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 two disease modifying therapies before providing coverage for Vumerity™ (diroximel fumarate).

Vumerity 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.¹

Members currently on Vumerity as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. **Coverage Criteria**:

A. **Relapsing Forms of Multiple Sclerosis (MS) or Clinically Isolated Syndrome (CIS)**

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

   a. Trial and failure (after trial of at least 4 weeks), contraindication, or intolerance to **two** of the following disease-modifying therapies for MS [document medication used, dose, and duration]:

   - Interferon β-1a (Avonex®, Rebit®, Plegridy™)
   - Interferon β-1b (e.g., Betaseron®)
   - Glatiramer acetate (e.g., Copaxone®)
   - Tecfidera® (dimethyl fumarate)
   - Aubagio® (teriflunomide)
   - Gilenya® ( fingolimod)
   - Mayzent® (siponimod)
   - Tysabri® (natalizumab)
   - Ocrevus® (ocrelizumab)
   - Lemtrada® (alemtuzumab)
-OR-

b. **Both** of the following:

   (a) Patient is currently on Vumerity

   -AND-

   (b) Patient has not received a manufacturer supplied sample at no cost in the
       prescriber’s office, or any form of assistance from a manufacturer
       sponsored program (e.g., sample card which can be redeemed at a
       pharmacy for a free supply of medication) as a means to establish as a
       current user of Vumerity*

* Patients requesting initial authorization who were established on therapy via the
  receipt of a manufacturer supplied sample at no cost in the prescriber’s office or any
  form of assistance from a manufacturer sponsored program **shall be required** to meet
  initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

B. **Other Diagnoses**

   1. Vumerity will be approved

      **Authorization will be issued for 12 months.**

* 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.
   - Supply limits may be in place.

4. **References:**
<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization/Step Therapy – Vumerity™ (diroximel fumarate)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change Control</strong></td>
<td></td>
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<tr>
<td>1/2020</td>
<td>New program.</td>
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