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); **AND**
II. Individual is able to ambulate without aid or rest for at least 100 meters; **AND**
III. If initiating therapy, individual has experienced at least two relapses within the previous two years or one relapse within the previous year or at least one T1 gadolinium-enhancing lesion on MRI within the previous year;

AND

IV. Documentation is provided that individual has been on Kesimpta. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **OR**
V. Documentation has been provided that individual has had a trial and inadequate response (including but not limited to confirmed clinical relapse, new or enlarged lesions on MRI or confirmed disability progression) or intolerance to generic dimethyl fumarate (generic Tecfidera). Medication samples/coupons/discount cards are excluded from consideration as a trial.; **OR**
VI. 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 T_2-hyperintense lesions in cranial MRI;

    OR

    C. At least one Gadolinium-enhancing lesion.

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, Tascenso 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 23, 2024.
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 27, 2024.
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 26, 2024. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 27, 2024.
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, 2024.