Clinical Policy: Fingolimod (Gilenya, Tascenso ODT)

Reference Number: ERX.SPA.121
Effective Date: 10.01.16
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Fingolimod (Gilenya®, Tascenso ODT™) is a sphingosine 1-phosphate receptor modulator.

FDA Approved Indication(s)

Gilenya and Tascenso ODT are indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. Gilenya is indicated in patients 10 years of age and older, while Tascenso ODT is indicated in pediatric patients 10 years of age and older and weighing less than or equal to 40 kg.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Gilenya and Tascenso ODT are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all)**:**

1. Diagnosis of one of the following (a, b, or c):
   a. Clinically isolated syndrome;
   b. Relapsing-remitting MS;
   c. Secondary progressive MS;
2. Prescribed by or in consultation with a neurologist;
3. If request is for Gilenya, age ≥ 10 years;
4. If request is for Tascenso ODT, all of the following (a, b, and c):
   a. Age between 10 to 17 years;
   b. Body weight ≤ 40 kg;
   c. Member must use Gilenya, unless contraindicated, clinically significant adverse effects are experienced, or documentation supports inability to swallow capsules;
5. The requested agent is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);
6. Documentation of baseline number of relapses per year and expanded disability status scale (EDSS) score;
7. At the time of request, member does not have baseline QTc interval ≥ 500 msec;
8. Dose does not exceed one of the following (a or b):
   a. Body weight > 40 kg: 0.5 mg (1 capsule) per day;
   b. Body weight ≤ 40 kg: 0.25 mg (1 capsule or orally disintegrating tablet) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Multiple Sclerosis (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member meets one of the following (a or b):
   a. If member has received < 1 year of total treatment: Member is responding positively to therapy;
   b. If member has received ≥ 1 year of total treatment: Member meets one of the following (i, ii, iii, or iv):
      i. Member has not had an increase in the number of relapses per year compared to baseline;
      ii. Member has not had ≥ 2 new MRI-detected lesions;
      iii. Member has not had an increase in EDSS score from baseline;
      iv. Medical justification supports that member is responding positively to therapy;
3. The requested agent is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);
4. If request is for Tascenso ODT, both of the following (a and b):
   a. Member continues to be < 18 years of age and weigh ≤ 40 kg;
   b. Documentation supports continued inability to swallow capsules;
5. If request is for a dose increase, new dose does not exceed one of the following (a or b);
   a. Body weight > 40 kg: 0.5 mg (1 capsule) per day;
   b. Body weight ≤ 40 kg: 0.25 mg (1 capsule or orally disintegrating tablet) per day.

Approval duration: first re-authorization: 6 months**; second and subsequent re-authorizations:** 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;

B. Primary progressive MS.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
EDSS: expanded disability status scale
FDA: Food and Drug Administration
MS: multiple sclerosis

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Recent myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure with hospitalization, or Class III/IV heart failure
  - History of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
  - Baseline QTc interval ≥ 500 msec

- Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs
- Hypersensitivity to fingolimod or its excipients
- Concomitant use with other products containing fingolimod (*Tascenso ODT only*)

- Boxed warning(s): none reported

Appendix D: General Information

- Disease-modifying therapies for MS are: glatiramer acetate (Copaxone®, Glatopa®), interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®), dimethyl fumarate (Tecfidera®), diroximel fumarate (Vumerity®), monomethyl fumarate (Bafiertam™), fingolimod (Gilenya®, Tascenso ODT™), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), ocrelizumab (Ocrevus®), cladribine (Mavenclad®), siponimod (Mayzent®), ozanimod (Zeposia®), ponesimod (Ponvory™), and ofatumumab (Kesimpta®).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Relapsing MS	*Gilenya*: Adults and pediatric patients 10 years of age and older weighing > 40 kg: 0.5 mg PO QD *Gilenya or Tascenso ODT*: Pediatric patients 10 years of age and older weighing ≤ 40 kg: 0.25 mg PO QD	Gilenya: 0.5 mg/day Tascenso ODT: 0.25 mg/day

VI. Product Availability

- Capsules (Gilenya): 0.25 mg, 0.5 mg
- Orally disintegrating tablet (Tascenso ODT): 0.25 mg

VII. References

1. Gilenya Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation; December 2019. Available at http://www.gilenya.com. Accessed February 4, 2022.
2. Tascenso ODT Prescribing Information. San Jose, CA: Handa Neuroscience, LLC; December 2021. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214962Orig2lbl.pdf. Accessed February 7, 2022.
3. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018; 90(17): 777-788. Full guideline available at: https://www.aan.com/Guidelines/home/GetGuidelineContent/904.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2018 annual review: No significant changes. References reviewed and updated.	01.05.18	05.18
No significant changes: updated policy with new pediatric age limit/language and new dosage form.	06.29.18	
2Q 2019 annual review: no significant changes; removed requirement for no concurrent use of Class Ia or III anti-arrhythmic drugs based on updated contraindication in FDA label; references reviewed and updated.	02.04.19	05.19
RT4: updated FDA Approved Indication(s) and initial approval criteria sections to include clinically isolated syndrome and SPMS per updated FDA labeling; references reviewed and updated.	09.23.19	
2Q 2020 annual review: no significant changes; clarified max dosing requirement per body weight; references reviewed and updated.	01.27.20	05.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization; modified continued approval duration to 6 months for the first re-authorization and 12 months for second/subsequent re-authorizations; references reviewed and updated.	05.27.20	08.20
2Q 2021 annual review: no significant changes; references reviewed and updated.	02.08.21	05.21
2Q 2022 annual review: no significant changes; RT4: added Tascenso ODT; references reviewed and updated.	02.07.22	05.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.