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

Reference Number: CP.PHAR.249
Effective Date: 09.01.16
Last Review Date: 05.26
Line of Business: Commercial, HIM/ICHRA, 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.

It is the policy of health plans affiliated with Centene Corporation® that dimethyl fumarate, 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** (Avonex®, Betaseron®^/Extavia®, Rebif®, or Plegridy®), **glatiramer** (Copaxone®, Glatopa®);†
      †For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395
   b. Relapsing-remitting MS, and:
      i. If request is for Vumerity or Bafiertam: Failure of all of the following at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated (1, 2, 3, and 4):†*
      †For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
         1) **Dimethyl fumarate** (generic Tecfidera);
         2) **Teriflunomide** (generic Aubagio®);

3) **Fingolimod** (Gilenya®);
4) An **interferon-beta agent** (Avonex, Betaseron^/Extavia, Rebif, or Plegridy) or **glatiramer** (Copaxone, Glatopa);

**Prior authorization may be required for all disease modifying therapies for MS*
^Betaseron is the preferred interferon beta-1b product for the Commercial and HIM/ICHRA lines of business

c. Secondary progressive MS;

2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;
4. For brand Tecfidera and brand Vumerity requests, member must use **generic dimethyl fumarate**, unless contraindicated or clinically significant adverse effects are experienced;†

†For Illinois HIM requests, the step therapy requirements above do not apply to Vumerity as of 1/1/2026 per IL HB 5395

5. The requested agent is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);
6. Dose does not exceed (a and b):
   a. Starting dose (i and ii):
      i. Tecfidera 240 mg, Vumerity 462 mg, or Bafiertam 190 mg per day for 7 days;
      ii. 2 capsules per day for 7 days;
   b. Maintenance dose (i and ii):
      i. Tecfidera 480 mg, Vumerity 924 mg, or Bafiertam 380 mg per day;
      ii. Tecfidera 2 capsules, Vumerity 4 capsules, or Bafiertam 4 capsules per day.

Approval duration: 12 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):

a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*

2. For brand Tecfidera and brand Vumerity requests, member must use **generic dimethyl fumarate**, unless contraindicated or clinically significant adverse effects are experienced;†
   †*For Illinois HIM requests, the step therapy requirements above do not apply to Vumerity as of 1/1/2026 per IL HB 5395*
3. Member is responding positively to therapy;
4. The requested agent is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);
5. If request is for a dose increase, new dose does not exceed (a and b):
   a. Tecfidera 480 mg, Vumerity 924 mg, or Bafiertam 380 mg per day;
   b. Tecfidera 2 capsules, Vumerity 4 capsules, or Bafiertam 4 capsules per day.

Approval duration: 12 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents;

B. Primary progressive MS.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
teriflunomide (Aubagio®)	7 mg or 14 mg PO QD	14 mg/day
Avonex®, Rebif® (interferon beta-1a)	*Avonex*: 30 mcg IM Q week *Rebif*: 22 mcg or 44 mcg SC TIW	*Avonex*: 30 mcg/week *Rebif*: 44 mcg TIW
Betaseron®, Extavia® (interferon beta-1b)	250 mcg SC QOD	250 mg QOD
Plegridy® (peginterferon beta-1a)	125 mcg SC Q2 weeks	125 mcg/2 weeks
glatiramer acetate (Copaxone®, Glatopa®)	20 mg SC QD or 40 mg SC TIW	20 mg/day or 40 mg TIW
fingolimod (Gilenya®)	0.5 mg PO QD	0.5 mg/day
dimethyl fumarate (Tecfidera®)	120 mg PO BID for 7 days, followed by 240 mg PO BID	480 mg/day

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

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): known hypersensitivity to dimethyl fumarate, diroximel 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®, Glatopa®), interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®), dimethyl fumarate (Tecfidera®), diroximel fumarate (Vumerity®), monomethyl fumarate (Bafiertam™), fingolimod (Gilenya®, Tascenso ODT™), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®, and biosimilar Tyruko®), ocrelizumab (Ocrevus®), ocrelizumab/hyaluronidase-ocsq (Ocrevus Zunovo™), cladribine (Mavenclad®), siponimod (Mayzent®), ozanimod (Zeposia®), ponesimod (Ponvory™), ublituximab-xiiy (Briumvi™), and ofatumumab (Kesimpta®).
- Of the disease-modifying therapies for MS that are FDA-labeled for clinically isolated syndrome, only the interferon products, glatiramer, and teriflunomide have demonstrated any efficacy in decreasing the risk of conversion to MS compared to placebo. This is supported by the American Academy of Neurology 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.; March 2024. Available at: http://www.tecfidera.com. Accessed January 30, 2026.
2. Vumerity Prescribing Information. Cambridge, MA: Biogen Inc.; September 2024. Available at: http://www.vumerity.com. Accessed January 30, 2026.
3. Bafiertam Prescribing Information. High Point, NC: Banner Life Sciences LLC; September 2025. Available at: https://www.bafiertam.com. Accessed January 30, 2026.
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, 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/898. Reaffirmed on October 19, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2022 annual review: no significant changes; added legacy WellCare line of business (WCG.CP.PHAR.249 to be retired); clarified interferon-beta product redirections for each line of business per SDC; references reviewed and updated.	02.07.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	
Added generic redirection in continued therapy section.	12.22.22	
2Q 2023 annual review: no significant changes; to be inclusive of members continuing therapy from a different benefit, revised continued approval duration to reference the duration of total treatment received rather than the number of re-authorizations; references reviewed and updated.	01.31.23	05.23

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Per August SDC, Commercial and HIM line of business added to policy (CP.PCH.41 retired); added generic references to Aubagio and Gilenya redirections.	08.22.23	11.23
2Q 2024 annual review: no significant changes; revised policy/criteria section to also include generic dimethyl fumarate; references reviewed and updated.	01.25.24	05.24
2Q 2025 annual review: per competitor analysis, removed requirements for documentation of baseline relapses/expanded disability status score and specific measures of positive response; per SDC, removed notation that Extavia is the preferred interferon beta-1b product for the Medicaid line of business as it is no longer available on market; for continued therapy, updated approval duration from "if member has received < 1 year of total treatment – up to a total of 12 months of treatment and if member has received ≥ 1 year of total treatment – 12 months" to "12 months"; references reviewed and updated.	02.11.25	05.25
Added step therapy bypass for IL HIM per IL HB 5395.	06.25.25	
2Q 2026 annual review: no significant changes; extended initial approval duration from 6 to 12 months for this maintenance medication for a chronic condition; references reviewed and updated. Added ICHRA line of business.	03.31.26	05.26

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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 clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.