



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2024 P 1311-5 |
| Program | Prior Authorization/Notification |
| Medication | Esperoct®[antihemophilic factor (recombinant), glycopegylated-exei]* |
| P&T Approval Date | 3/2020, 3/2021, 3/2022, 3/2023, 3/2024 |
| Effective Date | 6/1/2024 |

1. Background:

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

- 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^a:

A. Initial Authorization:

1. **Esperoct*** will be initially approved based on both of the following criteria:¹⁻³

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.

^a 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 |
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| Change Control | |
| 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. |
| 3/2024 | Annual review with no changes to coverage criteria. |