Pharmacy Policy Bulletin: J-1013 Kesimpta (ofatumumab) – Commercial and Healthcare Reform	
Number: J-1013	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Quantity Limits (1., 2., 3., or 4.):** **1.** Rx Mgmt Quantity Limits = Safety/Specialty **2.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt **3.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt + Watchful **4.** Rx Mgmt Performance = MRxC = Yes **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1013-006	**Original Date:** 10/07/2020
Effective Date: 10/28/2024	**Review Date:** 10/02/2024

Drugs Product(s):	• Kesimpta (ofatumumab)
FDA-Approved Indication(s):	• Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults

Background:	• Kesimpta is a CD20-directed cytolytic monoclonal antibody. It is presumed to bind to CD20, a cell surface antigen present on pre-B and mature B lymphocytes, resulting in antibody-dependent cellular cytolysis and complement-mediated lysis. • MS is an immune-mediated process in which an abnormal response of the body's immune system is directed against the central nervous system (CNS), causing symptoms such as fatigue, numbness, tingling, blurred vision, imbalance, and pain. Nearly 1 million people are living with MS in the United States. • There are 4 types of MS: clinically isolated syndrome (CIS), relapsing remitting (RRMS), secondary progressive (SPMS), and primary progressive (PPMS). CIS is the first episode of neurological symptoms caused by inflammation and demyelination in the central nervous system. RRMS is characterized by clearly

	defined attacks of new or increasing neurologic symptoms. The attacks are followed by periods of partial or complete recovery (remissions). SPMS follows an initial relapsing remitting course, with disability gradually increasing over time. • Prescribing Considerations: ○ Monitor the level of immunoglobulins at the beginning, during, and after discontinuation of treatment with Kesimpta until B-cell repletion. Consider discontinuing Kesimpta if a patient develops a serious opportunistic infection or recurrent infections if immunoglobulin levels indicate immune compromise. ○ May cause fetal harm based on animal data. Advise females of reproductive potential of the potential risk to a fetus and to use an effective method of contraception during treatment and for 6 months after stopping Kesimpta. ○ Kesimpta should be prescribed under the supervision of a neurologist.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Kesimpta may be approved when all of the following criteria are met **(A. and B.):**

A. The member is 18 years of age or older.

B. The member has a diagnosis of MS (ICD-10: G35), classified as one (1) of the following relapsing forms **(1., 2., or 3.):**

1. Clinically isolated syndrome

2. Relapsing-remitting disease

3. Active secondary progressive disease

II. Reauthorization

When a benefit, reauthorization of Kesimpta may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member has experienced a therapeutic response defined as one (1) of the following **(1., 2., or 3.)**:

1. Disease stability

2. Disease improvement

3. Delayed disease progression

III. Quantity Level Limits

When prior authorization is approved, Kesimpta may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
Relapsing MS	Four (4) pens within the first 4 weeks	One (1) pen per month

IV. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Combination use of disease modifying MS agents (e.g. Aubagio, Gilenya, interferons, Copaxone, Tysabri, etc) will not be authorized.

II. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

III. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 24 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Kesimpta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2024.
2. National Multiple Sclerosis Society. What Is MS? Available at: https://www.nationalmssociety.org/What-is-MS. Accessed August 26, 2024.