

Kesimpta (ofatumumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Kesimpta (ofatumumab) 20 mg/0.4 mL prefilled pen/syringe	1 prefilled pen/syringe per 28 days*

***Initiation of Kesimpta (ofatumumab) therapy:** May approve two additional pens/syringes during the first month of treatment.

APPROVAL CRITERIA

Requests for Kesimpta (ofatumumab) may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease).

Kesimpta (ofatumumab) may not be approved for the following:

- I. Use in combination with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Lemtrada, Mavenclad, Mayzent, Ocrevus, Ocrevus Zunovo, Plegridy, Ponvory, Rebif, Tasenso ODT, Tecfidera, Tyruko, Tysabri, Vumerity and Zeposia); **OR**
- II. Individual is using to treat non-active secondary progressive multiple sclerosis; **OR**
- III. Individual is using to treat primary progressive multiple sclerosis; **OR**
- IV. Individual has active hepatitis B or another active infection at initiation of therapy; **OR**
- V. 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 22, 2025.
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 22, 2025.
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: April 18, 2025. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 23, 2025.
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 23, 2025.

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.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.