



Government of Newfoundland and Labrador  
Department of Health and Community Services  
Provincial Blood Coordinating Program

<b>ADMINISTRATION OF INTRAVENOUS IMMUNE GLOBULIN (IVIG)</b>	<b>NLBCP-011</b>
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## Overview

The Newfoundland and Labrador Provincial Blood Coordinating Program (NLPBCP) provides policies and processes to the Regional Health Authorities (RHAs) to support appropriate utilization and safe administration of intravenous immune globulin (IVIG). This document is part of the IVIG toolkit and as such will cross-reference throughout the document. Additionally this document will identify specifics for IVIG and therefore is an addendum to the [Transfusion of Blood Components and Administration of Blood Products](#) policy.

IVIG is an expensive blood derived product. IVIG is a product made from large pools of human plasma by a combination of fractionation, precipitation, filtration and/or chromatography.

NLPBCP is part of the Atlantic Blood Utilization Strategy (ABUS). In 2018, ABUS released the [Atlantic Ministries of Health Common Policy for Intravenous and Subcutaneous Immunoglobulin](#). The objective of the Common Policy is to manage utilization of IVIG/SCIG in a safe and sustainable manner through clarification of the parameters under which IVIG/SCIG may be dispensed and used in the Atlantic Provinces. All NLPBCP IVIG resources are located at the following link <http://www.health.gov.nl.ca/health/bloodservices/resources/ivig.html>.

## Policy

RHAs shall implement policies, procedures, and guidelines for the safe administration of intravenous immune globulin (IVIG) for clinically indicated conditions that comply with NLPBCP and the National Advisory Committee on Blood and Blood Products <https://www.nacblood.ca/resources/guidelines/IVIG.html>.

1. RHAs shall ensure appropriate utilization of IVIG according to published guidelines. [Atlantic Clinical Indications and Criteria for Intravenous and Subcutaneous Immunoglobulin](#), and the [Atlantic Ministries of Health Common Policy for the Utilization of IVIG & SCIG](#).
2. Authorized prescribers shall obtain written consent for the blood product administration as per the [Consent or Refusal to Administration of Blood Components and Blood Products](#) policy.
3. Recipients shall be provided information on IVIG to ensure the recipient can make an informed decision on whether to consent to or refuse treatment with IVIG. A patient information sheet may be printed from the following link [Intravenous Immune Globulin Information Sheet](#).
4. The RHA will provide education on the safe administration of IVIG to facilitate competency for the transfusionist(s).

## Guidelines

1. The indications for IVIG are constantly evolving due to clinical practices and research. These indications are classified into the following three categories:

- 1.1. indicated,
- 1.2. possibly indicated, and
- 1.3. not indicated.

Approval processes vary by category. Refer to [Atlantic Clinical Indications and Criteria for Intravenous and Subcutaneous Immunoglobulin](#), and the [Atlantic Ministries of Health Common Policy for the Utilization of IVIG & SCIG](#) and [Review and Approval of Requests for Intravenous Immune Globulin for Adult Patients](#).

2. The Canadian Blood Services (CBS) maintain a table of licensed products that are approved and available for use: [https://blood.ca/sites/default/files/Intravenous\\_Immune\\_Globulins\\_Table.pdf](https://blood.ca/sites/default/files/Intravenous_Immune_Globulins_Table.pdf). The table may also include products that are not licensed by Health Canada but may be available under Special Access Program authorization only. Product availability with CBS does change due to the awarding of contracts. All changes are communicated to the RHAs by CBS via customer letters.
3. In prescribing IVIG for specific recipients, the authorized prescriber may need to consider the differences between the various brands. IVIG products vary in concentration, pH, stabilizing agents, osmolarity, osmolality, as well as sugar and sodium content. The variation in products must be considered for choosing the appropriate product for recipients with cardiac impairment, renal dysfunction, anti IgA antibodies, thrombolytic risk, (pre)diabetes, elderly and infants/children.

There is also variability in administration factors including the form of the drug (lyophilized or liquid), shelf life, approved means of administration, and prescribed infusion times. As a result, recipients may tolerate one IgG product over another.

Typically, individual recipients continue to receive the same product for the course of treatment unless tolerance issues have been identified. Careful monitoring during administration is recommended and any problems must be communicated to the authorized prescriber in a timely manner.

4. Mixing of brands from different manufacturers at a single administration should be avoided.
5. IVIG is contraindicated in recipients who are:
  - 5.1. hypersensitive to the active substance or in the formulation of the IVIG product,
  - 5.2. known to have had a previous history of a severe systemic or anaphylactic response to IVIG, or
  - 5.3. known to have anti-IgA antibodies with selective IgA deficiencies.

6. IVIG may interfere with the immune response of live virus vaccines. See product monographs for specifics and counsel the recipient/support person as required to plan immunizations.
7. Refer to product monographs for recommendations in special populations:
  - 7.1. pregnant women,  
Note: Because of hemodilution naturally occurring during pregnancy, higher doses of IgG should be considered in pregnant recipients with Common Variable Immune Deficiency.
  - 7.2. nursing women,
  - 7.3. pediatrics (1-18), and
  - 7.4. geriatrics (> 65 years of age).
8. The IVIG dose is dependent on the recipient's clinical condition and response to the treatment. The IVIG replacement therapy is generally given every three to four weeks at an approximate dose of 400-500 mg/kg/dose. It is important to note that each recipient may require a unique individualized infusion regime in order to achieve the desired response. This regime may vary as to the specific brand/manufacturer of IVIG used, the specific dose and rate ordered/tolerated, and to any premedication requirements as indicated/ordered.
9. The recipient's response to the infusion will determine an individualized maximum tolerable rate of infusion that may be lower than the manufacturer's recommendation. It is recommended **not to exceed** the manufacturer's recommended maximum rate.
10. There are recommendations for appropriate dosing for specific conditions but as each individual recipient will respond differently, titrating to lowest effective dose is ideal. This ensures the recipient receives adequate dosing but decreases their risks of side effects and adverse transfusion reactions.
11. IVIG is administered at room temperature or ambient temperature as specified in the product monograph. Solutions should be allowed to come to required temperature naturally. Please refer to specific product monograph for the brand being administered.
12. When a recipient's treatment involves multiple bottles of IVIG, it is recommended that the administration begin with the smallest volume bottles and end with the largest volume bottles for the following reasons:
  - 12.1. smaller volume bottles will achieve room temperature more quickly, and
  - 12.2. in most cases adverse reactions occur relatively early in the administration so less wastage if the smaller volume bottles are being administered at that time.
13. Vented tubing sets used for IVIG administration are changed as per manufacturer recommendations or with each treatment (at least every 24 hours) if not specified.
14. Assess vital signs when switching lot numbers. It is not necessary to slow down the infusion rate when switching lot numbers.

15. Assess the recipient for weight loss or gain. IVIG is prescribed based on weight. A significant (10%) change may indicate the need for a change in dosage. The recipients weight and height are assessed and recorded at least:
  - 15.1. every 6 months for adult recipients,
  - 15.2. at each cycle or visit for pediatric or pregnant recipients (verify with authorized prescriber any potential dose changes), or
  - 15.3. if the recipient reports any significant weight loss or gain.
16. It is estimated that 15-30% of recipients experience some kind of physiological reaction to IVIG infusions. These reactions can range from mild to severe. Most reactions will occur during the initial 30-60 minutes of the infusion. Protocols dictate to start with a slow infusion rate and monitor vital signs frequently. See Appendix A for IVIG Reaction Table.
17. Assess the recipient's health status and hydration status prior to administration. Any changes to health since the previous infusion or a new medication regime should be reported to the authorized prescriber. Additionally, if the recipient is poorly hydrated consideration should be given to providing hydration either via enteral or parenteral route prior to the IVIG infusion.
18. If the decision is made to **not** transfuse, contact the Transfusion Medicine Laboratory (TML) as soon as possible regarding return of product to inventory. [Returning Blood Components and Blood Products Into Inventory](#).
19. Reference documents to guide clinical practice include:
  - 19.1. [Atlantic Clinical Indications and Criteria for Intravenous and Subcutaneous Immunoglobulin](#),
  - 19.2. [Atlantic Ministries of Health Common Policy for the Utilization of IVIG & SCIG](#),
  - 19.3. [Review and Approval of Requests for Intravenous Immune Globulin for Adult Patients](#),
  - 19.4. [Ideal Body Weight Calculator with IVIG Dosing](#),
  - 19.5. [Intravenous Immune Globulin Information Sheet](#),
  - 19.6. [IVIG Infusion Rate Tables](#), and
  - 19.7. [Transfusion of Blood Components and Administration of Blood Products](#) policy.

## Materials

IVIG as per authorized prescriber order

5% Dextrose in water or specific compatible solution as indicated by manufacturer

Vented intravenous tubing

Venous access supplies

Infusion pump

Access to IVIG Dose Calculator

IVIG infusion rate tables  
Vital signs assessment equipment  
Personnel Protective Equipment

## Procedure

### Pre-administration Preparation:

1. The authorized prescriber will obtain an informed consent for IVIG administration and complete the **appropriate** preprinted order (PPO) form. The PPO shall be forwarded onto the TML upon completion to allow time for any required modifications and consultations. Additionally, the authorized prescriber shall provide pre/post administration orders related to the administration of IVIG.
  - 1.1. Medication orders as indicated.
  - 1.2. Blood work as indicated.
2. See [Transfusion of Blood Components and Administration of Blood Products](#) including:
  - 2.1. pre-transfusion preparation,
  - 2.2. at bedside,
  - 2.3. recipient education ([Intravenous Immune Globulin Information Sheet](#)) ,
  - 2.4. unequivocal identification,
  - 2.5. monitoring prior to, during and post transfusion,
  - 2.6. documentation, and
  - 2.7. checklist.
3. The Transfusionist's responsibility shall include:
  - 3.1. Confirmation of completion of the following steps.
    - 3.1.1. PPO form has been completed, signed by the authorized prescriber, and forwarded onto the TML as soon as received from prescriber to allow time for any modifications and/or consultations if required.
    - 3.1.2. Informed consent has been signed by the recipient prior to administration.
    - 3.1.3. Authorized prescriber order accurately identifies the recipient's first and last name, identification number, the recipient location, particular IVIG product/brand **if applicable**, dose, rate (as per monograph), and date and time.
    - 3.1.4. PPO form sent and received in the TML.
    - 3.1.5. Pre-administration bloodwork completed, if required, and results reviewed.
  - 3.2. Consult the IVIG monograph for product specific information, recommended doses, rate calculations with gradual stepwise increases, contraindications, cautionary notices, etc.

- 3.3. Confirm dosage using IVIG dose calculator. See [Ideal Body Weight Calculator with IVIG Dosing](#).

**At Bedside:**

1. Prepare supplies (vented tubing, priming solution, pump, etc).
2. Initiate venous access using aseptic technique.
3. Provide recipient/support person teaching on the plan of care, expected response, and potential adverse reactions. See [Intravenous Immune Globulin Information Sheet](#).
4. Assessment of recipient includes vital signs (temperature, pulse, blood pressure, respiratory rate) and other clinical assessments based on recipient's acuity level).  
If any changes/concerns in recipient's health status and/or hydration status are identified, consult authorized prescriber.
5. Continuous and unequivocal identification applies to the use of IVIG as per the [Transfusion of Blood Components and Administration of Blood Products](#) policy. In addition to [Positive Recipient Identification](#), verify:
  - 5.1. IVIG product lot/unit number shall match on the compatibility/label tag attached to IVIG,
  - 5.2. IVIG product label on the box,
  - 5.3. IVIG product label on the bottle, and
  - 5.4. IVIG product has not expired.
6. Administer pre-medications as ordered.
7. Monitor recipient's vital signs and physiological response to IVIG. Vital signs are assessed pre initiation, 15 minutes after initiation, with each rate change, minimum of hourly once maintenance rate reached, with each change in lot number, and within one hour of completion.
8. Initiate IVIG via infusion pump using vented intravenous tubing. Refer to product monograph and [IVIG Infusion Rate Tables](#) for weight based initial rates and gradual rate increase recommendations.
9. Adjust rate, if indicated, by recipient response and based on authorized prescriber order, product recommendations, and RHA guidelines.
10. If any symptoms of an adverse transfusion reaction occur (see IVIG reaction chart in appendix A) the following actions must be taken:
  - 10.1. Stop the administration immediately.
  - 10.2. Keep lines open with compatible intravenous solution (check specific product monograph).
  - 10.3. Assess the recipient for type of adverse reaction. [Transfusion Reactions NLPBCP](#).
  - 10.4. Initiate appropriate action to presenting signs and symptoms as per best practice recommendations.



- 10.5. Restart the infusion, if indicated and after consultation with the authorized prescriber, at a slower rate.
- 10.6. If symptoms continue and/or worsen, infusion may need to be stopped and alternate brand attempted with next treatment to assess tolerance. Ensure that with any change in brand and/or if prolonged period of time between treatments that the infusion is initiated at the lowest rate based on recipient weight and gradually increased as per product monograph and/or IVIG infusion rate tables.

#### Post Administration:

1. Flush IV line with compatible intravenous solution following the administration.
2. Complete RHA documentation and complete compatibility label/tag. The recipient's medical chart shall include:
  - 2.1 lot number or identification number traceable to the lot number,
  - 2.2 name of the product administered and volume/dose,
  - 2.3 data and time (both start and finish) of administration, and
  - 2.4 identity of the person who administered the product.
3. Return the lab portion of the compatibility label/tag to the Transfusion Medicine Laboratory.
4. Continue to monitor the recipient at least 30 minutes after the administration.
5. Dispose of IVIG product bottles or containers and tubing in compliance with RHA's standard precautions policies.
6. Provide teaching to recipient/support person on possible latent adverse reactions and remedies/need to return to RHA.

#### Quality Control

1. IVIG is a blood derived product and not risk free to recipients. Therefore, as recommended by the Krever inquiry, all usage is tracked and reported by the Canadian Blood Services and the Provinces/Territories.
2. Each RHA shall report their use of IVIG and transfusion reactions associated with IVIG.
3. IVIG is an expensive blood derived product. Health Canada publishes a list of licensed IVIG indications and others that are approved as off label therapy for diseases that may have an immune mediated or unknown pathogenic mechanism (possibly indicated). For possibly indicated conditions or situations in which IVIG is being used under extenuating circumstances, the treating clinician must complete a clinical outcome evaluation at regular intervals. The initial outcome questionnaire is completed at three months from the onset of IVIG therapy, another at six months from that date, and then every twelve months to ensure that the IVIG is of therapeutic value and that the minimal effective



dose is prescribed. Regular evaluations are required to ensure that the treatment continues to be effective and appropriate.

4. Each RHA shall have a quality system in place to ensure that any incidents, such as errors and accidents or deviations from normal operating procedures are identified, investigated, and evaluated and that corrective action is taken when required.
5. Internal audits shall be performed at least annually to verify the continuing effectiveness of the system.
6. Aseptic Technique is indicated for all administration of blood products. All blood administration equipment shall be designed to facilitate thorough cleaning and disinfection both internally and externally.
7. Blood product containers shall be disposed of in compliance with standard precautions according to hospital policy and procedures.

## Key Words

Intravenous immune globulin, IVIG

## Supplemental Materials

Appendix A: IVIG Reaction Chart

Appendix B: IVIG Administration Record

## References

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## Appendix A

### Intravenous Immune Globulin (IVIG) Reaction Chart

Signs and Symptoms	Reaction type/ frequency and Comments	Actions
Headache	<p>The most common side effect of IVIG. Can be immediate and/or delayed.</p> <p>Can be mild, moderate to severe.</p> <p>Headaches often diminish after first few infusions.</p>	<p><b>STOP infusion</b> until the symptoms subside spontaneously and/or are treated with sufficient management.</p> <p><b>Maintain IV Access.</b></p> <p>Hydrate if necessary with enteral or parenteral fluids.</p> <p>May resume treatment at a slower rate.</p> <p>Often treated with analgesia (acetaminophen- adult only) or nonsteroidal anti-inflammatory medications.</p>
Migraine Headache	<p>Delayed or late reaction. May be delayed as much as 48-72 hours following infusion associated with photophobia, nausea and vomiting, and/or other symptoms of migraine.</p>	<p>Pre-medicate with analgesia such as Acetaminophen (adult only), Aspirin, or NSAID may be required for subsequent IVIG treatments. If severe, may be treated with more intensive therapies. Notify authorized prescriber.</p>
Nausea and vomiting	<p>Common. Mild, moderate to severe. Occasional side effect.</p>	<p><b>STOP IVIG infusion and assess recipient. Maintain IV access.</b></p> <p>Report to authorized prescriber and medicate as ordered (eg. anti-emetics). If subsides, prescriber may order to resume infusion.</p>
Pain at the intravenous site		<p>Use of a large vein for infusion may avoid intravenous site pain.</p>
Fever, chills, chest discomfort, fatigue, malaise, back pain	<p>Immediate however may last up to 24 hours. Usually minor or transient. May develop in the first hour of infusion.</p> <p>Recommendation: when starting an IVIG infusion begin with a slow rate for the first 15-30 minutes and then gradually increase.</p>	<p><b>STOP IVIG infusion and assess recipient. Maintain IV access.</b></p> <p>Report to authorized prescriber and medicate as ordered. If subsides, prescriber may order to restart at a slower rate.</p>
Flushing, Pruritus, Urticaria	<p>Reactions resembling anaphylaxis. These are often rate related and often occur midway through IVIG infusion.</p> <p>If urticaria presents on several occasions, consideration is given to</p>	<p><b>STOP IVIG infusion and assess recipient.</b></p> <p>Notify authorized prescriber. Prescriber may order diphenhydramine and/ or antihistamines. Glucocorticoids may be added. If subsides, prescriber may order to restart at a slower rate.</p>

Signs and Symptoms	Reaction type/ frequency and Comments	Actions
	change to a different IVIG Brand or subcutaneous immune globulin.	
Tachycardia, chest tightness, wheezing, or dyspnea; anxiety.	Reactions resembling anaphylaxis. These are often rate related and often occur midway through IVIG infusion.	<b>Stop IVIG infusion and assess recipient.</b> Notify authorized prescriber. Treat symptoms. If subsides, prescriber may order to restart at a slower rate.
Muscle spasms		Medications, such as diazepam, may be required.
Facial and/or tongue swelling, chest tightness, airway edema, hypotension, tachycardia, nausea and vomiting, urticaria	<b>Anaphylactic Reaction.</b>  <b>Extremely rare event.</b> Symptoms become more severe upon re-exposure of the antigen.	<b>Stop IVIG infusion and assess recipient.</b> Notify authorized prescriber. Treat symptoms. May require epinephrine promptly. <b>Do Not Restart Infusion.</b>
Hemolytic Anemia	May occur due to antibodies from IVIG after an infusion. Reactions can range from direct antiglobulin (coombs test-DAT) positivity, mild extravascular hemolysis, and rarely, intravascular hemolysis.	Notify authorized prescriber.
Eczematous dermatitis	May occur days to weeks following infusion.	Notify authorized prescriber.
Reduced efficacy to vaccinations	May occur days to weeks following infusion.	Delay vaccinations if possible.
Transfusion Transmitted Infection	A theoretical risk exists however; IVIG is extremely unlikely to transmit infectious agents.	Notify authorized prescriber in the event of signs and symptoms of infection. Maintain records of brand, lot number, expiration date, and manufacturer for each dose administered.
Thromboembolic complications in at risk recipients	Additional preventative measures may be beneficial.	Pre-hydration. Use of low osmolality products. Use of antiplatelet agents. Avoid prolonged immobility post infusion (eg. airplane travel).
Acute kidney injury in at risk recipients	Monitor for hyponatremia.	Additional IV fluids before beginning IVIG to avoid hyper-viscosity. Recipients with underlying renal disease should avoid concentrated or sucrose containing products.

## Appendix B

### Intravenous Immune Globulin (IVIG) Administration Record

Date of IVIG administration: \_\_\_\_\_ Recipient weight (Kg): \_\_\_\_\_ Brand name of IVIG product: \_\_\_\_\_

Infusion Rate:

Rate increments recommended **every 30 minutes with first infusion**. For subsequent infusions gradually increase rate every 15-30 minutes, **as tolerated**, according to steps in table. For recipients who have received IVIG previously for **at least 3 doses, without incident**, the authorized prescriber may order a personalized rate and/or protocol for future infusions. For complete product information please refer to product monographs as recommended maximum infusion rates differ by product, by condition being treated, and for those at risk of thrombosis and/or renal failure.

	10% Gammagard liquid	Infusion rate/ initials	10% Gammunex & IGIVnex	Infusion rate/ initials	10% Privigen	Infusion rate/ initials	Time	Temp	Pulse	Resp	Blood Pressure	Pulse Oximetry
Initial Rate. Pre & 15 min vitals.	0.5 mL/kg/hr		0.01 mL/kg/min or 0.6 mL/kg/hr		0.3 mL/kg/hr							
Increase after 15-30 minutes	1 mL/kg/hr		0.02 mL/kg/min or 1.2 mL/kg/hr		0.6 mL/kg/hr							
Increase after 15-30 minutes	2 mL/kg/hr		0.04 mL/kg/min or 2.4 mL/kg/hr		1.2 mL/kg/hr							
Increase after 15-30 minutes	4 mL/kg/hr		0.06 mL/kg/min or 3.6 mL/kg/hr		2.4 mL/kg/hr							
Increase after 15-30 minutes	5.4 mL/kg/hr		0.08 mL/kg/min or 4.8 mL/kg/hr		3.6 mL/kg/hr							
Increase after 15-30 minutes	6 mL/kg/hr		0.10 mL/kg/min or 6.0 mL/kg/hr		4.8 mL/kg/hr							
Increase after 15-30 minutes	8 mL/kg/hr		0.12 mL/kg/min or 7.2 mL/kg/hr		6.0 mL/kg/hr							
Maximum rate			0.14 mL/kg/min or 8.4 mL/kg/hr		7.2 mL/kg/hr							

Initials	Signature	Initials	Signature	Initials	Signature