UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2115-9
Program	Prior Authorization/Medical Necessity
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

Ixinity [coagulation factor IX (recombinant)] is a human blood coagulation factor indicated in adults and children with hemophilia B for on-demand treatment and control of bleeding episodes, perioperative management, and for routine prophylaxis to reduce the frequency of bleeding episodes.

Ixinity is not indicated for induction of immune tolerance in patients with hemophilia B.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Ixinity** will be initially approved based on **all** of the following criteria:[1-3]

   a. Diagnosis of hemophilia B

   -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 **two** of the following recombinant factor products:

         (a) Benefix
         (b) Rixubis

      -OR-

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

         (a) Benefix
         (b) Rixubis

      -OR-

      (3) 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

-OR-

(4) **Both** of the following:

(a) Patient is currently on **Ixinity** therapy

-AND-

(b) Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from a Medexus Pharma sponsored Ixinity Savings Program™ (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of **Ixinity***

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a Medexus Pharma sponsored Ixinity Savings Program™ **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization of therapy will be issued for 12 months.

B. Reauthorization

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

a. Documentation of positive clinical response to **Ixinity** 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

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

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. Ixinity [package insert]. Chicago, IL: Medexus Pharma, Inc.; March 2024.
2. Malec L, Shapiro AD. Hemophilia A and B: Routine management including prophylaxis. In: UpToDate, Waltham, MA, 2024.
3. Hoots WK, Shapiro AD. Inhibitors in hemophilia: Mechanisms, prevalence, diagnosis, and eradication. In: UpToDate, Waltham, MA, 2024.
4. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. MASAC Document 284. April 11, 2024.
5. Benefix® [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals; November 2022.
6. Rixubis® [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.

Program	Prior Authorization/Medical Necessity - Ixinity
Change Control	
11/2016	New program.
12/2016	Administrative change. Revised formatting.
11/2017	Annual review. Revised formatting without change to clinical intent. Updated sample pack language and 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 reference.
11/2020	Annual review. Updated background and references.
11/2021	Annual review with no changes to clinical coverage criteria. Updated background and references.
11/2022	Annual review with no changes to clinical coverage criteria. Updated name of manufacturer sponsored savings program. 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 no changes to clinical coverage criteria. Updated background and references.