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 Recombinate® (antihemophilic factor [recombinant]).

All standard half-life recombinant factor VIII products are indicated for the control and prevention of bleeding episodes and for perioperative management in patients with hemophilia A. Most are also indicated for routine prophylaxis to reduce the frequency of bleeding in patients with hemophilia A. All preferred standard half-life recombinant antihemophilic Factor VIII products, Kogenate FS®, Kovaltry®, Novoeight®, and Nuwiq®, carry all three indications. Review of product characteristics, including but not limited to, manufacturing processes, product stability, vial size availability, infusion requirements, and pharmacokinetics identify very few if any product differentiators. All of the products are expected to produce similar clinical results.

2. **Coverage Criteria**:

A. **Hemophilia A**

1. **Recombinate** 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. **Both** of the following:

      (1) Patient is currently on **Recombinate** therapy
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(2) Patient has not received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from a Shire sponsored CoPay Assistance 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 Recombinate®

* 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 Shire sponsored CoPay Assistance Program™ shall be required to meet initial authorization criteria as if patient were new to therapy.

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.
   - Supply limits and/or Medical Necessity may be in place.

4. References:
<table>
<thead>
<tr>
<th>Program</th>
<th>Step Therapy - Recombinate (antihemophilic factor [recombinant])</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<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 sample pack and state mandate verbiage. Updated references.</td>
</tr>
<tr>
<td>10/2018</td>
<td>Annual review with no changes to coverage criteria. Updated reference.</td>
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<tr>
<td>10/2019</td>
<td>Annual review with no changes to coverage criteria. Updated references.</td>
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