

PHARMACY POLICY STATEMENT

North Carolina Marketplace

DRUG NAME	Ocrevus (ocrelizumab) and Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Ocrevus, approved by the FDA in 2017, is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. It is also indicated for treatment of primary progressive MS in adults. After loading doses, Ocrevus is administered by the provider as an IV infusion every 6 months. In 2024 the FDA approved Ocrevus Zunovo, a co-formulation with hyaluronidase to increase permeability of the subcutaneous tissue which allows for subcutaneous administration. It is given every 6 months by a healthcare provider like the IV formulation but takes much less time to administer (10 minutes vs. 2 hours).

Ocrevus (ocrelizumab) and Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) will be considered for coverage when the following criteria are met:

Primary Progressive Multiple Sclerosis (PPMS)

For **initial** authorization:

1. Member is at least 18 years of age; 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 has tested negative for active hepatitis B, or a hepatologist has been consulted; AND
5. Ocrevus will not be used concurrently with another disease-modifying agent for MS.
6. **Dosage allowed/Quantity limit:**
Ocrevus: 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion; then 600 mg intravenous infusion every 6 months.
 QL: 2 vials per 6 months
Ocrevus Zunovo: 920 mg/23,000 units (920 mg ocrelizumab and 23,000 units of hyaluronidase) administered as a single 23 mL subcutaneous injection every 6 months
 QL: 1 vial (23 mL) per 6 months

If all the above requirements are met, the medication will be approved for 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 all the above requirements are met, the medication will be approved for an additional 12 months.

Relapsing forms of Multiple Sclerosis (MS)

For **initial** authorization:

1. Member is at least 18 years of age; 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 documentation of at least **ONE** of the following:
 - a) Inadequate response to at least **ONE** preferred generic disease-modifying MS drug;
 - b) Highly active disease (aggressive or rapidly evolving) in the expert opinion of the prescriber; AND
5. Member has tested negative for active hepatitis B, or a hepatologist has been consulted; AND
6. Ocrevus will not be used concurrently with another disease-modifying agent for MS.
7. **Dosage allowed/Quantity limit:**
Ocrevus: 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion; then 600 mg intravenous infusion every 6 months.
 QL: 2 vials per 6 months
Ocrevus Zunovo: 920 mg/23,000 units (920 mg ocrelizumab and 23,000 units of hyaluronidase) administered as a single 23 mL subcutaneous injection every 6 months
 QL: 1 vial (23 mL) per 6 months

If all the above requirements are met, 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 all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Ocrevus (ocrelizumab) and Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
07/14/2022	Transferred to new template. Added new references. Simplified HBV language. For RRMS, added that they don't have to try another drug first if they have highly active disease.
10/29/2024	Added Ocrevus Zunovo to policy.
01/31/2025	MS: added that trial must be generic.

References:

1. Ocrevus [package insert]. South San Francisco, CA; Genentech, Inc.; 2024.
2. Ocrevus Zunovo [package insert]. South San Francisco, CA; Genentech, Inc.; 2024
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4. 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

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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.
9. Lin M, Zhang J, Zhang Y, Luo J, Shi S. Ocrelizumab for multiple sclerosis. *Cochrane Database Syst Rev*. 2022;5(5):CD013247. Published 2022 May 18. doi:10.1002/14651858.CD013247.pub2
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11. McGinley MP, Goldschmidt CH, Rae-Grant AD. Diagnosis and Treatment of Multiple Sclerosis: A Review [published correction appears in *JAMA*. 2021 Jun 1;325(21):2211]. *JAMA*. 2021;325(8):765-779. doi:10.1001/jama.2020.26858

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