

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 3078-3
Program	Step Therapy
Medication	Advate (antihemophilic factor [recombinant])
P&T Approval Date	10/2016, 10/2017, 10/2018
Effective Date	2/1/2019; Oxford only: N/A

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 Advate® (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:

A. Hemophilia A

1. **Advate** 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 **Advate** therapy

-AND-

(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 **Advate***

* 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:

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

4. References:

1. Advate® [package insert]. Westlake Village CA: Wyeth Baxter Healthcare Corporation., November 2016.
2. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. Med Bulletin #253, April 23, 2018..
3. Kogenate FS® [package insert]. Tarrytown, NY Bayer HealthCare LLC; May 2016
4. Kovaltry® [package insert]. Whippany, NJ: Bayer HealthCare LLC; March 2016.
5. Novoeight® [package insert]. Plainsboro, NJ: Novo Nordisk; May 2018.
6. Nuwiq® [package insert]. Hoboken, NJ: Octapharma; July 2017.

Program	Step Therapy - Advate (antihemophilic factor [recombinant])
Change Control	
Date	Change
10/2016	New program.
10/2017	Annual review with no change to clinical intent. Updated sample pack and state mandate verbiage. Updated references.
10/2018	Annual review with no changes to coverage criteria. Updated references.