

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Kesimpta under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Kesimpta is 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.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Kesimpta

Policy/Guideline:

Prescriber Specialty:

This medication must be prescribed by or in consultation with a neurologist.

Criteria for Initial Approval:

A. Relapsing forms of multiple sclerosis

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse) and patient is unable to take the required number of formulary alternatives (3) for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

B. Clinically isolated syndrome

Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome and patient is unable to take the required number of formulary alternatives (3) for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

Continuation of Therapy:



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Coverage Policy/Guideline				
Name: Kesimpta (ofatumu		ımab)	Page:	2 of 2
Effective Date: 3/6/2025		Last Review Date:	2/2025	
Applies to:	⊠Illinois □Florida		⊠Florida Kids	
	□New Jersey	⊠Maryland	□Michigan	
	🛛 Pennsylvania Kids	□Virginia	⊠Kentucky PRMD	

For all indications: Authorization of 12 months may be granted for members who are experiencing disease stability or improvement while receiving Kesimpta.

Other Criteria:

- A. Members will not use Kesimpta concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).
- B. Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limits:

- Initiation: THREE 20mg/0.4ml prefilled syringes/Sensoready pens for first 15 days (3 syringes/pens per 15 days
- Kesimpta (ofatumumab) 20 mg/0.4 mL prefilled syringe: 1 syringe per 28 days
- Kesimpta (ofatumumab) 20 mg/0.4 mL prefilled sensoready pen: 1 pen per 28 days

References:

1. Kesimpta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2024.