UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2187-6
Program	Prior Authorization/Medical Necessity
Medication	Esperoct® (antihemophilic factor [recombinant], glycopegylated-exei)*
P&T Approval Date	3/2020, 9/2020, 9/2021, 9/2022, 9/2023, 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
- Routine prophylaxis to reduce the frequency of bleeding episodes
- Perioperative management of bleeding

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 the following criteria:[1-3]

   a. **All** of the following:

      (1) Diagnosis of hemophilia A

      -AND-

      (2) **One** of the following:

         (a) Submission of documentation showing failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level) after a trial of **three** of the following recombinant factor products:

            1. Advate
            2. Kogenate FS
            3. Kovaltry
            4. NovoEight
            5. Nuwiq
            6. Recombinate

         -OR-

         (b) Submission of documentation showing history of hypersensitivity to **three** of the following recombinant factor products:

            1. Advate
            2. Kogenate FS

3. Kovaltry
4. NovoEight
5. Nuwiq
6. Recombinate

-OR-

(c) **Both** of the following:

1. Patient is currently on **Esperoct**

-AND-

2. Prescriber attestation that patient would preferentially benefit from **Esperoct** based on **one** of the following:

i. 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)
ii. Patient has developed inhibitors
iii. Patient has undergone immune tolerance induction/ immune tolerance therapy

-AND-

(3) **One** of the following:

(a) Patient is not to receive routine infusions more frequently than 2 times per week

-OR-

(b) **Both** of the following:

1. Patient is less than 12 years of age

-AND-

2. Pharmacokinetic (PK) testing results suggest that more frequent than 2 times per week dosing is required

Authorization of therapy will be issued for 12 months.

B. Reauthorization

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

a. Documentation of positive clinical response to **Esperoct** therapy.

-AND-

b. **One** of the following:

(1) Patient is not to receive routine infusions more frequently than 2 times per week

-OR-

(2) **Both** of the following:

(a) Patient is less than 12 years of age

-AND-

(b) PK testing results suggest that more frequent than 2 times per week dosing is required

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. Coverage reviews may be in place if required by law or the benefit plan.

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.

4. References:

1. Esperoct® [package insert]. Plainsboro, NJ: CSL Novo Nordisk, Inc., August 2022.
2. Hoots WK, Shapiro AD. Treatment of hemophilia. In: UpToDate, Waltham, MA, 2016.
3. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. MASAC Document #276, May 2, 2023.

Program	Prior Authorization/Medical Necessity - Esperoct
Change Control	
3/2020	New program.
9/2020	Modified program noting exclusion of coverage for majority of benefits. Updated reference.
9/2021	Annual review with no changes to clinical criteria. Updated exclusion statement with no change to clinical intent.

9/2022	Annual review. Added text “pharmacokinetic” to clarify abbreviation “PK” with no changes to clinical intent. Updated background per prescribing information and updated references.
9/2023	Annual review. Modified physician attestation to prescriber attestation. Updated references.
3/2024	Annual review with no changes to clinical criteria.