



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 3093-3
Program	Step Therapy
Medication	Ixinity [coagulation factor IX (recombinant)]*
P&T Approval Date	11/2016, 11/2017, 11/2018
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 IX products before providing coverage for Ixinity[®] [coagulation factor IX (recombinant)]

2. Coverage Criteria^a:

A. Ixinity will be approved based on **one** of the following criteria:

1. History of failure, contraindication, or intolerance to **two** of the following preferred products
 - a. Benefix
 - b. Rixubis

-OR-

2. Physician attestation that patient would preferentially benefit from **Ixinity** because **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 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



* Ixinity is excluded for the majority of our benefits

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. Ixinity [package insert]. Berwyn, PA: Aptevo BioTherapeutics LLC; April 2018.
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. Benefix[®] [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals; June 2017.
6. Rixubis[®] [package insert]. Westlake Village, CA: Baxalta US Inc; March 2016.

Program	Step Therapy - Ixinity [coagulation factor IX (recombinant)]
Change Control	
Date	Change
11/2016	New program.
11/2017	Annual review. Updated state mandate verbiage. Updated reference.
11/2018	Annual review. No changes to clinical coverage criteria. Updated references.