

# Specialty Guideline Management

## Fingolimod Products

### 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
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 Indications<sup>1-3</sup>

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 Sclerosis<sup>1-4</sup>

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 Syndrome<sup>1-4</sup>

Authorization of 12 months may be granted to members for 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; June 2024.
2. Fingolimod [package insert]. Dongguan, China. Sunshine Lake Pharma Co., Ltd.; October 2024.
3. Tascenso ODT [package insert]. Swindon, UK. Catalent Pharma Solutions (UK).; January 2025.
4. Rae-Grant A, Day G, Marrie R, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. *Neurology*. 2018;90(17):777-788.