

Ocrevus® (ocrelizumab)

Ocrevus Zunovo™ (ocrelizumab and hyaluronidase-ocsq)

When requesting an ocrelizumab product (Ocrevus®, Ocrevus Zunovo™), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Ocrevus and Ocrevus Zunovo are 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
- Primary progressive MS, in adults

Coverage Guidelines

Multiple Sclerosis (MS), Relapsing Forms

The individual must meet the following criteria for authorization:

- Has a relapsing form of multiple sclerosis (i.e., clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease);
- Is 18 years of age or older;
- Ocrevus or Ocrevus Zunovo is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.
- For re-authorization, the individual has been receiving Ocrevus or Ocrevus Zunovo for at least 12 months and meets one of the following:
 - o Has experienced a beneficial clinical response by at least one objective measure (e.g., stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging [MRI], stabilization or reduced worsening on the Expanded Disability Status Scale [EDSS] score, achievement in criteria for No Evidence of Disease Activity-3 [NEDA-3] or NEDA-4, improvement on the fatigue symptom and impact questionnaire-relapsing multiple sclerosis [FSIQ-RMS] scale, reduction or absence of relapses, improvement or maintenance on the six-minute walk test or 12-Item Multiple Sclerosis Walking Scale, improvement on the Multiple Sclerosis Functional Composite [MSFC] score, and/or attenuation of brain volume loss);
 - OR
 - o Has experienced stabilization, slowed progression, or improvement in at least one symptom (e.g., motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation).

Multiple Sclerosis, Primary Progressive

The individual must meet both of the following criteria for authorization:

- Is 18 years of age or older;
- Ocrevus or Ocrevus Zunovo is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

Approval duration (initial and renewal): 12 months

Dosing Recommendations

Ocrevus

The recommended initial dose is 300 mg intravenous infusion, followed 2 weeks later by a second 300 mg intravenous infusion. Subsequent maintenance doses are 600 mg intravenous infusion once every 6 months.

Ocrevus Zunovo

The recommended dose is 920 mg/23,000 units (920 mg ocrelizumab and 23,000 units of hyaluronidase) administered as a single 23 mL subcutaneous injection in the abdomen over approximately 10 minutes every 6 months.

References

1. Ocrevus® intravenous infusion [prescribing information]. San Francisco, CA: Genentech/Roche; August 2023.
2. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. Updated September 2019. Available at: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed on November 10, 2023.
3. McGinley MP, Goldschmidt C, Rae-Grant AD. Diagnosis and treatment of multiple sclerosis. A review. *JAMA*. 2021;325(8):765-779.
4. The Medical Letter on Drugs and Therapeutics. Drugs for multiple sclerosis. *Med Lett Drugs Ther*. 2021;63(1620):42-48.
5. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014;83:278-286.
6. 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.
7. Ocrevus Zunovo™ subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech, Inc. September 2024.