

Effective date: 03/01/2021
Review date: 12/2020, 06/2021, 05/2022, 7/2023, 6/2024, 6/2025
Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

KESIMPTA (ofatumumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendia 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.

II. CRITERIA FOR INITIAL APPROVAL

A. Relapsing forms of multiple sclerosis

Authorization of 6 months may be granted to members who meet all of the following:

- a. Member has documentation of being diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse)
- b. The medication must be prescribed by or in consultation with a neurologist.
- c. Documentation that the member has have had a failure, intolerance, or contraindication to Ocrevus (ocrelizumab) or Briumvi (ublituximab).

B. Clinically isolated syndrome

Authorization of 6 months may be granted to members who meet all of the following:

- a. Member has documentation of being diagnosed clinically isolated syndrome
- d. The medication must be prescribed by or in consultation with a neurologist.
- b. Documentation that the member has had a failure, intolerance, or contraindication to Ocrevus (ocrelizumab) or Briumvi (ublituximab).

III. CONTINUATION OF THERAPY

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

IV. QUANTITY LIMIT

- Kesimpta 20mg/0.4ml has a quantity limit of 1 pen every 28 days (daily dose of 0.015)
 - A quantity limit exception will be provided for 3 weekly doses initially for first month (daily dose of 0.043).

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V. OTHER CRITERIA

Members will not use Kesimpta concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

VI. REFERENCES

1. Kesimpta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2024. Accessed May 2025