

POLICY Document for OCREVUS (ocrelizumab)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall, clinically appropriate use. This document provides specific information to each of the three sections of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria Administration of Intravenous Ocrevus

POLICY

I. CRITERIA FOR APPROVAL FOR ADMINISTRATION IN OUTPATIENT HOSPITAL SETTING

This policy provides coverage for administration of Ocrevus in an outpatient hospital setting for up to 45 days when a member is new to therapy or is reinitiating therapy after not being on therapy for more than 6 months.

This policy provides coverage for administration of Ocrevus in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

- A. The member has experienced an adverse reaction to the drug that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.
- B. The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
- C. The member has severe venous access issues that require the use of special interventions only available in the outpatient hospital setting.
- D. The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
- E. Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
- F. The member is less than 14 years of age.

For situations where administration of Ocrevus does not meet the criteria for outpatient hospital infusion, coverage for Ocrevus is provided when administered in alternative sites such as physician office, home infusion or ambulatory care.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the site of care prior authorization review (where applicable):

- A. Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion

- B. Medical records supporting the member is medically unstable
- C. Medical records supporting the member has severe venous access issues that require specialized interventions only available in the outpatient hospital setting
- D. Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
- E. Records supporting alternative infusion sites are greater than 30 miles from the member's home.
- F. Medical records supporting the member is new to therapy

Section 2: Clinical Criteria

Specialty Guideline Management

Ocrevus-Ocrevus Zunovo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ocrevus	ocrelizumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹⁻²

- Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- Treatment of primary progressive MS, in adults.

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist.

Coverage Criteria

Relapsing Forms of Multiple Sclerosis¹⁻²

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

Clinically Isolated Syndrome¹⁻²

Authorization of 12 months may be granted to members for treatment of clinically isolated syndrome of multiple sclerosis.

Primary Progressive Multiple Sclerosis¹⁻²

Authorization of 12 months may be granted to members for treatment of primary progressive multiple sclerosis.

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section who are experiencing disease stability or improvement while receiving the requested drug.

Other Criteria

- Members will not use the requested drug concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).
- Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

REFERENCES

SECTION 1

1. Ocrevus [package insert]. South San Francisco, CA: Genentech Inc.; January 2024.

2. 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.
3. 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.

SECTION 2

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