UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2023 P 1151-10 |
| Program | Prior Authorization/Notification |
| Medication | Eloctate® [antihemophilic factor (recombinant), Fc fusion protein] |
| P&T Approval Date | 2/2015, 2/2016, 12/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, 11/2022, 11/2023 |
| Effective Date | 2/1/2024 |

**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:

- 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**

**Eloctate** will be initially approved based on **both** of the following criteria:

1. Diagnosis of hemophilia A

**-AND-**

2. **One** of the following:

   a. Treatment of bleeding episodes
   b. Prevention of bleeding in surgical interventions or invasive procedures (e.g., surgical prophylaxis)
   c. Prevention of bleeding episodes (i.e., routine prophylaxis)

**Authorization of therapy will be issued for 12 months.**

**B. Reauthorization**

1. **Eloctate** will be approved based on the following criterion:

   a. Documentation of positive clinical response to Eloctate 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. Eloctate® [package insert]. Waltham, MA: Bioverativ Therapeutics, Inc.; May 2023.

| Program | Prior Authorization/Notification - Eloctate |
|---|---|
| **Change Control** | |
| 2/2015 | New program. |
| 2/2016 | Annual review. Removed initial and reauthorization criteria for dosing and dosing interval requirement. |
| 12/2016 | Annual review. Updated background and references. |
| 11/2017 | Annual review. No changes to clinical coverage criteria. Updated references. |
| 11/2018 | Annual review. No changes to clinical coverage criteria. Updated references. |
| 11/2019 | Annual review. No changes to clinical coverage criteria. |
| 11/2020 | Annual review. Add initial authorization header for clarity but no change to clinical intent. Updated references. |
| 11/2021 | Annual review with no changes to clinical coverage criteria. Updated reference. |
| 11/2022 | Annual review with no changes to clinical coverage criteria. Added state mandate footnote. |
| 11/2023 | Annual review with no changes to clinical coverage criteria. Updated reference. |

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