Yukon Immunization Program Manual

Section 8 - Biological Products

Immune Globulins

SECTION 8 – BIOLOGICAL PRODUCTS

Contents

	2019 August
Hepatitis B Immune Globulin (HBIg) (BayHep BTM)	**Supplier: Bayer**
INDICATIONS**	**DOSAGE ❶❷**
(1) Infant born to HBsAG positive woman.	**(1)** Give HBIg 0.5 ml **IM immediately after birth**, along with first dose of hepatitis B vaccine series. ❸
(2) Infant born to woman at high risk for hepatitis B infection (i.e., intravenous drug use, sex trade work) whose infectious status is unknown or negative (possible window period).	**(2)** Give HBIg 0.5 ml **IM immediately after birth,** along with first dose of hepatitis B vaccine series. ❸
(3) Infant <12 months of age has mother with **acute** hepatitis B infection.	**(3)** Consider the immune stats of the infant and history of hepatitis B immunization and give HBIg 0.06ml/kg of body weight **IM** and hepatitis B vaccine as required. ❸❹❺
(4) Percutaneous or mucosal exposure to HBsAG positive source.	**(4)** Give HBIg 0.06ml/kg if body weight and hepatitis B vaccine **IM** as required, considering the client's immune status and history of hepatitis B immunization. ❹❺
(5) Sex with a person who has **acute or chronic** hepatitis B infection	**(5)** Give HBIg 0.06ml/kg of body weight **IM** as soon as possible following the last sexual exposure, along with hepatitis B vaccine series. ❹❺❻
REINFORCEMENTS	**Any at-high risk, known non-responder to two series of vaccine may require 2 doses of HBIG 4 weeks apart.**
CONTRAINDICATIONS	None
PRECAUTIONS	• Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible that unknown infectious agents may be present in such products. • Regarding HBIg and the administration of live vaccines see CIG (2013), visit: http://www.phac-aspc.gc.ca/publicat/cig- gci/p01-10-eng.php, Guidelines for the interval between Administration of Immune Globulin Preparations or Blood Products and MMR or Varicella Virus. • For full Hepatitis B Post-Exposure Prophylaxis guidelines see **Section 16, Blood & Body Fluid Exposure Management** or Yukon Communicable Disease Guidelines, **Hepatitis B** as appropriate. • Give HBIg with caution (i.e., in a setting capable of managing anaphylaxis) if the person has a history of anaphylactic reaction following receipt of any human Ig product, or a history of anaphylactic reaction to latex (assess risks versus benefits).

	2019 August
Hepatitis B Immune Globulin (HBIg) (BayHep B™)	**Supplier: Bayer**
PRECAUTIONS	• Clients with severe thrombocytopenia or coagulation disorders that contraindicate IM injections should not be given HBIg unless the benefits outweigh the risks. • HBIg does not contain preservatives. • **Vials are single dose use; discard unused contents.** • **HBIg must be given at a separate anatomic site from hepatitis B vaccine.** • The preferred site for the administration of HBIg is the ventrogluteal area, which may be used in those > 28 weeks of age. However, the vastus lateralis is most often used in infants and children up to 5 years of age.
ADVERSE EVENTS	Local pain and tenderness at injection site, urticarial and angioedema may occur.

❶ There is no upper limit to the volume of HBIg that can be administered.

❷ Provide a written record to a client who receives any immune globulin product.

❸ There is **no** outer time limit for administering HBIg in infants <12 months of age, when the infant's exposure to the known risk factor(s) is ongoing. For infants < 8.3 kg, give 0.5 ml HBIg.

❹ HBIg dose for all clients ≥8.3kg is 0.06ml/kg. Give HBIg as soon as possible, preferably within 48 hours of the exposure. For a percutaneous exposure, HBIg may be given up to 7days following the exposure. If the client presents >7 days following a percutaneous exposure, give Hepatitis B vaccine only. For permucosal or sexual exposures, see **Section 16, Blood & Body Fluid Management.**

❺ See CIG (2013) for maximum volume to be administered per site according to age.

❻ For **steady, long term** sexual partners of chronic hepatitis B carriers, test for HBsAg, anti-HBc and anti-HBs as per scope of practice. See **Yukon Communicable Disease Guidelines, Hepatitis B**

** **See Section 16, Blood & Body Fluid Management or Yukon Communicable Disease Guidelines, Hepatitis B, as appropriate, for complete guidelines**

2020 September

Human Rabies Immune Globulin (RabIg) (HYPERRAB® S/D)

Supplier: Grifols Canada Inc.

INDICATIONS❶	Doses and Schedule❷❸
RABIES POST-EXPOSURE PROPHYLAXIS (RPEP): ❹ • As determined by Yukon Chief Medical Officer of Health. • 1st dose of Rabies Vaccine is given in conjunction with RabIg. Rabies vaccine and RabIg must be administered with separate needles and syringes at **separate anatomical sites** If a rabies vaccine series has been started or completed elsewhere and it was not given in accordance with the current WHO standards, or if the vaccine was a nerve tissue vaccine (Semple vaccine), administer RabIg (on day 0) in conjunction with the 1st dose of another full course of rabies vaccine.	**RABIES POST-EXPOSURE PROPHYLAXIS:** • The recommended dosage for children and adults is the same: 20 IU/kg of body weight. **NOTE: IMPORTANT TO READ FORMULATION YOU HAVE IN STOCK, AS THERE ARE TWO:** • The dose of RabIg is calculated as: [20 IU/kg x weight in kg] = ___mL **150 IU/mL** **OR** [20 IU/kg x weight in kg] = ___mL **300 IU/mL** **Do not exceed recommended dose due to interference with active antibody production.**

ADMINISTRATION	
	Caution – There are two formulations in stock, be sure to check formulation before calculation of dosage and administration RabIg is supplied in 2 mL vials, each 1.0 mL = 150 IU **OR** RabIg is supplied in 1 mL vial, each 1.0 mL = 300 IU **Infiltrate as much RabIg as possible deep into and around the wound(s) in order to neutralize the virus.** • When more than one wound site exists, each site should be infiltrated with a portion of the RabIg, using a separate syringe and needle for each infiltration. • If there are extensive wounds, where the calculated dose of RabIg (by weight) is **not** adequate in volume to infiltrate all wounds, the HyperRAB® dose may be diluted with an equal volume of dextrose, 5% (DW5) in water to create an adequate volume to infiltrate all wounds. Do not dilute with normal saline. • Infiltration of wounds in some anatomical sites (finger tips) must be carried out with care in order to avoid increased pressure in the tissue compartment (compartment syndrome). • Any remaining volume should be injected intramuscularly at a site distant from vaccine administration. The deltoid should not be used for RabIg administration. Both deltoid sites should be reserved for administration of rabies vaccine.

	2020 September
Human Rabies Immune Globulin (RabIg) (HYPERRAB® S/D) **Supplier: Grifols Canada Inc.**	
ADMINISTRATION	• When there is no wound site, the preferred site for the administration of RabIg is age specific. The ventrogluteal area, which may be used in those > 28 weeks of age. However, the vastus lateralis is most often used in infants and children up to 5 years of age. • Large volumes of immune globulin for IM injection (greater than 2 mL for children or greater than 3-5 mL for adults, depending on muscle mass) should be divided and injected at two or more sites. • RabIg contains no preservatives. Vials are single dose use. Once entered, discard any unused contents.
BOOSTER DOSES	None
CONTRAINDICATIONS	None
PRODUCT COMPONENTS	Potential allergens: none. Other components: glycine.
PRECAUTIONS	• Give RabIg with caution (i.e., in an emergency room setting) if the client has a history of anaphylactic reaction • Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore, the risk of transmission is extremely low. However, it is possible, that unknown infectious agents may be present in such products. The benefits of use of rabies immunoglobulin after exposure to rabies far outweigh the theoretical risk of receipt of a blood product. • Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent blood products that contain IgA. Therefore, RabIg should only be given to such persons if the expected benefits of use of rabies immunoglobulin after exposure far outweigh the risks, and should be administered in an emergency room setting. • Special measures should be considered when administering IM injections to people with bleeding disorders. A smaller gauge needle (23 gauge or smaller) should be used and steady, firm pressure should be applied to the injection site for 5 minutes. If there is concern that the injection may stimulate bleeding, the client should connect with their medical specialist.
SPECIAL CONSIDERATIONS	• Document receipt of RabIg in the client's electronic record (e.g., Panorama) and/or chart. The following information must be recorded: trade name of product, date, lot number, dosage, route, and site(s). • Provide a written record to individuals who receive any immune globulin product. • Regarding RabIg and the administration of live vaccines see CIG guidelines.

	2020 September
Human Rabies Immune Globulin (RabIg) (HYPERRAB® S/D) **Supplier: Grifols Canada Inc.**	
ADVERSE EVENTS	**Local:** soreness or stiffness of local muscles. Systemic: fever A potential increased risk of thrombosis (blood clots) has been observed within 24 hours of receipt of immune globulin products, especially when given in large doses (i.e., more than 10 mL). Additional risk factors include: age 45 years and older, history of thrombosis or those with risk factors for thrombosis (e.g., obesity, high blood pressure, diabetes, prolonged periods of immobilization, use of estrogens, a history of heart disease, blood clotting disorders, indwelling central vascular catheters, or diseases that thicken the blood).

❶ Since vaccine induced antibodies begin to appear within one week, there is no value in administering RabIg more than 8 days after initiation of vaccine.

❷ When notification of an exposure is delayed, RPEP may be started as late as 24 weeks or more after an exposure.

❸ The deltoid should **not** be used for RabIg administration. Both deltoid sites should be reserved for administration of rabies vaccine.

❹ **See Yukon Communicable Disease Guidelines, Rabies for information on how obtain RabIg.**

	2019 August
Rh_o (D) Immune Globulin (RhIg) (WinRho™) ❶ ❷ ❸ **Supplier: Cangana Corporation**	
INDICATIONS	(1) Recommended for the prevention of Rh immunization of Rh_o (D) negative woman at risk of developing Rh antibodies, to prevent haemolytic disease of the newborn. The reduction of Rh alloimmunization is from 13% to 1 to 2 %
DOSE	Dose 1: 300 µg **IM 28 weeks of gestation** Dose 2: 300 µg **IM within 72hours after delivery**
CONTRAINDICATIONS	• **Do not give Ig intravenously** • Rh_o (D) positives individuals including babies • Rh_o (D) negative women who are Rh immunized as evidenced by standard manual Rh antibody screening tests. • Individuals with a history of anaphylactic or other severe systemic reaction to immune globulins.
PRECAUTIONS	• Human Ig products are amongst the safest blood-derived products available. As the method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV, the risk of transmission is considered to be extremely low. However, it is possible that unknown infectious agents may be present in such products. • Persons with severe thrombocytopenia or coagulation disorders that contraindicate IM injections should not be give IM Ig unless the benefits outweigh the risks. • Give Ig with caution (i.e., in a setting capable of managing anaphylaxis) if the client has a history of anaphylactic reaction following receipt of any human Ig product, or history of anaphylactic reaction to glycine or to latex (assess risks versus benefits). • Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent administration of blood products that contain IgA. Therefore, Ig should only be given to such persons if the expected benefits outweigh the risks. • Ig contains no preservatives. Vials are single use. Once entered, discard any unused contents. • The preferred site for the administration of Ig is the ventrogluteal area. • Should either be given at the same time as MMR or the MMR should be deferred 12 weeks post injection of the Rh_o (D) Immune Globulin. If administration of Ig is necessary less than **14 days** after MMR or varicella vaccine, repeat vaccine as per recommended intervals as in CIG.
ADVERSE EVENTS	**Local:** pain and injection site tenderness
❶ **A Physician's order by prescription is always required.** ❷ Order through Whitehorse General Hospital Lab on a stores order form, (and phone Lab and give the patient's name, estimated date of confinement, whether the request is for the 28 week or post-delivery injection, and the name of attending physician) ❸ See product monograph for further information.	

2019 August

Tetanus Immune Globulin (TIg) (HYPERTET®S/D)

Supplier: Grifols Canada Ltd.

INDICATIONS❶	DOSE
1) TIg is indicated for prophylaxis against tetanus following a major or unclean wound in individuals whose immunization history is incomplete or uncertain (See Tetanus Prophylaxis in Wound Management.) **2)** TIg is indicated when a contraindication to a tetanus toxoid-containing vaccine exists and an individual sustains a major or unclean wound. **3)** TIg is indicated in individuals known to have a significant immune deficiency state (i.e. HIV) regardless of their immunization history, following any major or unclean wound.	Give 250 units **IM** (entire syringe) to adults and children who require TIg. ❷ TIg is supplied in a 250unit single dose pre-filled disposable syringe. The syringe fill volume for each lot is adjusted to ensure a potency of 250 IU/syringe. The actual fill volume for HyperTet syringes typically ranges between 0.75 ml and 1.3 ml. The needle on the pre-filled syringe is fixed and cannot be changed.

REINFORCEMENTS	None if Td vaccine is given concurrently with TIg. ❸❹
CONTRAINDICATIONS	TIg should not be given intravenously.
PRECAUTIONS	• Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore, the risk of transmission is considered to be extremely low. However, it is possible that unknown infectious agents may be present in such products. • Regarding TIg and administration of live vaccines (MMR & Varicella) see Immune Globulin Preparations or Blood: Timing Intervals For Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus in CIG. • Give TIg with caution (i.e., in a setting capable of managing anaphylaxis) if the client has a history of anaphylactic reaction following receipt of any human Ig product, or a history of anaphylactic reaction to latex (assess risks versus benefits). • Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent administration of blood products that contain IgA. Therefore, TIg should only be given to such persons if the expected benefits outweigh the risks. • In clients who have severe thrombocytopenia or any coagulation disorder that would contraindicate IM injections, TIg should be given only if the expected benefits outweigh the risks. • **TIg must be given at separate anatomic sites from a tetanus toxoid-containing vaccine.** • The preferred site for the administration of TIg is the ventrogluteal area, which may be used in those > 28 weeks of age. However, the vastus lateralis is most often used in infants and children up to 5 years of age.

	2019 August
Tetanus Immune Globulin (TIg) (HYPERTET®S/D)	**Supplier: Grifols Canada Ltd.**
ADVERSE EVENTS	**Local:** tenderness, erythema and stiffness of local muscles that may persist for several hours. **Systemic:** mild fever or malaise

❶ Provide a written record to a client who receives any immune globulin product.

❷ As per CIG, The recommended dose of TIg for adults and children is 250 units by IM injection. It is advisable to administer the entire contents of the vial of TIg regardless of the child's size; theoretically the same amount of toxin will be produced in a child or adult's body by the infecting tetanus organism. For more info, see CIG.

❸ If a contraindication to a tetanus toxoid-containing vaccine exists or a client refuses a tetanus toxoid-containing vaccine, and a client sustains a major or unclean wound, consider offering a 2nd dose of TIg 30 days post the 1st dose of TIg.

❹ Tetanus Immune Globulin does not interfere with the development of active immunity from a tetanus toxoid-containing vaccine