# SPECIALTY GUIDELINE MANAGEMENT

# **KESIMPTA** (ofatumumab)

#### **POLICY**

#### I. 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 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 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).

## B. Clinically isolated syndrome

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

## **III. 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.

#### IV. OTHER CRITERIA

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

#### V. REFERENCES

1. Kesimpta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2020.

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