Eloctate® [Antihemophilic Factor (Recombinant), FC Fusion Protein] for Connecticut Lines of Business (for Oxford Only)

Policy Number: PHARMACY 283.22
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➲ Instructions for Use

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Related Policies

- Assisted Administration of Clotting Factors, Coagulant Blood Products & Other Hemostatics (for Oxford Only)
- Clotting Factors, Coagulant Blood Products & Other Hemostatics
- Home Health, Skilled, and Custodial Care Services

Application

This Medical Benefit Drug Policy only applies to Oxford Commercial plan membership.

Coverage Rationale

➲ See Benefit Considerations

Eloctate® [Antihemophilic Factor (Recombinant), FC Fusion Protein]

Antihemophilic Factor (recombinant), FC Fusion Protein [Eloctate] is proven when all of the following criteria are met:

- Diagnosis of hemophilia A; **and**
- **One** of the following:
  - Routine prophylactic treatment; **or**
  - Peri-operative management of surgical bleeding; **or**
  - Treatment of bleeding episodes

Additional Information to Support Medical Necessity Review

Antihemophilic Factor (recombinant), FC Fusion Protein [Eloctate] is medically necessary for the treatment of Hemophilia A when all of the following criteria are met:

- Diagnosis of hemophilia A; **and**
- Patient is not a suitable candidate for treatment with shorter half-life Factor VIII (recombinant) products (e.g., Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, or Recombinate) as attested by the prescriber; **and**
- **One** of the following:
  - **Both** of the following:
    - Dose does not exceed 50 i.u./kg; **and**
    - Infusing no more frequently than every 4 days

    or

- Requested dosage regimen does not exceed 12.5 i.u./kg/day; **or**
- **Both** of the following:
  - Patient is less than 6 years of age; **and**
  - **One** of the following:
    - PK testing results suggest that dosing more intensive than 50 i.u./kg is required; **or**
    - PK testing results suggest that dosing more frequently than every 3 **to** 5 days is required; **or**
    - PK testing results suggest that dosing more intensive that 14.5 i.u/kg/day is required

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

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.[1]

Benefit Considerations

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 Clinical Policies titled Clotting Factors, Coagulant Blood Products & Other Hemostatics and Assisted Administration of Clotting Factors, Coagulant Blood Products & Other Hemostatics (for Oxford Only).

For coverage of other clotting factors and their administration for Connecticut lines of business, refer to the Clinical Policy titled Home Health, Skilled, and Custodial Care Services.

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 ≥ 12 years with severe hemophilia A.[2] The study participants were divided up into 3 treatment arms: arm 1, individualized prophylaxis (25-65 i.u./kg every 3-5 days, n = 118); arm 2, weekly prophylaxis (65 i.u./kg, n = 24); and arm 3, episodic treatment (10-50 i.u./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 ≤ 2 injections. In arm 1, the median weekly dose was 77.9 i.u./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. The study was not designed to compare individualized and weekly prophylactic regimens (arms1 and 2, respectively). Thus, although both the individualized (median twice-weekly dosing) and weekly dosing regimens resulted in a significant reduction in ABR compared with episodic treatment, the superiority of one approach for prophylactic dosing over the other cannot be determined. 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).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Eloctate (antihemophilic factor (recombinant), Fc fusion protein) is FDA-labeled in adults and children with Hemophilia A for the following: on-demand treatment and control of bleeding episodes; perioperative management of bleeding; and routine prophylaxis to reduce the frequency of bleeding episodes. Eloctate is not for the treatment of von Willebrand disease.[1]

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. [2023D0047AH]

1. Eloctate® [package insert]. Waltham, MA: Bioverativ Therapeutics Inc., May 2023.
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. Micromedex® 2.0, (electronic version). Truven Health Analytics, Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed September 8, 2021.

Policy History/Revision Information

Date	Summary of Changes
11/01/2024	**Coverage Rationale** • Revised medical necessity criteria; replaced criterion requiring “infusing no more frequently than every ***4*** days” with “infusing no more frequently than every ***7*** days” **Supporting Information** • Archived previous policy version PHARMACY 283.21

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right 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. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies 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.