Pharmacy Policy Bulletin: J-0181 Fumarate Products - Commercial and Healthcare Reform	
Number: J-0181	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0181-019	**Original Date:** 06/06/2013
Effective Date: 12/20/2024	**Review Date:** 12/02/2024

Drugs Product(s):	• Bafiertam (monomethyl fumarate) • Tecfidera (dimethyl fumarate) • Vumerity (diroximel fumarate)
FDA-Approved Indication(s):	• Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Background:	• The exact mechanisms of action of Bafiertam, Tecfidera and Vumerity are unknown. Tecfidera and Vumerity are metabolized to the same active substance, monomethyl fumarate (MMF), once in the body. MMF is the active ingredient of Bafiertam. MMF has been shown to activate the Nuclear factor-like 2 (Nrf2) pathway involved in the cellular response to oxidative stress.
	• Clinically isolated syndrome is the first episode of neurological symptoms caused by inflammation and demyelination in the central nervous system. Relapsing-remitting MS (RRMS) is characterized by clearly defined attacks of new or increasing neurologic symptoms. The attacks are followed by periods of partial or complete recovery (remissions). Secondary progressive disease follows an initial relapsing remitting course, with disability gradually increasing over time.
	• Prescribing Considerations:
	  ○ Bafiertam, Tecfidera and Vumerity are to be prescribed under the supervision of a neurologist.
	  ○ Blood tests, including a complete blood count (CBC) with lymphocyte count, serum aminotransferase, alkaline phosphatase, and total bilirubin levels, are required prior to initiation of Bafiertam, Tecfidera, or Vumerity.
	  ○ Vumerity is not recommended in patients with moderate or severe renal impairment.
	  ○ Based on animal data, Bafiertam, Tecfidera and Vumerity may cause fetal harm. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Tecfidera during pregnancy.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Bafiertam, Tecfidera (dimethyl fumarate), or Vumerity may be approved when all of the following criteria are met **(A. through D.)**:

A. The member is 18 years of age or older.

B. The member has a diagnosis of MS (ICD-10: G35), classified as a relapsing form (clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease).

C. If the request is for brand Tecfidera, the member has experienced therapeutic failure or intolerance to generic dimethyl fumarate.

D. If the request is for Bafiertam or Vumerity, the member has experienced therapeutic failure or intolerance to plan-preferred generic dimethyl fumarate.

II. Reauthorization

When a benefit, reauthorization of Bafiertam, Tecfidera (dimethyl fumarate), or Vumerity may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The prescriber attests that the member has experienced a therapeutic response defined as one (1) of the following **(1., 2., or 3.)**:

1. Disease stability

2. Disease improvement

3. Delayed disease progression

B. If the request is for brand Tecfidera, the member has experienced therapeutic failure or intolerance to generic dimethyl fumarate.

C. If the request is for Bafiertam or Vumerity, the member has experienced therapeutic failure or intolerance to plan-preferred generic dimethyl fumarate.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations

Limitations of Coverage

I. Combination use of disease modifying MS agents (e.g. Tecfidera, Vumerity, Gilenya, interferons, Copaxone, Tysabri, Aubagio) will not be authorized.

II. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

III. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 24 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Bafiertam [package insert]. High Point, NC: Banner Life Sciences LLC; September 2024.
2. Tecfidera [package insert] Cambridge, MA: Biogen Inc.; March 2024.
3. Vumerity [package insert] Waltham, MA: Alkermes, Inc.; September 2024.
4. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed November 4, 2024.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.