CVS Caremark®

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

# Specialty Guideline Management fingolimod-Gilenya-Tascenso ODT

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
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| Gilenya | fingolimod hydrochloride |
| Tascenso ODT | fingolimod lauryl sulfate |

## 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 Indications1-3

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.

## Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist.

## Coverage Criteria

### Relapsing Forms of Multiple Sclerosis1-3

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).

### Clinically Isolated Syndrome1-3

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

## Continuation of Therapy

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

## Other

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

## References

1. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2023.
2. Fingolimod [package insert]. Iselin, NJ: Biocon Pharma, Inc.,; February 2024.
3. Tascenso ODT [package insert]. San Jose, CA: Handa Neuroscience, LLC; August 2023.