UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3132-6
Program	Step Therapy
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:

Step therapy programs are utilized to encourage use of lower-cost, preferred alternatives for certain therapeutic classes. This program requires a member to try Bafiertam™ (monomethyl fumarate) or dimethyl fumarate and at least two other preferred medications [(glatiramer acetate, Avonex (interferon β-1a), Betaseron (interferon β-1b), Plegridy (peginterferon β-1a), Aubagio (teriflunomide), Mayzent (siponimod), Gilenya (fingolimod), Zeposia (ozanimod), Kesimpta (ofatumumab)] before providing coverage for Vumerity™ (diroximel fumarate).

Vumerity, dimethyl fumarate, Bafiertam, glatiramer acetate, Avonex, Betaseron, Plegridy, Aubagio, Mayzent, Gilenya, Zeposia, and Kesimpta 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]

2. Coverage Criteria[a]:

1. **Vumerity** will be approved based on **both** of the following:

   a. Trial and failure (after trial of at least 4 weeks), contraindication, or intolerance to **both** of the following (document drug, date, and duration of trial):

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

   -AND-

   b. Trial and failure (after trial of at least 4 weeks), contraindication, or intolerance to **at least two** of the following (document drug, date, and duration of trial):

   - 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)

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.
- Medical Necessity, supply limits, and/or notification may be in place.

4. References:

1. Vumerity [package insert]. Cambridge, MA: Biogen Inc.; March 2024.
2. Bafiertam [package insert]. Banner Life Sciences LLC: High Point, NC; December 2023.
3. Avonex [package insert]. Cambridge, MA: Biogen Inc.; July 2023.
4. Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2023.
5. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2023.
6. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; December 2023.
7. Plegridy [package insert]. Cambridge, MA: Biogen Inc.; July 2023.
8. Mayzent [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2023.
9. Zeposia [package insert]. Celgene Corporation: Princeton, NJ; August 2023.
10. Kesimpta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.

Program	Prior Authorization/Step Therapy – Vumerity® (diroximel fumarate)
Change Control	
1/2020	New program.
11/2020	Revised step therapy medications due to PDL changes. Removed continuation of therapy allowance. Updated background and references.
5/2021	Updated step through both Bafiertam (monomethyl fumarate) and dimethyl fumarate (generic Tecfidera).
5/2022	Annual review. No changes to coverage 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.