UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1151-5
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
Effective Date	2/1/2019; Oxford only: N/A

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. Eloctate will be initially approved based on **both** of the following criteria:[1-3]

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.

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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]. Cambridge, MA: Biogen Inc., December 2017.
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. U. S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung and Blood Institute. (2013). How is hemophilia diagnosed? http://www.nhlbi.nih.gov/health/health-topics/topics/hemophilia/diagnosis#. Accessed November 3, 2016.
4. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. Med Bulletin #253, April 23, 2018.

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.

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