



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2023 P 1311-4
Program	Prior Authorization/Notification
Medication	Esperoct [antihemophilic factor (recombinant), glycopegylated-exei]*
P&T Approval Date	3/2020, 3/2021, 3/2022, 3/2023
Effective Date	6/1/2023; Oxford only: N/A

**1. Background:**

Esperoct® [antihemophilic factor (recombinant), glycopegylated-exei]\* is a recombinant coagulation Factor VIII concentrate indicated in adults and children with hemophilia A for: <sup>1</sup>

- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes

Esperoct\* is not indicated for the treatment of von Willebrand disease.

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

**A. Initial Authorization:**

1. **Esperoct\*** will be initially approved based on both of the following criteria:<sup>1-3</sup>

- a. Diagnosis of hemophilia A

**-AND-**

- b. **One** of the following:

- (1) Treatment of bleeding episodes
- (2) Prevention of bleeding in surgical interventions or invasive procedures (e.g., surgical prophylaxis)
- (3) Prevention of bleeding episodes (i.e., routine prophylaxis)

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

**B. Reauthorization**

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

- a. Documentation of positive clinical response to therapy.

**Authorization of therapy 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.

\*Esperoct is typically excluded from coverage.

**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. Esperoct® [package insert]. Plainsboro, NJ: CSL Novo Nordisk, Inc., August 2022.
2. Hoots WK, Shapiro AD. Hemophilia A and B: Routine management including prophylaxis. In: UpToDate, Waltham, MA, 2022.
3. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. Med Bulletin #272, April 2022.

Program	Prior Authorization/Notification - Esperoct
<b>Change Control</b>	
3/2020	New program.
3/2021	Annual review. No change to clinical criteria.
3/2022	Annual review. Noted that Esperoct is typically excluded from coverage. Updated references.
3/2023	Annual review with no changes to coverage criteria. Added state mandate and updated references.