

# ELOCTATE™ (ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC FUSION PROTEIN) FOR CONNECTICUT LINES OF BUSINESS

**Policy Number:** PHARMACY 283.8 T2

**Effective Date:** November 1, 2018

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Related Policies
<ul style="list-style-type: none"> <li>• <a href="#">Assisted Administration of Clotting Factors and Coagulant Blood Products</a></li> <li>• <a href="#">Clotting Factors and Coagulant Blood Products</a></li> <li>• <a href="#">Drug Coverage Guidelines</a></li> <li>• <a href="#">Home Health Care</a></li> </ul>

## INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

## CONDITIONS OF COVERAGE

Applicable Lines of Business/ Products	This policy applies to Oxford Commercial plan membership for Connecticut lines of business. <sup>2</sup>
Benefit Type	Medical <sup>1</sup>
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes <sup>1,3</sup>
Precertification with Medical Director Review Required	Yes <sup>1</sup>
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	Other

## Special Considerations

<sup>1</sup>Eloctate requires precertification with review by a Medical Director or their designee.

<sup>2</sup>For coverage of Eloctate for New Jersey large and small groups, and New York lines of business, refer to the policy titled [Clotting Factors and Coagulant Blood Products](#).

<sup>3</sup>Precertification is required for the assisted administration of all clotting factor drugs.

## BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

For coverage of clotting factors (including Eloctate), and their administration for New Jersey large and small groups, and New York lines of business, refer to the policy titled [Clotting Factors and Coagulant Blood Products](#) and [Assisted Administration of Clotting Factors and Coagulant Blood Products](#).

For coverage of other clotting factors and their administration for Connecticut lines of business, refer to the policies titled [Drug Coverage Guidelines](#) and [Home Health Care](#).

### **Essential Health Benefits for Individual and Small Group**

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

## COVERAGE RATIONALE

### **Eloctate™ (antihemophilic factor (recombinant), FC fusion protein)**

**Antihemophilic Factor (recombinant), FC Fusion Protein [Eloctate] is proven when all of the following criteria are met:**<sup>1</sup>

- Diagnosis of hemophilia A; **and**
- **One** of the following:
  - Routine prophylactic treatment; **or**
  - Peri-operative management of surgical bleeding; **or**
  - Treatment of bleeding episodes
- and**
- Prescribed dosage and interval utilized is within range as defined by the prescribing information

*Additional information to support medical necessity review:*

**Antihemophilic Factor (recombinant), FC Fusion Protein [Eloctate] is medically necessary for the treatment of Hemophilia A when one of the following criteria is met:**<sup>1,2,3</sup>

- **All** of the following:
    - Diagnosis of severe hemophilia A; **and**
    - Patient is not a suitable candidate for treatment with shorter half-life Factor VIII (recombinant) products [e.g., Kogenate FS, Kovaltry, Novoeight, or Nuwiq] as attested by the prescribing physician; **and**
    - **One** of the following:
      - Routine prophylactic treatment; **or**
      - Peri-operative management of surgical bleeding; **or**
      - Treatment of bleeding episodes
  - and**
  - **One** of the following:
    - **Both** of the following:
      - Dose does not exceed 50 IU/kg
      - Infusing no more frequently than every 4 days
    - or**
    - Requested dosage regimen does not exceed 12.5 IU/kg/day
- or**

- **All** of the following:
  - **One** of the following:
    - **Both** of the following:
      - Moderate hemophilia A
      - Endogenous factor VIII level 2% < 5% (0.02 IU/ml to less than 5 IU/ml)
    - or**
    - **Both** of the following:
      - Mild hemophilia A
      - Endogenous factor VIII level > 5% (greater than 0.05 IU/ml)
  - and**
  - Patient is not a suitable candidate for treatment with shorter half-life Factor VIII (recombinant) products [e.g., Kogenate FS, Kovaltry, Novoeight, or Nuwiq] as attested by the prescribing physician; **and**
  - **One** of the following:
    - Treatment of bleeding episodes
    - Prevention of bleeding in surgical interventions or invasive procedures (e.g., surgical prophylaxis)
    - Prevention of bleeding episodes (i.e., routine prophylaxis) with documentation of **one** of the following in an 8 week period:
      - ≥1 or more episodes of spontaneous/ traumatic bleeding into joint
      - ≥1 episode of spontaneous / traumatic bleeding into the central nervous system
      - ≥1 episode of severe soft tissue bleeding (i.e., ileopsoas)
  - and**
  - Documentation of **both** of the following:
    - Dose does not exceed 50 IU/kg
    - Infusing no more frequently than every 4 days

Authorization of therapy will be issued for 12 months.

### **Reauthorization**

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

- Dose does not exceed 50 IU/kg; **and**
- Dosing interval is no less than every 4 days

Authorization of therapy will be issued for 12 months.

Eloctate requires precertification with review by a Medical Director or their designee.

## U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Eloctate (antihemophilic factor (recombinant), Fc fusion proteins) is FDA-labeled in adults and children with Hemophilia A for the following: control and prevention of bleeding episodes; perioperative management (surgical prophylaxis); and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Eloctate is not indicated for the treatment of von Willebrand disease.<sup>1</sup>

## BACKGROUND

Antihemophilic Factor (recombinant), FC Fusion Protein is a fusion protein that temporarily replaces the missing Coagulation Factor VIII needed for effective hemostasis. It contains the Fc 12 region of human immunoglobulin G1 (IgG1), which binds to the neonatal Fc receptor (FcRn). FcRn is part of a naturally occurring pathway that delays lysosomal degradation of immunoglobulins by cycling them back into circulation and prolonging their plasma half-life.<sup>4</sup>

## APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

HCPCS Code	Description
J7199	Hemophilia clotting factor, not otherwise classified
J7205	Injection, Factor VIII Fc fusion protein (recombinant), per IU

## CLINICAL EVIDENCE

### Hemophilia A

Mahlangu et al. conducted a multi-center, prospective, open-label, phase 3 study which evaluated the safety, efficacy, and pharmacokinetics of a recombinant FVIII Fc fusion protein (rFVIIIFc) [Eloctate] for prophylaxis, treatment of acute bleeding, and perioperative hemostatic control in 165 previously treated males aged  $\geq 12$  years with severe hemophilia A.<sup>2</sup> The study participants were divided up into 3 treatment arms: arm 1, individualized prophylaxis (25-65 IU/kg every 3-5 days, n=118); arm 2, weekly prophylaxis (65 IU/kg, n=24); and arm 3, episodic treatment (10-50 IU/kg, n=23). A subgroup compared recombinant FVIII (rFVIII) and rFVIIIFc pharmacokinetics. Annualized bleeding rate (ABR) was the primary measured outcome; and inhibitor development and adverse events were secondary efficacy endpoints evaluated. The terminal half-life of rFVIIIFc (19.0 hours) was extended 1.5-fold vs rFVIII (12.4 hours;  $P < .001$ ). Across all arms, 757 bleeding episodes were treated with rFVIIIFc during the efficacy period. Overall, 87.3% of bleeding episodes were resolved with 1 injection, and 97.8% were controlled with  $\leq 2$  injections. In arm 1, the median weekly dose was 77.9 IU/kg; approximately 30% of subjects achieved a 5-day dosing interval (last 3 months on study). Adverse events were representative of events occurring in the general hemophilia population and no participants developed inhibitors. Authors concluded that rFVIIIFc was well-tolerated and efficacious in the prevention and treatment of bleeding events, including within the setting of major surgery, in adolescents and adults with severe hemophilia A. Additionally, efficacy results supported the potential for rFVIIIFc dosing 1 to 2 times per week (current treatment guidelines recommend dosing 3-4 times weekly).

## REFERENCES

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare Pharmacy, Clinical Pharmacy Program that was researched, developed and approved by the UnitedHealth Group National Pharmacy & Therapeutics Committee.

1. Eloctate™ [package insert]. Cambridge, MA: Biogen Inc., December 2017.
2. Mahlangu J, Powell JS, Ragni MV, et al. 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 January 16, 2015
4. Micromedex® 2.0, (electronic version). Truven Health Analytics, Greenwood Village, CO. Available at: <http://www.micromedexsolutions.com>. Accessed on June 2, 2016.

## POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
11/01/2018	<ul style="list-style-type: none"><li>• Updated coverage rationale:<ul style="list-style-type: none"><li>○ Reformatted coverage statements; separated content addressing “proven” and “medically necessary” guidelines/criteria</li></ul></li><li>• Updated supporting information to reflect the most current references</li><li>• Archived previous policy version PHARMACY 283.7 T2</li></ul>