

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 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 have had a failure, intolerance, or contraindication to Ocrevus (ocrelizumab).

B. Clinically isolated syndrome

Authorization of 6 months may be granted to members for the treatment of clinically isolated syndrome and have had a failure, intolerance, or contraindication to Ocrevus (ocrelizumab).

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

- a. Initial approval
 - i. First month: Kesimpta 20mg/0.4ml at weeks 0, 1, and 2
 1. 3 syringes per month
 - ii. Maintenance dosing after loading doses: Kesimpta 20mg/0.4ml
 1. 1 syringe per month
- b. Continuation of therapy Kesimpta 20mg/0.4ml
 - i. 1 syringe per month

V. OTHER CRITERIA

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

Effective date: 03/01/2021
Review date: 12/2020, 06/2021, 05/2022
Scope: Medicaid

VI. REFERENCES

1. Kesimpta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2021.