UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2041-12
Program	Prior Authorization/Medical Necessity
Medication	Eloctate® [antihemophilic factor (recombinant), Fc fusion protein]
P&T Approval Date	8/2014, 2/2015, 2/2016, 12/2016, 11/2017, 11/2018, 11/2019, 9/2020, 9/2021, 9/2022, 9/2023, 9/2024
Effective Date	12/1/2024

1. Background:

Eloctate [Antihemophilic Factor (Recombinant), Fc Fusion Protein] is a recombinant DNA derived, 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

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

2. Coverage Criteria[a]:

A. Initial Authorization

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

   a. Diagnosis of hemophilia A

   -AND-

   b. 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-

   c. **One** of the following:

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

         (a) Dose does not exceed 50 IU/kg

         -AND-

         (b) Patient is infusing no more frequently than every 4 days

-OR-

(2) Requested dosage regimen does not exceed 12.5 IU/kg/day

-OR-

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

(a) Patient is less than 6 years of age

-AND-

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

i. Pharmacokinetic (PK) testing results suggest that dosing more intensive than 50 IU/kg is required

-OR-

ii. PK testing results suggest that dosing more frequent than every 3.5 days is required

-OR-

iii. PK testing results suggest that dosing more intensive than 14.5 IU/kg/day is required

Authorization of therapy will be issued for 12 months.

B. Reauthorization

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

a. Documentation of positive response to Eloctate therapy

-AND-

b. **One** of the following:

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

(a) Dose does not exceed 50 IU/kg

-AND-

(b) Patient is infusing no more frequently than every 4 days

-OR-

(2) Requested dosage regimen does not exceed 12.5 IU/kg/day

-OR-

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

(a) Patient is less than 6 years of age

-AND-

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

i. PK testing results suggest that dosing more intensive than 50 IU/kg is required

-OR-

ii. PK testing results suggest that dosing more frequent than every 3.5 days is required

-OR-

iii. PK testing results suggest that dosing more intensive than 14.5 IU/kg/day 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. Eloctate® [package insert]. Waltham, MA: Bioverativ Therapeutics Inc., May 2023.
2. Mahlangu J, Powell JS, Ragni MV. Phase 3 study of recombinant factor VIII Fc fusion protein in severe hemophilia A. Blood. 2014 Jan 16;123(3):317-25.
3. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. MASAC Document #284, April 11, 2024.

Program	Prior Authorization/Medical Necessity - Eloctate
Change Control	
2/2015	New program. Version approved 8/2014 but implementation delayed.
2/2016	Annual Review. No changes to criteria. References updated.
12/2016	Annual Review. Updated short acting FVIII examples to preferred products. Updated background and references.
11/2017	Annual review. Removed criteria pertaining to severity of hemophilia A. Updated criteria pertaining to dosage regimens to allow for increased flexibility in dosage regimen. Updated criteria to allow for PK guided dosing in pediatric patients under 6 years old.
11/2018	Annual review. No changes to clinical coverage criteria. Updated references.
11/2019	Annual review. No changes to clinical coverage criteria.
9/2020	Updated preferred standard half-life recombinant products. Updated references.
9/2021	Annual review. No changes to clinical coverage criteria. Updated references.
9/2022	Annual review. Added text “pharmacokinetic” to clarify abbreviation “PK” with no changes to clinical intent. Updated references.
9/2023	Annual review. Modified physician attestation to prescriber attestation. Updated references.
9/2024	Annual review. No changes to clinical coverage criteria. Updated references.