Ocrevus®/Ocrevus Zunovo (ocrelizumab)/(ocrelizumab & hyaluronidase-ocsq)

FDA INDICATIONS AND USAGE[1]

Ocrevus®/Ocrevus Zunovo™ 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, and
- Primary progressive MS, in adults.

APPROVAL CRITERIA[1,2,3,4,5]

1. Patient meets FDA labeled age **AND**;
2. Patient has a diagnosis of relapsing form of multiple sclerosis, clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, or primary progressive MS **AND**;
3. Prescribed by or in consultation with a neurologist or a prescriber that specializes in MS **AND**;
4. Patient has had an ineffective response due to continued clinical relapse, intolerance or contraindication two or more MS drugs within the last 12 months.

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Ocrevus is being prescribed concurrently with other disease modifying therapies for MS **OR**;
3. Patient has an active hepatitis B infection

CAUTIONS[1]

- Ocrevus® administration should be delayed in patients with an active infection until the infection is resolved or receiving live-attenuated vaccines.
- Patients should pre-medicate with methylprednisolone (or an equivalent corticosteroid) and an antihistamine (e.g., diphenhydramine) prior to each administration.
- Monitor for a reduction in level of immunoglobulins at the beginning of treatment.
- An increased risk of malignancy, including breast cancer, may exist with Ocrevus® and Ocrevus Zunovo™.

- Cases of progressive multifocal leukoencephalopathy (PML) have been reported in patients with MS treated with ocrelizumab. At the first sign/symptom suggestive of PML ocrelizumab should be withheld.

DURATION OF APPROVAL

- Initial Approval: up to 6 months
- Reauthorization Approval: up to 12 months if the prescriber documents the patient has disease improvement or stabilization.

QUANTITY LIMIT[1,2]

- Ocrevus:
  - Initial dose: 300mg IV, followed by a second 300mg dose 2 weeks later
  - Maintenance dose: 600mg every 6 months.
  - HCPCS: J2350
- Ocrevus Zunovo:
  - Ocrelizumab 920mg/hyaluronidase 23,000units per 23ml administered subcutaneously once every 6 months
  - HCPCS: J3490/J3590

REFERENCES / FOOTNOTES:

1. Ocrevus® [prescribing information]. San Francisco, CA: Genentech, Inc. June 2024.
2. Ocrevus Zunovo™ [prescribing information]. San Francisco, CA: Genentech, Inc. September 2024.
3. Costello K, Halper J, Kalb R, Skutnik L, Rapp R. The use of disease-modifying therapies in multiple sclerosis, principles and current evidence – a consensus paper by the Multiple Sclerosis Coalition. Updated June 2019. Accessed February 1, 2022.
4. 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.
5. Gajofatto A, Turatti M, Benedetti MD. Primary progressive multiple sclerosis: current therapeutic strategies and future perspectives. Expert Rev Neurother. 2017;17(4):393-406.