UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1212-2
Program	Prior Authorization/Notification
Medication	Afstyla (antihemophilic factor [recombinant], single chain)
P&T Approval Date	3/2017, 3/2018
Effective Date	6/1/2018; Oxford only: N/A

1. Background:

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

- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes

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

2. Coverage Criteria:

A. Initial Authorization:

1. **Afstyla** will be initially approved based on both of the following criteria:[1-3]

   a. Diagnosis of hemophilia A

   -AND-

   b. **One** of the following:

      (1) Treatment of bleeding episodes
      (2) Prevention of bleeding in surgical interventions or invasive procedures (e.g., surgical prophylaxis)
      (3) Prevention of bleeding episodes (i.e., routine prophylaxis)

Authorization of therapy will be issued for 12 months.

B. Reauthorization

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

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

Authorization of therapy will be issued for 12 months.

3. Additional Clinical Programs:

- Medical necessity may be in place.

4. References:

1. Afstyla® [package insert]. Kankakee, IL: CSL Behring, LLC., September 2017.
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 #250, September 17, 2017.

Program	Prior Authorization/Notification - Afstyla
Change Control	
3/2017	New program.
3/2018	Annual review with no changes to coverage criteria.