

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.

Pre – PA Allowance

None

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 Limits**Quantity**

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

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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 <u>Approved Formulary Exception</u> 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* 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)

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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 <u>Approved Formulary Exception</u> ONLY	Quantity Limit
Tecfidera brand	240 mg capsules – 180 capsules per 90 days

Duration 12 months

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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