BlueCross BlueShield
Federal Employee Program

TECFIDERA* (**dimethyl fumarate**)

BAFIERTAM (monomethyl fumarate), VUMERITY (diroximel fumarate)

Preferred product: generic dimethyl fumarate.

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Tecfidera, Bafiertam, and Vumerity are used in the treatment of relapsing forms of multiple sclerosis, including relapsing-remitting multiple sclerosis (RRMS), which is the most common form of the disease. Tecfidera, Bafiertam, and Vumerity have been proven to significantly reduce important measures of disease activity, including relapses and development of brain lesions, as well as slow disability progression over time. Dimethyl fumarate and diroximel fumarate share the same active metabolite, monomethyl fumarate (MMF) which has been shown to activate Nuclear factor-like 2 (Nrf2) pathway which is involved in cellular response to oxidative stress (1-3).

Regulatory Status

FDA-approved indication: Tecfidera, Bafiertam, and Vumerity are 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 (1-3).

Tecfidera, Bafiertam, and Vumerity may decrease lymphocyte counts. A recent complete blood cell count (CBC) (i.e., within 6 months) is recommended before initiation of therapy to identify patients with pre-existing low lymphocyte counts. A CBC should be repeated annually and as clinically indicated. Withholding treatment should be considered in patients with serious infections until the infection(s) is resolved. Tecfidera, Bafiertam, and Vumerity have not been studied in patients with pre-existing low lymphocyte counts (1-3).

An increased incidence of elevations of hepatic transaminases in patients treated with Tecfidera, Bafiertam, and Vumerity has been observed, primarily during the first six months of treatment, and most patients with elevations had levels < 3 times the upper limit of normal (ULN) (1-3).

A case of progressive multifocal leukoencephalopathy (PML) has occurred in a patient with MS who received Tecfidera for 4 years while enrolled in a clinical trial. Vumerity shares the same active

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metabolite as Tecfidera, which is monomethyl fumarate (Bafiertam). At the first sign or symptom suggestive of PML, withhold Tecfidera, Bafiertam, or Vumerity and perform an appropriate diagnostic evaluation (1-3).

Live, attenuated vaccines are generally not recommended for a person with MS because their ability to cause disease has been weakened but not totally inactivated (4).

Safety and effectiveness in pediatric patients have not been established (1-3).

Summary

Tecfidera, Bafiertam, and Vumerity are FDA approved for the treatment of patients with relapsing forms of multiple sclerosis to help decrease relapse rates, and new or enlarging lesions observed on MRI. Tecfidera, Bafiertam, and Vumerity may decrease lymphocyte counts. A recent complete blood cell count (CBC) (i.e., within 6 months) is recommended before initiation of therapy to identify patients with pre-existing low lymphocyte counts, annually, and as clinically indicated. Withholding treatment should be considered in patients with serious infections until the infection(s) is resolved. Patients should be monitored for signs and symptoms of PML. Safety and effectiveness in pediatric patients have not been established (1-3).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Tecfidera, Bafiertam, and Vumerity while maintaining optimal therapeutic outcomes.

References

1. Tecfidera [package insert]. Cambridge, MA: Biogen Inc.; March 2024.
2. Bafiertam [package insert]. High Point, NC: Banner Life Sciences LLC; September 2024.
3. Vumerity [package insert]. Cambridge, MA: Biogen Inc.; September 2024.
4. Cahill JF, Izzo A, Garg N. Immunization in patients with multiple sclerosis. Neurological Bulletin. 2010;2(1):17-21.