UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3079-9
Program	Step Therapy
Medication	Xyntha® (antihemophilic factor [recombinant])
P&T Approval Date	10/2016, 10/2017, 10/2018, 10/2019, 9/2020, 9/2021, 9/2022, 9/2023, 9/2024
Effective Date	12/1/2024

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 Xyntha (antihemophilic factor [recombinant]).

All standard half-life recombinant factor VIII products are indicated for the control and prevention of bleeding episodes, for perioperative management in patients with hemophilia A and for the routine prophylaxis to reduce the frequency of bleeding episodes. Review of product characteristics, including but not limited to, manufacturing processes, product stability, vial size availability, infusion requirements, and pharmacokinetics identify very few if any product differentiators. All of the products are expected to produce similar clinical results.

2. Coverage Criteria[a]:

A. Hemophilia A

1. **Xyntha** 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 **Xyntha** 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.

[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.

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. Xyntha® [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc; July 2022.
2. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. MASAC Document #284, April 11, 2024.
3. Hoots WK, Shapiro AD. Hemophilia A and B: Routine management including prophylaxis. In: UpToDate, Waltham, MA, 2024.
4. Hoots WK, Shapiro AD. Inhibitors in hemophilia: Mechanisms, prevalence, diagnosis, and eradication. In: UpToDate, Waltham, MA, 2024.
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 - Xyntha (antihemophilic factor [recombinant])
Change Control	
Date	Change
10/2016	New program.
10/2017	Annual review with no change to clinical intent. Updated state mandate verbiage. Updated references.
10/2018	Annual review with no changes to coverage criteria. Updated reference.
10/2019	Annual review with no changes to coverage criteria. Updated reference.
9/2020	Modified program updating preferred agents, adding Advate and Recombinate. Updated reference.
9/2021	Annual review with no changes to coverage criteria. Updated references.
9/2022	Annual review with no changes to coverage criteria. Updated references.
9/2023	Annual review. Modified physician attestation to prescriber attestation. Updated references.
9/2024	Annual review with no changes to coverage criteria. Updated references.