UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1212-7
Program	Prior Authorization/Notification
Medication	Afstyla® (antihemophilic factor [recombinant], single chain)
P&T Approval Date	3/2017, 3/2018, 3/2019, 3/2020, 3/2021, 3/2022, 3/2023
Effective Date	6/1/2023; Oxford only: N/A

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
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes

Limitation of use:
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 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.

[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:

- 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.
- Medical necessity may be in place.

4. References:

1. Afstyla® [package insert]. Kankakee, IL: CSL Behring, LLC., April 2021.
2. Hoots WK, Shapiro AD. Treatment of bleeding and perioperative management in hemophilia A and B. In: UpToDate, Waltham, MA, 2022.
3. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. Med Bulletin #272, April 2022.

Program	Prior Authorization/Notification - Afstyla
Change Control	
3/2017	New program.
3/2018	Annual review with no changes to coverage criteria.
3/2019	Annual review with no changes to coverage criteria. Updated reference.
3/2020	Annual review with no changes to coverage criteria. Updated reference.
3/2021	Annual review with no changes to coverage criteria. Updated references.
3/2022	Annual review with no changes to coverage criteria. Updated references.
3/2023	Annual review with no changes to coverage criteria. Added state mandate and updated references.

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