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Clinical Guideline

Guideline Number: PG117, Ver. 1

Tascenso ODT (fingolimod)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Multiple Sclerosis (MS) is an autoimmune disease in which the body's immune system attacks its own tissues. This immune system malfunction destroys the fatty substance (myelin) that coats and protects nerve fibers in the brain and spinal cord, as known as the central nervous system. When the protective myelin is damaged and the nerve fiber is exposed, the messages that travel along that nerve fiber may be slowed or blocked. This can cause communication problems between the brain and the rest of the body. Eventually, the disease can cause irreversible damage or deterioration of the nerves leaving a person with the potential for permanent disability and a lack of functionality of the central nervous system.

While the causes of MS are largely unknown, genetics and environmental factors have contributing factors. Some symptoms of MS include numbness, tingling or tremor; vision changes; walking impairment; slurred speech; dizziness; and changes in bowel and bladder function or control. Multiple sclerosis is characterized by a "waxing and waning" course of the disease, meaning there are often periods of relapse or attacks followed by periods of improvement or remission. There is no cure for multiple sclerosis. However, treatments can help speed recovery from attacks, modify the course of the disease and manage symptoms.

All MS medications require prior authorization. Requests for non-preferred MS medications will be reviewed with the Non-Formulary pharmacy policy. Note: Oscar requires that preferred medications be used first.

The preferred treatments for multiple sclerosis are BRAND products: Aubagio, Betaseron, Copaxone, Gilenya, Mayzent, Rebif, Vumerity as well as generic Ampyra (dalfampridine) and generic Tecfidera (dimethyl fumarate). The preferred IV agent for multiple sclerosis is Tysabri (natalizumab).

This policy references the most recent Food and Drug Administration (FDA) prescribing information for each medication as well as guidelines and reports published by the National Multiple Sclerosis Society (NMSS) for consideration of approval of these medications. The FDA and NMSS set the treatment considerations. Please refer to the FDA website at www.fda.gov/drugs and NMSS website at www.nationalmssociety.org for more information.

Note: The Plan may require that preferred medications be used first.

Definitions

"CIS" or "clinically isolated syndrome" refers to the first symptomatic episode lasting at least 24 hours caused by inflammation and demyelination in the central nervous system. This episode is characteristic of multiple sclerosis but does not always result in a person developing MS. Early treatment of CIS has been shown to delay the onset of MS.

"Disease modifying therapy" refers to treatments found to reduce the number of relapses, delay progression of disability, and limit new disease activity according to research and clinical trials.

"EDSS" or "Expanded Disability Status Scale" refers to the most widely utilized MS assessment tool that consists of an ordinal clinical rating scale with half point increments ranging from 0 (normal neurologic examination) to 10 (death due to MS).

"MRI" or "Magnetic Resonance Imaging" refers to a medical imaging technique that creates detailed three-dimensional (3D) images of the organs and tissues in your body. A brain MRI can reveal areas of active MS disease called lesions within the central nervous system.

"Relapse" refers to an attack or exacerbation of MS (also known as a flare-up) resulting in the occurence new symptoms or the worsening of old symptoms.

"RRMS" or "relapsing-remitting MS" refers to the most common type of MS in which there are clearly defined attacks or relapses of increasing neurologic symptoms followed by periods of partial or complete recovery or remissions.

"SPMS" or "secondary progressive MS" refers to a version of disease progression that can follow an initial relapsing-remitting course in which there is a worsening of neurologic function and increased disability over time.

Medical Necessity Criteria for Initial Authorization

The Plan considers Tascenso ODT [fingolimod] medically necessary when ALL of the following criteria are met:

1. The member has a confirmed diagnosis of ONE of the following forms of multiple sclerosis:
    a. relapsing-remitting (RRMS); or
    b. secondary progressive (SPMS); or
    c. clinically isolated syndrome (CIS)
2. The member is 10-17 years of age; *and*
3. The member's weight is less than or equal to 40kg; *and*
4. The member is not or will not be taking the requested medication with any other disease modifying multiple sclerosis agents.
    a. NOTE: Ampyra (dalfampridine) and Nuedexta (dextromethorphan/quinidine) are not disease modifying agents; *and*
5. The member has no history of cardiovascular issues (e.g. arrhythmias, heart attack, heart failure, stroke).
6. The member has received all appropriate immunizations as recommended by current immunization guidelines prior to initiating Tascenso ODT [fingolimod] therapy.
7. Tascenso ODT [fingolimod] will be dosed within FDA approved limits or as recommended by case studies or clinical guidelines.
    a. If dosing outside normal limits, reviewers may consult with Medical Directors or other clinical resources to confirm appropriate dosing.
8. The requesting provider has submitted the required clinical documentation (chart notes, laboratory reports, disease progression, previous medications tried and failed, etc) for review.

<u>If the above prior authorization criteria are met, Tascenso ODT [fingolimod] will be approved for 6 months</u>

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if the member still meets the initial criteria and has chart documentation demonstrating ONE of the following:

a. The member has shown a clinical improvement in symptoms since starting the requested medication.
b. The member has experienced disease stability since starting the requested medication.

Table 1: Dosage and retreatment information

Indication	Initial dose	Subsequent dose	Considerations
Multiple sclerosis and clinical isolating syndrome	0.25 mg orally once daily	0.25 mg orally once daily	Patients whose weight exceeds 40 kg after treatment initiation with Tascenso ODT should be switched to another fingolimod product

Experimental or Investigational / Not Medically Necessary

Tascenso ODT [fingolimod] for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

1. Tascenso ODT [package insert]. San Jose, CA; Handa Neuroscience, LLC. Dec 2021.
2. Mayo Clinic.org - Multiple Sclerosis. Available at: https://www.mayoclinic.org/diseases-conditions/multiple-sclerosis/. Updated: June 2020. Accessed Feb 24, 2022
3. National MS Society. Available at: https://www.nationalmssociety.org/. Updated: December 2020. Accessed Feb 24, 2022.

Clinical Guideline Revision / History Information

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