



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2020 P 3147-1
Program	Step Therapy
Medication	Esperoct (antihemophilic factor [recombinant], glycopegylated-exei)*
P&T Approval Date	9/2020
Effective Date	1/1/2021; Oxford only: N/A

**1. Background:**

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try one or more preferred recombinant antihemophilic factor VIII products before providing coverage for Esperoct® (antihemophilic factor [recombinant], glycopegylated-exei)

**2. Coverage Criteria<sup>a</sup>:**

**A. Hemophilia A**

1. **Esperoct** will be approved based on **one** of the following criteria:

a. History of failure, contraindication, or intolerance to **three** of the following preferred products

- (1) Advate
- (2) Kogenate FS
- (3) Kovaltry
- (4) Novoeight
- (5) Nuwiq
- (6) Recombinate

**-OR-**

b. Physician attestation that patient would preferentially benefit from **Esperoct** because **one** of the following:

- (1) Patient is at high risk for the development of inhibitors (e.g., Family history of inhibitors and success with product, Current treatment less than 50 days, high risk genetic mutation, history of initial intensive therapy greater than 5 days)
- (2) Patient has developed inhibitors
- (3) Patient has undergone immune tolerance induction/immune tolerance therapy

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

<sup>a</sup> 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 Rules:**

- 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.
- Supply limits and/or Medical Necessity may be in place.
- \*Exclusion: Esperoct is excluded for the majority of benefits

**4. References:**

1. Esperoct<sup>®</sup> [package insert]. Plainsboro, NJ: CSL Novo Nordisk, Inc., October 2019.
2. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. Med Bulletin #259, March 16, 2020.
3. Hoots WK, Shapiro AD. Treatment of hemophilia. In: UpToDate, Waltham, MA, 2016.
4. Hoots WK, Shapiro AD. Factor VIII and factor IX inhibitors in patients with hemophilia. In: UpToDate, Waltham, MA, 2016.
5. MASAC Recommendation on SIPPET (Survey of Inhibitors in Plasma-Product-Exposed Toddlers): Results and Recommendations for Treatment Products for Previously Untreated Patients with Hemophilia A. MASAC Document #243, June 28 2016.
6. Kogenate FS<sup>®</sup> [package insert]. Tarrytown, NY Bayer HealthCare LLC; May 2016
7. Kovaltry<sup>®</sup> [package insert]. Whippany, NJ: Bayer HealthCare LLC; March 2016.
8. Novoeight<sup>®</sup> [package insert]. Plainsboro, NJ: Novo Nordisk; November 2018.
9. Nuwiq<sup>®</sup> [package insert]. Hoboken, NJ: Octapharma; July 2017.
10. Advate<sup>®</sup> [package insert]. Lexington, MA: Baxalta US Inc., December 2018.
11. Recombinate<sup>®</sup> [package insert]. Lexington MA: Baxalta US Inc., June 2018.

Program	Step Therapy - Esperoct (antihemophilic factor [recombinant], glycopegylated-exei)
<b>Change Control</b>	
Date	Change
9/2020	New program.