UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2123-9
Program	Prior Authorization/Medical Necessity
Medication	Afstyla® (antihemophilic factor [recombinant], single chain)
P&T Approval Date	3/2017, 3/2018, 3/2019, 3/2020, 9/2020, 9/2021, 9/2022, 9/2023, 3/2024
Effective Date	6/1/2024

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 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 [Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, or Recombinate] as attested by the prescriber

      -AND-

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

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

         -OR-

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

            1. Patient is less than 12 years of age

-AND-

2. Pharmacokinetic (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.

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.

4. References:

1. Afstyla® [package insert]. Kankakee, IL: CSL Behring, LLC., June 2023.
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. MASAC Document #276, May 2, 2023.

Program	Prior Authorization/Medical Necessity - 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.
9/2020	Updated preferred standard half-life recombinant products. Updated references.
9/2021	Annual review with no changes to coverage criteria. Updated reference.
9/2022	Annual review. Added text “pharmacokinetic” to clarify abbreviation “PK” with no changes to clinical intent. Updated background per prescribing information and updated references.
9/2023	Annual review. Modified physician attestation to prescriber attestation. Updated references.
3/2024	Annual review with no changes to coverage criteria.