UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2123-2
Program	Prior Authorization/Medical Necessity
Medication	Afstyla (antihemophilic factor [recombinant], single chain)
P&T Approval Date	3/2017, 3/2018
Effective Date	6/1/2018; Oxford only: 6/1/2018

1. Background

Afstyla® (antihemophilic factor [recombinant], single chain) 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
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- Perioperative management of bleeding

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

2. Coverage Criteria[a]:

A. Initial Authorization:

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

   a. **All** of the following:

      (1) Diagnosis of hemophilia A

      -AND-

      (2) Patient is not a suitable candidate for treatment with shorter acting half-life Factor VIII (recombinant) products [Kogenate FS, Kovaltry, Novoeight, or Nuwiq] as attested by the prescribing physician

      -AND-

      (3) **One** of the following:

         (a) Patient is not to receive routine infusions more frequently than 3 times per week

         -OR-

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(b) **Both** of the following:

1. Patient is less than 12 years of age

-AND-

2. PK testing results suggest that more frequent than 3 times per week dosing is required

Authorization of therapy will be issued for 12 months.

B. Reauthorization

1. **Afstyla** will be approved based on **all** of the following criteria:

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

   -AND-

   b. **One** of the following:

      (1) Patient is not to receive routine infusions more frequently than 3 times per week

      -OR-

      (2) **Both** of the following:

         (a) Patient is less than 12 years of age

         -AND-

         (b) PK testing results suggest that more frequent than 3 times per week dosing is required

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.

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3. Additional Clinical Programs:
N/A

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/Medical Necessity - Afstyla
Change Control	
3/2017	New program.
3/2018	Annual review with no changes to coverage criteria.

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