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 Manager, Provincial Blood Coordinating Program	**Issuing Authority** Dr. Lucinda Whitman Daphne Osborne
Author	Melissa Leonard
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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 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 in these recommendations.

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 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 intravenous immune globulin (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.

Guidelines

1. All hospitals in Newfoundland and Labrador obtain blood components and blood products from Canadian Blood Services. The provincial government pays for all plasma protein and related products (PPRPs). Patients are not required to pay for SCIG.
2. The cost of disposable supplies associated with home infusion is the responsibility of the patient. In some cases, personal health insurance providers may cover costs.
3. SCIG is contraindicated in:
    3.1. Individuals with a history of anaphylactic or severe adverse reactions to immune globulin; and,
    3.2. Individuals with immunoglobulin A (IgA) deficiency who have a known anti-IgA.
4. Benefits of SCIG:
    4.1. Provides a more stable immunoglobulin G (IgG) level;
    4.2. Difficult venous access is avoided;
    4.3. Less systemic adverse events reported;
    4.4. Convenient and time efficient for recipients;
    4.5. Avoidance of travel to Health Care Facility; and
    4.6. Offers flexibility in the infusion schedule.
5. Refer to Atlantic Clinical Indications and Criteria for Intravenous and Subcutaneous Immunoglobulin (IVIG/SCIG) for dosing guidelines and recommendations.
6. The dose is adjusted based on serum IgG levels, for PID and SID, and clinical response.
7. 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.
8. When switching patients from IVIG to SCIG, trough IgG levels must be obtained immediately before the patient's last infusion of IVIG and peak IgG levels obtained immediately before the initial infusion of SCIG. These results may assist the physician in determining the appropriate steady state IgG level for PID and SID.

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.).
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 IVIG 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.

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.
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 patient's 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 IVIG for Adults.
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

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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