Document Name: **SUBCUTANEOUS IMMUNOGLOBULIN (SCIG)- patient selection and management.**

Restrictions:

Governing requirements

For a hospital based SCIg program as per https://www.blood.gov.au/SCIg

Scope / Criteria

For patients to be approved to receive subcutaneous immunoglobulin (SCIg) they must fulfil the eligibility requirements of the Criteria for the clinical use of intravenous immunoglobulin in Australia 2nd Edition July 2012 (Criteria for use).
Approved access conditions for SCIg as per the National Blood Authority (NBA) SCIg is only approved for patients with a medical condition:
1. Where there is support for use cited in the *Criteria for the clinical use of intravenous immunoglobulin in Australia*, namely:

- primary immunodeficiency diseases with antibody deficiency
- specific antibody deficiency
- acquired hypogammaglobulinaemia secondary to haematological malignancies (chronic lymphocytic leukaemia, multiple myeloma, non-Hodgkin lymphoma and other relevant malignancies, and post-haemopoietic stem cell transplantation)
- secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency)

2. A patient-specific SCIg authorisation request submitted by treating specialist via BloodSTAR, and authorised by, the Australian Red Cross Blood Service (Blood Service).

Patient eligibility

Patients who are eligible for SCIg must also be physically and psychologically able to self-administer SCIg or have a carer who is willing and able to manage all aspects of care.
Consider: patient /carer ability to:
• Understand the importance of correct storage and handling of SCIg
• Understand correct equipment required to transport SCIg
• Draw up SCIg and manage consumables
• Perform the infusion and select correct infusion site/s
• Understand the infusion regimen
• Be able to record treatment in patient diary
• Understand the importance of reporting adverse effects or any concerns related to treatment
• Collect SCIg as scheduled
• Attend initial treatment training sessions and regular review by treating Medical Officer
Successful SCIg therapy depends on the patient's commitment to therapy and the education and support they receive. Patients should have input into what best suits their lifestyle/work commitments to establish a regimen that ensures maximum compliance.
Start the SCIg conversation - Introduce SCIg to patients using the conversation starter and NBA Patient information – https://www.blood.gov.au/system/files/documents/scig-trifold-patient-information-brochure20160307.pdf .

Contra-indications of SCIg:

- Anaphylactic or severe systemic reactions to immunoglobulin (Ig)
- Extensive skin conditions- psoriasis, eczema
- Cognitive impairment
- Poor manual dexterity, decreased hand grip, tremors, poor eyesight
- IgA deficiency – discuss with immunologist
- Patients with known hyperprolinemia should not receive Hizentra®.

Safety considerations

SCIG infusions have a very safe risk-profile. However, the risk cannot be guaranteed. To minimise any home-based complications, the treating clinicians will ensure:

- Only recipients who have previously received SCIG and who have not had an adverse reaction will be eligible to receive home transfusion.
- The recipient home shall have a working telephone, to access emergency services that can provide a rapid response at the recipient's location in the event of a severe or life threatening reaction.
- Another competent adult shall be available to assist the recipient for the entire period of the infusion and remain available to the recipient for at least 60 min thereafter.
- The patient will be informed of the appropriate method to seek medical assistance regarding home SCIG infusions.

Nurse competency

The nurse providing education to patients receiving SCIg should undertake in-service sessions to familiarise themselves with the available SCIg products, infusion systems and trouble shooting and demonstrate an understanding and competency in regards to the following:

- Patient assessment to ensure appropriate selection
- Contraindications of SCIg therapy
- SCIg policy and procedure documents
- Understanding of what immunoglobulins are, and why replacement is necessary
- SCIg product types
- SCIg and the criteria for use
- Documentation of SCIg batch number, expiry date, infusion site/s, dose given, volume per infusion site
- Product preparation
- Infusion techniques
- Infusion sites
- Equipment
- Storage and handling, transporting SCIg
- Laboratory tests required and frequency
- Adverse effect management and reporting
- Correct disposal of equipment
- Ordering of SCIg and where dispensed
- Patient education requirements and resources available

Patient identification process

- Yearly review of patients at organisation receiving Intravenous immunoglobulins (IVIg) eligible for SCIg per National Blood Authority (NBA) criteria.
- Patients identified by Nurse Unit Manager of Day procedure unit as being suitable on an adhoc basis, pending capacity to accept onto program.
- Patient identified by specialist / treating physician.
- Introduce SCIg to patients using the conversation starter publication and NBA Patient information – https://www.blood.gov.au/system/files/documents/scig-trifold-patient-information-brochure20160307.pdf ..

Specialist review

Once identified patients to see specialist/treating team to discuss with specialist transition to SCIg.

- Specialist to review/order IG levels via Dorevitch result CC to trak if none recent.
- Nurse to contact specialist re urgent appointment if patient having difficulty making appointment.
- To commence within 1-2 weeks of last IVIg dose if monthly / 1 week if fortnightly IVIg
- Complete section 2 of **SCIg - CSL Cares Nurse Care Patient Enrolment form**

Ordering

- Pharmacy require an outpatient prescription for all doses.
- Orders are written on the Medication chart for the training session.
- An Annual Blood Product Consent form completed.

SCIg approval / dispense process

Once the patient has been assessed by a relevant medical specialist and confirmed to meet criteria for SCIg therapy the following process applies:-

- Request for SCIg is created electronically by treating medical specialist or delegated Medical Officer (MO) via BloodSTAR
- Once request has been submitted via BloodSTAR the Australian Red Cross Blood Service (Blood Service) will review the request and if all the criteria are met the request is then approved.
- The requesting treating MO, and specialist are notified electronically via BloodSTAR and the affiliated pharmacy who issue/dispense the SCIg are notified electronically via BloodSTAR to BloodNet
- SCIg dose is then requested from the Blood Service and delivered to pharmacy
- SCIg is ordered and delivered to the pharmacy via BloodNet – traced via pharmacy system and dispensed and collected by patient.
- The amount of SCIG supplied to a patient should not exceed more than is required for two months' of treatment, with a number of repeats up to 6 months, as determined by the prescriber.

NB: SCIg is a Schedule 4 (S4) drug and is required to be dispensed via a pharmacy. "Schedule 4 Prescription Only Medicine or Prescription Animal Remedy – these drugs must be dispensed by a pharmacist and only on the prescription of a registered medical Practitioner or other authorised Practitioner"

Presentation

- Hizentra® which is a 20% concentrate comes [1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL) vials].
- *Evogam® is a 16% concentrate so has a larger volume per dose [0.8g (5mL), 3.2g (20mL) vials].*

Dosing

The treating medical specialist will ultimately determine the dose of SCIg to be provided for each patient.

As a guide patients will receive a dose 0.4g/kg in total per 4 week period.

- The dose can be divided into 4 weekly doses of 0.1g/kg or more depending on the volume per infusion site, dose and frequency as decided by clinician and as tolerated or decided by the patient
- **Example 1** patient weight =80kgs, 0.4g/kg = 32g, weekly dose of 0.1g/kg = 8g
- **Example 2** Patient is currently on 36 g IVIG every four weeks
    - The equivalent weekly SCIg = 9g / week
    - Calculation for Hizentra
        - 9g / 0.2 g/ml = 45 ml of SCIG Hizentra per week.
    - *Calculation for Evogam:*
        - *Volume in ml of SCIG that is needed for each dose would be:*
        - *SCIG dose (ml) = 9 g of SCIG / 0.160 g/ml = 56.25 ml of Evogam*
        - *This could be supplied by 55 ml of Evogam every week*
- Vials are available in different sizes and doses should be rounded to the nearest vial size.
- Patients may require a loading dose of IVIg 1-2 weeks prior to the commencement of SCIg to ensure adequate trough serum IgG level.
- Different patients will require different IgG levels to remain clinically well and free from infections and different dosing regimens to achieve and maintain appropriate trough IgG levels
- The choice of SCIg product is determined by the treating medical specialist in conjunction with the patient.
- Refer to product guides for further information
    - https://www.cslbehring.com.au/-/media/cslb-australia/documents/aus-pis-and-cmis/evogam-au-pi-800.pdf?la=en-us&hash=2FECE8E47F85B328F10996442028EC8F31F833DD Evogam®
    - https://www.cslbehring.com.au/-/media/cslb-australia/documents/aus-pis-and-cmis/hizentra-au-product-information-800.pdf?la=en-us&hash=852F1A8C1BA08F755B6BE1FE7209193EF0489F40 Hizentra®

Table 1: Product dosing guide

Evogam®	Hizentra®
• Evogam® dose and dosage interval must be individualized form each patient based on serum IgG trough levels and clinical response. • Dosage guideline: 0.2-0.6g/kg/body weight monthly. • Recommended initial infusion rate is 10mLs/hr gradually increased to 20mLs/hr as tolerated. • Maximum dose recommended is 40mLs/hr. • If larger doses are given >20mLs /site administration via multiple sites is recommended	• Hizentra® a loading dose of at least 0.2-0.5g/kg of body weight may be required. • Maintenance dose of 0.4 – 0.8g/kg of body weight depending on patients clinical response and serum IgG trough levels • Initial infusion rate depending on patient needs should not exceed 20mL/hr. If well tolerated infusion rate can be gradually increased to 35mL/hr/site (2nd or 3rd infusion). Then as tolerated by the patient. • If larger doses are given >25mLs /site administration via multiple sites is recommended (CSL Behring

Rate calculations

The infusion rate is dependent also on the equipment being used.
If using EMED pump and lines/ needles you can use the EMED calculator to work out the mL/hr per site and the expected length of time for the infusion. **SCIg EMED Versarate Plus flow calculator**

Patient education

Refer **SUBCUTANEOUS IMMUNOGLOBULIN (SCIG) – ADMINISTRATION**
Should be tailored to each individual's ability to learn, perform the procedure, the time involved and the number of training sessions required to feel comfortable and competent to home administer.
Note After the last IVIg infusion, the first training session would normally be at approximately 2 weeks (1 week if on fortnightly IVIg) to ensure the patient does not have too much of a trough in their IgG levels.
Please note that this timing may vary with different consultants.
Patients to be enrolled in CSL support program 'CSL Behring Cares Program' by first discussing the appropriate support offering with your patients receiving SCIg therapy.
– Complete **SCIg - CSL Cares Nurse Care Patient Enrolment form**
– Email form to **support@cslbehringcares.com.au** or fax the form to **1800 734 989**

Key align policies

MEDICATION Administration

Key align documents

SUBCUTANEOUS IMMUNOGLOBULIN (SCIG) – ADMINISTRATION
SCIg - CSL Cares Nurse Care Patient Enrolment form
SCIg- Doing your own Subcutaneous Immunoglobulin (SCIg) Infusion
SCIg EMED Versarate Plus flow calculator

Legislation, standards & best practice

POISONS CONTROL PLAN (PCP)

References

- https://www.transfusion.com.au/blood_products/fractionated_plasma/SCIg
- https://www.cslbehring.com.au/-/media/cslb-australia/documents/aus-pis-and-cmis/evogam-au-pi-800.pdf?la=en-us&hash=2FECE8E47F85B328F10996442028EC8F31F833DD Evogam®
- https://www.cslbehring.com.au/-/media/cslb-australia/documents/aus-pis-and-cmis/hizentra-au-product-information-800.pdf?la=en-us&hash=852F1A8C1BA08F755B6BE1FE7209193EF0489F40 Hizentra®

Contributors

	Name	Position	Involved in

	First initial. Surname	I.e. AUM Intensive care	Development / review	Ratification	Implementation	Compliance
Lead Reviewer:	C Polack	Transfusion Trainer	X			
Contributors:						
Committee/s:	Clinical policy, procedure and pathway committee			X		
Consumer input						
Executive sponsor	J Clift	Director of Nursing				

Implementation & communication Monthly Clinical policy, procedure and pathway committee memo
Education program

Compliance Riskman