Clinical Policy Title:	fingolimod
Policy Number:	RxA.751
Drug(s) Applied:	Tascenso ODT™
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Tascenso ODT™ is a sphingosine 1-phosphate receptor modulator 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 pediatric patients 10 years of age and older and weighing less than or equal to 40 kg.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
fingolimod (Tascenso ODT™)	Relapsing MS	Recommended dosage for pediatric patients (10 years of age and older) weighing less than or equal to 40 kg: 0.25 mg orally once daily, with or without food	0.25 mg orally once daily

Dosage Forms

- Orally disintegrating tablets: 0.25 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all):

1. Diagnosis of Relapsing MS with one of the following subtype (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. Member is ≥ 10 years of age;
4. Member is weighing less than or equal to 40 kg;
5. Documentation supports inability to use Gilenya® 0.25 mg capsules;

6. Tascenso ODT™ is not prescribed concurrently with other disease modifying therapies for MS (see Appendix D);
7. At the time of request, member does not have baseline QTc interval 500 msec or greater;
8. Dose does not exceed 0.25 mg orally once daily.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Multiple Sclerosis (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Tascenso ODT™ is not prescribed concurrently with other disease modifying therapies for MS (see Appendix D);
4. If request is for a dose increase, new dose does not exceed 0.25 mg orally once daily.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
MS: multiple sclerosis
CBC: Complete Blood Count
PML: Progressive Multifocal Leukoencephalopathy
PRES: Posterior Reversible Encephalopathy Syndrome
BP: Blood Pressure
ODT: Oral Disintegrating Tablet

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
Gilenya®	Pediatric patients 10 years of age and older weighing 40 kg or less: 0.25 mg orally once daily (with or without food)	0.5 mg/day

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

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.

  *Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Disease-modifying therapies for MS are:
  - Infusion therapies:
    - alemtuzumab (Lemtrada®)
    - mitoxantrone
    - natalizumab (Tysabri®)
    - ocrelizumab (Ocrevus™)
    - rituximab (Rituxan®)
  - Oral therapies:
    - cladribine (Mavenclad®)
    - dimethyl fumarate (Tecfidera®)
    - diroximel fumarate (Vumerity®)
    - fingolimod (Gilenya®)
    - ozanimod (Zeposia®)
    - siponimod (Mayzent®)
    - teriflunomide (Aubagio®)
  - Injection therapies:
    - glatiramer acetate (Copaxone®, Glatopa®),
    - interferon beta-1a (Avonex®, Rebif®)
    - interferon beta-1b (Betaseron®, Extavia®)
    - ofatumumab (Kesimpta®)
    - peginterferon beta-1a (Plegridy®)
- Bradyarrhythmia and Atrioventricular Blocks: Because of a risk for bradyarrhythmia and AV blocks, monitor during initiation of treatment
- Infections: Tascenso ODT™ may increase the risk. Obtain a complete blood count (CBC) before initiating Tascenso ODT™ (i.e., within 6 months). Monitor for infection during treatment and for 2 months after discontinuation. Do not start in patients with active infections.
- Progressive Multifocal Leukoencephalopathy (PML): Withhold Tascenso ODT™ at the first sign or symptom suggestive of PML.
- Macular Edema: Examine the fundus before and 3-4 months after treatment start. Diabetes mellitus and uveitis increase the risk.
- Liver Injury: Obtain liver enzyme results before initiation and periodically during treatment. Closely monitor patients with severe hepatic impairment. Discontinue if there is evidence of liver injury without other cause.
- Posterior Reversible Encephalopathy Syndrome (PRES): If suspected, discontinue Tascenso ODT™.
- Fetal Risk: May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use an effective method of contraception during treatment and for 2 months after stopping Tascenso ODT™.

- First-Dose Monitoring (including reinitiation after discontinuation greater than 14 days) and dose increases of any fingolimod product approved for use at a higher dose:
    - o Observe all patients for bradycardia for at least 6 hours; monitor pulse and blood pressure hourly. Electrocardiograms (ECGs) prior to dosing and at end of observation period required.
    - o Monitor until resolution if heart rate < 55 bpm in patients aged 12 years and above, or < 60 bpm in pediatric patients aged 10 to below 12 years, atrioventricular (AV) block, or if lowest postdose heart rate is at the end of the observation period.
    - o Monitor symptomatic bradycardia with ECG until resolved. Continue overnight if intervention is required; repeat first-dose monitoring for second dose.
    - o Observe patients overnight if at higher risk of symptomatic bradycardia, heart block, prolonged QTc interval, or if taking drugs with known risk of torsades de pointes.

References

1. 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 March 08, 2022.
2. Costello K, Halper J, Kalb R, Skutnik L, Rapp R. The use of disease-modifying therapies in multiple sclerosis, principles and current evidence – a consensus paper by the Multiple Sclerosis Coalition. June 2019. Available at: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed March 08, 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 . Accessed March 08, 2022.
4. Fingolimod, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: https://online.lexi.com/lco/action/search?q=tascenso%20odt&t=name&va=tascenso%20odt . Accessed March 08, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/08/2022	04/19/2022