AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Gilenya-Tascenso	Page:	1 of 2
Effective Date:	10/25/2023	Last Review Date:	10/2023

Applies to:	☒Illinois	☐Florida	☐Florida Kids
	☐New Jersey	☐Maryland	☐Michigan
	☐Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Gilenya (fingolimod) and Tascenso ODT (fingolimod) under the patient's prescription drug benefit.

Description:

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 Indication
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.

Applicable Drug List:

Fingolimod 0.5 mg capsule
Gilenya
Tascenso ODT

Policy/Guideline:

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

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).

- Requests for Tascenso ODT require that patient is unable to swallow solid dosage forms
- Requests for brand Gilenya 0.25 mg capsules or generic fingolimod capsules require that the patient is unable to take brand Gilenya 0.5 mg capsules for the

given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication

B. Clinically isolated syndrome

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

- Requests for Tascenso ODT require that patient is unable to swallow solid dosage forms
- Requests for brand Gilenya 0.25 mg capsules or generic fingolimod capsules require that the patient is unable to take brand Gilenya 0.5 mg capsules for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication

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 Criteria:

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

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limits:

- Gilenya (fingolimod hydrochloride) capsules 0.25mg: 30 capsules per 30 days
- Gilenya (fingolimod hydrochloride) capsules 0.5mg: 30 capsules per 30 days
- Tascenso ODT (fingolimod lauryl sulfate) tablets 0.25mg: 30 tablets per 30 days
- Tascenso ODT (fingolimod lauryl sulfate) tablets 0.5mg: 30 tablets per 30 days

References:

1. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2022.
2. Fingolimod [package insert]. Weston, FL: Apotex Corporation; February 2023.
3. Tascenso ODT [package insert]. San Jose, CA: Handa Neuroscience, LLC; December 2022.