SmartHealth

Ascension

Ocrelizumab

(Ocrevus®) J2350 (1mg)

Covered with prior authorization

Ocrelizumab (Ocrevus) may be authorized when the following criteria are met:

- Individual has a diagnosis of **primary progressive multiple sclerosis (PPMS)**; **AND**
    - Individual is able to ambulate more than 5 meters (not considered wheelchair bound);

OR

- Individual has a diagnosis of **relapsing multiple sclerosis (RMS**) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease); **AND**
    - Individual is able to ambulate without aid or rest for at least 100 meters; **AND**
- If initiating therapy, individual has experienced at least two relapses within the previous two years or one relapse within the previous year;

AND

- Individual has been on Ocrevus® (ocrelizumab); **OR**
- Previous trial in last 6 months of at least two MS drugs which are not tolerated or ineffective;
    - Evidence of treatment ineffectiveness defined as:
        - Increasing clinical relapses (defined as 2 or more relapses in a year or one severe relapse, associated with either poor recovery or MRI lesion progression); **OR**
        - CNS lesion progression by MRI (increased number or volume of gadolinium enhancing lesions, T2 hyperintense lesions or T1 hypointense lesions); **OR**
        - Worsening disability (sustained worsening of expanded disability status scale (EDSS) score or neurological examination findings); **OR**
        - Continues to have worsening disability as evidenced by decreased mobility and/or ability to perform activities of daily living;

AND

- Dose is 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion; **AND**
- Subsequent doses: 600 mg intravenous infusion every 6 months; **AND**
- Prescribed by, or in conjunction with Neurology.

Exclusion criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- All other indications not included above;
- Individual has active hepatitis B or another active infection at initiation of therapy;
- Individual has a history of life-threatening infusion reaction to Ocrevus (ocrelizumab);
- Individual is using to treat non-active secondary progressive multiple sclerosis;
- Individual is using to treat systemic lupus erythematosus;
- Individual is using to treat rheumatoid arthritis;

- Concurrent use with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Copaxone/ Glatiramer/Glatopa, Extavia, Gilenya, Kesimpta, Lemtrada, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tecfidera, Tysabri, Vumerity and Zeposia);
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.
OCREVUS 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
- Primary progressive MS, in adults

References:
Ocrevus Prescribing Information. South San Francisco, CA: Genentech, Inc; March 2021. Available at www.ocrevus.com. Accessed February 8, 2022.

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(17): 777-788. Full guideline available at: https://www.aan.com/Guidelines/home/GetGuidelineContent/904.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.

Ocrevus (ocrelizumab) label. (2021, March). Accessdata.fda.gov. Retrieved July 5, 2022, from https://www.gene.com/download/pdf/ocrevus_prescribing.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
June 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
July 2022	Criteria for use summary approved by Ascension Ambulatory Care Expert Review Panel
July 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.