

| |
|---------------------|
| Reference number(s) |
| 1842-A |

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) in patients 10 years of age and older.

All other indications are considered experimental/investigational and are not covered benefits.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted to members with a relapsing form of multiple sclerosis who are experiencing disease stability or improvement while receiving Gilenya.

IV. OTHER CRITERIA

Members will not use Gilenya concomitantly with other medications used for the treatment of multiple sclerosis, excluding Ampyra.

V. REFERENCE

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