UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 3079-3
Program	Step Therapy
Medication	Xyntha (antihemophilic factor [recombinant])
P&T Approval Date	10/2016, 10/2017, 10/2018
Effective Date	2/1/2019; Oxford only: N/A

1. **Background:**
Step therapy programs are utilized to encourage 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 and for perioperative management in patients with hemophilia A. Most are also indicated for routine prophylaxis to reduce the frequency of bleeding in patients with hemophilia A; however Xyntha® lacks this indication. All preferred standard half-life recombinant antihemophilic Factor VIII products, Kogenate FS®, Kovaltry®, Novoeight®, and Nuwiq®, carry all three indications. 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) Kogenate FS
      (2) Kovaltry
      (3) Novoeight
      (4) Nuwiq

      -OR-

   b. Physician 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:

- Supply limits and/or Medical Necessity may be in place.

4. References:

1. Xyntha® [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc; October 2014.
2. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. Med Bulletin #253, April 23, 2018.
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]. Tarrytown, NY Bayer HealthCare LLC; May 2016
7. Kovaltry® [package insert]. Whippany, NJ: Bayer HealthCare LLC; March 2016.
8. Novoeight® [package insert]. Plainsboro, NJ: Novo Nordisk; May 2018.
9. Nuwiq® [package insert]. Hoboken, NJ: Octapharma; July2017.

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.