Clinical Policy: Fingolimod (Gilenya, Tascenso ODT)

Reference Number: CP.PHAR.251
Effective Date: 09.01.16
Last Review Date: 05.23
Line of Business: 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, in patients 10 years of age and older.

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.

It is the policy of health plans affiliated with Centene Corporation® 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, and if age ≥ 18 years, failure of **generic dimethyl fumarate** at up to maximally indicated doses, unless contraindicated, clinically significant adverse effects are experienced, or member has highly active MS;
   c. Secondary progressive MS;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 10 years;
4. If request is for Tascenso ODT, member must use **Gilenya 0.25 mg or generic fingolimod 0.5 mg**, unless contraindicated, clinically significant adverse effects are experienced, or documentation supports inability to swallow capsules;
5. For brand Gilenya 0.5 mg requests, member must use **generic fingolimod**, unless contraindicated or clinically significant adverse effects are experienced;
6. The requested agent is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);
7. Documentation of both baseline number of relapses per year and expanded disability status scale (EDSS) score;
8. At the time of request, member does not have baseline QTc interval ≥ 500 msec;

9. Dose does not exceed both of the following (a and b):
   a. One of the following (i or ii):
      i. Body weight > 40 kg: 0.5 mg per day;
      ii. Body weight ≤ 40 kg: 0.25 mg per day;
   b. 1 capsule or orally disintegrating tablet per day.

Approval duration: 6 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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, documentation supports continued inability to swallow capsules;

5. For brand Gilenya 0.5 mg requests, member must use **generic fingolimod**, unless contraindicated or clinically significant adverse effects are experienced;
6. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. One of the following (i or ii):
      i. Body weight > 40 kg: 0.5 mg per day;
      ii. Body weight ≤ 40 kg: 0.25 mg per day;
   b. 1 capsule or orally disintegrating tablet per day.

Approval duration:
If member has received < 1 year of total treatment – up to a total of 12 months of treatment
If member has received ≥ 1 year of total treatment – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

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 policies – CP.PMN.53 for Medicaid 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
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
dimethyl fumarate (Tecfidera®)	Initial: 120 mg PO BID for 7 days Maintenance: 240 mg PO BID	480 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

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™), ublituximab-xiiy (Briumvi™), and ofatumumab (Kesimpta®).
- Per the American Academy of Neurology 2018 MS practice guidelines, definitions of highly active MS vary and can include measures of relapsing activity and MRI markers of disease activity, such as numbers of gadolinium-enhanced lesions.

V. Dosage and Administration

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

VI. Product Availability

- Hard capsules (Gilenya): 0.25 mg, 0.5 mg*
- Orally disintegrating tablets (Tascenso ODT): 0.25 mg, 0.5 mg

**Available generically*

VII. References

1. Gilenya Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2022. Available at http://www.gilenya.com. Accessed January 30, 2023.
2. Tascenso ODT Prescribing Information. San Jose, CA: Handa Neuroscience, LLC; December 2022. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214962s000lbl.pdf. Accessed January 30, 2023.
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. Reaffirmed on September 18, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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: clarified max dosing requirement per body weight; modified Commercial approval durations from Length of Benefit to 6/12 months; references reviewed and updated.	01.27.20	05.20
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
Per November SDC and prior clinical guidance, removed Commercial and HIM LOB from policy (CP.PCH.38 created); added requirement for trial of generic dimethyl fumarate for Medicaid LOB, unless member has highly active MS.	11.11.20	
Per November SDC and prior clinical guidance, modified to reflect that trial of generic dimethyl fumarate applies only to RRMS.	02.09.21	
2Q 2021 annual review: no significant changes; references reviewed and updated.	02.10.21	05.21
2Q 2022 annual review: no significant changes; added legacy WellCare line of business (WCG.CP.PHAR.251 to be retired); RT4: added Tascenso ODT; references reviewed and updated.	02.07.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.11.22	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2023 annual review: no significant changes; added redirection to generic for Gilenya 0.5 mg requests per SDC; RT4: for Tascenso ODT, added new 0.5 mg dosage strength and updated indication/criteria to remove prior upper age limit and weight requirement per revised FDA labeling; to be inclusive of members continuing therapy from a different benefit, revised continued approval duration to reference the duration of total treatment received rather than the number of re-authorizations; references reviewed and updated.	01.30.23	05.23

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.