CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Kesimpta (ofatumumab)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Kesimpta, approved by the FDA in 2020, is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Kesimpta is self-administered by subQ injection once a month after loading doses. Of note, ofatumumab was originally approved in 2009 as Arzerra for the treatment of leukemia.

Kesimpta (ofatumumab) will be considered for coverage when the following criteria are met:

Relapsing forms of Multiple Sclerosis (MS)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a confirmed diagnosis of relapsing multiple sclerosis, including clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS), or active secondary progressive disease (SPMS); AND
4. Member has documentation of at least one of the following:
   a) Inadequate response to at least one preferred disease-modifying MS drug
   b) Highly active disease (aggressive or rapidly evolving) in the expert opinion of the prescriber; AND
5. Member has tested negative for active hepatitis B, or a hepatologist has been consulted; AND
6. Kesimpta will not be used concurrently with another disease-modifying agent for MS.
7. **Dosage allowed/Quantity limit:** 20 mg administered by subcutaneous injection at weeks 0, 1, and 2, followed by 20 mg once monthly starting at week 4.
   (3 pens/syringes per 28 days for the first month only, then 1 pen/syringe per 28 days going forward)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing an improvement or stabilization in signs and symptoms of disease (e.g., fewer relapses, slowed disability progression, stable or reduced number or volume of brain lesions).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Kesimpta (ofatumumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
11/16/2020	New policy for Kesimpta created.
07/14/2022	Transferred to new template. Added new references. Removed baseline clinical measure. Changed trial of at least 2 other drugs to trial of 1 or have highly active disease.

References:

1. Kesimpta [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation. August 2020.
2. Bar-Or A, Grove RA, Austin DJ, et al. Subcutaneous ofatumumab in patients with relapsing-remitting multiple sclerosis: The MIRROR study [published correction appears in Neurology. 2018 Sep 11;91(11):538]. *Neurology*. 2018;90(20):e1805-e1814. doi:10.1212/WNL.0000000000005516
3. Hauser SL, Bar-Or A, Cohen JA, et al. Ofatumumab versus Teriflunomide in Multiple Sclerosis. *N Engl J Med*. 2020;383(6):546-557. doi:10.1056/NEJMoa1917246
4. 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 [published correction appears in Neurology. 2019 Jan 8;92(2):112]. *Neurology*. 2018;90(17):777-788
5. Gärtner J, Hauser SL, Bar-Or A, et al. Efficacy and safety of ofatumumab in recently diagnosed, treatment-naive patients with multiple sclerosis: Results from ASCLEPIOS I and II [published online ahead of print, 2022 Mar 10]. *Mult Scler*. 2022;13524585221078825. doi:10.1177/13524585221078825
6. McGinley MP, Goldschmidt CH, Rae-Grant AD. Diagnosis and Treatment of Multiple Sclerosis: A Review [published correction appears in JAMA. 2021 Jun 1;325(21):2211]. *JAMA*. 2021;325(8):765-779. doi:10.1001/jama.2020.26858

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Revised date: 07/14/2022