CVS Caremark®

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| Reference number(s) |
| 4129-A |

# Specialty Guideline Management

# Kesimpta

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Kesimpta | ofatumumab |

## Indications

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 Indication1

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.

## Prescriber Specialties

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

## Coverage Criteria

### Relapsing forms of multiple sclerosis1

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).

### Clinically isolated syndrome1

Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome.

## Continuation of Therapy

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

## Other Criteria

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

## Reference

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