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. 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, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, 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 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
7. Academy of Neurology. Neurology. 2018; 90: 777-788. Available from: https://www.aan.com/Guidelines/home/GuidelineDetail/898. Accessed: October 27, 2023.