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5.60.001

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	May 1, 2013
Subject:	Tecfidera Bafiertam Vumerity	**Page:**	1 of 7

Last Review Date: March 7, 2025

Tecfidera Bafiertam Vumerity

Description

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.

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 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).

Related policies

Acthar Gel, Ampyra, Aubagio, Gilenya, Kesimpta, Lemtrada, Mavenclad, Mayzent, MS Injectables, Ocrevus, Ponvory, Tysabri, Zeposia

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tecfidera, Bafiertam, and Vumerity may be considered **medically necessary** if the conditions indicated below are met.

Tecfidera, Bafiertam, and Vumerity may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AND ALL of the following:

1. Recent CBC (within 6 months) before initiation
    a. Baseline lymphocyte count must be obtained and monitored annually
2. **NO** active serious infections, or
    a. If present, treatment will be held until resolved
3. Monitor for the signs and symptoms of progressive multifocal leukoencephalopathy (PML) and discontinue if present
4. **NOT** to be used with other disease modifying medications for MS
5. **NOT** given concurrently with live vaccines
6. **Bafiertam and Vumerity ONLY:** Patient **MUST** have tried dimethyl fumarate (generic Tecfidera) **AND ONE** of the other preferred MS medications (see Appendix 1) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AND ALL of the following:

1. Lymphocyte count must be monitored annually
2. **NO** active serious infections, or

   a. If present, treatment will be held until resolved
3. Continue to monitor for signs and symptoms of PML and discontinue if present
4. **NOT** to be used with other disease modifying medications for MS
5. **NOT** given concurrently with live vaccines
6. **Bafiertam and Vumerity ONLY:** Patient **MUST** have tried dimethyl fumarate (generic Tecfidera) **AND ONE** of the other preferred MS medications (see Appendix 1) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Medication	Quantity Limit
Bafiertam	95 mg capsules – 360 capsules per 90 days **OR**
dimethyl fumarate (generic Tecfidera)	120 mg capsules – 14 day (starter pack) **AND** 240 mg capsules – 180 capsules per 90 days **OR**
Vumerity	231 mg capsules – 360 capsules per 90 days

Medication with Approved Formulary Exception ONLY	Quantity Limit
Tecfidera brand	120 mg capsules – 14 day (starter pack) **AND** 240 mg capsules – 180 capsules per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity

Medication	Quantity Limit
Bafiertam	95 mg capsules – 360 capsules per 90 days **OR**

dimethyl fumarate (generic Tecfidera)	240 mg capsules – 180 capsules per 90 days **OR**
Vumerity	231 mg capsules – 360 capsules per 90 days

Medication with Approved Formulary Exception ONLY	**Quantity Limit**
Tecfidera brand	240 mg capsules – 180 capsules per 90 days

Duration 12 months

Rationale

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.

Policy History

Date	Action
May 2013	Addition to PA
September 2013	Annual editorial review by PMPC

June 2014	Removal of lymphocyte count of ≥ 910 lymphocytes /microliter Addition of not to be used with other disease modifying medications for MS
September 2014	Annual editorial review
December 2014	Annual editorial review and reference update
March 2015	Annual editorial review and reference update
June 2016	Annual editorial review and reference update Addition of monitoring for PML Policy code changed from 5.06.10 to 5.60.01
December 2016	Annual editorial review and reference update Addition of not given concurrently with live vaccines
March 2017	Annual review
June 2017	Annual review
November 2018	Annual review and reference update
September 2019	Annual editorial review and reference update. Revised relapsing MS indication to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
November 2019	Addition of Vumerity. Changed policy name to Tecfidera Vumerity
March 2020	Annual review and reference update
April 2020	Added statement that Tecfidera is a preferred product
June 2020	Annual review and reference update
August 2020	Addition of Bafiertam. Changed policy name to Tecfidera Bafiertam Vumerity
September 2020	Annual review
December 2020	Annual review and reference update. Added requirement that Bafiertam, Tecfidera brand, and Vumerity have to t/f generic Tecfidera: dimethyl fumarate and one of the other preferred MS medications. Added Appendix 1 with a list of the preferred medications
February 2021	Removal of Vumerity starter pack due to being discontinued
March 2021	Annual review and reference update
June 2021	Annual review
December 2021	Removed Medex requirement for brand Tecfidera and added brand Tecfidera to FE + PA only
December 2022	Annual review and reference update. Changed policy number to 5.60.001
June 2023	Annual review and reference update
December 2023	Annual review
December 2024	Annual review and reference update
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.

Appendix 1 - List of Preferred Multiple Sclerosis (MS) Medications

Medication Name	Route of Administration
dimethyl fumarate* (generic Tecfidera) *must try this drug plus one other preferred MS medication oral or injectable	Oral
fingolimod (generic Gilenya)	Oral**
Mayzent	Oral**
teriflunomide (generic Aubagio)	Oral**
Zeposia	Oral**

****** indicates separate criteria will need to be met

Medication Name	Route of Administration
Avonex	Injectable
Betaseron	Injectable
glatiramer acetate (generic Copaxone)	Injectable
Glatopa	Injectable
Plegridy	Injectable
Rebif	Injectable