UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2109-11
Program	Prior Authorization/Medical Necessity
Medication	Xyntha® (antihemophilic factor [recombinant])
P&T Approval Date	10/2016, 12/2016, 4/2018, 3/2019, 10/2019, 9/2020, 9/2021, 9/2022, 9/2023, 9/2024, 9/2025
Effective Date	11/16/2025

1. Background:

Xyntha® (antihemophilic factor [recombinant]) is a recombinant antihemophilic factor indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for:

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

Xyntha is not indicated for the treatment of von Willebrand's disease.

2. Coverage Criteria[a]:

A. Initial Authorization

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

   a. Diagnosis of hemophilia A

   -AND-

   b. **One** of the following:

      (1) 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:

         (a) Advate
         (b) Kogenate FS
         (c) Kovaltry
         (d) NovoEight
         (e) Nuwiq
         (f) Recombinate

      -OR-

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

         (a) Advate

(b) Kogenate FS
(c) Kovaltry
(d) NovoEight
(e) Nuwiq
(f) Recombinate

-OR-

(3) Prescriber attestation that patient would preferentially benefit from **Xyntha** based on **one** of the following:

(a) 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)
(b) Patient has developed inhibitors
(c) Patient has undergone immune tolerance induction/immune tolerance therapy

Authorization of therapy will be issued for 12 months.

B. Reauthorization

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

a. Documentation of positive clinical response to Xyntha 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

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. Xyntha® [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals, Inc., July 2022.
2. ter Avest PC, Fischer K, Mancuso ME, et al. Risk stratification for inhibitor development at first treatment for severe hemophilia A: a tool for clinical practice. J Thromb Haemost. 2008; 6: 2048–54.
3. Malec L, Shapiro AD. Hemophilia A and B: Routine management including prophylaxis . In: UpToDate, Waltham, MA, 2025.
4. Malec L, Shapiro AD. Inhibitors in hemophilia: Mechanisms, prevalence, diagnosis, and eradication. In: UpToDate, Waltham, MA, 2025.

5. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. MASAC Document #290, October 2, 2024.
6. 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.

Program	Prior Authorization/Medical Necessity - Xyntha
Change Control	
10/2016	New program.
12/2016	Updated criteria to allow for use in routine prophylaxis in addition to acute treatment and perioperative management.
4/2018	Annual review with no change to clinical intent. Revised formatting. Updated state mandate verbiage. Updated references.
3/2019	Annual review with no changes to coverage criteria. Updated reference.
10/2019	Annual review with no changes to coverage criteria.
9/2020	Updated background to include new indication for routine prophylaxis. Modified program updating preferred agents, adding Advate and Recombinate. Updated reference.
9/2021	Annual review with no changes to coverage criteria. Updated background.
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. Revised outline of coverage criteria without change to clinical intent. Updated references.
9/2025	Annual review with no changes to coverage criteria. Updated references.