UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2184-6
Program	Prior Authorization/Medical Necessity
Medication	Vumerity® (diroximel fumarate)* *Vumerity is excluded from coverage for the majority of our benefits
P&T Approval Date	1/2020, 11/2020, 5/2021, 5/2022, 5/2023, 5/2024
Effective Date	8/1/2024

1. Background:

Vumerity (diroximel fumarate) is 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.

Coverage will be provided for members who meet the following criteria.

2. Coverage Criteria[a]:

1. **Authorization**

a. **Vumerity** will be approved based on **all** of the following criteria:

(1) Diagnosis of clinically isolated syndrome (CIS) or a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary progressive MS with relapses)

-AND-

(2) Prescribed by or in consultation with a specialist in the treatment of MS (e.g., neurologist)

-AND-

(3) **Both** of the following:

(a) Submission of medical records documenting the trial and failure (after trial of at least 4 weeks), contraindication, or intolerance to **at least two** of the following:

- glatiramer acetate (e.g., Copaxone®)
- interferon β-1a (e.g., Avonex®, Rebif®)
- interferon β-1b (e.g., Betaseron®)
- peginterferon β-1a (Plegridy®)
- teriflunomide (Aubagio®)
- Mayzent® (siponimod)
- fingolimod (Gilenya®)
- Zeposia® (ozanimod)

- Kesimpta® (ofatumumab)

-AND-

(b) Submission of medical records documenting the trial and failure (after trial of at least 4 weeks), contraindication, or intolerance to **both** of the following:

- Bafiertam® (monomethyl fumarate)
- dimethyl fumarate (generic Tecfidera®) with trial date that started August 20, 2020 or later

-AND-

(4) Patient is **not** receiving Vumerity in combination with another disease modifying therapy for multiple sclerosis [e.g., interferon beta preparations, glatiramer acetate, dimethyl fumarate (Tecfidera®), Tysabri® (natalizumab), fingolimod (Gilenya®), Ocrevus® (ocrelizumab), Lemtrada® (alemtuzumab), Mavenclad® (cladribine), teriflunomide (Aubagio®), Bafiertam® (monomethyl fumarate), Kesimpta® (ofatumumab), Zeposia® (ozanimod) or Mayzent® (siponimod)]

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Exclusion: Vumerity is excluded from coverage for the majority of our benefits.
- Supply limits, notification, and/or Step Therapy may be in place.

4. References:

1. Vumerity [package insert]. Cambridge, MA: Biogen Inc.; March 2024.

Program	Prior Authorization/Medical Necessity – Vumerity® (diroximel fumarate)
Change Control	
1/2020	New program
11/2020	Revised step therapy medications due to changes in preferred products. Removed continuation of therapy allowance and reauthorization section. Updated references.
5/2021	Updated step through both Bafiertam (monomethyl fumarate) and dimethyl fumarate (generic Tecfidera). Added requirement of medical record submission.
5/2022	Annual review with no change to clinical criteria. Updated references.
5/2023	Annual review. Removed diagnosis header on coverage criteria. Changed dimethyl fumarate (generic Tecfidera) wording. Updated references.
5/2024	Annual review. Updated the listing of the brand names of step therapy medications. Updated references.