

Ocrevus™ (ocrelizumab)

When requesting Ocrevus (ocrelizumab), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Ocrevus is indicated for the treatment of adult patients with relapsing or primary progressive forms of multiple sclerosis (MS).

Coverage Guidelines

Multiple Sclerosis (MS)

The individual must meet **all** of the following criteria for initial authorization:

- Has either relapsing form of multiple sclerosis (examples include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease) or primary progressive multiple sclerosis;
- Is 18 years of age or older;
- Ocrevus is prescribed by or in consultation with a physician who specializes in the treatment of multiple sclerosis and/or a neurologist;
- For relapsing forms of MS, the individual has experienced inadequate efficacy or significant intolerance to at least one disease-modifying agent used for multiple sclerosis (e.g., Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Lemtrada, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tasckenso ODT, Tecfidera, Tysabri, Vumerity or Zeposia).

The individual must meet **all** of the following criteria for reauthorization:

- Is ≥ 18 years of age;
- Has either relapsing form of multiple sclerosis (examples include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease) or primary progressive multiple sclerosis;
- Ocrevus is prescribed by or in consultation with a physician who specializes in the treatment of multiple sclerosis and/or a neurologist;
- If the individual with a relapsing form of MS has received Ocrevus for 1 year or more, he/she must meet one of the following:
 - 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
- Has experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation.

Approval duration (initial and renewal): 12 months

Recommended Dosing

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

References

1. Ocrevus® injection for intravenous infusion [prescribing information]. San Francisco, CA: Genentech, Inc (a Member of the Roche Group); May 2020.
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 January 20, 2023.
3. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014;83:278-286.
4. 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.