

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

## 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.

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

- I. Concurrent use with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, 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.

### 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: August 20, 2020.

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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: April 7, 2020. Available at: [http://www.va.gov/MS/Professionals/Diagnosis/Kurtzke\\_Expanded\\_Disability\\_Status\\_Scale.asp](http://www.va.gov/MS/Professionals/Diagnosis/Kurtzke_Expanded_Disability_Status_Scale.asp). Accessed: August 20, 2020.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: July 23, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 29, 2020.
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: July 31, 2020.

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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