

Policy Type: PA/SP

Pharmacy Coverage Policy: COMM334

Description

Factor XIII concentrate, human works by replacing the missing coagulation factor in people with congenital Factor XIII deficiency. It is involved with cross-linking of fibrin strands and other proteins during coagulation, helps form strong, stable clots at the site of injury, and protects clots from fibrinolysis.

Length of Authorization

- Initial:
 - i. Prophylaxis: 12 months
 - ii. Perioperative: One month
- Renewal:
 - i. Prophylaxis: 12 months
 - ii. Perioperative: Cannot be renewed; See Initial criteria

Quantity limits

Product Name	Dosage Form	Indication/FDA Labeled Dosing	Quantity Limit
Factor XIII Concentrate, human (Corifact)	1000-1600 units/vial	<p>Factor XIII deficiency: Routine prophylaxis 40 IU/kg given every 28 days. Adjust dose \pm 5 IU/kg to maintain 5% to 20% trough level of FXIII activity</p> <p>Perioperative management 40 IU/kg given every 28 days. Dosing should be individualized based on Factor XIII activity level, type of surgery, and clinical response.</p>	4,600 IU/28 days

For medical unit guidance, please see appendix

Initial Evaluation

- I. **Factor XIII concentrate, human (Corifact)** may be considered medically necessary when the following criteria below are met:
 - A. Treatment is prescribed by, or in consultation with a hematologist; **AND**
 - B. A diagnosis of **congenital Factor XIII deficiency** when the following are met:
 1. Diagnosis confirmed by blood coagulation testing; **AND**
 2. Used for routine prophylaxis to reduce the frequency of bleeding episodes; **OR**
 3. Used for perioperative management of surgical bleeding
- II. Factor XIII concentrate, human (Corifact) is considered investigational when used for all other conditions.

Renewal Evaluation

- I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
- II. Any increases in dose must be supported by an acceptable clinical rationale (i.e. weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.) as verified by a Moda Health pharmacist; **AND**
 - A. Used for routine prophylaxis to reduce the frequency of bleeding episodes; **OR**
 - B. Used for perioperative management of surgical bleeding; **AND**
- III. Prescriber attestation that the patient has demonstrated a clinical benefit with therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

Supporting Evidence

- I. Factor XIII concentrate, human (Corifact) is indicated for the prevention of bleeding episodes and in the perioperative setting for patients with congenital Factor XIII deficiency.
- II. For routine prophylaxis, Factor XIII concentrate, human (Corifact) should be administered every 28 days. The starting dose is 40 international units (IU) per kg body weight. Dose adjustments are based on FXIII activity trough level.
- III. For perioperative bleeding management, dosing should be individualized based on the patient's Factor XIII activity level, type of surgery, and clinical response.

Investigational or Not Medically Necessary Uses

- I. There is no evidence to support the use of Factor XIII concentrate, human (Corifact) in any other condition.

References

1. Corifact [package insert]. Kankakee, IL; CSL Behring LLC; September 2020. Accessed January 2026.

Appendix

HCPCS Code:	Medication:	Unit Conversion:
J7180	Factor XIII concentrate, human (Corifact)	1 IU = 1 billing unit (1:1 conversion)*

**Current billing unit conversion as of 01/2026. This is subject to change pending new information.*

Policy Implementation/Update:

Action and Summary of Changes	Date
New Policy	01/2026