

5.60.01

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| Section: | Prescription Drugs | Effective Date: | April 1, 2021 |
| Subsection: | Central Nervous System Drugs | Original Policy Date: | May 1, 2013 |
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Last Review Date: March 12, 2021

Tecfidera Bafiertam Vumerity

Description

Tecfidera (**dimethyl fumarate***)

Bafiertam (monomethyl fumarate), Vumerity (diroximel fumarate)

* Bolded medications are the preferred products

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

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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, 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** in patients 18 years of age and older with relapsing multiple sclerosis and if the conditions indicated below are met.

Tecfidera, Bafiertam, and Vumerity are considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

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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, Tecfidera brand, and Vumerity only:** Patient **MUST** have tried generic Tecfidera: dimethyl fumarate **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

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4. **NOT** to be used with other disease modifying medications for MS
5. **NOT** given concurrently with live vaccines
6. **Bafiertam, Tecfidera brand, and Vumerity only:** Patient **MUST** have tried generic Tecfidera: dimethyl fumarate **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 |
| 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 |

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity

| Medication | Quantity Limit |
|------------|--|
| Bafiertam | 95 mg capsules – 360 capsules per 90 days OR |
| Tecfidera | 240 mg capsules – 180 capsules per 90 days OR |
| Vumerity | 231 mg capsules – 360 capsules per 90 days |

Duration 12 months

Rationale

Summary

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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.; January 2021.
2. Bafiertam [package insert]. High Point, NC: Banner Life Sciences LLC; April 2020.
3. Vumerity [package insert]. Cambridge, MA: Biogen Inc.; January 2021.
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 |

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|----------------|---|
| 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 |

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

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

| Medication Name | Route of Administration |
|--|-------------------------|
| Aubagio | Oral** |
| dimethyl fumarate* (generic Tecfidera) *must try this drug plus one other preferred oral or injectable | Oral |
| Gilenya | Oral** |
| Mayzent | 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 |