# SPECIALTY GUIDELINE MANAGEMENT

# GILENYA (fingolimod)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-Approved Indication:

Gilenya 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 patients 10 years of age and older.

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 of multiple sclerosis.

## **III. CONTINUATION OF THERAPY**

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

### **IV. OTHER CRITERIA**

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

#### V. REFERENCE

1. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2019.

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