



Effective Date: 04/2021  
 Last P&T Approval/Version: 04/27/2022  
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 Policy Number: C21104-A

## Kesimpta (ofatumumab)

### PRODUCTS AFFECTED

Kesimpta (ofatumumab)

### COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

#### Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

#### DIAGNOSIS:

FDA labeled, and compendia diagnoses here combined

#### REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

#### A. RELAPSING FORMS OF MULTIPLE SCLEROSIS:

1. Documentation of a definitive diagnosis of a relapsing form of multiple sclerosis as defined by the McDonald criteria (see Appendix), including: Relapsing- remitting multiple sclerosis [RRMS], secondary-progressive multiple sclerosis [SPMS] with relapses, and progressive-relapsing multiple sclerosis [PRMS] or First clinical episode with MRI features consistent with multiple sclerosis  
 AND

## Drug and Biologic Coverage Criteria

2. Documentation of screening for hepatitis B virus AND for patients who are negative for surface antigen [HBsAg] and positive for HB core antibody [HBcAb+] or are carriers of HBV [HBsAg+], documentation of a consult with a liver disease expert before starting treatment. AND
3. Documentation member had testing for serum immunoglobulins if low: documentation includes consultation notes from an immunologist] AND
4. Member is not currently being treated with a disease modifying agent (DMA) other than the requested agent, B cell targeted therapy (e.g. rituximab, belimumab, ofatumumab), or lymphocyte trafficking blocker (e.g. alemtuzumab, mitoxantrone) AND
5. (a) Documentation of \*\*inadequate response (trial of 3 months) to ONE of the following: i) Interferon therapy (Avonex, Rebif, Extavia, Betaseron, Plegridy) OR ii) Glatiramer OR iii) Aubagio(teriflunomide), Tecfidera (dimethyl fumerate), Gilenya (fingolimod)  
\*\*Inadequate response is defined as meeting at least TWO (2) of the following three criteria during treatment: 1) Clinical relapses (at least two relapses within the past 12 months), 2) CNS lesions progression as measured by MRI, OR 3) Worsening disability (e.g., sustained worsening of EDSS score or neurological exam findings; worsening disability include, but not limited to, decreased mobility, decreased ability to perform activities of daily living due to disease progression, or EDSS > 3.5)  
OR  
(b) Documentation member has indicators of a highly active course of multiple sclerosis: (i) age of MS onset  $\geq$  40 years of age, (ii) male gender, (iii) African American, (iv) motor, sphincter, brainstem-cerebellar symptoms, (v) MRI lesions in brainstem or spinal cord, OR (vi)  $\geq$  2 acute relapses in first 2 years of onset with significant sustained disability following relapse  
AND
6. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to KESIMPTA® (ofatumumab) include: Active hepatitis B virus infection] AND
7. IF REQUEST IS FOR A NON-FORMULARY PRODUCT: Documentation of trial/failure of, or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for \*\*treatment failure(s).  
\*\*May be defined as meeting at least TWO (2) of the following three criteria during treatment:
  - a. Clinical relapses (at least two relapses within the past 12 months), 2) CNS lesions progression as measured by MRI, OR 3) Worsening disability (e.g., sustained worsening of EDSS score or neurological exam findings; worsening disability include, but not limited to, decreased mobility, decreased ability to perform activities of daily living due to disease progression, or EDSS > 3.5)

### B. ACTIVE SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS:

1. Documentation of a diagnosis of secondary progressive multiple sclerosis(SPMS) AND
2. Documentation of screening for hepatitis B virus AND for patients who are negative for surface antigen [HBsAg] and positive for HB core antibody [HBcAb+] or are carriers of HBV [HBsAg+], documentation of a consult with a liver disease expert before starting treatment AND

## Drug and Biologic Coverage Criteria

3. Member is not currently being treated with a disease modifying agent (DMA) other than the requested agent, B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab), or lymphocyte trafficking blocker (e.g., alemtuzumab, mitoxantrone)  
AND
4. Documentation member had testing for serum immunoglobulins [If low: documentation includes consultation notes from an immunologist]  
AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to KESIMPTA® (ofatumumab) include: Active hepatitis B virus infection]

### CONTINUATION OF THERAPY:

#### A. RELAPSING FORM OF MULTIPLE SCLEROSIS:

1. (a) Documentation of a stable number or decrease in acute attacks (relapses) within the last 6 months  
OR  
(b) Documentation of lack of progression or sustained disability OR  
(c) Recent (within the last 6 months) MRI shows lack of development of new asymptomatic lesions  
AND
2. Documentation member has been adherent to therapy at least 85% of the time as verified by Prescriber and member's medication fill history  
AND
3. Member has not experienced any intolerable adverse effects or drug toxicity

#### B. ACTIVE SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS:

1. (a) Documentation of lack of progression or sustained disability  
OR  
(b) Recent (within the last 6 months) MRI shows lack of development of new asymptomatic lesions  
AND
2. Documentation member has been adherent to therapy at least 85% of the time as verified by Prescriber and member's medication fill history  
AND
3. Member has not experienced any intolerable adverse effects or drug toxicity

### DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of therapy: 12 months

### PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified neurologist or a multiple sclerosis specialist. If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests.

### AGE RESTRICTIONS:

18 years of age or older

### QUANTITY:

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

## Drug and Biologic Coverage Criteria

### PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location.

## DRUG INFORMATION

### ROUTE OF ADMINISTRATION:

Subcutaneous

### DRUG CLASS:

Multiple Sclerosis Agents - Monoclonal Antibodies

### FDA-APPROVED USES:

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

### COMPENDIAL APPROVED OFF-LABELED USES:

None

## APPENDIX

### APPENDIX:

#### Summary of 2017 McDonald Criteria for the Diagnosis of MS

CLINICAL PRESENTATION	ADDITIONAL CRITERIA TO MAKE MS DIAGNOSIS
<b>...in a person who has experienced a typical attack/CIS at onset</b>	
<ul style="list-style-type: none"><li>2 or more attacks and clinical evidence of 2 or more lesions; OR</li><li>2 or more attacks and clinical evidence of 1 lesion with clear historical evidence of prior attack involving lesion in different location</li></ul>	None. DIS and DIT have been met.
<ul style="list-style-type: none"><li>2 or more attacks and clinical evidence of 1 lesion</li></ul>	DIS shown by <u>one</u> of these criteria: <ul style="list-style-type: none"><li>additional clinical attack implicating different CNS site</li><li>1 or more MS-typical T2 lesions in 2 or more areas of CNS: periventricular, cortical, juxtacortical, infratentorial or spinal cord</li></ul>
<ul style="list-style-type: none"><li>1 attack and clinical evidence of 2 or more lesions</li></ul>	DIT shown by <u>one</u> of these criteria: <ul style="list-style-type: none"><li>Additional clinical attack</li><li>Simultaneous presence of both enhancing and non-enhancing MS-typical MRI lesions, or new T2 or enhancing MRI lesion compared to baseline scan (without regard to timing of baseline scan)</li><li>CSF oligoclonal bands</li></ul>
<ul style="list-style-type: none"><li>1 attack and clinical evidence of 1 lesion</li></ul>	DIS shown by <u>one</u> of these criteria: <ul style="list-style-type: none"><li>Additional attack implicating different CNS site</li><li>1 or more MS-typical T2 lesions in 2 or more areas of CNS: periventricular, cortical, juxtacortical, infratentorial or spinal cord</li></ul> <b>AND</b> DIT shown by <u>one</u> of these criteria: <ul style="list-style-type: none"><li>additional clinical attack</li><li>Simultaneous presence of both enhancing and non-enhancing MS-typical MRI lesions, or new T2 or enhancing MRI lesion compared to baseline scan (without regard to timing of baseline scan)</li><li>CSF oligoclonal bands</li></ul>
<b>...in a person who has steady progression of disease since onset</b>	
1 year of disease progression (retrospective or prospective)	DIS shown by at least <u>two</u> of these criteria: <ul style="list-style-type: none"><li>1 or more MS-typical T2 lesions (periventricular, cortical, juxtacortical or infratentorial)</li><li>2 or more T2 spinal cord lesions</li><li>CSF oligoclonal bands</li></ul>

DIT = Dissemination in time

DIS = Dissemination in space

CNS = central nervous system

T2 lesion = hyperintense lesion on T2-weighted MRI

CSF = cerebrospinal fluid

**BACKGROUND AND OTHER CONSIDERATIONS****BACKGROUND:**

Kesimpta, a CD20-directed cytolytic monoclonal antibody, is the first B-cell therapy that is intended for patient self-administration by subcutaneous injection. It is believed to work by binding to CD20, a cell surface antigen present on pre-B and mature B lymphocytes, thereby inducing B-cell lysis and depletion. The approval was based on efficacy and safety data from the phase 3 ASCLEPIOS I and II trials that compared ofatumumab with teriflunomide, a pyrimidine synthesis inhibitor, in 1882 adult patients with RMS. Findings from the studies showed ofatumumab significantly lowered the annualized relapse rate (primary end point) compared with teriflunomide. Additionally, ofatumumab significantly reduced the risk of 3-month confirmed disability progression vs teriflunomide, as well as the number of T1 gadolinium-enhancing lesions and the rate of new or enlarging T2 lesions. As for safety, ofatumumab demonstrated a similar profile to teriflunomide with the most common adverse reactions being upper respiratory tract infection, headache, injection-related reactions, and local injection site reactions.

**CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**

All other uses of Kesimpta (ofatumumab) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Other exclusions for coverage include, but are not limited to: Active hepatitis B or hepatitis C virus infection or another active infection at initiation of therapy; History of life-threatening infusion reaction to Kesimpta (ofatumumab); Prescribed to treat any of the following conditions: secondary progressive multiple sclerosis, systemic lupus erythematosus; or rheumatoid arthritis; Use in combination with other immune-modulating or immunosuppressive therapies, including immunosuppressant doses of corticosteroids; Concurrent use with live vaccines or live attenuated vaccines

**OTHER SPECIAL CONSIDERATIONS:**

None

**CODING/BILLING INFORMATION**

*Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement*

HCP CODE	DESCRIPTION
J3590	Unclassified biologics

**AVAILABLE DOSAGE FORMS:**

KESIMPTA Sensoready Pen: Carton of one 20 mg/0.4 mL single-dose prefilled Sensoready pen  
 KESIMPTA Prefilled Syringe: Carton of one 20 mg/0.4 mL single-dose prefilled syringe

**REFERENCES**

1. Kesimpta (ofatumumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; August 2020.
2. Hauser SL, Bar-Or A, Comig G, et al, for the OPERA I and OPERA II Clinical Investigators. Ocrelizumab versus interferon beta-1a in relapsing multiple sclerosis. N Engl J Med. 2016 Dec 21. [Epub ahead of print].

## Drug and Biologic Coverage Criteria

3. Montalban X, Hauser SL, Kappos L, et al, for the ORATORIO Clinical Investigators. Ocrelizumab versus placebo in primary progressive multiple sclerosis. N Engl J Med. 2016 Dec 21. [Epub ahead of print].
4. Clinical bulletin. Information for health professionals. Overview of multiple sclerosis. Rosalind Kalb and Nancy Reitman. © 2012 National Multiple Sclerosis Society. Available at: Accessed on March 7, 2017.
5. Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis: principles and current evidence. July 2014. Available at: Accessed on March 7, 2017.
6. Gajofatto A, Turatti M, Benedetti MD. Primary progressive multiple sclerosis: current therapeutic strategies and future perspectives. Expert Rev Neurother. 2016 Nov 15:1- 14.[Epub ahead of print]
7. 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;92(2):112]. Neurology. 2018;90(17):777-788. doi: 10.1212/WNL.0000000000005347. [PubMed 29686116]
8. Thompson, A., Banwell, B., et al. (2018). Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. The Lancet Neurology, 17(2), pp.162-173

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Duration of Approval Prescriber Requirements Place of Administration References	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file