UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2300-2
Program	Prior Authorization/Medical Necessity
Medication	Altuviiio™ [antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl]
P&T Approval Date	4/2023, 4/2024
Effective Date	7/1/2024

1. Background:

Altuviiio™ [antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl)] is a recombinant DNA-derived, Factor VIII concentrate indicated for use in adults and children with hemophilia A (congenital factor VIII deficiency) for:[1]

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

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

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Altuviiio** will be approved based on **all** of the following criteria:[1,2]

   a. Diagnosis of hemophilia A

   -AND-

   b. **Altuviiio** is being prescribed for **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)

   -AND-

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

   -AND-

   d. **Both** of the following:

      (1) Dose does not exceed 50 IU/kg

   -AND-

(2) Patient is infusing no more frequently than every 7 days

Authorization of therapy will be issued for 12 months.

B. <u>Reauthorization</u>

1. **Altuviiio** will be approved based on **<u>all</u>** of the following criteria:

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

   -AND-

   b. **<u>Both</u>** of the following:

      (1) Dose does not exceed 50 IU/kg

      -AND-

      (2) Patient is infusing no more frequently than every 7 days

   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. Altuviiio™ [package insert]. Waltham, MA: Bioverativ Therapeutics Inc., March 2023.
2. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. MASAC Document #272, April 27, 2022.

Program	Prior Authorization/Medical Necessity - Altuviiio
Change Control	
4/2023	New program.
4/2024	Annual review. No changes to coverage criteria. Updated reference.