Government of Newfoundland and Labrador

Department of Health and Community Services
Provincial Blood Coordinating Program

SUBCUTANEOUS IMMUNE GLOBULIN (SCIG) HOME INFUSION PROGRAM	NLBCP-055

Office of Administrative Responsibility Medical Advisor to the Provincial Blood Coordinating Program Provincial Blood Coordinating Program	**Issuing Authority** Dr. Christopher Sharpe Daphne Osborne
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Overview

Subcutaneous immune globulin (SCIG) is a plasma protein product produced from human blood. The Atlantic Blood Utilization Strategy (ABUS), in consultation with Atlantic clinical experts, prepared this document to ensure intravenous immune globulin (IVIG) and SCIG are used for appropriate indications and in doses recommended by the current literature and expert clinical opinion. SCIG is indicated for treatment of adult and pediatric patients with primary immune deficiency (PID) and secondary immune deficiency (SID) and select Neurology conditions.

Blood components and plasma protein and related products (PPRP) such as SCIG are provided to recipients at no cost.

Policy

1. The treating physician shall determine eligibility for enrollment in the SCIG home infusion program.
2. The recipient's physician shall obtain informed consent before starting home infusion. See attached Informed Consent Policy.
3. A physician shall be available by telephone for immediate consultation should urgent medical care be required.
4. Patients shall have appropriate training for home infusion of SCIG.
5. Patients shall use SCIG appropriately and submit transfusion records to the Transfusion Medicine Laboratory (TML) according to facility policy.
6. Patients shall report and document all adverse events
7. The home infusion program is a privilege for patients. Failure to comply with policies will require patients to revert to hospital administered IVIG treatment.
8. Patients shall receive an initial one month supply of SCIG, after training is complete.
9. After initial one month supply is complete, patients shall receive a maximum of three (3) months' supply at a time.
10. Treatment plan shall be re-evaluated if:
    - 10.1. The patient develops any severe infection;
    - 10.2. There is a lack of expected response;
    - 10.3. There is continued failure to thrive in pediatric patients;
    - 10.4. Autoimmune complications develop; and/or

10.5. Any other situation as determined by the physician or designate.

11. SCIG with recombinant human hyaluronidase (HyQvia) shall be available for PID and SID only.

12. HyQvia follows the same processes as SCIG, except for:

12.1. Enrollment and Consent form (Appendix A) shall be considered the original order request for HyQvia; and,

12.2. HyQvia requires initial 'Ramp Up' dosing. HyQvia Patient Pick-up Form (Appendix B) shall be sent to the TML by One Path, which contains Ramp-Up dose.

13. Issuing of HyQvia to patient is as follows:

13.1. Week 1 and 2 of Ramp Up Dose shall be issued at the same time in Week 1.

13.2. Week 4 shall be issued in Week 4.

13.3. Week 7 shall be issued in Week 7 (this would be the first dose outside of training and Ramp Up dosing)

13.4. Starting Week 11, a three-month supply shall be issued going forward, provided the patient did not experience issues in Week 7.

Guidelines

1. SCIG is contraindicated in:

1.1. Individuals with a history of anaphylactic or severe adverse reactions to immune globulin; and,

1.2. Individuals with immunoglobulin A (IgA) deficiency who have a known anti-IgA.

2. Refer to Atlantic Clinical Indications and Criteria for Intravenous and Subcutaneous Immunoglobulin (IVIG/SCIG) for dosing guidelines and recommendations.

3. The dose is adjusted based on serum IgG levels, for PID and SID, and clinical response.

4. A steady state serum IgG level of at least 7 g/L should be maintained. IgG levels should be measured at three (3) months and six (6) months after start of treatment with SCIG for PID and SID. When IgG levels reach a steady state, testing can be performed at least every 12 months or at the discretion of the physician.

5. Benefits of SCIG:

5.1. Provides a more stable immunoglobulin G (IgG) level;

5.2. Difficult venous access is avoided;

5.3. Less systemic adverse events reported;

5.4. Convenient and time efficient for recipients;

5.5. Avoidance of travel to Health Care Facility; and

5.6. Offers flexibility in the infusion schedule.

Roles and Responsibilities

Physician:

1. 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. Careful consideration must be given to patients who:

   1.1. Have been recently vaccinated;

   1.2. Have kidney disease; or,

   1.3. Have a history of thrombotic events.

2. Obtain written consent for home administration of SCIG every 12 months.
3. Complete and fax the enrollment form.
4. Discuss with patients/families the potential adverse reactions and how to manage them.
5. Prepare all necessary new preprinted orders (PPO) at appropriate intervals.
6. Provide patient with a requisition for IgG testing at appropriate intervals for PID and SID. Initially, three (3) months and six (6) months, then, every 12 months to allow for dose adjustment if necessary.
7. Review IgG levels and taper SCIG dose to minimal effective dose for PID and SID.
8. Be available for telephone consultation in the event of severe adverse reactions or have an alternate physician available to address these issues.

Nurse Case Manager and Nurse Educator:

Note: Nursing support is provided by a third party company and consists of a nurse case manager and a nurse educator. The nurse case manager works remotely and is the patients' first point of contact for all issues regarding SCIG. The nurse educator is local and provides all training and follow up clinic visits.

1. Review and complete, with the patient, the Responsibility Agreement and maintain a record of the completed Agreement.
2. Educate the patient on safe and appropriate self-administration of SCIG.

3. Educate the patient on adverse reactions to SCIG and appropriate actions which include:
   3.1. Call nurse case manager (0800hrs to 2000hrs EST);
   3.2. Call the Newfoundland and Labrador Heathline at 811 or 1-888-709-2929; or,
   3.3. Call 911 or go to the closest emergency department for any emergency requiring immediate action.
4. Organize all necessary prescriptions:
   4.1. Prior to the patient running out of product (minimum 2 weeks), the patient will call the nurse case manager who will fax the product pick up form to the TML;
   4.2. When a new PPO is required, the TML will contact the nurse case manager, who will contact the physician to obtain the new PPO. The nurse case manager will then provide a copy to the TML prior to the patient arriving to pick up their next product batch; and,
   4.3. Should it occur that the blood bank lab does not have a valid PPO or current IgG level, and product is requested, the TML will contact the nurse case manager.
5. Organize the provision of infusion pumps and ancillary products (tubing, syringes, swabs, etc.).

   Note: The patient or their health insurance plan is responsible for the cost of disposable supplies.
6. Advise patient/caregiver on proper transportation and storage of SCIG.
7. Organize clinic follow up visits (coordination with pick-up of SCIG with TML is preferable).
8. Observe patient self-infusion technique periodically after initial training has been completed (suggest one month after initial education sessions and scheduled periodically thereafter).

Transfusion Medicine Laboratory:

1. Review SCIG requests using review and approval process for Ig found here to decide on PPO expiry based on condition.
2. Issue SCIG to the patient/caregiver as per facility policy in the lab information system (LIS).
3. Document the appropriate transportation and storage temperature of SCIG on the transport container.
4. Update infusion information from returned issue/transfuse cards into the LIS.
5. Notify TSO or designate of any adverse reactions noted on the returned issue/transfusion cards and/or any SCIG home infusion adverse reaction report forms returned to the TML.

6. Complete Adverse Events form if required (TSO or designate).
7. Report utilization of SCIG in the same manner as for IVIG in the Atlantic database Intravenous Immunoglobulin Network (IVIN).

Patient:

1. Complete home infusion training; demonstrate competence prior to initiation of self-administration regimen and one month after self-administration was initiated.
2. Undergo periodic reassessment regarding infusion technique as per an established review schedule discussed in training or based on needs during subsequent follow up.
3. Follow the instructions for home infusion as per the patient education materials or written modified program provided by nurse educator/physician.
4. Store SCIG in a temperature-controlled environment according to instructions provided in the product monograph.
5. Administer doses as scheduled by the attending physician.
6. 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.
7. Maintain and dispose of equipment as instructed.
8. Contact the nurse educator when questions regarding supplies or the home infusion process arise.
9. Contact the nurse case manager a minimum of two (2) weeks before additional product will be required, to arrange product pick-up.
10. Complete a letter of authorization for product pick-up for any person retrieving product from the TML, form NLSCIG-008 SCIG Letter of Authorization for Product Pick-up.
11. Document all adverse reactions on the SCIG home infusion adverse reaction form and forward the form to the TML. (Any adverse reaction that requires emergency medical attention should be reported to the prescribing physician before administering any other doses).
12. Attend all scheduled clinic appointments.
13. Follow physician prescribed schedule for having blood drawn to test IgG levels.
14. Complete the issue/transfusion cards for the SCIG and return them to the TML when retrieving the next SCIG inventory.

Quality Control

1. Conditions that are possibly indicated or not indicated for SCIG will follow the same process referenced in Review and Approval of Requests for IG.
2. Audits shall be performed, as per facility policy, to ensure home infusion patients complete and return the issue/transfusion cards.
3. SCIG shall be stored at temperature and duration specified in product monograph.
4. Products that are past the expiry date written on the product label shall not be transfused.

Key Words

Subcutaneous immune globulin, home infusion, primary immune deficiency, secondary immune deficiency

Supplemental Materials

Appendix A HyQvia Enrollment and Consent Form

Appendix B HyQvia Patient Pick-up Form

Forms

NLSCIG-002 SCIG Home Infusion Responsibility Agreement
NLSCIG-004 SCIG Order/Pick-up Notification
NLSCIG-008 SCIG Letter of Authorization for Product Pick-up
NLSCIG-009 SCIG Home Infusion Travel Letter
NLSCIG-010 SCIG Transfusion Medicine Laboratory Home Infusion Product Pick-up Record
NLSCIG-011 SCIG Home Infusion Adverse Reaction Form

Note: Patient and health care provider education and training is provided by third party nursing company. These resources are separate for the NLBBCP.

SCIG – Roles and Responsibilities

Physician	• Complete and fax the enrolment form. • Complete PPO and forward to Transfusion Medicine Laboratory. • Provide Patient with a requisition for IgG level testing. • Ensure PPOs are sent to Transfusion Medicine Laboratory when required. • Ensure IgG levels are tested when required.
Nurse Case Manager and Nurse Educator	• Contact patient to arrange training. • Provide training and education. • Verify prescriptions and bloodwork are ordered by physician. • Organize supplies. • Notify Transfusion Medicine Laboratory of product pick-up. • Follow-up with patient.
Transfusion Medicine Laboratory	• Receive order for product pick-up. • Confirm current PPO and IgG level. • Prepare product for patient pick-up. • Updates LIS when transfusion cards are returned. • TSO to complete adverse events form for any noted reactions. • Report SCIG utilization in IVIN database.
Patient	• Complete training and demonstrate competence in self-administration. • Undergo periodic assessments. • Store SCIG appropriately. • Follow dosing schedule. • Pick-up product from Transfusion Medicine Laboratory. • Document and report all adverse reactions. • Ensure required blood testing is completed. • Attend all scheduled appointments. • Complete and return all issue/transfusion cards.

References

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Canadian Society for Transfusion Medicine. (2022). *Standards for Hospital Transfusion Services.* (Version 5.0). Markham, ON: Author.

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Appendix A

ONEPATH SUPPORT FOR YOU, WITH YOU

HyQvia
Human Normal Immunoglobulin (10%)
Recombinant Human Hyaluronidase

Enrolment and Consent Form
Tel: 1-844-691-7284 Fax: 1-844-951-7284
Email: support@onepathprogram.ca

PATIENT INFORMATION

☐ Initial order ☐ Renewal/Update

Patient's Last Name: _____ Patient's First Name: _____
Health Card Number _____ Date of Birth: MM/DD/YYYY Gender: ☐ M ☐ F
Address: _____ City: _____ Province: _____ Postal Code: _____
Home Phone: (___) _____ Leave Message: ☐ Yes ☐ No
Alternate Phone: (___) _____ Leave Message: ☐ Yes ☐ No
Preferred Time to Call: ☐ AM ☐ PM ☐ Evening Preferred Language: ☐ English ☐ French ☐ Other: _____
Email: _____ Preferred Method of Communication: ☐ Phone ☐ Email

ONEPATH® PROGRAM SERVICES

Supplies Only (No additional program services required): ☐ Yes ☐ No Self-infusion Training*: ☐ Yes ☐ No
*The program provides up to 5 injection training visits. Additional support beyond initial training will be evaluated on an individual basis. It is recommended that a caregiver is present during training.

PRESCRIPTION INFORMATION

Patient Weight: _____ ☐ lbs ☐ kgs Height: _____ ☐ in ☐ cm Dose: _____ grams or _____ full vials (round up/down to full vial)
Frequency: ☐ Q3 weeks ☐ Q4 weeks # of Repeats: _____
Indication: ☐ Primary Immunodeficiency ☐ Secondary Immunodeficiency Other: _____
Other Instructions: _____

Health Care Provider Signature: _____ Date: MM/DD/YYYY
Has an order been sent to the blood bank? ☐ Yes ☐ No
If yes, which blood bank has the order been sent to? _____

☐ Patient previously on IVIG: First dose given approximately 1-2 weeks after last IVIG treatment

☐ Patient previously on SCIG: First dose given 1 week after last SCIG treatment

Available vial sizes: 2.5g, 5g, 10g, 20g, 30g

Suggested Ramp-up Schedule (see table below) to be used?
☐ Yes ☐ No (if no, ramp-up instructions to be given above in "Other Instructions" section)

Infusion #	Week	Proportion of target dose (Q3 weeks)	Proportion of target dose (Q4 weeks)
1st infusion	1	25%	25%
2nd infusion	2	50%	50%
3rd infusion	4	100%	75%
4th infusion	7	100%	100%

PHYSICIAN INFORMATION

Physician Name: _____ License: _____
Address: _____
City: _____ Province: _____ Postal Code: _____
Office Contact Person: _____
Phone: (___) _____ Fax: (___) _____
Email: _____

PATIENT CONSENT

I have read and understand the terms and conditions of this Consent and have agreed to enroll in the Program. By signing below, I hereby knowingly and voluntarily authorize the collection, use, disclosure and/or storage of my Health Information in connection with the Program in the manner described on page 2.

Signature of Patient or Legal Representative(s) _____

Printed Name of Patient or Legal Representative(s) _____ Date: MM/DD/YYYY

Relationship of Legal Representative(s) to Patient: _____

VERBAL CONSENT

IMPORTANT: If unable to obtain patient signature, please indicate that patient has provided consent

☐ Check here to acknowledge that verbal consent was obtained by the patient's health care provider.

Health Care Provider Signature: _____ Date: MM/DD/YYYY

Appendix B

HyQvia Patient Pick-up Form

Blood Bank: _____ Fax: _____

Patient's Name:
DOB:
Health Card: <<HC#>>
Patient's Phone Number:

Prescribing Physician:

Product being picked up: HyQvia (Immune Globulin Subcutaneous [human], 10% solution)
Number of vials required for initial Ramp-Up supply: <<number>> or see table below
Date product will be pick up by patient/designate: <<Date>>

Initial Treatment Interval/Dosage Ramp-Up Schedule					
Dose ___g/ Q3WEEKS	HyQvia 2.5g (25ml)	HyQvia 5g (50ml)	HyQvia 10g (100ml)	HyQvia 20g (200ml)	HyQvia 30g (300ml)
Week & Total Dose %					
Week 1 – 25%: X g/X ml					
Week 2 – 50%: X g/X ml					
Week 3	***NO INFUSION***				
Week 4 – 100%: X g/X ml					
TOTALS					
Then follow RX ongoing thereafter.					

The above listed patient will be picking up their initial supply of HyQvia on <<date>>. Please contact the OnePath® Program if you have any further questions or require an alternate pick-up date. If the patient has not picked up their product within 5 days of the requested date, please contact the OnePath® Program at 1-844-691-7284 so we can follow up accordingly.

If you have any questions or concerns, please feel free to call the OnePath® Patient Support Program toll-free at 1-844-691-7284, Monday-Friday; 8AM-8PM EST.

Sincerely,

[NCM Name]
Care Manager
OnePath® Patient Support Program