

ALASKA MEDICAID
Prior Authorization Criteria

**Kesimpta®
(ofatumumab)**

FDA INDICATIONS AND USAGE¹

Kesimpta® 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.

APPROVAL CRITERIA^{1,2,3}

1. Patient is 18 years of age or older **AND;**
2. The medication is being prescribed by or in consultation with a neurologist or physician that specializes in MS **AND;**
3. Patient has a confirmed diagnosis of a relapsing form of MS to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **AND;**
4. Prescriber agrees to monitor immunoglobulins at the beginning, during and after discontinuation of therapy **AND;**
5. Patient has not received any live or live-attenuated vaccinations in the 4-weeks prior to, or non-live vaccinations in the 2-weeks prior to, the start of therapy **AND;**
6. Patient has been screened for Hepatitis B prior to therapy initiation and confirmed negative.
7. The patient has had an adequate trial and failure of at least one drug with the same specific indication form of MS.

DENIAL CRITERIA^{1,3}

1. Failure to meet approval criteria **OR;**
2. Patient will be using Kesimpta® in combination with another MS disease-modifying agent or other immune-modulating or immunosuppressive therapies, including immunosuppressant doses of corticosteroids **OR;**
3. Patient has an active infection.

CAUTIONS¹

- Patients of reproductive potential should use an effective form of contraception do to possible fetal risks.
- Consider discontinuing KESIMPTA if a patient develops a serious opportunistic infection or recurrent infections if immunoglobulin levels indicate immune compromise.

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- Injection site reactions have occurred and should be treated based on severity.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- 4 injections for the initial month load dosing
- 1 injection every 4 weeks for maintenance dosing

REFERENCES / FOOTNOTES:

1. Kesimpta [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Inc.; August 2020.
2. Gawronski KM, Rainka MM, Patel MJ, Gengo FM. Treatment Options for Multiple Sclerosis: Current and Emerging Therapies. *Pharmacotherapy*. 2010; 30(9):916-927.
3. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018 Feb;17(2):162-173
4. Montalban X, Gold R, Thompson AJ, et al. (2018),ECTRIMS/EAN guideline on the pharmacological treatment of people with multiple sclerosis. *Eur J Neurol*, 25 Iss 2, Jan2018: 215–237.