

Medical Drug Clinical Criteria

Subject:	Kesimpta (ofatumumab)		
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Overview

This document addresses the use of Kesimpta (ofatumumab), an injectable disease modifying therapy approved by the Food and Drug Administration (FDA) to treat relapsing multiple sclerosis in adults, including clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. Ofatumumab is also available as Arzerra, approved by the FDA to treat chronic lymphocytic leukemia. Arzerra is addressed in separate clinical criteria (ING-CC-0122).

Multiple sclerosis is an autoimmune inflammatory demyelinating disease of the central nervous system. Common symptoms of the disease include fatigue, numbness, coordination and balance problems, bowel and bladder dysfunction, emotional and cognitive changes, spasticity, vision problems, dizziness, sexual dysfunction and pain. Multiple sclerosis can be subdivided into four phenotypes: clinically isolated syndrome (CIS), relapsing remitting (RRMS), primary progressive (PPMS) and secondary progressive (SPMS). Relapsing multiple sclerosis (RMS) is a general term for all relapsing forms of multiple sclerosis including CIS, RRMS and active SPMS.

The treatment goal for multiple sclerosis is to prevent relapses and progressive worsening of the disease. Currently available disease-modifying therapies (DMT) are most effective for the relapsing-remitting form of multiple sclerosis and less effective for secondary progressive decline. DMT include injectable agents, infusion therapies and oral agents. Kesimpta is administered via monthly subcutaneous self-injection.

Kesimpta demonstrated clinical efficacy in two identically designed double-blind, double-dummy randomized controlled trials. The phase III trials enrolled 1,882 study participants who were randomized 1:1 to receive Kesimpta or Aubagio. Notable inclusion criteria included diagnosis of multiple sclerosis according to the revised McDonald criteria, neurologic stability for at least the past 30 days at baseline and expanded disability status scale (EDSS) score of 0-5.5. Participants also had to have experienced at least two relapses within the two years prior to screening or one relapse within the year prior to screening or at least one T1 gadolinium-enhancing lesion on MRI within the previous year. The primary endpoint in the studies was annualized relapse rate. Kesimpta demonstrated superior efficacy with annual relapse rates of 0.11 and 0.10 compared to Aubagio's relapse rates of 0.22 and 0.25 (p<0.001).

The American Academy of Neurology (AAN) guidelines suggest starting disease-modifying therapy in individuals with relapsing forms of multiple sclerosis with recent clinical relapses or MRI activity. The guidelines also suggest DMT for individuals who have experienced a single clinical demyelinating event and two or more brain lesions consistent with multiple sclerosis if the individual wishes to start therapy after a risks and benefits discussion. The guidelines do not recommend one DMT over another.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Kesimpta (ofatumumab)

Requests for Kesimpta (ofatumumab) may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease); **AND**
- II. Individual is able to ambulate without aid or rest for at least 100 meters; **AND**
- III. If initiating therapy, individual has experienced at least two relapses within the previous two years or one relapse within the previous year or at least one T1 gadolinium-enhancing lesion on MRI within the previous year.

Kesimpta (ofatumumab) may not be approved for the following:

- I. Use in combination with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Lemtrada, Mavenclad, Mayzent, Ocrevus, Ocrevus Zunovo, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Tyruko, Tysabri, Vumerity and Zeposia); **OR**
- II. Individual is using to treat non-active secondary progressive multiple sclerosis; **OR**
- III. Individual is using to treat primary progressive multiple sclerosis; **OR**
- IV. Individual has active hepatitis B or another active infection at initiation of therapy; **OR**
- V. May not be approved when the above criteria are not met and for all other indications.

Quantity Limits

Kesimpta (ofatumumab) Quantity Limit

Drug	Limit
Kesimpta (ofatumumab) 20 mg/0.4 mL prefilled pen/syringe	1 prefilled pen/syringe per 28 days
Override Criteria	
Initiation of Kesimpta (ofatumumab) therapy: May approve two additional pens/syringes during the first month of treatment.	

Step Therapy

Note: When Kesimpta (ofatumumab) is deemed approvable based on the clinical criteria referenced above, the benefit plan may have additional criteria requiring the use of a preferred¹ agent or agents.

Kesimpta Step Therapy

A list of the preferred fumaric acid derivatives is available [here](#).

Requests for Kesimpta (ofatumumab) may be approved when the following criteria are met:

- I. Documentation is provided that individual has been on Kesimpta (ofatumumab);

OR

- II. Documentation has been provided that individual has had a trial and inadequate response (including but not limited to clinical relapse, new or enlarged, lesions on MRI or confirmed disability progression) or intolerance to the following:
 - A. Preferred fumaric acid derivative;

OR

- III. Documentation is provided that individual has high disease activity despite treatment with fingolimod (Gilenya, Tascenso ODT) defined as the following (AAN 2018, Devonshire 2012):
 - A. At least one relapse in the previous year while on therapy; **AND**
 - B. At least 9 T₂-hyperintense lesions in cranial MRI;

OR

- C. At least one Gadolinium-enhancing lesion;

¹Preferred, as used herein, refers to agents that were deemed to be clinically comparable to other agents in the same class or disease category but are preferred based upon clinical evidence and cost effectiveness.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J3490	Unclassified drugs (when specified as [Kesimpta]) (ofatumumab)
J3590	Unclassified biologics (when specified as [Kesimpta]) (ofatumumab)
C9399	Unclassified drugs or biologicals (when specified as [Kesimpta]) (ofatumumab)

ICD-10 Diagnosis

All diagnoses pend

Document History

Revised: 11/15/2024

Document History:

- 11/15/2024 – Annual Review: Add Ocrevus Zunovo and Tyruko to exclusion for concurrent use with other disease modifying therapy criteria. Coding Reviewed: No changes.
- 03/01/2024 – Administrative update to add documentation.
- 11/17/2023 – Annual Review: Add Briumvi and Tascenso ODT to exclusion for concurrent use with other disease modifying therapy criteria. Coding Reviewed: No changes.
- 07/05/2023 – Step therapy table updates.
- 03/27/2023 – Step therapy table updates.
- 09/12/2022 – Select Review: Add Tascenso ODT to the Kesimpta Step Therapy. Coding Reviewed: No changes.
- 08/19/2022 – Annual Review: Wording and formatting changes. Coding Reviewed: No changes.
- 08/20/2021 – Annual Review: Update drug list in exclusion for concurrent use with other disease modifying therapy. Wording and formatting changes. Coding reviewed: No changes.
- 07/26/2021 – Step Therapy table update.
- 11/20/2020 – Annual Review: Clarify inadequate response step therapy language.
- 11/01/2020 – Addition of step therapy.
- 08/28/2020 – Annual Review: Add new clinical criteria document for Kesimpta. Coding Reviewed: Added HCPCS J3490, J3590, C9399, Added ICD-10-CM All diagnosis pend.

References

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4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
5. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: April 26, 2024. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 27, 2024.
6. 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. Available from: <https://www.aan.com/Guidelines/home/GuidelineDetail/898>. Accessed: October 27, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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Commercial

Effective Date	Preferred Agents	Non-Preferred Agents
3/1/2021	Fumaric acid derivative: generic dimethyl fumarate	Kesimpta

Medicaid

Effective Date	Preferred Agents	Non-Preferred Agents
8/1/2021: GA, MD, NJ, NV, NY, SC, WNY 04/01/2023: DC	Fumaric acid derivative: generic dimethyl fumarate	Kesimpta

Medicare Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
N/A	N/A	N/A