

PRIOR AUTHORIZATION POLICY

- POLICY:** Multiple Sclerosis – Tascenso ODT Prior Authorization Policy
- Tascenso ODT™ (fingolimod orally disintegrating tablets – Handa/Catalent/Cycle)

REVIEW DATE: 08/17/2022; selected revision 01/04/2023

OVERVIEW

Tascenso ODT, a sphingosine 1-phosphate receptor modulator, is 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.¹ The FDA-approved dose for pediatric patients ≥ 10 years of age who weigh less than or equal to 40 kg is 0.25 mg once daily. For adults and pediatric patients 10 years of age and older weighing more than 40 kg, the dose is 0.5 mg once daily. Administer Tascenso ODT with or without water. Place the tablet directly on the tongue and allow it to dissolve before swallowing. Tascenso ODT is available in 0.25 mg and 0.5 mg orally disintegrating tablets. Fingolimod doses higher than two times the recommended Tascenso ODT dosage are associated with a greater incidence of adverse events without additional benefit.

Disease Overview

MS is a chronic, inflammatory, demyelinating, autoimmune disease of the central nervous system that impacts almost 1,000,000 people in the US.²⁻⁴ The condition is marked by inflammation and demyelination, as well as degenerative alterations. Patients usually experience relapses and remissions in their neurological symptoms. For most patients, the onset of MS symptoms occurs when patients are 20 to 40 years of age; however, children can get MS and new onset disease can occur in older adults. The MS disease course is heterogeneous but has some patterns. Approximately 85% to 90% of patients have a relapsing pattern at onset. However, this transitions over time in patients who are untreated to a worsening with very few or no relapses or magnetic resonance imaging (MRI) activity (secondary progressive MS). Around 10% to 15% of patients have a steady progression of symptoms over time (primary progressive MS), marked by some clinical manifestations or by MRI activity. Primary progressive MS is generally diagnosed in patients on the upper level of the typical age range (e.g., almost 40 years of age) and the distribution is equivalent among the two genders. Advances in the understanding of the MS disease process, as well as in MRI technology, spurred updated disease course descriptions in 2013,⁵ as well as in 2017.⁶ The revised disease courses are clinically isolated syndrome, relapsing remitting MS, primary progressive MS, and secondary progressive MS.²⁻⁶ Clinically isolated syndrome is now more recognized among the course descriptions of MS. It is the first clinical presentation of MS that displays characteristics of inflammatory demyelination that may possibly be MS but has yet to fulfill diagnostic criteria. It is notable that the other MS designations can be further characterized considering whether patients have active disease (or not active), as well as if disease is worsening or stable. Disability in MS is commonly graded on the deterioration of mobility per the Expanded Disability Status Scale an ordinal scale that ranges from 0 to 10, with higher scores indicating greater disability.

Guidelines

In September 2019, a consensus paper was updated by the MS Coalition that discusses the use of disease-modifying therapies in MS.² Many options from various disease classes, involving different mechanisms of action and modes of administration, have shown benefits in patients with MS.² The American Academy of Neurology has practice guidelines regarding disease-modifying therapies for adults with MS.⁷ The guidelines cites fingolimod as one of the agents to consider for patients with MS who have highly active disease.

Safety

The initiation of Tascenso ODT leads to decreases in heart rate.¹ The first dose of Tascenso ODT should be given in a setting in which resources to appropriately manage symptomatic bradycardia are available. Monitor all patients for 6 hours after the first dose for signs and symptoms of bradycardia with hourly pulse and blood pressure measurement. Patients with prolonged QTc interval at baseline or during the 6-hour observation period, or taking medications with known risks of torsades de pointes, should be observed overnight with continuous electrocardiographic monitoring in a medical facility. When restarting Tascenso ODT after discontinuation for more than 14 days after the first treatment month, perform first-dose monitoring. There are several contraindications for use which mainly include patients with background cardiovascular disease. Tascenso ODT is associated with serious toxicities such as decreased heart rate and/or atrioventricular condition after the first dose; an increased risk of infections; macular edema; pulmonary toxicity; and elevated liver enzymes. Cases of progressive multifocal leukoencephalopathy have occurred in patients with multiple sclerosis who were given fingolimod in the postmarketing setting.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tascenso ODT. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Tascenso ODT as well as the monitoring required for adverse events and efficacy, approval requires Tascenso ODT to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tascenso ODT is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Multiple Sclerosis.** Approve for 1 year if the patient meets one of the following (A or B):
 - A) **Initial Therapy.** Approve if the patient meets the following (i, ii, and iii):
 - i. Patient has a relapsing form of multiple sclerosis; AND
Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease.
 - ii. Patient is ≥ 10 years of age; AND
 - iii. Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; OR
 - B) **Patient is Currently Receiving Tascenso ODT for ≥ 1 Year.** Approve if the patient meets the following (i, ii, iii, and iv):
 - i. Patient has a relapsing form of multiple sclerosis; AND
Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease.
 - ii. Patient is ≥ 10 years of age; AND
 - iii. Patient meets one of the following (a or b):
 - a) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
Note: Examples include stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging (MRI) [absence or a decrease in gadolinium enhancing

lesions, decrease in the number of new or enlarging T2 lesions]; stabilization or reduced worsening on the Expanded Disability State Scale (EDSS) score; achievement in criteria for No Evidence of Disease Activity (NEDA)-3 or NEDA-4; improvement on the fatigue symptom and impact questionnaire-relapsing multiple sclerosis (FSIQ-RMS) scale; reduction or absence of relapses; improvement or maintenance on the six-minute walk test or 12-Item MS Walking Scale; improvement on the Multiple Sclerosis Functional Composite (MSFC) score; and/or attenuation of brain volume loss.

- b) Patient experienced stabilization, slow progression, or improvement in at least one symptoms such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation; AND
- iv. Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tascenso ODT is not recommended in the following situations:

1. **Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis.** These agents are not indicated for use in combination (See [Appendix](#) for examples). Additional data are required to determine if use of disease-modifying multiple sclerosis agents in combination is safe and provides added efficacy.
2. **Non-Relapsing Forms of Multiple Sclerosis.** In the INFORMS trial fingolimod did not slow disease progression in patients with primary progressive multiple sclerosis.⁸
Note: An example of a non-relapsing form of multiple sclerosis is primary progressive multiple sclerosis.
3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tascenso ODT™ orally disintegrating tablets [prescribing information]. San Jose, CA/Swindon, UK/Cambridge, UK: Handa/Catalent/Cycle; December 2022.
2. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. September 2019. Available at: http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. Accessed on December 27, 2022.
3. McGinley MP, Goldschmidt C, Rae-Grant AD. Diagnosis and treatment of multiple sclerosis. A review. *JAMA*. 2021;325(8):765-779.
4. No authors listed. Drugs for multiple sclerosis. *Med Lett Drugs Ther*. 2021;63(1620):42-48.
5. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014;83:278-286.
6. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173.
7. 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;90:777-788.
8. Lublin F, Miller DH, Freedman MS, et al, on behalf of the INFORMS Study Investigators. Oral fingolimod in primary progressive multiple sclerosis (INFORMS): a phase 3, randomized, double-blind, placebo-controlled trial. *Lancet*. 2016;387:1075-1084.

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/17/2022
Selected Revision	<p>Multiple Sclerosis: For both Initial and Patients Currently Receiving Therapy, removed the requirement that the patient is < 18 years of age, as well as the criteria requiring that the patient is ≤ 40 kg. It was noted in the Appendix that Gilenya is now available as a generic. In the Appendix, Briumvi was added as an example of a disease modifying agent used for multiple sclerosis.</p>	01/04/2023

APPENDIX