JIVI®

APPLICABILITY: This document applies to AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***Other Names:*** *recombinant Factor VIII, Antihemophilic Factor* ***Company:*** *Bayer* ***Class:*** *Manufactured anti-hemophilic recombinant factor*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	No	No	No	No	N/A

*** Professionals performing these restricted activities have received authorization from their regulatory college and have the knowledge and skill to perform the skill competently.**

**** Transfusion of Blood Components and Products Learning Module Section Three: Direct IV Administration of Blood Products. RNs may administer direct IV blood products. Not to be confused with medication administration.**

DESCRIPTION OF PRODUCT:

- JIVI® is a sterile, white to slightly yellow lyophilized concentrate of recombinant factor VIII, manufactured using recombinant DNA technology.
- JIVI is B-domain deleted and PEGylated.
- Each JIVI® vial contains the labeled amount of recombinant antihemophilic factor activity expressed in IU per vial.
- Specific activity is approximately 10 000 IU/mg protein.
- Available in 500, 1000, 2000, and 3000 IU vials.
- Also contains calcium chloride, glycine, histidine, polysorbate 80, sodium chloride, and sucrose.
- **Latex-free**

AVAILABILITY

- Supplied by Canadian Blood Services.
- Patient-specific requests must be approved through the CBS Named Patient Program. Consult your transfusion service / laboratory for requesting information.
- Contact your local laboratory/transfusion service regarding stock availability on site.

INDICATIONS FOR USE:

- Previously treated adults and adolescents (≥12 years of age) with hemophilia A for:
  - Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes
  - Control and prevention of episodic bleeding
  - Peri-operative management of bleeding (surgical prophylaxis)

CONTRAINDICATIONS:

- History of life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including mouse or hamster proteins.
- Patients with von Willebrand disease (does not contain von Willebrand factor).

WARNINGS:

- Development of activity-neutralizing antibodies has been detected in patients receiving Factor VIII-containing products. If expected plasma factor VIII activity levels are not attained, or if bleeding is not controlled with an expected dose, an assay that measures factor VIII inhibitor concentration should be performed.
- Patients may develop hypersensitivity to mouse or hamster protein (present in trace amounts in the product)

DOSE (Refer to Product Insert):

- Dosage and duration of treatment depend on the severity of the factor VIII deficiency, the location and extent of bleeding, presence of inhibitors, Factor VIII level desired, and the patient's clinical condition. Consult with Hematologist or bleeding disorders clinic.
- Dose issued may slightly vary (+/- 10%) from dose ordered (based on vial sizes).
- Total recommended maximum dose per infusion is approximately 6000 IU (rounded to vial size).
- **Prophylaxis:** Recommended initial dose = 30-40 IU/kg twice weekly. Based on the bleeding episodes, the regimen may be adjusted to 45 – 60 IU/kg every 5 days.
- **On-demand treatment guide:**
  - Dose necessary will depend on the type and severity of bleeding.
  - **Minor Bleeding:** recommended dose to achieve 20-40% Factor VIII activity is 10-20 IU/kg every 24-48 hours until bleeding is resolved.
  - **Moderate Bleeding**: recommended dose to achieve 30-60% Factor VIII activity is 15-30 IU/kg every 24-48 hours until bleeding is resolved.
  - **Major Bleeding:** recommended dose to achieve 60-100% Factor VIII activity is 30-50 IU/kg every 8-24 hours until bleeding is resolved.
- **Perioperative Management:**
  - **Minor surgery:** Recommended dose is 15 – 30 IU/kg every 24 hours for at least 1 day, until healing is achieved.
  - **Major surgery:** Recommended dose is 40 – 50 IU/kg every 12-24 hours until adequate wound healing, then therapy for at least another 7 days to maintain Factor VIII activity of 30 – 60 %.

ADMINISTRATION:

Confirm written (signed) consent has been obtained and documented prior to requesting blood component from lab/transfusion service where possible.

Pre-Infusion: Ensure recent patient weight is on file and pertinent labs are available. Perform the appropriate pre-transfusion checks per nursing protocol.

Access: Product can be given via CVC, PICC, or peripheral IV line,

Reconstitution Supplies:

- JIVI® Product (lyophilized powder)
- 2.5 mL sterile water for injection (prefilled syringe included with product)
- Vial adapter (included with product)
- Alcohol swabs (not included with product)

Administration Supplies:

- IV administration set (included with product).
- Sterile plastic luer lock syringe, large enough to contain dose*

*Note: The pre-filled glass syringe with diluent used to reconstitute and administer product may not be compatible with all needless connectors for intravenous catheters (e.g. ICU Medical MicroClave® Neutral Connector). You may need to withdraw reconstituted product into a sterile 10 mL plastic syringe with a standard luer-lock connector.

Reconstitution:

- Refer to Bayer Vial Adapter reconstitution instructions. http://www.albertahealthservices.ca/assets/wf/labwf-lab-clin-tm-bayer-vial-adapter-reconst.pdf

Administration:

- JIVI® must be administered within 3 hours after reconstitution.
- It is recommended to use the administration set provided to minimize losses of product due to adsorption and volume retention.
- JIVI should not be mixed with other medicinal products or solutions
- **Administration rate:**
  - Administration rate should be specified by the MRHP after patient assessment.
  - Recommended direct IV administration over a period of 1 – 15 minutes, depending on the total volume.
  - Maximum infusion rate 2.5 mL /minute

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires.

Patients receiving blood product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up instructions to a transfusion reaction, go to: www.albertahealthservices.ca/lab/page4240.aspx

Documentation:

- The transfusion documentation should be double signed (where required) to indicate infusion.
- Start and stop time of infusion and assessment of patient tolerability should also be documented in appropriate flow chart or clinical record (electronic or paper) as required.
- Provide patient notification documentation where required.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Potential adverse events related to a blood product transfusion range in severity from minor with no sequelae to life-threatening.
- All adverse events occurring during a transfusion should be evaluated to determine whether or not the transfusion can be safely continued/restarted.
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) should be reported to your local transfusion service.
- The most commonly reported adverse reactions in patients receiving JIVI® are headache, cough, and pyrexia

Side Effects - Flushing - Headache - Nausea - Itching and redness at the venipuncture site	→	**Action** Slow rate of infusion
Potential Allergic Reaction - Stuffy nose - Hives/severe itching - Cough - Chest pain - Wheezing - Facial swelling - Fainting	→	**Action** **STOP** infusion **IMMEDIATELY** and contact physician

STORAGE & STABILITY OF PRODUCT:

- Stored at 2-8°C.
- The lyophilized powder may be stored at up to 25°C for up to 6 months, or up to 30°C for up to 6 months. Ensure the date the product is removed from the refrigerator is recorded. Once stored at room temperature, do not return the product to refrigerated storage
- **Do not freeze**.
- Protect from light during storage.
- Shelf life is 24 months from the date of manufacture
- Do not use expired product.

COMMENTS:

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For questions or comments regarding this document please contact: Transfusion.SafetyTeam@ahs.ca

REFERENCES:

JIVI® Product Monograph. Available from www.bayer.ca