UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2108-3
Program	Prior Authorization/Medical Necessity
Medication	Advate (antihemophilic factor [recombinant])
P&T Approval Date	10/2016, 10/2017, 10/2018
Effective Date	2/1/2019; Oxford only: 2/1/2019

1. Background

Advate® (antihemophilic factor [recombinant]) is a recombinant antihemophilic factor indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for:[1]

- Control and prevention of bleeding episodes
- Perioperative management
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

Advate is not indicated for the treatment of von Willebrand disease.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Advate** will be approved based on **all** of the following criteria:[1-3]

   a. Diagnosis of hemophilia A

   -AND-

   b. **One** of the following:

      (1) Submission of documentation showing failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level) after a trial of **three** of the following recombinant factor products:

         i. Kogenate FS
         ii. Kovaltry
         iii. NovoEight
         iv. Nuwiq

   -OR-

(2) Submission of documentation showing history of hypersensitivity to **three** of the following recombinant factor products:

i. Kogenate FS
ii. Kovaltry
iii. NovoEight
iv. Nuwiq

-OR-

(3) **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 of therapy will be issued for 12 months

B. Reauthorization

1. **Advate** will be approved based on the following criterion:

a. Documentation of positive clinical response to **Advate** therapy.

Authorization of therapy 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 Programs:
N/A

4. References:

1. Advate® [package insert]. Westlake Village CA: Wyeth Baxter Healthcare Corporation., November 2016.
2. Hoots WK, Shapiro AD. Treatment of hemophilia. In: UpToDate, Waltham, MA, 2016.
3. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. Med Bulletin #253, April 23, 2018.

Program	Prior Authorization/Medical Necessity - Advate
Change Control	
10/2016	New program.
12/2016	Administrative change. Revised formatting
10/2017	Annual review with no change to clinical intent. Revised formatting. Updated sample pack and state mandate verbiage. Updated references.
10/2018	Annual review with no changes to coverage criteria. Updated reference.