UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

<table>
<thead>
<tr>
<th>Program Number</th>
<th>2019 P 3080-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program</td>
<td>Step Therapy</td>
</tr>
<tr>
<td>Medication</td>
<td>Adynovate (antihemophilic factor [recombinant], pegylated)*</td>
</tr>
<tr>
<td>P&amp;T Approval Date</td>
<td>10/2016, 10/2017, 10/2018, 10/2019</td>
</tr>
<tr>
<td>Effective Date</td>
<td>2/1/2020; Oxford only: N/A</td>
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</table>

1. **Background:**
   
   Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try one or more preferred recombinant antihemophilic factor VIII products before providing coverage for Adynovate® (antihemophilic factor [recombinant])

2. **Coverage Criteria**:

   A. **Hemophilia A**

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

   a. History of failure, contraindication, or intolerance to three of the following preferred products

      (1) Kogenate FS
      (2) Kovaltry
      (3) Novoeight
      (4) Nuwiq

   -OR-

   b. Physician attestation that patient would preferentially benefit from Adynovate because one of the following:

      (1) Patient is at high risk for the development of inhibitors (e.g., Family history of inhibitors and success with product, Current treatment less than 50 days, high risk genetic mutation, history of initial intensive therapy greater than 5 days)
      (2) Patient has developed inhibitors
      (3) Patient has undergone immune tolerance induction/immune tolerance therapy

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

   ^a State mandates may apply. Any federal regulatory requirements and the member

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specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

* Adynovate is excluded for the majority of our benefits

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 and/or Medical Necessity may be in place.

4. **References:**

<table>
<thead>
<tr>
<th>Program</th>
<th>Step Therapy - Adynovate (antihemophilic factor [recombinant])</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change Control</td>
<td></td>
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<tr>
<td>Date</td>
<td>Change</td>
</tr>
<tr>
<td>10/2016</td>
<td>New program.</td>
</tr>
<tr>
<td>10/2017</td>
<td>Annual review with no change to clinical intent. Updated state mandate verbiage. Updated references.</td>
</tr>
<tr>
<td>2/2018</td>
<td>Administrative change to correct effective date.</td>
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<tr>
<td>10/2018</td>
<td>Annual review with no changes to coverage criteria. Updated reference.</td>
</tr>
<tr>
<td>10/2019</td>
<td>Annual review with no changes to coverage criteria. Updated references.</td>
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