CareSource

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Vumerity (diroximel fumarate)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 30-day Starter dose bottle (bottle of 106 capsules), 30-day Maintenance dose bottle (bottle of 120 capsules)
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Vumerity (diroximel fumarate) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RELAPSING-REMITTING MULTIPLE SCLEROSIS, CLINICALLY ISOLATED SYNDROME, ACTIVE SECONDARY PROGRESSIVE DISEASE

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
3. Chart notes have been provided confirming diagnosis of Multiple Sclerosis;
4. Baseline of complete blood cell count (CBC), including lymphocyte count, serum aminotransferase, alkaline phosphatase, and total bilirubin levels must be submitted with chart notes.
5. **Dosage allowed:** 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.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. A complete blood cell count (CBC), including lymphocyte count, serum aminotransferase, alkaline phosphatase, and total bilirubin levels must be submitted with chart notes.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Vumerity (diroximel fumarate) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
11/12/2019	New policy for Vumerity created.

References:

1. Vumerity [prescribing information]. Cambridge, MA; Biogen, Inc; October 2019.

2. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002 Jan;58(2):169-78.
3. Polman CH, Reingold SC, Banwell B, et al. Diagnostic criteria for multiple sclerosis: 2010 Revisions to the McDonald criteria. Annals of Neurology. 2011;69(2):292-302. doi:10.1002/ana.22366.
4. 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.
5. Arnold, Douglas L., et al. "Diroximel Fumarate (DRF) in Patients With Relapsing-Remitting Multiple Sclerosis: Interim Efficacy and Safety Results From the Phase 3 EVOLVE-MS-1 Study (P3. 2-060)." (2019): P3-2.
6. 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.

Effective date: 04/01/2020
Revised date: 11/12/2019