UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3147-5
Program	Step Therapy
Medication	Esperoct® (antihemophilic factor [recombinant], glycopegylated-exei)*
P&T Approval Date	9/2020, 9/2021, 9/2022, 9/2023, 3/2024
Effective Date	6/1/2024

1. Background:
Step therapy programs are utilized to encourage the 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[a]:

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. Prescriber attestation that patient would preferentially benefit from **Esperoct** based on **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.

[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 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.

4. **References:**

   1. Esperoct® [package insert]. Plainsboro, NJ: CSL Novo Nordisk, Inc., August 2022.
   2. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. MASAC Document #276, May 2, 2023.
   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® [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
   7. Kovaltry® [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2022.
   8. Novoeight® [package insert]. Plainsboro, NJ: Novo Nordisk; July 2020.
   9. Nuwiq® [package insert]. Paramus, NJ: Octapharma, USA, Inc.; June 2021.
   10. Advate® [package insert]. Lexington, MA: Baxalta US Inc., March 2023.
   11. Recombinate® [package insert]. Lexington MA: Baxalta US Inc., March 2023.

Program	Step Therapy - Esperoct (antihemophilic factor [recombinant], glycopegylated-exei)
Change Control	
Date	Change
9/2020	New program.
9/2021	Annual review with no changes to clinical criteria. Updated references and exclusion statement with no changes to clinical intent.
9/2022	Annual review with no changes to clinical criteria. Updated references.
9/2023	Annual review. Modified physician attestation to prescriber attestation. Updated references.
3/2024	Annual review with no changes to clinical criteria.