CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Kesimpta (ofatumumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 1 prefilled pen/30 days*
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

*may approve 2 additional pens during initial month of treatment

Kesimpta (ofatumumab) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RELAPSING MULTIPLE SCLEROSIS

For **initial** authorization:

1. Member is 18 years old or older; 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), and active secondary progressive disease (SPMS); AND
4. Member's baseline relapse rate or number of lesions prior to starting treatment are documented in chart notes; AND
5. Member has documented trial and failure or contraindication to at least **two** preferred multiple sclerosis agents; AND
6. Member does NOT have any of the following:
   a) Active Hepatitis B as evidenced by a negative HBV screening;
   b) Concurrent use with another disease-modifying agent for MS.
7. **Dosage allowed:** 20 mg administered by subcutaneous injection at week 0, 1, and 2, followed by 20 mg once monthly starting at week 4.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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CareSource considers Kesimpta (ofatumumab) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
11/16/2020	New policy for Kesimpta (ofatumumab) created.

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. Montalban, Xavier, et al. "Ofatumumab Reduces Disability Progression Independent of Relapse Activity in Patients with Relapsing Multiple Sclerosis (1845)." (2020).

Effective date: 04/01/2021
Revised date: 11/16/2020