessed; AND
 - Clinical documentation patient has baseline serum aminotransferases (alanine aminotransferase [ALT] and aspartate aminotransferase [AST], alkaline phosphatase and bilirubin levels assessed; AND
 - Provider attests 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
 - Provider attests drug to be used as single agent therapy; AND
 - Clinical documentation 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
 - Clinical documentation patient has a diagnosis**** of primary progressive MS (PPMS); AND
 - Patient is less than 65 years; AND
 - Clinical documentation 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

- Provider attests patient has not received a dose of ocrelizumab within the past 5 months; AND
- Provider attests patient has not experienced any unacceptable toxicities from the drug.
 - Examples of unacceptable toxicity include the following: severe infusion reactions, severe infections, malignancy, hypogammaglobulinemia, liver toxicity, etc.; AND
- Clinical documentation demonstrates patient has experienced a beneficial response to therapy or disease stabilization
 - 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 typically develop new lesions on MRI

- PPMS: Clinical documentation patient continues to be ambulatory, defined as EDSS score of <7.5

- **Dosage/Administration**

Ocrevus® (ocrelizumab)	
Indication	Dose
Multiple Sclerosis	Initial dose: <ul style="list-style-type: none"> • 300 mg intravenous infusion, followed two weeks later by a second 300 mg IV infusion Subsequent doses: <ul style="list-style-type: none"> • 600 mg IV infusion every 6 months • Administer first subsequent dose 6 months after infusion of the initial dose
Ocrevus Zunovo® (ocrelizumab and hyaluronidase-ocsa)	
Indication	Dose
Multiple Sclerosis	Initial dose: <ul style="list-style-type: none"> • 920 mg/23,000 units as a single subcutaneous injection Subsequent doses: <ul style="list-style-type: none"> • 920 mg/23,000 units subcutaneously every 6 months

NDC: Ocrevus® 300 mg/10 mL single-dose vial: 50242-0150-01

NDC: Ocrevus Zunovo® 920 mg and 23,000 units/23 mL single-dose vial: 50242-554-01

References:

1. Ocrevus® [package Insert]. South San Francisco, CA; Genentech, Inc.; March 2021. Accessed August 2021.
2. Montalban X, Hauser SL, Kappos L, et al. Ocrelizumab versus Placebo in Primary Progressive Multiple Sclerosis. *N Engl J Med*. 2017 Jan 19;376(3):209-220.
3. Hauser SL, Bar-Or A, Comi G, et al. Ocrelizumab versus Interferon Beta-1a in Relapsing Multiple Sclerosis. *N Engl J Med*. 2017 Jan 19;376(3):221-234.
4. Gawronski KM, Rainka MM, Patel MJ, Gengo FM. Treatment Options for Multiple Sclerosis: Current and Emerging Therapies. *Pharmacotherapy*. 2010; 30(9):916-927.
5. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. *Neurology*. 2002 Jan 22; 58(2):169-78.
6. Freedman MS, Selchen D, Arnold DL, et al. Treatment optimization in MS: Canadian MS Working Group updated recommendations. *Can J Neurol Sci*. 2013 May;40(3):307-23.
7. Polman CH, Reingold SC, Banwell B, et al. Diagnostic criteria for multiple sclerosis: 2010 Revisions to the McDonald criteria. *Ann Neurol*. 2011 Feb; 69(2): 292–302. doi: 10.1002/ana.22366.
8. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014 Jul 15;83(3):278-86.
9. Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis: principles and current evidence. 2017 March. http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. Accessed 4/2018.
10. Rae-Grant, A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology®* 2018;90:777-788.
11. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018 Feb;17(2):162-173. doi: 10.1016/S1474- 4422(17)30470-2.
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>.

Covered Diagnosis Codes

ICD-10	ICD-10 Description
G35.A	Relapsing-remitting multiple sclerosis
G35.B0	Primary progressive multiple sclerosis, unspecified
G35.B2	Non-active primary progressive multiple sclerosis
G35.C1	Active secondary progressive multiple sclerosis
G35.D	Multiple sclerosis, unspecified