RX.PA.100.MPC Jivi™ (Factor VIII, recombinant human pegylated)

The purpose of this policy is to define the prior authorization process for Jivi™ (intravenous infusion)

Jivi, antihemophilic factor (recombinant), PEGylated-aucl, is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for:

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

Severity	Clotting Factor Level % Activity	Bleeding Episodes
Severe	< 1%	Spontaneous bleeding episodes, predominantly into joints and muscles Severe bleeding with trauma, injury or surgery
Moderate	1% to 5%	Occasional spontaneous bleeding episodes Severe bleeding with trauma, injury or surgery
Mild	6% to 40%	Severe bleeding with serious injury, trauma or surgery

PROCEDURE

A. Initial Authorization Criteria:

Hemophilia A (Congenital factor VIII deficiency). All requests must meet the following criteria:

- Must have a documented diagnosis of severe hemophilia A (less than 1% endogenous Factor VIII)
- Must be ≥12 years of age
- Must have documentation that Jivi will be prescribed for one of the following:
    a) Treatment of bleeding episodes
    b) Prevention of bleeding in surgical interventions or invasive procedures (surgical prophylaxis)
    c) Prevention of bleeding episodes/routine prophylaxis
- Must not be using Jivi for the treatment of von Willebrand disease
- If member has a past trial and failure with other Factor VIII agents (i.e. Adynovate, Altuviiio, Eloctate, etc.), must provide documentation that failure was not due to a

decreased response (clinical signs or symptoms) to the product
- Must not have a major surgery within 8 weeks
- Must not concurrently be using other factor VIII products or Hemlibra (emicizumab-kxwh)
- Must monitor the member for potential development of neutralizing antibodies/inhibitors to Factor VIII within the first 50 days of treatment
- Must provide documentation of a platelet count ≥ 100,000 cells/µL (within 60 days)
- Dose does not exceed FDA approved indication
- The medication is prescribed by or in consultation with a hematologist

B. Reauthorization Criteria:
All prior authorization renewals are reviewed on a 1 year interval basis to determine the Medical Necessity for continuation of therapy.

MPC Renewal:
- Chart documentation from the prescriber that the member's condition has stabilized or improved based upon the prescriber's assessment while on therapy (e.g., reduced frequency or severity of bleeds)
- The medication is prescribed by or in consultation with a hematologist
- Must not concurrently be using other factor VIII products or Hemlibra (emicizumab- kxwh)
- Must monitor the member for potential development of neutralizing antibodies/inhibitors to Factor VIII every 6 months throughout treatment
- Must provide documentation of a platelet count ≥ 100,000 cells/µL (within 60 days)
- Surgical prophylaxis renewal requests: no reauthorization allowed

Renewal from Previous Insurer:
- Members who have received prior approval (from insurer other than MPC) and have been using Jivi, or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).
- Provider has documented positive clinical response to therapy for the member from baseline

C. Jivi will be considered investigational or experimental for any other use and will not be covered.

Dosing for Treat of Bleeding Episodes				
Degree of Bleeding Hemorrhage/Hemorrhagic Event	**Factor VIII Level Required (IU/dL or % of normal)**	**Dose (IU/kg)**	**Frequency of Doses (hours)**	**Duration of Treatment**

Minor (e.g., early hemarthrosis, minor muscle bleeding, oral bleeds)	20–40	10–20	Repeat every 24–48 hours	Until bleeding is resolved
Moderate (e.g., more extensive hemarthrosis, muscle bleeding, or hematoma)	30–60	15–30	Repeat every 24–48 hours	Until bleeding is resolved
Major (e.g., intracranial, intra-abdominal or intrathoracic hemorrhages, gastrointestinal bleeding, central nervous system bleeding, bleeding in the retropharyngeal or retroperitoneal spaces, or iliopsoas sheath, life- or limb- threatening hemorrhage)	60–100	30–50	Repeat every 8–24 hours	Until bleeding is resolved

Dosing for Perioperative Management				
Type of Surgery	**Factor VIII Level Required (IU/dL or % of normal)**	**Dose (IU/kg)**	**Frequency of Doses (hours)**	**Duration of Treatment (days)**
Minor (e.g., tooth extraction)	30–60 (pre- and postoperative)	15–30	Repeat every 24 hours	At least 1 day until healing is achieved
Major (e.g., intracranial, intraabdominal, intrathoracic, or joint replacement surgery)	80–100 (pre- and postoperative)	40–50	Repeat every 12–24 hours	Until adequate wound healing is complete, then continue therapy for at least another 7 days to maintain Factor VIII activity of 30–60% (IU/dL)

Dosing for Routine Prophylaxis		
	Dose (IU/kg)	**Frequency of Doses**
Initial	30–40 IU/kg	twice weekly
Additional Doses Based on Bleeding Episodes	45–60 IU/kg	every 5 days (may be further adjusted to less or more frequent dosing based on clinical response)

Estimate the required dose for on-demand treatment and control of bleeding and perioperative management using the following formula:

Required dose (IU) = body weight (kg) x desired Factor VIII rise (% of normal or IU/dL) x reciprocal of expected recovery (or observed recovery, if available) (e.g., 0.5 for a recovery of 2 IU/dL per IU/kg)

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Up to 3 months
Reauthorization	• Up to 1 year • Surgical prophylaxis: no reauthorization allowed

Codes:

Code	Description
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.

REFERENCES

1. Jivi (antihemophilic factor [recombinant {pegylated}]) [prescribing information]. Whippany, NJ: Bayer HealthCare LLC; August 2018.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/2026*
Annual Review	*02/2025*

New Policy	*10/2024*