

## Clinical Policy: Dimethyl Fumarate (Tecfidera), Diroximel Fumarate (Vumerity), Monomethyl Fumarate (Bafiertam)

Reference Number: IL.ERX.SPA.116

Effective Date: 06.01.21

Last Review Date: 05.21

Line of Business: Illinois Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

### Description

The following are nuclear factor-like 2 activators requiring prior authorization: dimethyl fumarate (Tecfidera®), diroximel fumarate (Vumerity®), and monomethyl fumarate (Bafiertam™).

### FDA Approved Indication(s)

Tecfidera, Vumerity, and Bafiertam are indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Tecfidera, Vumerity, and Bafiertam are **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Multiple Sclerosis (must meet all):

1. Diagnosis of one of the following (a, b, or c):
  - a. Clinically isolated syndrome, and:
    - i. If request is for Vumerity or Bafiertam: Member is contraindicated to both, or has experienced clinically significant adverse effects to one, of the following at up to maximally indicated doses: an interferon-beta agent (*Betaseron® and Rebif® are preferred agents*), glatiramer (*Copaxone® 20 mg is preferred*);
  - b. Relapsing-remitting MS, and:
    - i. If request is for Vumerity or Bafiertam: Failure of the following at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced: dimethyl fumarate (*Tecfidera brand is preferred*) and any of the following: an interferon-beta agent (*Betaseron and Rebif are preferred agents*) or glatiramer (*Copaxone 20 mg is preferred*);  
*\*Prior authorization is required for all disease modifying therapies for MS*
  - c. Secondary progressive MS;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;
4. The requested agent is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);
5. Documentation of baseline number of relapses per year and expanded disability status scale (EDSS) score;
6. Dose does not exceed:
  - a. Starting dose: Tecfidera 240 mg (2 capsules) or Vumerity 462 mg (2 capsules) or Bafiertam 190 mg (2 capsules) per day for 7 days;

- b. Maintenance dose: Tecfidera 480 mg (2 capsules) or Vumerity 924 mg (4 capsules) or Bafiertam 380 mg (4 capsules) per day.

**Approval duration: 6 months**

**B. Other diagnoses/indications**

- 1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. Multiple Sclerosis (must meet all):**

- 1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
- 2. Member meets one of the following (a or b):
  - a. If member has received < 1 year of total treatment: Member is responding positively to therapy;
  - b. If member has received ≥ 1 year of total treatment: Member meets one of the following (i, ii, iii, or iv):
    - i. Member has not had an increase in the number of relapses per year compared to baseline;
    - ii. Member has not had ≥ 2 new MRI-detected lesions;
    - iii. Member has not had an increase in EDSS score from baseline;
    - iv. Medical justification supports that member is responding positively to therapy;
- 3. The requested agent is not prescribed concurrently with other disease modifying therapies for MS (see Appendix D);
- 4. If request is for a dose increase, new dose does not exceed Tecfidera 480 mg (2 capsules) or Vumerity 924 mg (4 capsules) or Bafiertam 380 mg (4 capsules) per day.

**Approval duration: first re-authorization: 6 months; second and subsequent re-authorizations: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

- 1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

**Approval duration: Duration of request or 6 months (whichever is less); or**

- 2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;

- B.** Primary progressive MS.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

EDSS: expanded disability status scale

FDA: Food and Drug Administration

MS: multiple sclerosis

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria.*

*The drugs listed here may not be a formulary agent and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Rebif® (interferon beta-1a)	22 mcg or 44 mcg SC TIW	44 mcg TIW

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Betaseron <sup>®</sup> (interferon beta-1b)	250 mcg SC QOD	250 mg QOD
glatiramer acetate (Copaxone <sup>®</sup> )	20 mg SC QD or 40 mg SC TIW	20 mg/day or 40 mg TIW
dimethyl fumarate (Tecfidera <sup>®</sup> )	120 mg PO BID for 7 days, followed by 240 mg PO BID	480 mg/day

Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.

**Appendix C: Contraindications/Boxed Warnings**

- Contraindication(s): known hypersensitivity to dimethyl fumarate, diroximel fumarate, monomethyl fumarate, or any of the excipients of Tecfidera, Vumerity, or Bafiertam; coadministration of Tecfidera, Vumerity, and Bafiertam
- Boxed warning(s): none reported

**Appendix D: General Information**

- Disease-modifying therapies for MS are: glatiramer acetate (Copaxone<sup>®</sup>, Glatopa<sup>®</sup>), interferon beta-1a (Avonex<sup>®</sup>, Rebif<sup>®</sup>), interferon beta-1b (Betaseron<sup>®</sup>, Extavia<sup>®</sup>), peginterferon beta-1a (Plegridy<sup>®</sup>), dimethyl fumarate (Tecfidera<sup>®</sup>), diroximel fumarate (Vumerity<sup>®</sup>), monomethyl fumarate (Bafiertam<sup>™</sup>), fingolimod (Gilenya<sup>®</sup>), teriflunomide (Aubagio<sup>®</sup>), alemtuzumab (Lemtrada<sup>®</sup>), mitoxantrone (Novantrone<sup>®</sup>), natalizumab (Tysabri<sup>®</sup>), ocrelizumab (Ocrevus<sup>®</sup>), cladribine (Mavenclad<sup>®</sup>), siponimod (Mayzent<sup>®</sup>), ozanimod (Zeposia<sup>®</sup>), and ofatumumab (Kesimpta<sup>®</sup>).
- Of the disease-modifying therapies for MS that are FDA-labeled for clinically isolated syndrome, only the interferon products, glatiramer, and Aubagio have demonstrated any efficacy in decreasing the risk of conversion to MS compared to placebo. This is supported by the AAN 2018 MS guidelines.
- Tecfidera and Vumerity are both prodrugs of Bafiertam.

**V. Dosage and Administration**

Drug Name	Dosing Regimen	Maximum Dose
Dimethyl fumarate (Tecfidera)	Starting: 120 mg PO BID for 7 days Maintenance: 240 mg PO BID	480 mg/day
Diroximel fumarate (Vumerity)	Starting: 231 mg PO BID for 7 days Maintenance: 462 mg PO BID	924 mg/day
Monomethyl fumarate (Bafiertam)	Starting: 95 mg PO BID for 7 days Maintenance: 190 mg PO BID	380 mg/day

**VI. Product Availability**

Drug Name	Availability
Dimethyl fumarate (Tecfidera)	Delayed-release capsules: 120 mg, 240 mg
Diroximel fumarate (Vumerity)	Delayed-release capsule: 231 mg
Monomethyl fumarate (Bafiertam)	Delayed-release capsule: 95 mg

**VII. References**

1. Tecfidera Prescribing Information. Cambridge, MA: Biogen Inc.; January 2021. Available at <http://www.tecfidera.com>. Accessed February 8, 2021.
2. Vumerity Prescribing Information. Cambridge, MA: Biogen Inc.; January 2021. Available at <http://www.vumerity.com>. Accessed February 8, 2021.
3. Bafiertam Prescribing Information. High Point, NC: Banner Life Sciences LLC; April 2020. Available at: <https://bafiertam.com/prescribing-information>. Accessed February 8, 2021.
4. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis: report of the Guideline Development,

## CLINICAL POLICY

### Dimethyl Fumarate, Diroximel Fumarate, Monomethyl Fumarate

Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018; 90(17): 777-788. Full guideline available at: <https://www.aan.com/Guidelines/home/GetGuidelineContent/904>.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.19.21	05.21

#### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2021 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.