Alberta Health Services

This document applies to all Covenant and AHS sites.

CUVITRU

Class: *Manufactured blood product, derived from human plasma*

OTHER NAMES: CUVITRU Subcutaneous Immune Globulin (Human), SCIG, 20%
Company: Shire (formerly Baxalta)

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	No	No	No	Yes	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.**

DESCRIPTION OF PRODUCT:

- A purified, ready-to-use normal immunoglobulin G (IgG) liquid biologic at 20% w/v concentration prepared from pooled human plasma for subcutaneous infusion
- Viral reduction steps include solvent/detergent (S/D) treatment, nanofiltration, and incubation at low ph and elevated temperature
- Contains at least 98% IgG and trace amounts of IgA (<280mcg/mL)
- Available in 1g 5mL, 2g 10mL, 4g 20mL and 8g 40mL vial sizes at a concentration of 200 mg of protein per mL
- Contains glycine as stabilizing agent (nonmedicinal clinically relevant ingredient)
- **Latex-free, Sucrose-free**

AVAILABILITY:

- Supplied by CBS
- Contact your local laboratory/transfusion service regarding stock availability on site.

INDICATIONS FOR USE:

- Treatment of adult and pediatric patients greater than 2 years of age with primary immune deficiency (PID) and Secondary Immune Deficiency (SID) who require immune globulin replacement therapy

CONTRAINDICATIONS:

- History of anaphylactic or severe systemic response to immune globulin preparations or to components of CUVITRU
- Patients with severe IgA-deficiency
- Patients who have had an anaphylactic or severe reaction to subcutaneous administration of human immune globulin

WARNINGS:

- **DO NOT** administer intravenously or intramuscularly
- Rarely, human normal immunoglobulin can induce a drop in blood pressure with anaphylactic reaction, even in patients who had tolerated previous treatment with human normal immunoglobulin. Suspicion of allergic or anaphylactic type reactions requires immediate discontinuation of the injection. In case of shock, standard medical treatment should be administered.
- Thrombotic and thromboembolic events have been reported in association with immune globulin products

DOSE (Refer to Product Insert):

- Dose and dosing interval may vary based on patients pharmacokinetic and clinical response
- Monitor renal function and consider lower, more frequent dosing for patients at risk of renal dysfunction
- Dose regime should achieve a trough level of 5 to 6 g/L
- Recommended monthly dose = 0.3-1.0 g/Kg body weight (bw)
- *Loading Dose:* If a loading dose is required: CUVITRU may be given at least 0.2 to 0.5 g/Kg bw [1.0 to 2.5 mL/Kg bw] divided over several days.
- *Switching from IVIG:* For patients switching from intravenous treatment, the monthly dose is usually divided into equivalent weekly doses. Example: Divide the previous IVIG dose in grams by the number of weeks between doses (dosing interval) during the patient's IVIG treatment (i.e., 3 or 4 weeks).
- *Switching from another SCIG:* For patients already on SCIG treatment the dosing recommendation is to start with an initial weekly CUVITRU dose that is equal to the previous (weekly) SCIG dose.
- To convert the CUVITRU dose (in grams) to milliliters (mL), multiply the dose by 5 (0.2 g per 1 mL).

ADMINISTRATION:

Ensure patient consent has been obtained prior to requesting blood product from lab/transfusion service where possible.

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

Access: Subcutaneous injection **ONLY** in any four quadrants of the abdomen, thighs or lateral aspects of the hip, and upper arm

Administration Supplies:

- Infusion administration set(s) (tubing and needle i.e.butterflies or "multisite" sets)
- Antiseptic wipes or alcohol swabs
- Syringe(s)
- Transfer needles
- Pump (If required. Be sure to follow manufacturer's instructions for use)

Administration:

- May be administered by pump or by push.
- Bring CUVITRU vial(s) to room temperature.
- **Do not shake product.**
- Visually inspect for discoloration and particulate matter. Solution should be clear and pale yellow to light brown.
- Wash hands. Ensure aseptic technique when preparing and administering CUVITRU
- Remove cap and cleanse stopper with alcohol swab. Allow to dry.
- Using a sterile syringe and transfer needle, prepare to draw up CUVITRU by first injecting air into the vial equal to the amount of CUVITRU to be withdrawn. Then withdraw desired volume of CUVITRU. Repeat for each vial needed.
- Follow manufacturer's instructions to prepare pump and/or administration tubing where applicable.
- Prepare injection site.

Rate

- Start the infusion promptly after drawing CUVITRU into the syringe(s). It is suggested to complete the administration within 2 hours.
- Infuse CUVITRU, following manufacturer's instructions for the pump or by push at a rate of 1mL/min.
- For the first two (2) infusions of CUVITRU, the maximum recommended rate is 10-20 mL per hour per site. For subsequent infusions, the flow rate may be increased to a maximum of 60 mL per hour per site as tolerated. For multiple sites, do not exceed a maximum of 240 mL/hr for all sites combined.

Additional Notes

- Multiple injection sites may be used and should be at least four (4) inches apart. For patients <40kg not already on SCIG, volume should not exceed 15 mL per site, for patients ≥ 40kg, volume should not exceed 60 mL per site. After second infusion, you may infuse to a maximum of 60 mL per infusion site, as tolerated.
- Ensure CUVITRU is **NOT** injected into a blood vessel ("pinch an inch" to inject into fatty subcutaneous tissue). Avoid bony prominences.
- Rotate site with each administration.
- **Important notes:**
  - In hospital/facility storage of CUVITRU must be in a Transfusion Service approved location. Product stored by the patient for home use must be in compliance with the manufacturer's recommendations.
  - **DO NOT** mix CUVITRU with other products
  - Discard any unused portion immediately after it has been accessed

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Potential adverse events related to a blood product transfusion range in s everity, 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. Acute reactions need medical involvement
- 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 common adverse reactions include local injection-site reactions (swelling, redness, and itching), headache, nausea, rash, asthenia, and gastrointestinal disorder.**
- **Aseptic meningitis syndrome, transfusion related acute lung injury (TRALI) and delayed hemolytic anemia due to blood group antibodies are associated with pooled immune globulin products.**

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

NURSING IMPLICATIONS (where applicable):

	Pre Transfusion Vitals?	Initial Monitoring: Stay At Patient Bedside?			Vital Signs During Transfusion		Post Transfusion Monitoring
		First 5 min	First 10 min	First 15 min	After 15 min	Remainder of transfusion	
ADULTS	Yes		**NO**, but must be immediately available		Yes	q1h	Set of V/S then monitor prn
PEDIATRICS	Yes	YES			Yes	**1st hour**→q 15 min **2nd and 3rd hours**→ q30 min then q1h until complete	For 30-60 minutes following
NEONATES	Yes				Yes	**q15 min** for duration of transfusion	For 30-60 minutes following

Note: Vital signs/patient monitoring may be conducted more frequently as determined by clinical condition of patient.

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: http://www.albertahealthservices.ca/4240.asp

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.
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper).
- Provide patient notification of transfusion documentation where required.
- Documentation for home use of CUVITRU must follow the policies of the clinical program.

STORAGE & STABILITY OF PRODUCT:

Stored at 2-8°C for up to 36 months, or
at room temperature (not to exceed 25°C for up to 12 months from the date of manufacture
Do not freeze.
Do not use product that has been frozen.
Do not shake
Protect from light
Product issued for home use and returned will be discarded.

COMMENTS:
Date Revised: Mar 2019
Date Effective: 22 Mar 2019
Version: 1.2
Approved By: Transfusion Medicine
Document#: PTMGNR00050
Reference: CUVITRU product monograph
For questions or concerns regarding this document contact: transfusion.safetyteam@albertahealthservices.ca

LINK to WEBSITE for PRESCRIBING INFORMATION
Product Monograph available at:
http://www.shirecanada.com/