UnitedHealthcare

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3093-9
Program	Step Therapy
Medication	Ixinity® [coagulation factor IX (recombinant)]*
P&T Approval Date	11/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, 11/2022, 11/2023, 11/2024
Effective Date	2/1/2025

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** 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 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 typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

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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]. Chicago, IL: Medexus Pharma, Inc.; March 2024.
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. Malec L, 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. Benefix® [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals; November 2022.
6. Rixubis® [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.

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.
11/2019	Annual review. No changes to clinical coverage criteria. Updated references.
11/2020	Annual review. No changes to clinical coverage criteria. Updated references.
11/2021	Annual review with no changes to clinical coverage criteria. Updated references.
11/2022	Annual review with no changes to clinical coverage criteria. Updated references.
11/2023	Annual review with no changes to clinical coverage criteria. Updated exclusion footnote to standard language and updated references.
11/2024	Annual review with language changes with no change to clinical intent. Updated background and references.

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