



Anti-Hemophilic

FACTOR VIII (Human, Pegylated-Recombinant J7190, Factor VIII (Porcine) J7191, Fusion-Recombinant, Recombinant NOS) J7192, Afstyla J7210, Jivi J7208, Kovaltry J7211, Novoeight J7182, Nuwiq J7209, Obizur J7188, Xyntha J7185, Esperoct J7204, Eloctate J7205, Adynovate J7207

**Prior Authorization Request
Medicare Part B Form**

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCP Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Self-administered Provider-administered Home Infusion

Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

Provider has reviewed the attached “Criteria for Approval” and attests the member meets ALL required PA criteria.

If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

Provider has reviewed the attached “Criteria for Continuation” and attests the member meets ALL required PA Continuation criteria.

Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Coagulation Factors PA

Drug Name(s):

FACTOR VIII (Recombinant)
FACTOR VIII (Human)
FACTOR VIII (Porcine)
FACTOR VIII (Pegylated-Recombinant)
FACTOR VIII (FC Fusion Recombinant)
FACTOR VIII (Recombinant NOS)
AFSTYLA (FACTOR VIII (RECOMBINANT) SINGLE CHAIN)
JIVI (FACTOR VIII (RECOMBINANT) PEGYLATED-AUCL)
KOVALTRY (FACTOR VIII RECOMBINANT)
NOVOEIGHT (FACTOR VIII RECOMBINANT)
NUWIQ (FACTOR VIII RECOMBINANT)
OBIZUR (FACTOR VIII RECOMBINANT, PORCINE SEQUENCE)
XYNTHA (FACTOR VIII RECOMBINANT, PLASMA/ALBUMIN-FREE)
ELOCTATE (FACTOR VIII RECOMBINANT, FC FUSION PROTEIN)
ADYNOVATE (FACTOR VIII RECOMBINANT, PEGYLATED)

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Treatment purpose is appropriate (MUST choose at least one):
 - a. On-demand treatment and control of bleeding episode
 - b. Routine prophylaxis to reduce the frequency of bleeding episodes
 - c. Perioperative management of bleeding
3. Prescribed dose is less than 6000 international units per infusion (rounded to vial size)
4. Drug is not prescribed for the treatment of Von Willebrand disease.
5. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

Treatment of Von Willebrand disease

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 12 months

FDA Indications:

All Factor VIII Products:

- Diagnosis of Hemophilia A
 - On-demand treatment and control of bleeding episodes
 - Routine prophylaxis to reduce the frequency of bleeding episodes
 - Perioperative management of bleeding

Off-Label Uses:

N/a

Other Clinical Consideration:

Maximum dosage: 6000 international units per infusion (rounded to vial size)

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/D80EF7/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYN C/50D494/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegrat edSearch?SearchTerm=factor%20viii&UserSearchTerm=factor%20viii&SearchFilter=filterNone&navitem=searchGlobal

Clinical / CMS
Only