UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3132-2
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
Effective Date	1/1/2021; Oxford only: N/A

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]:

A. <u>Relapsing Forms of Multiple Sclerosis (MS) or Clinically Isolated Syndrome (CIS)</u>

1. Vumerity will be approved based on **<u>both</u>** of the following:

a. Trial and failure (after trial of at least 4 weeks), contraindication, or intolerance to Bafiertam (monomethyl fumarate) or dimethyl fumarate (generic Tecfidera) (document drug, date, and duration of trial)

-AND-

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

- Glatiramer acetate

- Avonex (interferon β-1a)
- Betaseron (interferon β-1b)
- Plegridy (peginterferon β-1a)
- Aubagio (teriflunomide)
- Mayzent (siponimod)
- Gilenya (fingolimod)
- 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.; August 2020.
2. `Bafiertam [package insert]. Banner Life Sciences LLC: High Point, NC; April 2020.
3. Avonex [package insert]. Cambridge, MA: Biogen Inc.; March 2020.
4. Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; August 2019.
5. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2019.
6. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; September 2019.
7. Plegridy [package insert]. Cambridge, MA: Biogen Inc.; March 2020.
8. Mayzent [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
9. Zeposia [package insert]. Celgene Corporation: Summit, NJ; March 2020.
10. Kesimpta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2020.

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.