CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Vumerity (diroximel fumarate)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Vumerity 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 adults. It has been shown to activate the nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway, which is involved in the cellular response to oxidative stress.
Vumerity is a fumarate like Tecfidera (dimethyl fumarate), with the same active metabolite, monomethyl fumarate (MMF). However, due to its different chemical structure, Vumerity has less reactivity toward off-target receptors in the gastrointestinal (GI) tract, resulting in a lower incidence of GI side effects compared to Tecfidera.

Vumerity (diroximel fumarate) will be considered for coverage when the following criteria are met:

Multiple Sclerosis (MS)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of a relapsing form of MS, to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease; AND
4. The member has tried generic Tecfidera but experiences intolerable gastrointestinal side effects; AND
5. The following baseline assessments have been or will be completed before starting treatment:
   a) Complete blood cell count (CBC) including lymphocyte count
   b) Liver function (ALT, AST, ALP, total bilirubin)
6. **Dosage allowed/Quantity limit:** Starting dose: 231 mg twice a day, orally, for 7 days. Maintenance dose after 7 days: 462 mg (administered as two 231 mg capsules) twice a day, orally. (QL: 106 capsules for the first 30 days; then 120 capsules per 30 days thereafter)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing stability or improvement in signs and symptoms of disease (e.g., fewer relapses, slowed disability progression, reduced number or volume of brain lesions).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Vumerity (diroximel fumarate) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
11/12/2019	New policy for Vumerity created.
07/21/2022	Transferred to new template. Updated and added references. Added trial of generic Tecfidera. Changed initial approval duration from 6 mo to 12 mo. Added clinical criteria for renewal.
06/23/2025	Updated references.

References:

1. Vumerity [prescribing information]. Cambridge, MA; Biogen, Inc; 2024.
2. Naismith, Robert T., et al. "Diroximel fumarate (DRF) in patients with relapsing–remitting multiple sclerosis: Interim safety and efficacy results from the phase 3 EVOLVE-MS-1 study." Multiple Sclerosis Journal (2019): 1352458519881761.
3. Palte, Michael J., et al. "Improving the gastrointestinal tolerability of fumaric acid esters: Early findings on gastrointestinal events with diroximel fumarate in patients with relapsing-remitting multiple sclerosis from the phase 3, open-label EVOLVE-MS-1 Study." Advances in therapy (2019): 1-12).
4. Naismith RT, Wundes A, Ziemssen T, et al. Diroximel Fumarate Demonstrates an Improved Gastrointestinal Tolerability Profile Compared with Dimethyl Fumarate in Patients with Relapsing-Remitting Multiple Sclerosis: Results from the Randomized, Double-Blind, Phase III EVOLVE-MS-2 Study. *CNS Drugs*. 2020;34(2):185-196. doi:10.1007/s40263-020-00700-0
5. Hauser SL, Cree BAC. Treatment of Multiple Sclerosis: A Review. *Am J Med*. 2020;133(12):1380-1390.e2. doi:10.1016/j.amjmed.2020.05.049
6. National Multiple Sclerosis Society. The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A Consensus Paper by the Multiple Sclerosis Coalition; 2019. Available from: https://cdn.sanity.io/files/y936aps5/production/76159995e7f4c6c0c2e6de5c4ba6a5881ab368f7.pdf. Accessed June 23, 2025.
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 [published correction appears in Neurology. 2019 Jan 8;92(2):112. doi: 10.1212/WNL.0000000000006722.]. *Neurology*. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347

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