

Ocrevus (ocrelizumab)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Ocrevus (ocrelizumab)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Ocrevus (ocrelizumab) may be approved if the following criteria are met:

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

OR

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

AND

- VI. Documentation is provided that individual has been on Ocrevus (ocrelizumab). Medication samples/coupons/discount cards are excluded from consideration as a trial.;

OR

- VII. Documentation has been provided that individual has had a trial and inadequate response (including but not limited to clinical relapse, new or enlarged lesions on MRI or disability progression) or intolerance to dimethyl fumarate (generic Tecfidera). Medication samples/coupons/discount cards are excluded from consideration as a trial.;

OR

- VIII. Documentation is provided that individual has high disease activity despite treatment with fingolimod (Gilenya, Tascenso ODT) defined as the following (AAN 2018, Devonshire 2012):

- A. At least one relapse in the previous year while on therapy; **AND**
- B. At least 9 T₂-hyperintense lesions in cranial MRI;

OR

- C. At least one Gadolinium-enhancing lesion;

OR

- IX. Documentation is provided that individual is requesting Ocrevus for the treatment of primary progressive multiple sclerosis.

Ocrevus (ocrelizumab) may not be approved for the following:

- I. Individual has active hepatitis B or hepatitis C virus infection or another active infection at initiation of therapy; **OR**
- II. Individual has a history of life-threatening infusion reaction to Ocrevus (ocrelizumab); **OR**
- III. Individual is using to treat non-active secondary progressive multiple sclerosis; **OR**
- IV. Individual is using to treat systemic lupus erythematosus; **OR**
- V. Individual is using to treat rheumatoid arthritis; **OR**
- VI. Use in combination with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Copaxone/ Glatiramer/Glatopa, Extavia, Gilenya, Kesimpta, Lemtrada, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Tysabri, Vumerity and Zeposia); **OR**
- VII. May not be approved when the above criteria are not met and for all other indications.

Key References:

- 1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 20, 2023.
- 2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 3. Expanded Disability Status Scale (EDSS). Department of Veterans Affairs: Multiple Sclerosis Centers for Excellence. Last updated: March 18, 2021. Available at: https://www.va.gov/MS/Professionals/diagnosis/Kurtzke_Expanded_Disability_Status_Scale.asp. Accessed: October 20, 2023.
- 4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
- 5. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: August 30, 2023. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 19, 2023.
- 6. 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. Available from: <https://www.aan.com/Guidelines/home/GuidelineDetail/898>. Accessed: October 27, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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