Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	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:

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

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.
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. 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 polices may take precedence over the application of this clinical criteria.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.