

Gilenya (**fingolimod**), Tascenso ODT (fingolimod)

Preferred product: fingolimod

Pre - PA Allowance

None

Prior-Approval Requirements

Age 10 years of age or older

Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AND ALL of the following:

1. Member must be observed for 6 hours after the first dose for signs and symptoms of bradycardia with hourly pulse and blood pressure measurements and an ECG prior to dosing and at the end of the observation period
2. Prescriber has reviewed baseline complete blood count (CBC) including lymphocyte count
3. **NO** history (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
4. **NO** history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
5. **NO** significant QTc prolongation (QTc greater than or equal to 500 msec)
6. Patients with a history of uveitis and/or diabetes **ONLY**: will have an ophthalmic evaluation of the fundus, including the macula, prior to initiation of therapy
7. **NO** concurrent use with other MS disease modifying agents
8. **NOT** given concurrently with live vaccines
9. **Tascenso ODT only**: Patient is unable to swallow or has difficulty swallowing capsules
10. **Brand Gilenya 0.5mg only, Age 10-17**: Patient **MUST** have tried fingolimod (generic Gilenya) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance,

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contraindication)

11. **Brand Gilenya 0.5mg only, Age 18+:** Patient **MUST** have tried fingolimod (generic Gilenya) **AND ONE** of the other preferred MS medications (see Appendix 1) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior - Approval Limits

Quantity

Medication/Strength	Quantity Limit
Gilenya 0.25 mg capsule	90 units per 90 days OR
Gilenya 0.5 mg capsule	90 units per 90 days OR
Tascenso 0.25 mg ODT	90 units per 90 days
Tascenso 0.5 mg ODT	

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 10 years of age or older

Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AND ALL of the following:

1. **NO** history (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure.
2. **NO** history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
3. **NO** significant QTc prolongation (QTc greater than or equal to 500 msec)
4. **NO** concurrent use with other MS disease modifying agents
5. **NOT** given concurrently with live vaccines
6. **Brand Gilenya 0.5mg only, Age 10-17:** Patient **MUST** have tried

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fingolimod (generic Gilenya) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

7. **Brand Gilenya 0.5mg only, Age 18+:** Patient **MUST** have tried fingolimod (generic Gilenya) **AND ONE** of the other preferred MS medications (see Appendix 1) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior - Approval *Renewal* Limits

Same as above

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Appendix 1 - List of Preferred Multiple Sclerosis (MS) Medications for Age 18+

Medication Name	Route of Administration
Aubagio	Oral**
dimethyl fumarate (generic Tecfidera)	Oral**
fingolimod* (generic Gilenya) *must try this drug plus one other preferred MS medication oral or injectable	Oral
Mayzent	Oral**
Zeposia	Oral**

** indicates separate criteria will need to be met

Medication Name	Route of Administration
Avonex	Injectable
Betaseron	Injectable
glatiramer acetate (generic Copaxone)	Injectable
Glatopa	Injectable
Plegridy	Injectable
Rebif	Injectable