Atlantic Guideline for Subcutaneous Immune Globulin Home Administration Programs

September 2016
Prepared by the Atlantic SCIG Working Group

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1 Background

Prior to January 2009, the distribution of Subcutaneous Immune Globulin (SCIG) was limited to patients with urgent medical requirements. A comprehensive review through a joint evaluation process between Canadian Blood Services (CBS), the Canadian Agency for Drugs and Technologies in Health (CADTH), and the Provinces and Territories resulted in approving the inclusion of SCIG as a regular product within CBS’s plasma protein products portfolio. The National Advisory Committee on Blood and Blood Products (NAC) provides medical and technical advice on the utilization management of blood and blood products to the provincial and territorial Ministries of Health and CBS. In May 2008, NAC provided the following recommendations on the utilization of SCIG:

1) The use of SCIG should be restricted to immunodeficiency patients, which is the patient group in which the product has been evaluated and deemed eligible for funding.
2) There should be prospective tracking of use of the product to ensure it is being used in appropriate patients at recommended doses.
3) Adverse safety outcomes should be reported.
4) The use of SCIG should be administered through a provincial program or specialty clinic for the purposes of education, tracking, monitoring outcomes, and optimizing dosing.

Since 2003, the four Atlantic Provinces have participated in an Atlantic Blood Utilization Strategy (ABUS) with the Nova Scotia Provincial Blood Coordinating Program (NSPBCP) functioning as the secretariat. Intravenous Immune Globulin (IVIG) has been the focus of the Strategy with standardized data elements being developed, collected and submitted to the NSPBCP where analysis occurred. The analyses have lead to the recommendation, development and implementation of strategies to facilitate appropriate ordering for the most common indications for the use of IVIG. To date, the strategies include the development of Atlantic guidelines and supplementary tools for adult neurologic, hematologic and immunologic conditions and pediatric indications and incorporation of a UL-N list.

In September 2008 ABUS (Appendix A) expanded its mandate to include SCIG. The expansion involved the collection of SCIG utilization data and the development of Atlantic guidelines for SCIG. In response to the expanded mandate, the NSPBCP added SCIG data elements to the existing Atlantic IVIG Data Collection System and an Atlantic SCIG Working Group was convened to develop Atlantic guidelines for the implementation of SCIG home administration programs in hospitals across the Atlantic Provinces. These guidelines were distributed in November 2009 as a one-year pilot.

In December 2010, the Atlantic Guidelines for the Use of IVIG and SCIG in Primary Immune Deficiencies (Appendix B) was developed by the collaboration of the NSPBCP and the Atlantic Clinical Expert Primary Immune Deficiency Working Group. Feedback and recommendations from the Atlantic SCIG Working Group were then obtained from the Atlantic Guidelines for the Use of SCIG Home Administration Programs 2010. These, along with the recommendations from
the Atlantic Clinical Expert Working Group on Primary Immune Deficiency, guided the revisions to the 2012 document.

The *Atlantic Guidelines for the Use of SCIG Home Administration Programs 2016* incorporates the revisions made in the *Atlantic Guidelines for the Use of SCIG Home Administration Programs 2012*, including the revised mode of dosing IVIG/SCIG based on Dosing Body Weight (DBW).

## 2 Introduction

The Canadian Standards Association’s (CSA) Standards for Blood and Blood Components Z902-15 Home Transfusion Section 17.1.2 state “Home transfusion shall take place under a formalized program with documented operating procedures”. Even though the subcutaneous self-administration of SCIG may not be considered a typical home “transfusion” the clauses from this section of the standards will be applied to a SCIG administration program and forms many of the sections in this document. Where relevant, the text of the CSA Standards has been included.

**Note:** Reading this document is not a substitute for reading the full monograph of any SCIG product.

## 3 Eligibility Criteria

### 3.1 Clinical Criteria

SCIG is indicated for the treatment of adult and pediatric patients with immune deficiencies (primary immune deficiency and secondary immune deficiency) who require immune globulin replacement therapy.

The subcutaneous route of administration is especially beneficial for patients who:

- Require a more stable or higher trough IgG level, e.g., patients who feel fatigued prior to the next IVIG infusion.
- Require a different mode of administration of immune globulins in order to potentially decrease systemic adverse reactions with their current IVIG preparations or who have venous access issues.
- Require an improved quality of life.

The eligibility criteria, according to the CSA Standards for Blood and Blood Components Z902-15, include:
• Only recipients who have previously received a blood transfusion and who have not had an adverse transfusion reaction should be eligible to receive home transfusion (Clause 17.2.1).
• Policies and procedures shall be in place to ensure that the home environment is evaluated to confirm it is safe for transfusion (Clause 17.2.3).
• The home shall have a working telephone, and the transfusionist should have access to emergency services that can provide a rapid response at the recipient’s location (Clause 17.2.4).
• Another competent adult shall be available to assist the transfusionist for the entire period of the transfusion and to remain available to the recipient for at least 60 minutes thereafter (Clause 17.2.5).
• A physician shall be available by telephone for immediate consultation should urgent medical care be required (Clause 17.6.2).
• An operating procedure for handling potential complications shall be available (Clause 17.6.3).
• A written protocol for administration of medications shall be in place to treat adverse reactions. The medications shall be available throughout the transfusion and should only be administered as specified by a physician’s prescription (Clause 17.6.4).

With proper instruction, patients can self-administer SCIG at home. This makes it an option for patients who have a busy schedule and cannot afford the time/money to go to the hospital for their infusions; prefer to self infuse in the comfort of their home or while traveling; live far away from the infusion centers; and/or want increased flexibility in scheduling their therapy.

3.2 Contraindications

Contraindications are conditions which make a particular treatment or procedure potentially inadvisable. They often highlight the balance of risk versus the balance of a particular treatment.

The general contraindications to SCIG include the following:

• Individuals with a history of anaphylactic or severe systemic response to immunoglobulin preparations.
• Individuals with selective IgA deficiency (serum IgA less than 0.05 g/L) who have known antibody against IgA.
• Individuals with hypersensitivity to SCIG or any ingredient in the formulation or any component of the container. Refer to the product monograph for the ingredients in the formulation.
• Individuals with hyperprolinemia.
• Young children less than 1-2 years of age.
• Pregnant women.
• Nursing women.
• Individuals who have been recently vaccinated.
• Individuals with kidney disease.

Consult the most recent product monograph for current and complete contraindications relevant to the specific SCIG product.

3.3 Mode of Administration of SCIG

Although SCIG is typically administered weekly by an infusion pump, administration by a push technique may provide a greater degree of convenience. The Push Method of administration is now offered as an option in addition to the infusion by an electronic pump device.

4 Clinical Guidelines

Clinical practice guidelines are intended to help physicians and other health care professionals provide the very best care for their patients. This guideline provides recommendations on dosing, monitoring IgG levels and monitoring patient outcomes.

4.1 Dosing

The dosing of SCIG for immunodeficiencies (primary and secondary immunodeficiency) is based on dosing body weight rather than actual body weight using the dosing body weight calculator. (See Appendix B - Atlantic Guidelines for the Use of IVIG/SCIG in Primary Immune Deficiency.)

SCIG is administered at a dose of 400 to 600 mg/kg every four weeks in adult patients and 600 to 700 mg/kg every three to four weeks in pediatric patients. SCIG is given in weekly divided doses. Over time it may be necessary to adjust the dose based on serum IgG levels and clinical response. The weight-based dosing is the same for pediatric patients; however, the safety and efficacy of SCIG has not been studied in young children. For patients who are switching from IVIG to SCIG, the initial dose can be calculated based on the previous IVIG dose. Patients will require the same amount as IVIG, but divided into weekly doses.
NOTE: Administering the infusion requires the amount of product be measured in ml.

\[
\text{SCIG dose (ml)} = \frac{\text{SCIG dose (g)}}{\text{Vial concentration in g/ml}}
\]

For example, if the SCIG vial concentration is 0.2 g/ml. The following equation can be used to calculate the total volume required for a single daily dose:

\[
\text{SCIG dose (ml)} = \frac{\text{SCIG dose (g)}}{0.2 \text{ g/ml}}
\]

Sample calculation: A patient needs to infuse a 17.4 g daily dose each week. The volume in ml of SCIG that is needed for each dose would be:

\[
\text{SCIG dose (ml)} = \frac{17.4 \text{ g of SCIG}}{0.2 \text{ g/ml}} = 87 \text{ ml of SCIG}
\]

The weekly dose may be divided in daily, bi-weekly or tri-weekly doses and rounded off to minimize the wastage when Push Method is chosen for SCIG administration. For patients switching from IVIG to SCIG, the first dose is given within one week after the last IVIG dose.

Vials are available in different sizes and doses are rounded to the nearest vial size. Some dose adjustments may be required over time to achieve the intended clinical response and serum IgG level.

In-hospital and home infusion orders are completed on the SCIG Pre Printed Order Form (Appendix D1). It is recommended the dosage on Pre Printed Order Forms be reviewed periodically.

### 4.2 Monitoring of IgG Levels

A target serum IgG trough level of at least 7 g/L should be maintained. IgG levels are measured monthly at the beginning of the treatment with SCIG, but as IgG levels stabilize, monitoring can be less frequent, i.e., every five months.

### 4.3 Monitoring of Patient Outcomes

Patients must use the Patient Infusion Log Sheet for Pump Method (Appendix D2) or the Patient Home Infusion Log Sheets for Push Method (Appendix D3) to document each infusion, as well as any infections and adverse reactions.
The NSPBCP, in collaboration with the immunologists of Nova Scotia, concluded the inability to submit the infusion log sheets would result in limiting dispense of SCIG to a one week’s supply only. Each province is to follow its own policy.

It is recommended the laboratory technologists receive log sheets from the patient, verify the contents, dispense the product and then forward a copy to the responsible clinic, when applicable. Log sheets that are resubmitted by the patient with revisions or corrections shall follow the same process. Laboratory technologists are to coordinate with clinic staff to ensure both parties obtain copies of the infusion log sheets in a suitable and timely manner.

**Pediatric**
- Copies of the SCIG User Log Sheets need to be forwarded to the responsible clinic.

  **Note:** If the patient received the product from a different facility, fax log sheets to the dispensing site.

**Adult**
- Copies of the SCIG User Log Sheets are not required to be forwarded to the responsible clinic.

### 5 Funding of Home Administration

All hospitals in the Atlantic region obtain their blood and blood products from the national blood operator, Canadian Blood Service (CBS). The blood and blood products used in each province are paid for by their provincial government. As a result, patients are not required to pay for SCIG.

Each province is to follow its’ own policy for the provision of supplies to patients for use in home administration. In cases where supplies are not funded, patients will be expected to pay for their own supplies. Private insurance may cover items such as an epinephrine device. If the supplies are not provided by the facility, there could be delays in transitioning patients to SCIG.

The Syringe Driver Pump is a costly item required for the infusion. CSL Behring has a pump donation program; to inquire about this program call Customer Service at 1-866-773-7721 to obtain the local area manager’s contact information. More information about pumps can be found in Section 9 - Supplies Required for Administration.

**Supplies for the Push Method of Administration:**
- SCIG vial(s) (at room temperature)
- Patient Infusion Log Sheet
- Chlorohexidine swabs and alcohol swabs
- 18 gauge blunt fill needle(s)
- 10 ml syringe(s)
• 25G X ½” butterfly needle
• Sharps disposal container
• Gloves (if recommended)
• 2X2 gauze
• Band-aid

6 Patient Education

6.1 Qualified Patient Educators

To implement a home infusion program, a facility must have access to qualified personnel to provide the necessary patient education. Prior to delivering the initial teaching sessions, patient educators need to familiarize themselves with the teaching materials and other information such as the product monograph and Pump/Push Instruction Manual.

Only CSL Behring has a training program for patient educators. To arrange training, contact CSL Behring Customer Service at 1-866-773-7721 to obtain the contact information for the local Area Manager.

6.2 Patient Learning

Each patient will require approximately two to four sessions (1-3 hours each) to learn safe and effective self-administration in the home. To complement the instructions provided by a health care professional, a set of detailed instructions for both Push and Pump Methods have been created for patient and family use. They are to be used during education session and as a resource when at home.

To assist with patient education sessions, a Skills Checklist for Pump Method (Appendix D4) and Skills Checklist for Push Method (Appendix D5) are provided.

6.3 Patient Quick Reference Sheet

A Patient Quick Reference Sheet records the patient-specific information and contact information for issues related to the handling and administration of SCIG. Educators are to fill the required information on the sheet for patients/families. When a patient is comfortable with self administration and less reliant on the details of the education package they will refer to the Patient Quick Reference Sheet (Appendix D6).
7 Roles and Responsibilities

It is important principle health care professionals and patient/family involved in the SCIG home administration program understand their roles and responsibilities. This section provides an overview of the relationships between all those involved in the program.

7.1 Physician Roles and Responsibilities

- In compliance with CSA Standard Clause 17.1.4, SCIG intended for home transfusion shall be prescribed by a licensed physician.
- Determine patient eligibility for SCIG home infusion program based on the clinical criteria, contraindications, and the patient’s ability to comply with guidelines for administration.
- Obtain the consent for home administration of SCIG.
- Discuss with patients/families potential adverse reactions and how to manage them.
- Report the adverse reactions to BTS.
- Prepare all necessary prescriptions, i.e., epinephrine device.
- Monitor patient progress through regular follow-up assessments and serum IgG levels.
- Be available for telephone consultation to address adverse reactions occurring in the home. An alternate on-call physician can be made available for evenings, weekends, and/or holidays.
- Provide patient with a requisition or serum IgG testing at appropriate intervals as recommended in the Atlantic Guidelines for the Use of IVIG/SCIG in Primary Immune Deficiencies.

7.2 Nursing Roles and Responsibilities

The Nursing Roles and Responsibilities may be that of a single nurse or divided between a nurse educator and a clinic nurse. In some jurisdictions the nursing support is provided in partnership with Innomar Strategies and consists of a nurse case manager and a nurse educator. The nurse case manager is remote and the patients’ first point of contact for all issues regarding SCIG. The nurse educator is local and provides all training and follow up Innomar clinic visits.

- Educate patients on safe and effective self administration of SCIG. Topics include:
  - Aseptic technique and infection control
  - Pump care and use
  - Priming infusion set/removing air from the tubing
  - Site selection/catheter choice
- Subcutaneous needle/catheter insertion
- Proper storage and disposal of supplies
- Expected adverse reactions and how to address them
- Use of the patient log sheets
- Important contacts and when to use them

- Review and complete the patient agreement with the patient/family.
- Follow up technique observation (suggest one month after initial education sessions and scheduled periodically thereafter).
- Organize the provision of infusion pumps and ancillary products, e.g., tubing, syringes, swabs, etc.
- Organize clinic follow-up visits. Synchronization with pick up of SCIG at BTS, if desirable.
- Organization of all necessary prescriptions, e.g., epinephrine device.
- Document and notify the physician and Blood Transfusion Services if any adverse reactions are observed during training.
- Review and complete with the patient the Responsibility Agreement and maintain a record of the completed agreement.
- Provide a copy of confirmation and training document and Patient Responsibility Agreement Sheet to the BTS.

7.3 Blood Transfusion Services and Responsibilities

- Receive request for product.
- Verify receipt of the:
  - Current Pre-Printed Order Form,
  - Copy of the Consent Form, and
  - Copy of the Skills Checklist (unavailable if the request is for the training dose).
- Order product from CBS.
- Complete the Issuing Form (Appendix D9) when the product arrives with patient’s details, lot number, number of boxes, volume per box, and expiry date.
- At time of dispense, receive and review Patient Infusion Log Sheet for completeness and adverse reactions.
- Review Home Fridge Temperature Log Sheet, (Appendix D11), if required.
- Issue the product in the puncture proof transport container provided by the patient and have the patient sign the Issuing Form.
  - In the event a Nova Scotian patient does not bring their log sheets to Blood Transfusion Services at the time of dispense, the dispensing BTS will restrict the dispensing of SCIG to a one week supply. Upon submission of the log sheets the remainder of the product will be dispensed. Each province should follow its own policy.
• Report any adverse events according to the provincial reporting standard.
• Log sheet data to be entered into Intravenous Immunoglobulin Network (IVIN).
• File *Issuing Form* along with the log sheets.
• If necessary, validate a thermometer for patient/family use in monitoring the temperature of the refrigerator used to store SCIG.

7.4 **Patient Roles and Responsibilities**

• Complete home infusion training and demonstrate self-administration until competency is established.
• Undergo periodic reassessment regarding the infusion technique as per established review schedule or based on needs during subsequent follow-up.
• Follow the instructions for home infusion as per the patient education materials or the written modified program provided by the nurse educator.
• Contact the nurse educator when questions regarding supplies or the home infusion process arise.
• Maintain and dispose of equipment, as instructed.
• Perform home infusion in a safe and clean environment.
• Administer doses on the schedule determined by the physician.
• Ensure an adult, who is not undergoing the infusion, is present for the duration of the infusion and for 60 minutes following the completion of the infusion.
• Complete a *Patient Infusion Log Sheet* for each infusion and submit a copy to BTS.
• Document all adverse reactions on the *Patient Infusion Log Sheet*. Any adverse reactions that require emergency medical attention should be reported to the patient’s physician before administering any further doses. **Do not** call a nurse educator to report or seek advice concerning clinical symptoms or reactions to infusions.
• Notify BTS one week prior to needing subsequent dose.
• Transport and store SCIG according to the instructions provided.
• Obtain a validated thermometer if you are planning to refrigerate the product at home and complete *Home Fridge Temperature Log Sheets*.
• Attend all scheduled clinic appointments.
• Have a clear understanding of the risks associated with administration of SCIG outside the hospital environment.
• If hospitalized, leave home product at home. If required, product will be dispensed from the BTS.
8 Consent for Home Infusion

According to CSA Standard 17.3.1 and 17.3.2 respectively, “Informed consent shall be obtained before starting home transfusion. This should be the responsibility of the recipient’s physician. The informed consent shall be documented. Recipients shall be made aware that transfusion in the home is associated with additional risk”.

Consent for treatment with SCIG shall cover the items from the CSA Standard 11.2.1 which states “An operating procedure shall be in place for obtaining informed consent of the recipient prior to the transfusion of blood components or the administration of blood products. Information given to the recipient shall include:

• a description of the blood or blood components;
• the associated risks and benefits, including life-threatening risks; and
• alternatives, if appropriate to clinical circumstances, including benefits and risks.”

Facilities should use a consent form that has been approved by legal counsel in the respective health district or region. The consent form does not need to be specific to SCIG or home infusion as long as the points listed in Table 1 are addressed in the conversation between patient/family and physician. A sample Transfusion Consent Form is provided for both Pump Method and Push Method. This sample form was developed by the NSPBCP with advice from legal counsel at the Nova Scotia Department of Health and Wellness.

In addition to consent, the Patient Responsibility Agreement described in the Safety and Adverse Events section below shall be completed.

Table 1: Points to be Addressed When Obtaining Consent for Treatment with SCIG

<table>
<thead>
<tr>
<th>Points to be Addressed When Obtaining Consent for Treatment with SCIG</th>
</tr>
</thead>
<tbody>
<tr>
<td>• SCIG is derived from human plasma and, even though all donors are carefully screened by medical history and sensitive laboratory tests, and the manufacturing process includes viral removal and inactivation steps. These measures cannot completely eliminate the risk of infection or other adverse reactions including serious injury and/or death.</td>
</tr>
<tr>
<td>• Post-marketing surveillance of SCIG use has shown rare cases of the following adverse events:</td>
</tr>
<tr>
<td>- Allergic reactions including a fall in blood pressure, dyspnea, cutaneous reactions in isolated cases reaching as far as anaphylactic shock, even when patients have shown no hypersensitivity to previous administration.</td>
</tr>
<tr>
<td>- Generalized reactions such as chills, fever, headache, malaise, nausea, vomiting, arthralgia, and moderate back pain.</td>
</tr>
<tr>
<td>- Cardiovascular reactions particularly if the product is inadvertently infused intravascularly.</td>
</tr>
<tr>
<td>- Local reactions at the injection site or infusion site, such as swelling, soreness, redness, induration, local heat, itching, bruising or rash.</td>
</tr>
</tbody>
</table>
Administration of SCIG in the home is associated with additional risk related to the absence of health care professionals along with the absence of the assessments and treatments they provide related to adverse reactions.

9 Supplies Required for Administration

There are two methods of SCIG transfusion 1) Pump Method and 2) Push Method. A physician will determine what method is best for the patient. For the Pump Method, one of the more costly items required for the infusion is the pump. The patient instructions that accompany these guidelines are based around the use of the EMED SCIG 60 Smiths Medical Graseby MS 16A Hourly Rate Syringe Driver. This pump is covered with a life time limited warranty under normal use. Provinces can decide if the EMED SCIG 60 Graseby syringe driver or a different type of pump should be used based on their particular needs. The freedom 60 syringe driver pump is presently being used with numerous pediatric patients but all future pediatric patients will now be trained on the new EMED SCIG 60 home infusion pump which will be used along with all the EMED subcutaneous infusion sets. The Freedom 60 pump is no longer available to order. The detailed information of EMED SCIG 60 pump can be found at http://emedicaldevices.com/scig60-infusion-system-demo.shtml.

The following should be considered when selecting a pump:

- Capable of accommodating a rate of delivery in milliliters per hour (approximately 20 ml/hr required). A syringe driver style pump may have the rate of delivery in mm/hr but can be converted from ml/hr based on the ml/mm of the syringe to be used.
- Capable of delivering a large enough dose (15 ml per injection site is recommended and multiple sites can be infused simultaneously when multi-needle infusion tubing is used).
- Easy for patients to set up and operate.
- Lightweight and portable.
- Suitable for use in the home setting.
- CSL Behring is the only SCIG manufacturer with a pump donation program. Contact 1-866-773-7721 to obtain the name and contact information of the local area manager.

Facilities should consider having one or more spare syringe drivers or pumps available to lend to patients in the event there is a problem with a patient-owned device.

Several other items are required for infusion of SCIG. The following is the list of suggested supplies required for both Pumps and Push Methods:

- Puncture proof transportation container (for carrying SCIG from hospital to the home).
- Validated fridge thermometer (in case planning to store in the fridge).
• Epinephrine device (for possible anaphylactic reactions).
• Syringes (for syringe driver).
• Alcohol swabs (for disinfecting the rubber stoppers of the vials).
• Antiseptic-treated wipe (for preparing administration sites).
• Adhesive tape (for holding tubing in place during administration).
• Transparent dressings (for topical anesthetic and subcutaneous needle).
• Transfer (fill) needles, 18 gauge, 1 inch, blunt (for drawing SCIG from the vials into syringes).
• Topical anesthetic (for preparing administration sites).
• Biohazard sharps container (large size) (for disposal of items after administration) – check local drugstores for sharps exchange programs.
• Multi-needle subcutaneous infusion set (e.g. Trifurcated 36” MCT1360924G 9mm needle 24 gauge, wing set) for administration.
  - Needle gauges of less than or equal to 25 are recommended to minimize resistance when product travels through the bore of the needle.
  - Choice of needle length will depend on the subcutaneous tissue available:
    o For children, lengths of 6–9 mm are recommended
    o For adults, lengths of 9–12 mm are recommended
  - Validated thermometer, if required.

10 Safety and Adverse Events

The recipient’s vital signs are monitored and documented (CSA Standard 17.6.1). Based on current practice with other self-administered blood products, such as clotting factors, self-monitoring of vital signs by the patient or family is not required. The first infusion should occur in the hospital to monitor for anaphylaxis. For infusions occurring outside the hospital, patients are required to have an epinephrine device.

Please refer to the SCIG product monograph for current and complete safety and adverse events information.

10.1 Responsibility Agreement

To reinforce the importance of safety, patients are to complete the Responsibility Agreement. This provides a list of the responsibilities required for self-administering SCIG in a safe and effective manner, and a responsibility waiver for the hospital and staff in the event there is an adverse outcome related to administration (Appendix D8).
10.2 Reaction Documentation and Reporting

Patients are to document all reactions to SCIG using the Patient Infusion Log Sheets, regardless of the severity. The PDF version can also be given to patients so they may print more copies if required.

A severe reaction, such as anaphylaxis, is to be reported immediately to the patient’s physician or the on-call immunologist and BTS. Laboratory technologist staffs are to report all reactions according to their provincial reporting standard. Each province is to follow its’ own policy. Laboratory technologists are to coordinate with clinic staff to ensure both parties receive copies of the Patient Infusion Log Sheets in a suitable and timely manner. Only pediatric population should be forwarded to the responsible clinic. Log sheets that are resubmitted by the patient with revisions or corrections should follow the same process.

10.3 Safe Disposal of Waste

All items that come into contact with SCIG during the preparation and administration of the infusion are to be disposed in a large biohazard sharps container. These include: syringes, needles, administration sets, and vials. The disposal items must not be placed in garbage, recycling bags, flushed down the toilet, or burned. Opened vials must be discarded even if they contain residual product.

Sharp container exchange programs may be available at local drug stores. If an exchange program is not available, patients are to purchase their own biohazard sharps containers. Contact the local municipality or public health unit for proper method for disposal.

During transportation, care must be taken to ensure the lid is securely sealed on filled containers. Containers must not be filled beyond the manufacturer’s full line mark.

11 Product Issuing and Tracking

Patients are to call BTS to make arrangements for issuing each batch of SCIG. A time frame shall be agreed upon to ensure enough lead time between the date of the call and the date the product is required for infusion. It is suggested to coincide the date of issuing with clinic appointments.

To simplify transportation and storage of SCIG, issuing of product should occur only once or twice a month at the outset. The issuing interval may later be increased according to the comfort level of both BTS and the patient/family.
Traceability of product is very important and can be maintained using an *Issuing Form* along with the *Patient Infusion Log Sheet*.

As described in Section 10.2 - Reaction Documentation and Reporting, laboratory technologist staff are to obtain *Patient Infusion Log Sheets* before dispensing the product. They are to receive the log sheets from the patient, verify the contents, and then dispense the product. Log sheets that are resubmitted by the patient with revisions or corrections will be accepted in the same way. In Nova Scotia, the NSPBCP in collaboration with the immunologists of Nova Scotia, concluded the inability to obtain the *Patient Infusion Log Sheets* at the time of dispense will restrict the dispensing of SCIG to one week’s supply. Each province is to follow its’ own policy.

Each time product is dispensed, an *Issuing Form* will be completed and copies of the *Patient Infusion Log Sheets* for the infusions since the previous dispense should be collected. Patients may be asked to fax their log sheets on a more frequent basis, if desired. Copies of the log sheets shall be retained at BTS and the relevant information will be entered into the blood bank information system. Infusion dates shall be documented for utilization reporting purposes (*Section 13 - SCIG Utilization Reporting*).

For pediatric patients, laboratory technologists are to coordinate with clinic staff to ensure both parties obtain copies of the log sheets in a suitable and timely manner (not applicable for adult patients). It is the responsibility of BTS staff to obtain the log sheets from the patient, verify content and share a copy with the pediatric clinic.

It is important patients record the SCIG lot numbers from each vial used on the *Patient Infusion Log Sheet*. If the product is stored in the refrigerator, *Home Fridge Temperature Log Sheets* (Appendix D11) shall also be verified for completion and required temperatures before dispensing additional product. Storage information for SCIG in refrigerator is available in Appendices D10.

A copy of the physician’s order for SCIG shall be kept in BTS and patients should only be provided with the prescribed amount. Expired, broken, or spoiled product will only be replaced if the original vials are returned. Any discards will be documented on the same issuing form which documents the issue of the discarded vial(s).

### 12 Transportation and Storage

Clause 17.5 of the CSA Standards states “*The transportation procedure shall ensure that components will remain at the required conditions until time of transfusion.*”

The most commonly used product Hizentra® can be stored for 30 months at room temperature of up to 25°C. With this allowance for room temperature storage, patients/families may transport and
store SCIG without the use of refrigeration; as long as there is no chance the home temperatures will exceed 25°C for any vials. If another SCIG is product is used, follow the storage and transportation guidelines from its product monograph.

The vials of SCIG must be protected during transportation and storage. It is recommended to transport product in a puncture proof plastic container. The transport container should not be used for any other purpose than for transporting SCIG.

Care must be taken to ensure storage temperature does not exceed +25 °C. Vials must be kept away from direct sunlight, heaters, and any other heat sources.

13 SCIG Utilization Reporting

Utilization of SCIG is to be reported by BTS staff using the existing IVIG data collection tools. SCIG data is entered in the same manner as IVIG except SCIG is selected for Type of Ig. Doses are reported based on dates of infusion and not the dates of issue. SCIG discards are reported in the discards section of the IVIG data collection tool.

14 Patient Relocation

A patient may receive his/her teaching and first doses at one hospital (referring facility), then move to another location (target facility) for the remainder of the course of treatment. Other relocation situations include: patients moving from one province or territory to another, for a vacation or other purpose, possibly long term in nature; or patients visiting a province or territory from another country.

Follow-up requires coordination between the health care professionals in each jurisdiction (province, territory). Early identification and communication are the important elements of such a transition. Table 2 shows the process steps required for a patient relocation.

Table 2: Patient Relocation Process

<table>
<thead>
<tr>
<th>Steps</th>
<th>Most Responsible Persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiate contact with the target facility through the target physician who will be taking over the care of the patient.</td>
<td>Referring Physician</td>
</tr>
<tr>
<td>Notify nursing and laboratory transfusion service staff at the target facility; identify status of facility regarding use of the product.</td>
<td>Target Physician</td>
</tr>
</tbody>
</table>
Facilities unfamiliar with the product need additional support and documentation in order to establish protocols.

<table>
<thead>
<tr>
<th>Prepare for receiving patient by obtaining and reviewing specific information on the treatment and follow up, and patient’s training status for using product</th>
<th>Target Physician Referring Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepare for receiving patient by reviewing procedures for product ordering, issuing, storage and any other relevant details specific to the patient.</td>
<td>Referring Facility Nursing Staff Target Facility Nursing Staff</td>
</tr>
<tr>
<td>Relevant documents should also be obtained and transferred. Consent documents and infusion logs are examples of relevant documents.</td>
<td>Laboratory Transfusion Service Staff</td>
</tr>
<tr>
<td>Staff at the target facility may also wish to consider arranging an education session provided by the manufacturer of the SCIG product.</td>
<td>Target Facility Nursing Laboratory Staff</td>
</tr>
</tbody>
</table>

15 **References**


2. CSL Behring Canada. (2016) [Hizentra Product Monograph](#). Ottawa, ON.

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Appendix B  Atlantic Guidelines for the Use of IVIG/SCIG in Primary Immune Deficiencies

The guidelines presented in this document are based on those authored by the NAC in 2010 and were modified and ratified for use in the Atlantic Provinces by the Atlantic IVIG Clinical Expert Working Group-Primary Immune Deficiency in December 2010.

1. Start IVIG at a dose of 400 to 600 mg/kg every 4 weeks in adult patients and 600 to 700 mg/kg every 3 to 4 weeks in pediatric patients. SCIG is given in weekly divided doses.

   Note: With respect to clinical efficacy for reducing infections, IVIG and SCIG preparations should be considered equivalent. For patients previously receiving IVIG, the SCIG dose should normally be equivalent to the IVIG dose the patient was receiving, i.e. 1:1.

Clinical considerations: If there is bronchiectasis, dose and frequency of IG may be increased. Dosage of IG should be adjusted to prevent unnecessary wastage.

2. Patients with primary immune deficiency should be monitored by an expert in the treatment of patients with primary immune deficiency at least annually.

3. Aim to achieve a minimum IgG trough level of 7g/L in most patients.

4. Monitor IgG trough levels every 5 months in growing and in adult patients.

   Clinical considerations: The IgG trough generally stabilizes after 3 to 4 months of treatment with IVIG. After this time, regular monitoring of IgG trough levels allows adjustment of immunoglobulin dosage. Measurement of IgG trough levels may be necessary between regularly scheduled monitoring if the clinical situation changes.

5. The following conditions should prompt re-evaluation of the IG dosage regimen before the annual visit:
   A. Any severe infection.
   B. Lack of expected reduction in frequency or severity of infection.
   C. Continued failure to thrive in pediatric patients.
   D. Development of autoimmune complications.

   Clinical considerations: Clinical judgment should be used as there may be other situations that would prompt reevaluation.

6. To minimize rate-related reactions, follow product specifications.
**Clinical considerations:** As patients tolerate different rates of IG administration, adjust rates individually to optimize the rate of infusion. Reducing the rate of infusion often ameliorates rate-related reactions.
### Appendix C  Guide to Acronyms and Abbreviations

The following is a list of the acronyms and abbreviations used in the text of this document:

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABUS</td>
<td>Atlantic Blood Utilization Strategy</td>
</tr>
<tr>
<td>CBS</td>
<td>Canadian Blood Services</td>
</tr>
<tr>
<td>CSA</td>
<td>Canadian Standards Association</td>
</tr>
<tr>
<td>IVIG</td>
<td>Intravenous Immunoglobulin</td>
</tr>
<tr>
<td>NAC</td>
<td>National Advisory Committee on Blood and Blood Products</td>
</tr>
<tr>
<td>NSPBCP</td>
<td>Nova Scotia Provincial Blood Coordinating Program</td>
</tr>
<tr>
<td>PID</td>
<td>Primary Immune Deficiency</td>
</tr>
<tr>
<td>SCIG</td>
<td>Subcutaneous Immunoglobulin</td>
</tr>
<tr>
<td>SID</td>
<td>Secondary Immune Deficiency</td>
</tr>
</tbody>
</table>
Subcutaneous Immunoglobulin (SCIG) Patient Teaching Guide for Self Administration Using A Syringe Driver (PUMP)
What is SCIG?

SCIG is a blood product used to treat adults and children with immune deficiency conditions.
What are Immune Deficiencies?

*Primary Immune deficiencies (PID)* include a variety of disorders in which there is an intrinsic defect in the immune system that renders patients more susceptible to infections.

*Secondary Immune deficiencies (SID)* are a group of conditions caused by other factors than Primary/genetic causes, such as diseases, malignancies or medications, which result in low antibody levels rendering the patient susceptible to infections.

SCIG product replaces the antibodies that are missing or defective. It is called antibody replacement therapy.

- This treatment supports the prevention and treatment of infections.
SCIG Contraindications

*Allergic Reactions* - SCIG should be avoided in persons with a history of severe allergic reactions to immunoglobulin treatment.

*IgA Deficiency* - SCIG should be avoided in persons with selective IgA deficiency who are known to have antibodies against IgA.

Hyperprolinemia
The Ingredients of the Product:

SCIG is made from human plasma and is a highly purified product. It contains immunoglobulin G (IgG), an antibody normally found in the blood of healthy people.

IgG helps the body fight disease and infections.

The other important non medical ingredients in SCIG products include L Proline
Serious Warnings and Precautions

SCIG is a product made from donated plasma which is treated to reduce the risk of it containing infectious agents, but there is still a small possibility it could transmit disease.

Human Immune Globulin products have been associated with the following:

- aseptic meningitis syndrome
- renal dysfunction
- anemia (hemolysis, hemolytic)
- TRALI (transfusion-related acute lung injury)
- thrombo-embolism

**NOTE:** Risk factors in thrombotic event are pre-existing cardiovascular disorders, prior thrombotic event, obesity, oral estrogen use, hyperlipoproteinemia, in-dwelling catheter, immobility, hyperviscosity from any cause including dehydration, hypercoagulable disorders, and multiple cardiac risk factors. **Inform your physician if you have any such risk factor.**

**Interactions** SCIG should not be mixed with any other products.
What Happens If I Miss A Dose?

• Use the missed dose as soon as you remember, and dose weekly from there. If a certain daily schedule is more convenient, then you can modify the schedule to dose every 6 or 8 days to get you back on schedule.

• Skip the missed dose if it is less than 48h from your next scheduled dose.
What Should I Avoid While Using SCIG?

When you are on SCIG and receive a “live” vaccine, the vaccine may not work as well during this time, and may not fully protect you from disease.

Live vaccines include measles, mumps, rubella (MMR), oral polio, chickenpox (varicella), BCG (Bacillus Calmette and Guérin), and nasal flu vaccine.

Inform the doctor who is giving you the vaccine of recent treatments with SCIG so that appropriate precautions can be taken.
Transporting and Storing SCIG

SCIG can be transported and stored at room temperature.

Care must be taken to protect the vials of SCIG during transportation.

- A puncture-proof plastic container such as a hard-sided cooler or plastic storage bin is recommended.

- The transport container should not be used for any other purpose than for transporting SCIG.

- During transport, the container should be kept in the passenger compartment of the car to avoid extreme heat or cold that can occur in the trunk.

- Care must be taken to ensure temperature does not exceed +25 °C. Vials must be kept away from direct sunlight, heaters and any other heat sources.
Transporting and Storing SCIG

- Home fridge storage is only necessary if there is a chance the home temperature may exceed 25°C. When stored at room temperature (up to 25°C), Hizentra (the most commonly used SCIG product) is stable for up to 30 months, as indicated by the expiration date printed on the outer carton and vial labels.
  - If storing in the fridge temperature log and thermometer is required to ensure consistent temperature.

Proceed directly home with the transportation container containing SCIG.
How to Infuse SCIG

SCIG is given as an injection under the skin (subcutaneously).

SCIG must not be given into a blood vessel (vein or artery) as it is not known if this is safe.

If you experience a serious allergic reaction at any time, STOP the infusion of SCIG and contact your doctor or an emergency health care professional immediately.
Safety Requirements

Safety requirements related to self-administering SCIG are as follows:

• The home (or any administration location) must be clean and safe.

• The home (or any administration location) must have a working telephone, and there must be access to rapidly available emergency assistance, e.g. 911.

• A competent adult should be available to assist the recipient for the entire period of the administration and should remain available to the recipient for at least 60 minutes after administration has been completed.

• An epinephrine device should be available during all infusions administered outside the hospital.
Instructions for Administering SCIG

Patient name: ___________________________
Your weekly dose of SCIG is: _____ml every ______.
You will use _____ vials for each dose.
Each dose is given over _____ minutes.
You will use _____ injection sites for each dose.
The maximum volume for each injection site is _____ ml as directed by your health care provider.
Step 1: Gather Your Supplies

On a clean table, gather all the supplies:

- SCIG vial(s) (at room temperature)
- Infusion Log Sheet
- Syringe driver
- Administration set _____
- Alcohol swabs
- Antiseptic skin preps
- _____ syringe(s), size _____
- _____ needles(s), size _____
- Transparent or gauze dressing(s)
- Tape
- Sharps disposal container
- Gloves (if recommended)
Step 3: Wash and Dry Your Hands

Wash and dry your hands thoroughly prior to preparing your SCIG infusion.
Step 4: Inspect Each Vial of SCIG

Check each vial of SCIG for any discoloration or presence of particles in the solution by gently turning the vial (do not shake).

If the solution is cloudy, has particles in it, or if the cap is missing, do not use it. Keep it and return it to the hospital when you go to pick up more product.

Check the expiry date on each vial. Do not use past the expiry date. Call ____________ for a replacement.
Step 5: Prepare the Vial

Remove the cap from the vial(s).

Disinfect the rubber stopper by wiping it with an alcohol swab.

Let it dry.
Be careful not to shake the vial(s).
Step 6: Prepare the Syringe and Needle

- You will need ___ size ___ syringe(s).
- You will need ___ needle(s).
- Open the syringe and needle packages. Do not touch the ends where they will connect.
- Attach the needle to the syringe by pushing them together and turning until snug.
- Repeat these steps if you need to fill more than one syringe.
Step 7: Inject Air into the Vials

- Pull the syringe plunger back to draw ____ ml of air into the syringe.

- Remove the cap from the needle. Do not touch the needle.

- Insert the needle into the center of the stopper of SCIG vial, but not all the way into the solution.

- Inject the air into the vial by pushing down on the plunger but avoid injecting any air into the solution. (Holding the vial horizontally may help). Keep pressure on the plunger so air stays in the vial.
Step 8: Fill the Syringe

• Leaving the needle in the vial, carefully turn the vial upside down.

• Draw the solution into the syringe and remove the needle from the vial.

• Draw the solution from each of your other vials into the syringe as directed.
Step 8 (continued): Fill the Syringe

• Remove any large air bubbles by tapping the syringe and pushing on the plunger. Be careful not to waste any solution.

• When you have finished filling this syringe, carefully recap your needle and put the filled syringe on your clean table.

• If you use more than one syringe, follow the same steps to fill the next syringe.

• Remove the capped needle from the first syringe and discard into a sharps disposal container.
Step 9a: The following instructions are specifically for the EMED SCIg 60 Syringe Driver (pump). Please refer to the brochure if using Grasbey or any other syringe driver.

- Ensure you load SCIg into a 60 mL syringe when using the SCIg60 pump.
- When syringe is filled with product connect syringe male luer lock to infuset female luer lock (step 1).
- Connect male luer lock to patient administration set female luer lock (step 2).
- Prime tubing gently pushing on the syringe plunger to fill the tubing with SCIg.
- Use slide clamp provided to prevent flow of SCIg (step 3).
- Open SCIg60 Infuser driver by turning the handle counterclockwise until it stops (step 4).
- Load syringe into SCI60 Infuser by inserting the syringe plunger into the SCIg60 infuser.
Step 9b: Priming a Multi-Site Set

If you are using an administration set with more than one tubing (lumen) for use with multiple sites:

• Attach the filled syringe to the end of the administration set.

• Close the clamps on all lumens, except the one you want to prime.

• Gently push on the syringe plunger until you see the solution approaching the inner part of the first needle. Close the clamp.

• Open the clamp on the 2nd lumen. Prime with solution. Close the clamp.

Repeat these steps for all other lumens.
Step 10: Select Injection Site(s)

- You will need to use ____ injection sites.

- Select injection site(s) from these areas:
  - Abdomen
  - Thighs (outer or inner)
  - Upper arms
  - Hip

Follow your healthcare providers advice on how often you should change or rotate your sites.
Step 11: Prepare Injection Site(s)

- Clean the site(s) with antiseptic skin prep(s).
- Start cleaning at the center of the site and work outward to cover a circle of about 4 inches.
- Let the sites dry.
- If using more than one site, make sure each site is at least two inches apart.
Step 12: Insert the Needle(s)

- Insert the butterfly needle at either a $45^\circ$ or $90^\circ$ angle.
- Pinch the skin where you are to put the needle in.
- Insert the needle using “pinch an inch” technique, as directed.
- Insert the needle into the fatty tissue under the skin as directed.
Step 13: Check for Correct Placement

After you insert a needle, you must check that the needle has not gone into a blood vessel:

1. Open the clamp.
2. Gently pull back on the syringe plunger.
3. Look to see if any blood is flowing back into the administration set.

If you do not see blood, go to step 14.

If you see any blood, remove the needle and discard the administration set. Then repeat steps 9-13 using a new administration set and a new injection site.
Step 14: Securing Each Needle to the Skin

Cover the needle with transparent dressing or gauze and tape it in place.
Step 15: Load Pump

Lock syringe into SCIg infuser by turning the syringe 90 in either direction until you feel a click.

Verify the syringe flange is in the window of the SCIg 60 infuser to confirm the syringe is properly locked in place.

Close the infuser by turning the handle until it stops.

Use slide clamp to start infusion once infuser is fully loaded and the needle is inserted and secure.

Use slide clamp to stop flow as necessary during the infusion or when the session is complete.
Step 16: Infusing the SCIG

Your syringe of SCIG will take _____ minutes to infuse.

Your total dose will take _____ minutes.

While Infusing, check that:

- The set is on a flat surface and the pump is running,
- The solution appears to be going at the right rate.

When the syringe is empty:

Close clamp(s)

Remove the syringe from the pump.

Connect the next filled syringe to your administration set.

**OR**

Prepare a new administration set (follow your directions).

Open clamp to begin infusion.
Step 17: Stopping the Pump

The syringe driver will automatically stop when the syringe is empty.

When session is complete, remove the 60mL syringe by rotating the handle counterclockwise until it stops. Then unlock the syringe by turning it 90 in either direction.

Dispose of the syringe and infusion line as appropriate.
Step 18a: Following the Infusion

When your treatment has finished, leave the needle(s) in place for about 1 minute before removing.

Apply pressure to site with gauze.

Cover your injection site(s) with gauze or __________.
Step 18b: Following the Infusion

- Discard all preparation and administration equipment in a large biohazard sharps disposal container.

- Once opened even by mistake SCIG cannot be saved. Discard it in the biohazard sharps disposal container.

- Report the discard (if any) in patient infusion log sheet Appendix D2 for pump.

- Sharps containers are available from various sharps exchange programs. Your health care provider will tell you about the options in your area.

- Ensure to keep product and Sharps container away from children.

- Store pump as directed.
Notes on Sharps Containers

Items for disposal should only be placed in a biohazard sharps container. The items must not be placed in garbage or recycling bags and must not be flushed down the toilet or burned.

Use a LARGE size sharps container and do not fill beyond the manufacturer’s full line.

During transportation, care must be taken to ensure the lid is securely sealed on filled containers.
Step 19: Record the Infusion

On your Infusion Log Sheet you must:

- Record the date and time of the infusion.
- Record the exact dose of your infusion.
- Record the lot number and expiration date from the vials used.
- Record any reactions that occurred as a result of the SCIG infusion.
- Record discards if any.
- Fill in all the other sections according to the instructions from your healthcare provider.

Provide ALL your completed log sheets to Blood transfusion Service (BTS) when picking up subsequent product. They will forward copies of your log sheets to the physicians if needed. Failure to return completed sheets will result in less product being supplied by BTS.
Managing the Side Effects of SCIG
Anaphylaxis

Although **rare** in occurrence, anaphylaxis is the most severe potential reaction that can occur as a result of infusing SCIG.

It is a life-threatening allergic reaction that affects many areas of the body. Anaphylaxis can lead to death in a matter of minutes if left untreated.

Symptoms of an anaphylactic reaction, as well as instructions for *when* to give epinephrine, are listed in the following table.

Note that during an anaphylactic reaction, not all symptoms may occur.

Your doctor may prescribe for you an epinephrine injection device, you should have it available when infusing SCIG and ensure the device has not expired.

**Expiry date of current injection device: ______________**

*Early recognition of symptoms and immediate treatment could save a person’s life. Delay in treatment could cause a more severe anaphylaxis episode. When in doubt, treat with epinephrine.*
### Symptoms of an Anaphylactic Reaction

<table>
<thead>
<tr>
<th>Body Region</th>
<th>Symptoms [Note that during a reaction not all symptoms may occur]</th>
<th>Should You Give Epinephrine?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face/Head</td>
<td>Redness, itchy eyes/nose, swelling of eyes, runny nose, sneezing</td>
<td>If symptoms are severe</td>
</tr>
<tr>
<td></td>
<td>Swelling of lips and tongue, itchy mouth or tongue</td>
<td>Yes</td>
</tr>
<tr>
<td>Skin</td>
<td>Itching, redness, warmth, hives, rash or swelling in areas other than infusion sites.</td>
<td>If symptoms are severe</td>
</tr>
<tr>
<td>Throat</td>
<td>Itching, tightness, hoarse voice, hacking cough, trouble swallowing, trouble speaking, choking</td>
<td>Yes</td>
</tr>
<tr>
<td>Lungs</td>
<td>Trouble breathing, shortness of breath, repeating cough, wheezing</td>
<td>Yes</td>
</tr>
<tr>
<td>Stomach</td>
<td>Nausea, vomiting, stomach pain or cramps, diarrhea</td>
<td>If symptoms are severe</td>
</tr>
<tr>
<td>General</td>
<td>Dizziness, unsteadiness, drowsiness, sense of doom, feeling faint or fainting</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Epinephrine Devices

Epinephrine is a life-saving treatment and is the antidote for anaphylaxis.

There is one common type of epinephrine devices:

• Epi Pen®

Techniques on using this device should be reviewed regularly. Instructions are available on DVDs and websites. Instructions are also found directly on the devices themselves.

This device can be used through clothing.
How to Use Epi Pen®

Remove the device from its carrying case.

Grasp the Epi Pen® with the black tip pointing downward.

Pull off the grey safety cap.

Place the BLACK tip against the mid-outer thigh and press firmly until the Epi Pen® activates.

This device can be used through clothing.

Hold while counting for 10 seconds, then remove.
After Epinephrine is Given

Call 911 and tell them someone is having a life-threatening allergic reaction. Ask them to send an ambulance immediately.

You must have medical attention and monitoring if epinephrine is given, even if symptoms have improved.

How to Dispose of Epinephrine Device

Carefully place the used auto-injector (needle end first) into the storage tube.

Screw the cap of the carrying case on completely.

This automatically bends the needle back and secures the pen so it won’t fall out of the tube.

Give any used auto-injectors to emergency responders or emergency room personnel.
Trouble Shooting Subcutaneous Administration of Immunoglobulin

| Leaking                                                                 | • Check connections between tubing and syringe.  
|                                                                       | • Is the butterfly needle inserted properly.     
|                                                                       | • Volume administered too quickly therefore leaking at the site. |
| Insertion site: reaction                                              | • Volume administered too quickly.                
| Redness                                                               | • Decrease the volume and spread over a longer period of time. |
| Swelling                                                              | • Apply cold compress or ice cube to the area before administering subcutaneous immunoglobulin. |
| Itchiness                                                             | • Apply warm compress to the area before administering subcutaneous immunoglobulin. |
|                                                                       | • If taping the needle down, you could be getting a reaction to the tape. |
|                                                                       | • Did any immunoglobulin get on the needle while flushing the tubing? (Use 2X2 gauze to wipe off the needle). |
|                                                                       | • After cleaning the skin wait a min or two then administer the immunoglobulin. The area should be dry prior to puncturing the site. |
|                                                                       | • Rotate the sites regularly.                     |
| Needle Discomfort                                                     | • Needle length too long.                        |
|                                                                       | • Rotate sites regularly.                        |
|                                                                       | • Apply warm compress to the area before administering subcutaneous immunoglobulin. |
|                                                                       | • Apply cold compress or ice cube to the area before administering subcutaneous immunoglobulin. |
| Blood in tubing                                                       | • Discard butterfly needle and start over.       |
## Other Reactions to SCIG Signs and Symptoms

<table>
<thead>
<tr>
<th>Site Reaction</th>
<th>Non-pharmacological interventions</th>
</tr>
</thead>
</table>
| **Itching**   | • Slow down on the infusion  
• Needle in correctly  
• Apply cold compress  
• Ensure you are rotating the sites  
• When priming the needle, do not allow excess SCIG droplets on outside of the needle |
| **Redness**   | • Slow down the infusion  
• Apply cold compress |
| **Burning**   | • Stop infusion for 5–10 minutes then restart  
• Slow the infusion down  
• Cold compress  
• Gentle massage  
• Change site |
| **Swelling**  | • Warm compress for 5-10 minutes |
| **Urticaria (hives)** | • Stop SCIG  
• Seek medical attention  
• Determine with physician if treatment should continue |
| **Discomfort** | • Slow infusion  
• If intolerable pain – may be in muscle, remove catheter  
• Once needle removed, warm compress and gentle message |
Injection Site Reaction

Mild

Moderate
Injection Site Reaction

Injection site reactions can be identified by what is usually mild to moderate redness, swelling, discomfort, and itching.

This is a normal and common reaction which should fade over 24 – 48 hours.

Reactions tend to decrease with subsequent infusions.

Keep a record of any injection site reactions on your Infusion Log Sheet.

Your physician can recommend ways to lessen discomfort related to injection site reactions.
Injection Site Reaction (Cont.)

Use of ice during administration or dividing dose between abdomen and thighs can lessen the discomfort.

If the injection site reactions are severe or if you are concerned about them, call your doctor or nurse using the contact information provided.

If itchiness persists you can consult your physician.
Other Common Reactions

There are some other common reactions that can occur related to the administration of SCIG. If any of these occur, make a note on your log sheet:

- **Headache:** Some patients get headaches in the beginning, but they decreased after some time. You could take Tylenol 1-2 tablets orally every 4-6 hours, may last two to three days. The headache could also be triggered by stress or stressors (i.e. anxiety, tension).

- If your headache is prolonged contact the clinic.

- **Fever and/or Chills** (for a fever - note on the log sheet your temperature and how long after the infusion it began).

- **Nausea**

- **Mild or Moderate Rash**

Any other reactions that are felt to be a result of the administration of SCIG should also be noted on the log sheet.

For more information on side effects see the SCIG product insert.
Uncommon Side Effects

- Diarrhea
- Gastrointestinal
- Allergic
- Increased Cough
- Pain
- Sore Throat

If, at any time, you are concerned about anything related to the administration of SCIG, or if you have any unusual reactions call your doctor or nurse.

You should also call the clinic if any of the following occur post infusion:

- Shortness of breath
- Chest discomfort
- Pain to shoulder, arm or leg
- Injection site continues to bleed
- Fever lasting > 24 hours
Traveling with SCIG

When planning your trip you should:

Get a travel letter from your clinic, it will have:

A. Your name and diagnosis
B. Name of the drug
C. Dosage
D. The reason you are to carry gel/ice packs.
E. Contact information.

Make a list of the supplies you will need.

Always carry an extra week in case of unexpected delays. Outside Canada advance notice will be needed so arrangements can be made with the nearest clinic and/or hospital.
Packing SCIG

A. The product must be kept in its original box.

B. Use a container that can hold freezer/ice packs.

C. When using ice packs:
   • SCIG should not be placed in direct contact with the ice.
   • Use towel or something to separate the two.
   • If there is a chance of the box getting wet place in a zip lock bag to keep it dry.

Your product must be kept with you at all times. It is considered a “carry on bag”.

Always consider travel insurance.
When Traveling with SCIG Outside of Canada and the USA

Check with your travel agent for restrictions on traveling with liquids at points of departure.

Check Customs requirements.

You will need stickers from the hospital to put on every box you are taking.

When travelling through customs, you will need to remove the product from the box. When you have cleared customs place all product back into the boxes for safety.
References


CSL Behring Canada Hizentra - Product Monograph. 2015, retrieved on September 14 2015 from:

http://www.cslbehring.ca/docs/1021/805/2015-07-08_184118_En_Hizentra_PM_Approved.pdf
Subcutaneous Immunoglobulin (SCIG) Patient Teaching Guide for Self Administration Using PUSH Method
What is SCIG?

SCIG is a blood product used to treat adults and children with immune deficiency conditions.
What are Immune Deficiencies?

*Primary Immune deficiencies (PID)* include a variety of disorders in which there is an intrinsic defect in the immune system that renders patients more susceptible to infections.

*Secondary Immune deficiencies (SID)* are a group of conditions caused by other factors than Primary/genetic causes, such as diseases, malignancies or medications, which result in low antibody levels rendering the patient susceptible to infections.

SCIG product replaces the antibodies that are missing or defective. It is called antibody replacement therapy.

- This treatment supports the prevention and treatment of infections.
SCIG Contraindications

*Allergic Reactions* - SCIG should be avoided in persons with a history of severe allergic reactions to immunoglobulin treatment.

*IgA Deficiency* - SCIG should be avoided in persons with selective IgA deficiency who are known to have antibodies against IgA.

Hyperprolinemia
The Ingredients of the Product

SCIG is made from human plasma and is a highly purified product. It contains immunoglobulin G (IgG), an antibody normally found in the blood of healthy people.

IgG helps the body fight disease and infections.

The other important non medical ingredients in SCIG products include L Proline.
Serious Warnings and Precautions

SCIG is a product made from donated plasma which is treated to reduce the risk of it containing infectious agents, but there is still a small possibility it could transmit disease.

Human Immune Globulin products have been associated with the following:

- aseptic meningitis syndrome
- renal dysfunction
- anemia (hemolysis, hemolytic)
- TRALI (transfusion-related acute lung injury)
- thrombo-embolism

NOTE: Risk factors in thrombotic event are pre-existing cardiovascular disorders, prior thrombotic event, obesity, oral estrogen use, hyperlipoproteinemia, in-dwelling catheter, immobility, hyperviscosity from any cause including dehydration, hypercoagulable disorders, and multiple cardiac risk factors. Inform your physician if you have any such risk factor.

Interactions SCIG should not be mixed with any other products.
What Happens If I Miss A Dose?

- Use the missed dose as soon as you remember, and dose weekly from there. If a certain daily schedule is more convenient, then you can modify the schedule to dose every 6 or 8 days to get you back on schedule.

- Skip the missed dose if it is less than 48h from your next scheduled dose.
What Should I Avoid While Using SCIG?

When you are on SCIG and receive a “live” vaccine the vaccine may not work as well during this time, and may not fully protect you from disease.

Live vaccines include measles, mumps, rubella (MMR), oral polio, chickenpox (varicella), BCG (Bacillus Calmette and Guérin), and nasal flu vaccine.

Inform the doctor who is giving you the vaccine of recent treatment with SCIG so that appropriate precautions can be taken.
Transporting and Storing SCIG

SCIG can be transported and stored at room temperature.

Care must be taken to protect the vials of SCIG during transportation.

- A puncture-proof plastic container such as a hard-sided cooler or plastic storage bin is recommended.
- The transport container should not be used for any other purpose than for transporting SCIG.
- During transport, the container should be kept in the passenger compartment of the car to avoid extreme heat or cold that can occur in the trunk.
- Care must be taken to ensure temperature does not exceed +25 °C. Vials must be kept away from direct sunlight, heaters and any other heat sources.
Transporting and Storing SCIG

Care must be taken to ensure temperature does not exceed +25 °C. Vials must be kept away from direct sunlight, heaters and any other heat sources.

- Home fridge storage is only necessary if there is a chance the home temperature may exceed 25° C. When stored at room temperature (up to 25° C), Hizentra (the most commonly used SCIG product) is stable for up to 30 months, as indicated by the expiration date printed on the outer carton and vial labels.
  - If storing in the fridge temperature log and thermometer is required to ensure consistent temperature.

Proceed directly home with the transportation container containing SCIG.
How to Infuse SCIG

SCIG is given as an injection under the skin (subcutaneously).

SCIG must not be given into a blood vessel (vein or artery) as it is not known if this is safe.

If you experience a serious allergic reaction at any time, STOP the infusion of SCIG and contact your doctor or an emergency health care professional immediately.
Safety Requirements

Safety requirements related to self-administering SCIG are as follows:

• The home (or any administration location) must be clean and safe.

• The home (or any administration location) must have a working telephone, and there must be access to rapidly available emergency assistance, e.g. 911.

• A competent adult should be available to assist the recipient for the entire period of the administration and should remain available to the recipient for at least 60 minutes after administration has been completed.

• An epinephrine device should be available during all infusions administered outside the hospital.
Instructions for Administering SCIG:

Patient name: ___________________________

Your weekly dose of SCIG is: _____ml every ______.

You will use _____ vials for each dose.

Each dose is given over _____ minutes.

You will use _____ injection sites for each dose.

The maximum volume for each injection site is _____ ml as directed by your health care provider.
Step 1: Gather Your Supplies

On a clean table, gather all the supplies:

- SCIG vial(s) (at room temperature)
- Infusion Log Sheet
- Chlorohexidine swabs and alcohol swabs
- 18 gauge blunt fill needle(s)
- 10 ml syringe(s)
- 25G X ½” butterfly needle
- Sharps disposal container
- Gloves (if recommended)
- 2X2 gauze
- Band-Aid
Step 2: Wash and Dry Your Hands

Wash and dry your hands thoroughly prior to preparing your SCIG infusion.
Step 3: Inspect Each Vial of SCIG

Check each vial of SCIG for any discoloration or presence of particles in the solution by gently turning the vial (do not shake).

If the solution is cloudy, has particles in it, or if the cap is missing, do not use it. Keep it and return it to the hospital when you go to pick up more product.

Check the expiry date on each vial. Do not use past the expiry date. Call ________________ for a replacement.
Step 4: Prepare the Vial

Remove the cap from the vial(s).

Disinfect the rubber stopper by wiping it with an alcohol swab.

Let it dry. Be careful not to shake the vial(s).
Step 5: Prepare the Syringe and Needle

- You will need 10 ml syringe.
- You will need 18 gauge blunt fill needle.
- Open the syringe and needle packages. Do not touch the ends where they will connect.
- Attach the needle to the syringe by pushing them together and turning clockwise until snug.
Step 6: Inject Air into the Vials

Pull the syringe plunger back to draw ____ ml of air into the syringe.
Step 7: Injecting Air into the Vial

• Remove the cap from the needle. Do not touch the needle.

• Insert the needle into the center of the stopper of SCIG vial but not all the way into the solution.

• Inject the air into the vial by pushing down on the plunger but avoid injecting any air into the solution. (Holding the vial horizontally may help). Keep pressure on the plunger so air stays in the vial.
Step 8: Fill the Syringe

• Turn the vial upside down making sure the tip of the needle is in the liquid and pull back on the plunger to draw the product into the syringe.

• Draw up ______ ml into the syringe.

• Remove any large air bubbles by tapping the syringe and pushing on the plunger. Be careful not to waste any solution. Pull back slightly on the plunger to get the fluid from the needle.

• When you have finished filling this syringe, carefully recap your needle and put the filled syringe on your clean table.

• Repeat these steps if you need to fill more than one syringe.
Step 9: Connecting the Butterfly Needle

- Straighten the tubing attached to your butterfly needle.

- Twist off 18 gauge needle from the syringe and discard into a sharps disposal container.

- Remove the plastic cap from the end of the butterfly tubing.

- Connect the butterfly tubing to the syringe.
Step 10: Removing Air from the Tubing

Remove the air from the butterfly tubing by pushing on the syringe plunger until the solution reaches the bottom of the wings on the butterfly.

If fluid reaches the tip of the butterfly needle, wipe the tip of the needle with your 2X2 gauze.

Avoid getting product on the tip of the butterfly needle as it causes skin irritation.
Step 11: Select Injection Site(s)

- Select an area approved for subcutaneous injection (see diagram).

- The best area is the abdomen. Stay approximately two inches away from the umbilicus (belly button) in any direction.

- Do not inject into an area that is scarred, bruised or there is a large blood vessel under the skin.
Step 12: Prepare Injection Site(s)

- Wipe the area with a chlorohexidine swab in a circular motion, avoid going over the already cleaned area.

- Start cleaning at the center of the site and work outward to cover a circle of about 4 inches.

- Let the skin dry.

- If using more than one site, make sure each site is at least two inches apart.
Step 13: Insert the Needle

• Insert the butterfly needle at either a $45^\circ$ or $90^\circ$ angle.

• Pinch the skin where you plan to put the needle in.

• Insert the needle using “pinch an inch” technique, as directed.

• Insert the needle into the fatty tissue under the skin as directed.
Making Sure You Are Not in a Blood Vessel

When the needle is in, pull back slightly on the plunger to make sure you are not in a blood vessel.

If you pull back on the plunger and see blood in the butterfly tubing, pull out the butterfly needle and apply pressure to the site. Discard the butterfly needle and start over.
Injecting SCIG

Cover the needle with transparent dressing or gauze and tape it in place.
Completing the Administration
Step 14: Applying Pressure

- Once the SCIG has been given, keep pressure on the syringe plunger for 30 seconds before removing the butterfly needle (You may choose to slowly count “1 Mississippi-2 Mississippi- ……29 Mississippi” for timing).

- Place 2X2 gauze over the insertion site and pull out the butterfly while applying pressure.

- This may be uncomfortable but this helps seal the tissue and prevent leakage.
Step 15: Following the Infusion

It is not uncommon to notice blood coming from the insertion site. Do not worry as you may have nicked a small blood vessel either on insertion or removal of the butterfly needle.

Apply pressure to the site with the 2X2 gauze.

A small amount of clear fluid (product) may appear via the insertion site. This could be some of the product that has followed the needle track to the surface.

Clean the area with chlorohexidine swab and apply pressure with 2X2 gauze.
Step 16: Following the Infusion

- Discard all preparation and administration equipment in a large biohazard sharps disposal container.

- Once opened, even by mistake, SCIG cannot be saved. Discard it in the biohazard sharps disposal container.

- Report the discard (if any) on the patient infusion log sheet.

- Sharps containers are available from various sharps exchange programs. Your health care provider will tell you about the options in your area.

- Ensure to keep product and sharps container away from children.
Notes on Sharps Containers

Items for disposal should only be placed in a biohazard sharps container. The items must not be placed in garbage or recycling bags and must not be flushed down the toilet or burned.

Use a LARGE size sharps container and do not fill beyond the manufacturer’s full line.

During transportation, care must be taken to ensure the lid is securely sealed on filled containers.
Step 17: Record the Infusion

On your Infusion Log Sheet you must:

• Record the date and time of the infusion.
• Record the exact dose of your infusion.
• Record the lot number and expiration date from the vials used.
• Record the discards, if any.
• Record any reactions that occurred as a result of the SCIG infusion.
• Fill in all the other sections according to the instructions from your healthcare provider.

Provide ALL your completed log sheets to Blood transfusion Service (BTS) when picking up subsequent product. They will forward copies of your log sheets to the physicians if needed. Failure to return completed sheets will result in less product being supplied by BTS.
Managing the Side Effects of SCIG
Anaphylaxis

Although rare in occurrence, anaphylaxis is the most severe potential reaction that can occur as a result of infusing SCIG.

It is a life-threatening allergic reaction that affects many areas of the body. Anaphylaxis can lead to death in a matter of minutes if left untreated.

Symptoms of an anaphylactic reaction, as well as instructions for when to give epinephrine, are listed in the following table.

Note that during an anaphylactic reaction, not all symptoms may occur.

Always have an epinephrine injection device with you when infusing SCIG and ensure the device has not expired.

Expiry date of current injection device: ________________

*Early recognition of symptoms and immediate treatment could save a person’s life. Delay in treatment could cause a more severe anaphylaxis episode. When in doubt, treat with epinephrine.*
## Symptoms of an Anaphylactic Reaction

<table>
<thead>
<tr>
<th>Body Region</th>
<th>Symptoms</th>
<th>Should You Give Epinephrine?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Face/Head</strong></td>
<td>Redness, itchy eyes/nose, swelling of eyes, runny nose, sneezing</td>
<td>If symptoms are severe</td>
</tr>
<tr>
<td></td>
<td>Swelling of lips and tongue, itchy mouth or tongue</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Skin</strong></td>
<td>Itching, redness, warmth, hives, rash or swelling in areas other than infusion sites.</td>
<td>If symptoms are severe</td>
</tr>
<tr>
<td><strong>Throat</strong></td>
<td>Itching, tightness, hoarse voice, hacking cough, trouble swallowing, trouble speaking, choking</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Lungs</strong></td>
<td>Trouble breathing, shortness of breath, repeating cough, wheezing</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Stomach</strong></td>
<td>Nausea, vomiting, stomach pain or cramps, diarrhea</td>
<td>If symptoms are severe</td>
</tr>
<tr>
<td><strong>General</strong></td>
<td>Dizziness, unsteadiness, drowsiness, sense of doom, feeling faint or fainting</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Epinephrine Devices

Epinephrine is a life-saving treatment and is the antidote for anaphylaxis.

There is one type of common epinephrine devices:

- Epi Pen®

Techniques on using this device should be reviewed regularly. Instructions are available on DVDs and websites. Instructions are also found directly on the devices themselves.

These devices can be used through clothing.
How to Use Epi Pen®

• Remove the device from its carrying case.
• Grasp the Epi Pen® with the black tip pointing downward.
• Pull off the grey safety cap.
• Place the BLACK tip against the mid-outer thigh and press firmly until the Epi Pen® activates.
• This device can be used through clothing.
• Hold while counting for 10 seconds, then remove.
After Epinephrine is Given

Call 911 and tell them someone is having a life-threatening allergic reaction. Ask them to send an ambulance immediately.

You must have medical attention and monitoring if epinephrine is given, even if symptoms have improved.

How to Dispose of Epinephrine Device

Carefully place the used auto-injector (needle end first) into the storage tube.

Screw the cap of the carrying case on completely.

This automatically bends the needle back and secures the pen so it won’t fall out of the tube.

Give any used auto-injectors to emergency responders or emergency room personnel.
# Trouble Shooting Subcutaneous Administration of Immunoglobulin

| Leaking | • Check connections between tubing and syringe.  
|         | • Is the butterfly needle inserted properly.  
|         | • Volume administered too quickly therefore leaking at the site.  |

| Insertion site: | Reaction  
| Reaction  
| Redness  
| Swelling  
| Itchiness | • Volume administered too quickly.  
| • Decrease the volume and spread over a longer period of time.  
| • Apply cold compress or ice cube to the area before administering subcutaneous immunoglobulin  
| • Apply warm compress to the area before administering subcutaneous immunoglobulin.  
| • If taping the needle down, you could be getting a reaction to the tape.  
| • Did any immunoglobulin get on the needle while flushing the tubing? (Use 2X2 gauze to wipe off the needle.)  
| • After cleaning the skin wait a min or two then administer the immunoglobulin. The area should be dry prior to puncturing the site.  
| • Rotate the sites regularly  |

| Needle Discomfort | • Needle length too long.  
| • Rotate sites regularly.  
| • Apply warm compress to the area before administering subcutaneous immunoglobulin.  
| • Apply cold compress or ice cube to the area before administering subcutaneous immunoglobulin  |

| Blood in tubing | • Discard butterfly needle and start over |
Other Reactions to SCIG Signs and Symptoms

<table>
<thead>
<tr>
<th>Site Reaction</th>
<th>Non-pharmacological interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Itching</strong></td>
<td>• Slow down on the infusion.</td>
</tr>
<tr>
<td></td>
<td>• Needle in correctly.</td>
</tr>
<tr>
<td></td>
<td>• Apply cold compress.</td>
</tr>
<tr>
<td></td>
<td>• Ensure you are rotating the sites.</td>
</tr>
<tr>
<td></td>
<td>• When priming the needle, do not allow excess SCIG droplets on outside of the needle.</td>
</tr>
<tr>
<td><strong>Redness</strong></td>
<td>• Slow down the infusion.</td>
</tr>
<tr>
<td></td>
<td>• Apply cold compress.</td>
</tr>
<tr>
<td><strong>Burning</strong></td>
<td>• Stop infusion for 5–10 minutes then restart.</td>
</tr>
<tr>
<td></td>
<td>• Slow the infusion down.</td>
</tr>
<tr>
<td></td>
<td>• Cold compress.</td>
</tr>
<tr>
<td></td>
<td>• Gentle massage.</td>
</tr>
<tr>
<td></td>
<td>• Change site.</td>
</tr>
<tr>
<td><strong>Swelling</strong></td>
<td>• Warm compress for 5-10 minutes.</td>
</tr>
<tr>
<td><strong>Urticaria</strong></td>
<td>• Stop SCIG.</td>
</tr>
<tr>
<td>(hives)</td>
<td>• Seek medical attention.</td>
</tr>
<tr>
<td></td>
<td>• Determine with physician if treatment should continue.</td>
</tr>
<tr>
<td><strong>Discomfort</strong></td>
<td>• Slow infusion.</td>
</tr>
<tr>
<td></td>
<td>• If intolerable pain – may be in muscle, remove catheter.</td>
</tr>
<tr>
<td></td>
<td>• Once needle removed, warm compress and gentle message.</td>
</tr>
</tbody>
</table>
Injection Site Reaction

Mild

Moderate
Injection Site Reaction

Injection site reactions can be identified by what is usually mild to moderate redness, swelling, discomfort, and itching.

This is a normal and common reaction which should fade over 24 – 48 hours.

Keep a record of any injection site reactions on your Infusion Log Sheet. Your physician can recommend ways to lessen discomfort related to injection site reactions.

Use of ice during administration or dividing dose between abdomen and thighs can lessen the discomfort.

If the injection site reactions are severe or if you are concerned about them, call your doctor or nurse using the contact information provided.

If itchiness persists you can consult your physician.
Other Common Reactions

There are some other common reactions that can occur related to the administration of SCIG. If any of these occur, make a note on your log sheet:

**Headache:** Some patients get headaches in the beginning, but they decreased after some time. You could take Tylenol 1-2 tablets orally every 4-6 hours, may last two to three days. The headache could also be triggered by stress or stressors. (I.e. anxiety, tension). If your headache is prolonged contact the clinic.

**Fever and/or Chills** (for a fever - note on the log sheet your temperature and how long after the infusion it began).

**Nausea**

**Mild or Moderate Rash**

Any other reactions that are felt to be a result of the administration of SCIG should also be noted on the log sheet.

For more information on side effects see the SCIG product insert.
Uncommon Side Effects

Diarrhea
Gastrointestinal
Allergic
Increased Cough
Pain
Sore Throat

If, at any time, you are concerned about anything related to the administration of SCIG, or if you have any unusual reactions call your doctor or nurse.

You should also call the clinic if any of the following occur post infusion:

- Shortness of breath
- Chest discomfort
- Pain to shoulder, arm or leg
- Injection site continues to bleed
- Fever lasting > 24 hours
Traveling with SCIG

When planning your trip you should:

Get a travel letter from your clinic, it will have:

A. Your name and diagnosis
B. Name of the drug
C. Dosage
D. The reason you are to carrying gel/ice packs.
E. Contact information

Make a list of the supplies you will need.

Always carry an extra week in case of unexpected delays.

Outside Canada advance notice will be needed so arrangements can be made with the nearest clinic and/or hospital.
Packing SCIG

A. The product must be kept in its original box.
B. Use a container that can hold freezer/ice packs.
C. When using ice packs:
   • SCIG should not be placed in direct contact with the ice.
   • Use a towel or something to separate the two.
   • If there is a chance of the box getting wet place in a zip lock bag to keep it dry.

Your product must be kept with you at all times. It is considered a “carry on bag”.

Always consider travel insurance.
When Traveling with SCIG Outside of Canada and USA

Check with your travel agent for restrictions on traveling with liquids at points of departure.

Check Customs requirements.

You will need stickers from the hospital to put on every box you are taking.

When travelling through customs, you will need to remove the product from the box. When you have cleared customs place all product back into the boxes for safety.
References


Appendix D3:
Pre-Printed Order Form

**PRE-PRINTED ORDER**
Nova Scotia Provincial Blood Coordinating Program (NSPBCP)
Subcutaneous Immunoglobulin (SCIG)

Patient: ___________________ Allergies: ___________________

1. Height __________ cm

2. Actual body weight _______ kg  
   Dosing Body Weight _______ kg  
   NSPBCP DBW calculator [http://novascotia.ca/dhw/nspbcp/] or insert  
   [http://www.gov.ns.ca/DHW/nspbcp/mobile] into browser of phone  
   (Dosing body weight is not applicable in patients less than 5 feet or 152.4cms in height)

3. Dose Calculation:
   Total dose over FOUR weeks = _____ g/kg x _____ kg = _____ g (Rounded down to nearest 5g)
   Single dose = 
   Total Dose SCIG (g) = _____ g = _____ g for each dose
   Number of doses to be administered in 4 weeks (# doses)

   Immunoglobulin _____ grams (______ mL) subcutaneously
   Infuse starting on _____/_____/_____. Repeat q______ days for a total of _____ treatments
   (yyyy/mm/dd)

<table>
<thead>
<tr>
<th>PHYSICIAN’S NAME (PRINT):</th>
<th>CPSNS NO.</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHYSICIAN’S SIGNATURE:</td>
<td>DATE:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indication</th>
<th>Prerequisites – Checkboxes must be completed</th>
<th>Dose</th>
</tr>
</thead>
</table>
| □ Primary Immune Deficiency Conditions | Must meet both of the following 2 criteria:  
   Patient has been referred to an Immunologist for consultation.  
   Physician name: ___________________  
   IgG levels checked within last 5 months  
   Level: ________ g/L  
   Date: __________ | Adult: 0.4-0.6 g/kg over 4 weeks; Administer in divided doses  
   Pediatric: 0.6-0.7 g/kg over 4 weeks; Administer in divided doses |
| □ Secondary Immune Deficiency Conditions | Must meet 1 of the following 2 criteria:  
   A recent life threatening infection related to low levels of polyclonal immunoglobulin  
   Recurrent clinically significant infections related to low levels of polyclonal immunoglobulin  
   Specify condition ___________________ | Adult: 0.4-0.6 g/kg over 4 weeks; Administer in divided doses  
   Pediatric: 0.6-0.7 g/kg over 4 weeks; Administer in divided doses |

NSPBCP
SCIG Pre-Printed Order August 2016
**Appendix D4: Patient Infusion Log Sheet for Pump Method**

The following shows the Patient Infusion Log Sheet. Electronic versions may be given to patients to allow them to print their own copies at home.

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Physician Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ID:</td>
<td>Hospital Name:</td>
</tr>
<tr>
<td>Nurse Name:</td>
<td>Fax/Email:</td>
</tr>
<tr>
<td>Infusion Date:</td>
<td></td>
</tr>
<tr>
<td>Infusion Start Time:</td>
<td></td>
</tr>
<tr>
<td>Infusion End Time:</td>
<td></td>
</tr>
<tr>
<td>Total Dose: ml</td>
<td></td>
</tr>
<tr>
<td>ml per site:   ml</td>
<td></td>
</tr>
<tr>
<td>Infusion rate: ml/hr</td>
<td></td>
</tr>
<tr>
<td>Discards (if any) ________ grams</td>
<td></td>
</tr>
</tbody>
</table>

Record the Lot Numbers of all vials used in this dose:

Side effects related to this dose:

I have taken the following medications:

<table>
<thead>
<tr>
<th>I have had an infection during the past week (explain):</th>
<th>Fever temperature associated with the infection: ______ °C</th>
</tr>
</thead>
</table>

After my SCIG therapy last week, I felt (circle one): [Better] [Same] [Not as Well]

Please Explain:

Sites Infused (mark each site with an X along with the infusion date)

Questions to ask my doctor or nurse:

Log Verification (for Hospital Use Only)

<table>
<thead>
<tr>
<th>Name:</th>
<th>Title:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital:</td>
<td>Date:</td>
</tr>
</tbody>
</table>

Patient Signature:

Witness Signature:
### Appendix D3: Patient Home Infusion Log Sheet for Push Method

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Physician Name:</th>
<th>Month/Year:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ID:</td>
<td>Hospital Name:</td>
<td>Product Name:</td>
</tr>
<tr>
<td>Nurse Name:</td>
<td>Fax/Email:</td>
<td>Number of Infusions per Week:</td>
</tr>
</tbody>
</table>

#### Infusion Details:

- **Infusion Date:**
- **Dose of Infusion (ml):**
- **Site Used:**
  - R/L/U/Lo/F Abd/ Leg
- **Lot Number:**
- **Discards (if any) in Grams with Reason:**
- **Side Effects Related to This Dose:**
- **I have Taken the Following Medications:**
- **I have had an Infection During past Week(explain):**
  - Fever Temperature Associated with the Infection: ______ °C
- **Comments/Problems/Reactions/Blood Tests:**

#### Symbols:
- R – right
- L – left
- U – upper
- Lo – lower
- Abd – abdomen
- F – love handles

#### Questions to ask my Doctor or Nurse:

**Patient Signature:**

**Witness Signature:**

#### Log Verification for Hospital Use Only:

<table>
<thead>
<tr>
<th>Name:</th>
<th>Title:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital:</td>
<td>Date:</td>
</tr>
</tbody>
</table>
Appendix D5: Skills Checklist for Pump Method

The following shows the Skills Checklist.

**Subcutaneous Immunoglobulin Home Infusion Skills Checklist**

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Name &amp; Role of Person Responsible for Infusions (if different from patient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Skills</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Initials</td>
</tr>
<tr>
<td>Define subcutaneous administration and location of tissue</td>
<td></td>
</tr>
<tr>
<td>Describe appropriate sites for catheter placement.</td>
<td></td>
</tr>
<tr>
<td>Describe appropriate care of infusion site.</td>
<td></td>
</tr>
<tr>
<td>Describe signs/symptoms of subcutaneous needle complications.</td>
<td></td>
</tr>
<tr>
<td>Gather appropriate supplies for procedures.</td>
<td></td>
</tr>
<tr>
<td>Drawing up SCIG and priming tubing</td>
<td></td>
</tr>
<tr>
<td>Insert subcutaneous catheter and check for blood return.</td>
<td></td>
</tr>
<tr>
<td>Insert syringe on pump and setting rate</td>
<td></td>
</tr>
<tr>
<td>Accurately administer SCIG</td>
<td></td>
</tr>
<tr>
<td>Discontinuing subcutaneous infusion.</td>
<td></td>
</tr>
<tr>
<td>Identify appropriate interventions for complications. <strong>Scenarios to be discussed:</strong></td>
<td></td>
</tr>
<tr>
<td>A) Blood return in tubing upon pull back</td>
<td></td>
</tr>
<tr>
<td>B) Pump malfunction</td>
<td></td>
</tr>
<tr>
<td>C) Site issues</td>
<td></td>
</tr>
<tr>
<td>Disposal of biological waste</td>
<td></td>
</tr>
<tr>
<td>Post-infusion site care.</td>
<td></td>
</tr>
<tr>
<td>Care and maintenance of infusion pump</td>
<td></td>
</tr>
<tr>
<td>Use of epinephrine device.</td>
<td></td>
</tr>
<tr>
<td>Additional patient-specific tasks (if applicable):</td>
<td></td>
</tr>
</tbody>
</table>

**Comments:**

**To be completed after the final education session:**
I have been instructed on subcutaneous infusion and I understand and feel competent in all the above skills above. I accept the responsibility for using proper and safe techniques to carry out the prescribed home infusion therapy.

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<thead>
<tr>
<th>Signature of Patient/Parent/Trainee</th>
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<table>
<thead>
<tr>
<th>Signature of Patient Educator</th>
<th>Date</th>
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</table>
### Appendix D6: Skills Checklist for Push Method

The following shows the Skills Checklist.

**Subcutaneous Immunoglobulin Home Infusion Skills Checklist**

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Name &amp; Role of Person Responsible for Infusions (if different from patient)</th>
</tr>
</thead>
</table>

*The educator should enter the date & his/her initials to document when each skill is (I) introduced, (R) reinforced, & (M) mastered.*

<table>
<thead>
<tr>
<th>Patient Skills</th>
<th>/yyyy/m</th>
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<th>/YYYY/m</th>
<th>/yyyy/mm</th>
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<td>Transportation and storage requirements for SCIG</td>
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<td>Describe appropriate sites for catheter placement.</td>
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<tr>
<td>Describe appropriate care of infusion site.</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Describe signs/symptoms of subcutaneous needle complications.</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gather appropriate supplies for procedures.</td>
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<tr>
<td>Drawing up SCIG and priming tubing</td>
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<tr>
<td>Insert subcutaneous catheter and check for blood return.</td>
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</tr>
<tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<tr>
<td>Identify appropriate interventions for complications.</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Scenarios to be discussed:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A) Blood return in tubing upon pull back</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>B) Site issues</td>
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<tr>
<td>Disposal of biological waste</td>
<td></td>
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<tr>
<td>Post-infusion site care.</td>
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<tr>
<td>Use of epinephrine device.</td>
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<tr>
<td>Additional patient-specific tasks (if applicable):</td>
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</tr>
</tbody>
</table>

**Comments:**

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**To be completed after the final education session:**

I have been instructed on subcutaneous infusion and I understand and feel competent in all the above skills above. I accept the responsibility for using proper and safe techniques to carry out the prescribed home infusion therapy.

<table>
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<tr>
<th>Signature of Patient/Parent/Trainee</th>
<th>Date</th>
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</table>

<table>
<thead>
<tr>
<th>Signature of Patient Educator</th>
<th>Date</th>
</tr>
</thead>
</table>
Appendix D7: Patient Quick Reference Sheet

The following shows the Patient Quick Reference Page.

**Subcutaneous Immunoglobulin Home Infusion**

**Patient Quick Reference Sheet**

Patient name: _______________________________________

Product name: ______________________________________

My dose of SCIG is: _______ ml every

My vial size is _______ ml and I will use _______ vials for each dose.

Each dose is given over _______ minutes or hours. I will use _____ injection sites for each dose.

I need _____ size _______ syringes. I will need _______ needles.

The pump speed should be set to _______ mm per hour.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Who to Call</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaphylactic Reaction</td>
<td>911</td>
<td>911</td>
</tr>
<tr>
<td>Concerned about a possible reaction</td>
<td>Immunologist on call</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>to SCIG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questions Regarding supplies</td>
<td>Patient Educator: [name]</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>or the infusion process</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appointment Times</td>
<td>Immunology Clinic</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Submitting Log sheets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questions regarding treatment</td>
<td>Immunologist: [name]</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Ordering and pick up of</td>
<td>Blood Bank</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>SCIG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ordering and Pick up of</td>
<td>[name and location]</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Infusion Supplies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other medications</td>
<td>Local drug store</td>
<td></td>
</tr>
<tr>
<td>Problem with syringe pump</td>
<td>Patient Educator: [name]</td>
<td>[insert phone number]</td>
</tr>
<tr>
<td>Only applicable for Vivaglobin</td>
<td>Manufacturer: Smiths Medical</td>
<td>(905) 477-2000</td>
</tr>
<tr>
<td>Other?</td>
<td></td>
<td>[insert phone number]</td>
</tr>
</tbody>
</table>

NSPBCP Atlantic Guideline for SCIG Home Administration Programs, September 2016 133
Appendix D8: Sample Consent Form

The following shows the sample consent form.

Consent for Transfusion of Blood, Blood Components and/or Plasma Derivatives

I, __________________________, have been informed by my physician, __________________________, that in the course of my medical/ surgical treatment I may need a transfusion of blood, blood components or plasma derivatives, i.e., red blood cells, plasma, platelets, factor concentrate or cryoprecipitate. Autologous blood and other appropriate alternatives to the use of human blood have also been discussed.

I have been informed of and understand the benefits and risks associated with this therapy. I understand that risks exist even though the blood and/or blood components or plasma derivatives have been tested. I understand that all blood donors are volunteers and are carefully screened by medical history and sensitive laboratory tests in order to minimize the risk of infectious disease transmission, however these measures cannot completely eliminate these risks or the risks of other adverse reactions including serious injury and/or death.

I have been given information, including a pamphlet, Benefits and Risks of a Transfusion, on blood, blood components and plasma derivatives and the chance to ask questions about the benefits and risks. My physician has answered all my questions to my satisfaction.

I have read (or has been read to me) and understand all the above. I consent to the transfusion of blood, blood components and/or plasma derivatives if it becomes necessary during the course of treatment.

______________________________  __________________
Signature of Patient       Date

Or

______________________________  __________________
Signature of Substitute Decision Maker    Date

Substitute Decision Maker (Print Name)

STATEMENT OF TREATING PHYSICIAN:
I confirm that I have explained the nature, associated benefits, potential risks, and likely consequences of consenting to or refusing the transfusion of blood, blood components or plasma derivatives and alternative therapies and provided an opportunity to ask questions and answered all questions that were asked.

______________________________  __________________
Signature of Physician        Practice Registration #

Print Name

Date
Appendix D9: Responsibility Agreement

The following shows the Responsibility Agreement.

Subcutaneous Immunoglobulin Home Infusion
Responsibility Agreement

Patient Name: _______________________________________________________

The following is a list of responsibilities required of a patient to participate in the SCIG home infusion program:

- Complete home infusion training and demonstrate self-administration until competency is established.
- Undergo periodic reassessment regarding the infusion technique as per an established review schedule or based on needs during subsequent follow up.
- Follow the instructions for home infusion as per the patient education materials or the written modified program provided by the nurse educator.
- Contact the nurse educator when questions regarding supplies or the home infusion process arise.
- Maintain and dispose of equipment as instructed.
- Perform home infusion in a safe and clean environment.
- Administer doses on the schedule determined by the physician.
- Ensure an adult who is not undergoing the infusion is present for the duration of the infusion and for 60 minutes following the completion of the infusion.
- Complete a Patient Infusion Log Sheet for each infusion and submit a copy as instructed.
- Document all adverse reactions on the Patient Infusion Log Sheet. Any adverse reaction that requires emergency medical attention should be reported to the patient’s physician before administering any further doses. Do not call a nurse educator to report or seek advice concerning clinical symptoms or reactions to infusions.
- Order, transport, and store SCIG according to the instructions provided.
- Attend all scheduled clinic appointments.
- Have a clear understanding of the risks associated with administration of SCIG outside the hospital environment.

I understand that failure to comply with the above responsibilities may pose a threat to my safety and may result in termination of home infusion therapy and reversion to in-hospital treatment with intravenous immunoglobulin.

I understand that I am participating in the SCIG home infusion program at my own risk and I hereby waive any and all claims and release from all liability and agree not to sue any hospital staff or representatives for any and all personal injury, death, or loss sustained by me as a result of preparing, infusing, handling, or storing SCIG in my home or at any location outside of the hospital due to any cause whatsoever.

I declare that I have read and understood these conditions.

___________________________________________    _______________________
Signature of Patient     Date

___________________________________________    _______________________
Signature of Parent or Legal Guardian  Date
Appendix D10: Sample Issuing Form

The following shows the sample issuing form. Changes can be made to this sample to suit local processes. This form stays in the blood bank and is not meant to be issued to patients.

**Subcutaneous Immunoglobulin Home Infusion**

**SCIG product Issuing Form**

**Department of Laboratory Medicine - Transfusion Medicine Service**

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Health Card or Hospital Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordering Physician:</td>
<td>Ordered Dose:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lot #:</th>
<th>Number of Boxes:</th>
<th>ml per box:</th>
<th>Expiry Date: (dd/mm/yy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot #:</td>
<td>Number of Boxes:</td>
<td>ml per box:</td>
<td>Expiry Date: (dd/mm/yy)</td>
</tr>
<tr>
<td>Lot #:</td>
<td>Number of Boxes:</td>
<td>ml per box:</td>
<td>Expiry Date: (dd/mm/yy)</td>
</tr>
<tr>
<td>Lot #:</td>
<td>Number of Boxes:</td>
<td>ml per box:</td>
<td>Expiry Date: (dd/mm/yy)</td>
</tr>
</tbody>
</table>

Date Issued:

Computer Numbers:

Pool Numbers:

Issuing Technologist’s Name:

Issued to (signature):

Issued/Transfused in Computer:  ☐ Yes  ☐ No

Discards Returned:

<table>
<thead>
<tr>
<th>Lot #:</th>
<th>Amount Discarded:</th>
<th>Reason for Discard:</th>
<th>Received by (initials):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot #:</td>
<td>Amount Discarded:</td>
<td>Reason for Discard:</td>
<td>Received by (initials):</td>
</tr>
</tbody>
</table>

**Tracking of Corresponding Patient Log Sheets:**

<table>
<thead>
<tr>
<th>Issuing Tech</th>
<th>Received</th>
<th>Forwarded to MLT II</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLT II</td>
<td>Reviewed</td>
<td>Forwarded to Clinic</td>
</tr>
</tbody>
</table>
Appendix D11: Storage of SCIG in Refrigerator

Patients should be advised to proceed directly home with the product and to place the product in the fridge within ten minutes of arriving. During transport, the cooler should be kept in the passenger compartment of the car to avoid temperature extremes that can occur in the trunk.

In the home, product must be kept in the refrigerator within a temperature range of +2°C and not exceeding +25°C. Ideally, a National Institute of Standards and Technology (NIST) certified thermometer should be used to monitor the refrigerator temperature. Considering the expense of such a thermometer, a reasonable option would be to use a thermometer verified against a calibrated, NIST-certified thermometer in Blood Transfusion Services.

SCIG may be stored in the regular food refrigerator or in a separate designated refrigerator. If stored in the food refrigerator care must be taken to keep SCIG away from any items that could spill. Regardless of the type of refrigerator, the boxes of vials must be kept away from the back of the refrigerator to prevent freezing that can occur when contact is made with the back inside wall of the refrigerator. SCIG vials must be kept in their boxes during storage.

The refrigerator temperature should be recorded daily. A template temperature log sheet can be found in Appendix D-9. An electronic version of this template is included on the included USB. Patients should bring the temperature log sheets when picking up product so that adherence to daily temperature logging and temperature requirements can be verified. Copies of the logging sheets should be retained in Blood Transfusion Services.

Patients/families should have a plan in place to deal with a power failure and associated loss of refrigeration. A variety of options are available as long as the temperature is maintained in the range of 2–8 °C.

Options include:

- Moving the product to the transport cooler with cold packs.
- Using the transport cooler to transport product to a refrigerator in a home not affected by the power failure.
- Using the transport cooler to transport product to the hospital blood bank. The blood bank should be notified in advance of this transfer.

In each situation, a certified or verified thermometer as described above should be used to monitor the temperature. The thermometer must not be in direct contact with any of the cold packs.
1 x 36 oz Blue Gel Pack (Item #80502) preconditioned at -16.5 °C. For temperatures over +38 °C add 1 additional gel pack.

2 x 12 ml/cell 12 x 4 flexible insulating blanket (Item #85000); preconditioned at +5 °C; fan folded to fit.

SCIG vials in boxes; pre-conditioned at +5 °C.

1 x 12 ml/cell 12 x 4 flexible insulating blanket (Item #85000); preconditioned at +5 °C; wrapped around vials.

1 x 96 oz Blue Gel Pack (Item #80503); pre-conditioned at +5 °C; placed in bottom of cooler.

Igloo Cool 16 Quart cooler; pre-conditioned at +22 °C (Home Hardware Item #6450-770).

All packing items, with the exception of the cooler, can be obtained from Cryopak using the item numbers listed with each item. Call 1-888-423-7251 for the name of your local Cryopak sales representative.
All packing items, with the exception of the cooler, can be obtained from Cryopak using the item numbers listed with each item. Call 1-888-423-7251 for the name of your local Cryopak sales representative.
Appendix D12: Home Refrigerator Temperature Log Sheet

The following shows the Home Refrigerator Temperature Log Sheet. For a printable version, see the Microsoft Word file on the USB provided with these guidelines.

Subcutaneous Immunoglobulin Home Infusion
Home Refrigerator Temperature Log Sheet

Patient Name: _______________________________________

Note: the temperature in the refrigerator used to store SCIG must be in the range above +2 to +25 °C, the refrigerator temperature goes outside the recommended range, the product should be moved to another location where the proper temperature can be maintained. Options include:

- Moving the product to the transport cooler with cold packs.
- Using the transport cooler to transport product to a working refrigerator (for example, in a neighbor’s or friend’s home). Ensure the refrigerator temperature is within the recommended range.
- Using the transport cooler to transport product to the hospital. In this case, please call the blood bank ahead of time.

In each situation, place the refrigerator thermometer with the product to monitor the temperature. The thermometer must not be in direct contact with any of the cold packs. Frozen cold packs should not come in contact with the product boxes.

<table>
<thead>
<tr>
<th>Date</th>
<th>Temp.</th>
<th>Date</th>
<th>Temp.</th>
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</table>

Log Verification - Name: ____________________________  Title: ____________________________

Hospital: ____________________________  Date: ____________________________