MEDICAL MUTUAL®

Drug Policy

Policy:	**2020910**	**Initial Effective Date: 09/17/2020**
Code(s):	**J3490**	**Annual Review Date: 09/21/2023**
SUBJECT:	**Kesimpta (ofatumumab)**	**Last Revised Date: 09/21/2023**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

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.

POLICY STATEMENT

This policy involves the use of Kesimpta. Prior authorization is recommended for pharmacy and medical benefit coverage of Kesimpta Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Kesimpta as well as the monitoring required for AEs and long-term efficacy, initial approval requires Kesimpta be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Kesimpta is recommended in those who meet the following criteria:

The patient does NOT have a Non-Relapsing Form of Multiple Sclerosis (MS) [e.g., primary progressive MS]. The efficacy of Kesimpta have not been established in patients with MS with non-relapsing forms of MS. AND;

The patient will not use the requested medication concurrently with Other Disease-Modifying Agents Used for Multiple Sclerosis (MS). Note: Examples of disease modifying agents used for multiple sclerosis include Aubagio® (teriflunomide tablets), Avonex® (interferon beta-1a injection [intramuscular]), Bafiertam® (monomethyl fumarate delayed-release capsules), Betaseron®/Extavia® (interferon beta-1b injection), Copaxone, Gilenya® (fingolimod tablets), Glatopa (glatirmer acetate), Lemtrada® (alemtuzumab injection for intravenous use),

Mavenclad® (cladribine tablets), Mayzent® (siponimod tablets), Ocrevus® (ocrelizumab injection for intravenous use), Plegridy® (peginterferon beta-1a injection), Ponvory™ (ponesimod tablets), Rebif® (interferon beta-1a injection [subcutaneous]), Tecfidera® (dimethyl fumarate delayed-release capsules), Tysabri® (natalizumab injection for intravenous infusion), Vumerity® (diroximel fumarate delayed-release capsules), and Zeposia® (ozanimod capsules).[2] These agents are not indicated for use in combination. Additional data are required to determine if use of disease-modifying MS agents in combination is safe provides added efficacy. AND;

1. **Multiple Sclerosis.** Approve for the duration noted below if the patient meets one of the following (A or B):
   - **A)** Initial Therapy. Approve for 1 year if the patient meets the following (i, ii, and iii):
     - **i.** Patient has a relapsing form of multiple sclerosis; AND
       Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease.
     - **ii.** Patient is ≥ 18 years of age; AND
     - **iii.** Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; OR
   - **B)** Patient is Currently Receiving Kesimpta for ≥ 1 Year. Approve for 1 year if the patient meets the following (i, ii, iii, and iv):
     - **i.** Patient has a relapsing form of multiple sclerosis; AND
       Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease.
     - **ii.** Patient meets one of the following (a or b):
       - **a)** Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
         Note: Examples include stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging (MRI) [absence or a decrease in gadolinium enhancing lesions, decrease in the number of new or enlarging T2 lesions]; stabilization or reduced worsening on the Expanded Disability State Scale (EDSS) score; achievement in criteria for No Evidence of Disease Activity-3 (NEDA-3) or NEDA-4; improvement on the fatigue symptom and impact questionnaire-relapsing multiple sclerosis (FSIQ-RMS) scale; reduction or absence of relapses; improvement or maintenance on the six-minute walk test or 12-Item MS Walking Scale; improvement on the Multiple Sclerosis Functional Composite (MSFC) score; and/or attenuation of brain volume loss.
       - **b)** Patient experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation; AND
     - **iii.** Patient is ≥ 18 years of age; AND
     - **iv.** Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

Dosing in Multiple sclerosis (MS) (relapsing): *Dosing must meet the following: (medical benefit only)*

Initial dosing of 20 mg by subcutaneous injection at Weeks 0, 1, and 2, followed by subsequent dosing of 20 mg by subcutaneous injection once monthly starting at Week 4.

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Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

Duration of Therapy in MS is indefinite.

Labs/Diagnostics. None.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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9. 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.
10. 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. doi: 10.1016/S1474-4422(17)30470-2.

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FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Edits and Denials:

Prior approval: Prior approval is required for Kesimpta **(HCPCS Code J3490)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Code J3490** will pend with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.