CareSource

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Ocrevus (ocrelizumab)
BILLING CODE	J2350 (1 unit = 1 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— Max 600 mg every 6 months
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Ocrevus (ocrelizumab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

PRIMARY PROGRESSIVE MULTIPLE SCLEROSIS (PPMS)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of PPMS; AND
4. Member must have documented negative results on Hepatitis B screening (negative results for both HBsAg and anti-HBV). For those who are negative for surface antigen (HBsAg) and positive for HB core antibody (HBcAb+) or are carriers of HBV (HBsAg+), a hepatologist must be consulted; AND
5. Member does not have an active infection; AND
6. Ocrevus is not being used in combination with other multiple sclerosis drugs.
7. **Dosage allowed:** 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion; then 600 mg intravenous infusion every 6 months.

If member meets all the requirements listed above, the medication will be approved 12 months.

For **reauthorization**:

1. Chart notes must indicate positive clinical response such as slowed or stabilized rate of disability progression or MRI outcomes (e.g., volume of lesions, change in brain volume).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

RELAPSING FORMS OF MULTIPLE SCLEROSIS

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of relapsing-remitting multiple sclerosis (RRMS), active secondary progressive multiple sclerosis (SPMS), or clinically isolated syndrome (CIS); AND
4. Member has tried and failed at least one preferred disease-modifying MS drug; AND
5. Member must have documented negative results on Hepatitis B screening (negative results for both HBsAg and anti-HBV). For those who are negative for surface antigen (HBsAg) and positive for HB core antibody (HBcAb+) or are carriers of HBV (HBsAg+), a hepatologist must be consulted; AND

6. Member does not have an active infection; AND
7. Ocrevus is not being used in combination with other disease-modifying MS drugs.
8. **Dosage allowed:** 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion; then 600 mg intravenous infusion every 6 months.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes must indicate a positive clinical response such as fewer relapses, slowed or improved disability, or effect on MRI measures (e.g., no new or enlarged brain lesions).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Ocrevus (ocrelizumab) not medically necessary for the treatment of diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/09/2017	New policy for Ocrevus created.
12/06/2017	Age coverage expanded.
08/16/2021	Updated all references. Removed CIS as an exclusion and added it to RRMS criteria. Changed trial of 2 preferred drugs first for RRMS to trial of 1. Removed incorrect diagnostic requirement from RRMS section. Removed diagnostic specifics for PPMS from outdated McDonald criteria. Removed vaccination details. Removed note about switching products. Simplified HBV phrasing. Revised renewal criteria. Added office as site of care.

References:

1. Ocrevus [package insert]. South San Francisco, CA; Genentech, Inc: March, 2021.
2. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173. doi:10.1016/S1474-4422(17)30470-2
3. Hauser SL, Bar-Or A, Comi G, et al. Ocrelizumab versus Interferon Beta-1a in Relapsing Multiple Sclerosis. *N Engl J Med*. 2017;376(3):221-234. doi:10.1056/NEJMoa1601277
4. Montalban X, Hauser SL, Kappos L, et al. Ocrelizumab versus Placebo in Primary Progressive Multiple Sclerosis. *N Engl J Med*. 2017;376(3):209-220. doi:10.1056/NEJMoa1606468
5. Hauser SL, Kappos L, Arnold DL, et al. Five years of ocrelizumab in relapsing multiple sclerosis: OPERA studies open-label extension. *Neurology*. 2020;95(13):e1854-e1867. doi:10.1212/WNL.0000000000010376
6. Zimmermann M, Brouwer E, Tice JA, et al. Disease-Modifying Therapies for Relapsing-Remitting and Primary Progressive Multiple Sclerosis: A Cost-Utility Analysis. *CNS Drugs*. 2018;32(12):1145-1157. doi:10.1007/s40263-018-0566-9
7. 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 [published correction appears in Neurology. 2019 Jan 8;92(2):112]. *Neurology*. 2018;90(17):777-788
8. National Multiple Sclerosis Society. The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A Consensus Paper by the Multiple Sclerosis Coalition; 2019. Available from: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed August 18, 2021.

Effective date: 01/01/2022
Revised date: 08/16/2021