Effective date: 03/01/2021
Review date: 12/2020, 06/2021, 05/2022,7/2023 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 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).

VI. REFERENCES

1. Kesimpta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2022.