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Subcutaneous immunoglobulin (SCIg) Clinical Practice Guidance Principles


Purpose of clinical practice guidance principles:
To administer subcutaneous immunoglobulin (SCIg) safely and according to the manufacturers’ instructions (product information). This information is a guide only. Health service procedures based on the information contained in this document should be implemented and monitored for compliance with best practice, safety guidelines and all other requirements specific to the products available. All health service policies/procedures should be developed in accordance with local procedure development policies and should be approved/endorsed by the appropriate committee/s

Organisation requirements for SCIg

Indications:
For patients to be approved to receive subcutaneous immunoglobulin (SCIg) they must fulfil the eligibility requirements of The Criteria for Immunoglobulin use in Australia (the Criteria) Version 3 (22 October 2018).
This is only available on line in BloodSTAR and at: www.criteria.blood.gov.au

Requirements for hospitals participating in national SCIg programs

Health services participating in the national SCIg programs are required to provide an acknowledgement of the governing requirements by the Chief Executive or Director of Clinical Services (or equivalent) prior to ordering and providing SCIg products to their patients. To access acknowledgement form go to: https://www.blood.gov.au - search SCIg managing hospitals to locate.

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. Being treated by a clinical specialist within a health service based SCIg program (see below), where the health service provides access to all resources and takes full accountability for the management and use of the SCIg product, at no additional cost to patients, and
3. Following a patient-specific SCIg authorisation request submitted via BloodSTAR, (www.blood.gov.au) and authorised by, the Australian Red Cross Blood Service (Blood Service).
To register and create a BloodSTAR account go to www.blood.gov.au select the Blood Portal tab, select New user? Create an account

Figure1: Login example
Subcutaneous immunoglobulin (SCIg) Clinical Practice Guidance Principles

Governing requirements for a hospital based SCIg program

Quality assurance
The health service must have in place policies and procedures that provide quality assurance and monitor compliance for the management and use of SCIg in line with the National Safety and Quality Health Service (NSQHS) Standards, particularly Standards 1 and 7.

Clinical oversight
The health service must have a recognised treatment program for the management and use of immunoglobulin for the relevant indications, including an appropriate supervising specialist as outlined in the National Blood Authority Governing requirements for a hospital based SCIg program pg. 2 https://www.blood.gov.au - search Governing requirements for a hospital based SCIg program to locate.
The health service based SCIg program must provide ongoing clinical oversight and support for participating patients. This may include community nursing, hospital in the home or contact persons for both routine and emergency support as required.
The responsible clinician must consider patient suitability for the self-management and administration of SCIg, to ensure appropriate management and use of SCIg product.

Equipment and facilities
The health service based SCIg program must ensure that patients have access to all necessary equipment and consumables to administer the product, at no additional cost to patients.

Education and training
The health service based SCIg program must provide education and training for staff and patients to ensure the appropriate management and use of SCIg, including for transport, storage, use of equipment and infusion techniques.

Regular review
Regular review to assess clinical benefit of treatment for ongoing therapy should be conducted at periods specified by the responsible clinician in line with the Criteria for Use. Patients should be encouraged to maintain a diary to record SCIg product use and any adverse reactions, as well as collection and management of the product to aid clinician at the assessment.

Resource considerations
The success of a SCIg program is dependent on appropriate resourcing which may include:

- Dedicated Registered Nurse specialist/s
- Consultant Medical specialist/s
- Pharmacist
- Consumables
- Availability of patient education and support resources

(Ozerovitch 2013)Nurse competency
The nurse providing education to patients receiving SCIg should demonstrate an understanding and competency in regards to the following:

- Patient assessment to ensure appropriate selection
- Contraindications of SCIg therapy
- Health service policy and procedure documents

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Subcutaneous immunoglobulin (SCIg) Clinical Practice Guidance Principles

- 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
- BloodSTAR – login
- Patient education requirements and resources available

[Younger et. al. 2015]

Medical considerations

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

Contraindications 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®

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.
Education 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. A range of education materials should be utilised to meet individual needs. Early and frequent reassessment during the first few months of therapy may be required to achieve this. (Younger et. al. 2015)

Patient information brochures can be found on the NBA website – click picture for link.

CSL Behring also has a range of patient information, treatment diaries and educational material and can be sourced by contacting Customer Service at: customerservice@cslbehring.com.au
For customer service enquiries for plasma-derived therapies within Australia phone: 1800 063 892

**SClg approval / dispense process**

All SClg approved health services will have an allocated facility administrator. The facility administrator will ensure all staff (medical, nursing; laboratory/pharmacy) have access to the relevant health service patients via BloodSTAR. Relevant staff are responsible for creating their own BloodSTAR log in account via the Blood Portal [www.blood.gov.au](http://www.blood.gov.au) Once created the facility administrator can then approve access as above.

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

- 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 laboratory/pharmacy who issue/dispense the SClg are notified electronically via BloodSTAR to BloodNet
- SClg dose is then requested from the Blood Service and delivered to the requesting laboratory/pharmacy

**NB:** SClg is a Schedule 4 (S4) drug and is required to be dispensed via a pharmacy. [Traceability regulations for blood products also need to be adhered to.](#)

“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
Options

1. SCIg is ordered and delivered to the laboratory via BloodNet – traced via the laboratory management system. SCIg is delivered from the laboratory to the pharmacy to be dispensed and collected by the patient.
2. SCIg is ordered and delivered to the pharmacy via BloodNet – traced via pharmacy system and dispensed and collected by patient.
3. Regional patients once competent to infuse at home may collect SCIg from a local pharmacy if required/more convenient. The NBA and Blood Service customer service can assist with setting up this process if the pharmacy is new to the dispensing of SCIg. www.blood.gov.au

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 the clinician and as tolerated or decided by the patient (Younger 2013, NBA criteria 2012).

Example patient weight = 80kgs, 0.4g/kg = 32g, weekly dose of 0.1g/kg = 8g

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 (Jolles 2014).

Evogam® is a 16% concentrate so has a larger volume per dose [0.8g (5mL), 3.2g (20mL) vials] than Hizentra® which is a 20% concentrate [1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL) vials]. The choice of SCIg product is determined by the treating medical specialist in conjunction with the patient. Refer to Appendix A for further information.

Table 1: Product dosing guide

<table>
<thead>
<tr>
<th>Product</th>
<th>Dose and Dosage Interval</th>
<th>Maintenance Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evogam®</td>
<td>0.2-0.6g/kg/monthly</td>
<td>0.2-0.5g/kg/monthly</td>
</tr>
<tr>
<td>Hizentra®</td>
<td>0.4 – 0.8g/kg/monthly</td>
<td>0.4 – 0.8g/kg/monthly</td>
</tr>
</tbody>
</table>

- Evogam® dose and dosage interval must be individualized form each patient based on serum IgG trough levels and clinical response.
- 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 (CSL Behring Evogam® PI).
- 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 15mL/hr. If well tolerated infusion rate can be gradually increased to 25mL/hr/site.
- If larger doses are given >25mLs/site administration via multiple sites is recommended (CSL Behring Hizentra® PI).
Nursing considerations

Infusion process: In the health service

Prior to commencing the infusion check:

- The patient has consented to receive SCIg
- SCIg has been prescribed
- The correct SCIg presentation has been issued (check that the dose for administration matches the dose authorised and matches the authorised product)
- SCIg has reached room temperature prior to infusion
- The correct corresponding infusion protocol for the patient has been identified (manual push or via infusion device/pump). The choice of administration technique and equipment is at the discretion of the treating healthcare professional and the patient, based on availability of devices and personal preference.
- Baseline observations have been taken and recorded
- Any pre-infusion symptom which may be confused with an adverse reaction has been noted

Checking the infusion:

- Check patient identity following usual health service protocol
- Check you have the right product as prescribed for this patient
- Check you have the right dose for this patient
- Check you have the right date/time the infusion is due
- Check you have the right rate of infusion. Different SCIg products are given according to different infusion schedules and patient clinical need.

Infusion: subcutaneous

- Please be aware that infusion volumes vary between products/presentations (see Table 1)
- Products/preparations are not interchangeable
- Administration techniques – may be via manual push infusion device/pump
- Infusion site selection – most common is lower abdomen - ensure site is at least 5cms from umbilicus
- Site rotation is not recommended - using the same site for infusion can help to reduce the amount of swelling and redness that can occur post infusion.

Observations

Perform and document the patient’s temperature, pulse, respiration rate and blood pressure at the following points as a minimum:

- prior to commencing
- on completion
- observe patient for 20 minutes post completion.

Please be aware that local policies may require more frequent observations. Similarly, if a patient experiences an adverse reaction to SCIg infusion more frequent observations may be required.
Nursing/patient considerations

Patient education

Patients should receive a personalised education programme in the health service by a clinical nurse specialist trained in how to administer SCIg therapy at home (Ozerovitch, 2013).

Home treatment: patient education requirements

- Treatment must be documented /recorded by patient/carer in patient treatment diary
- Patients must:
  - Receive appropriate training and education prior to self-administering at home
  - Understand transportation & storage requirements of specific product
  - Describe SCIg administration and appropriate sites for infusion
  - Understand and demonstrate care of infusion site
  - Describe appropriate supplies necessary to complete procedure
  - Understand how to use infusion device/pump, and what to do when not working or if alarm sounds
  - Understand “push” method as an alternative or when infusion device/pump is unavailable
  - Understand how to check and prepare product, how to report wastage and return unused product
  - Demonstrate ability to prepare infusion site and draw up product from single or multiple vials and prime tubing
  - Demonstrate insertion of subcutaneous needle/catheter /checking for blood/what actions to take if blood is present
  - Demonstrate appropriate aseptic technique
  - Demonstrate accurate administration of treatment, and removal and safe disposal of needle
  - Demonstrate ability to accurately record infusion treatment information in diary
  - Understand potential situations/reactions which could result from the infusion
  - Understand correct management of any reactions to treatment

Specific steps to be assessed prior to patient/carer considered competent to self-administer medication in a home setting. The number of training sessions should be individualised according to patient’s/carer’s needs (Wasserman 2008).


CSL Behring has a large range of patient information, treatment record diaries and other resources available for both patients and health care providers contact customerservice@cslbehring.com.au

Refer Appendix C for patient education template

Refer Appendix E for patient record template

For pictorial information on checking, drawing up and administering SCIg please contact CSL Behring customerservice@cslbehring.com.au
SCIg may be administered at a number of possible sites according to patient preference. Usually the lower abdomen will be used. Ensure selected site is at least 5cms from umbilicus “belly button”. The outer edge of the thigh or back of the upper arm can also be used. The shaded areas in Figure 2 can be used for insertion of the needle. [https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Clinical_Update_PID_2017.pdf](https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Clinical_Update_PID_2017.pdf)

NB: Rotation of infusion sites is not recommended. Using the same site for infusion can help to reduce the amount of swelling and redness that may occur post infusion. Avoid areas of rash, bruising, irritation.

**Adverse effects**

Adverse effects tend to most commonly be infusion site related. Table 2 and 3 outline possible effects and management.

Consideration should be given to patients who receive SCIg:
- for the first time
- when there has been a long interval since the previous infusion (8 weeks).

**Table 2: Possible side effects**

<table>
<thead>
<tr>
<th>Very Common</th>
<th>Common</th>
<th>Rare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infusion site related</td>
<td>Chills</td>
<td>Allergic reactions</td>
</tr>
<tr>
<td>Fever</td>
<td>Back pain</td>
<td>Anaphylactic shock</td>
</tr>
<tr>
<td>Nausea</td>
<td>Arthralgia</td>
<td>Thrombotic reactions</td>
</tr>
<tr>
<td>Vomiting</td>
<td>Hypotension</td>
<td>Urticaria</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 3: Adverse effect management at home [Ensure to record all adverse effects in patient diary]**

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Action 1</th>
<th>Action 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild (common skin reaction)</td>
<td>Apply cold pack to the area</td>
<td>Take paracetamol or antihistamine if instructed/ordered. Swelling should resolve over next 24-48hrs</td>
</tr>
<tr>
<td>Large swelling and redness at insertion site</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>STOP infusion for 30 minutes</td>
<td>Restart when symptoms have gone, Take paracetamol / antihistamine if instructed /ordered</td>
</tr>
<tr>
<td>Headache, flushing, nausea, shivering, itching,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>muscle aches, anxiety, dizziness, irritability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>STOP infusion</td>
<td>Tell your doctor or nurse specialist as soon as able</td>
</tr>
<tr>
<td>Chest pain, wheezing severe itching or any mild</td>
<td>Call 000 to get urgent medical</td>
<td></td>
</tr>
<tr>
<td>or moderate symptoms as above become worse</td>
<td>help</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lie or sit down as comfortable</td>
<td></td>
</tr>
</tbody>
</table>
Subcutaneous immunoglobulin (SCIg) Clinical Practice Guidance Principles

General considerations

Troubleshooting

<table>
<thead>
<tr>
<th>Troubleshooting Site reactions</th>
<th>Mild</th>
<th>Moderate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site reactions</td>
<td>Assess for tape allergy – change to paper/ hypoallergenic tape</td>
<td>Assess for tape allergy – change to paper/ hypoallergenic tape</td>
</tr>
<tr>
<td></td>
<td>Assess needle size- choose needle that is consistent with volume to be</td>
<td>Assess needle size- choose needle that is consistent with volume to be</td>
</tr>
<tr>
<td>- Blanching</td>
<td>infused</td>
<td>infused</td>
</tr>
<tr>
<td>- Redness/Rash</td>
<td>Assess length of needle – may be too short and infusing into the</td>
<td>Assess length of needle – may be too short and infusing into the</td>
</tr>
<tr>
<td>- Itching</td>
<td>intradermal layer</td>
<td>intradermal layer</td>
</tr>
<tr>
<td>- Discomfort</td>
<td>Assess site location – may be too close to muscle layer</td>
<td>Assess site location – may be too close to muscle layer</td>
</tr>
<tr>
<td>- Swelling</td>
<td>Decrease rate of infusion or volume per site</td>
<td>Decrease rate of infusion or volume per site</td>
</tr>
<tr>
<td></td>
<td>Avoid tracking of lg through the intradermal layer check needle tip is</td>
<td>Avoid tracking of lg through the intradermal layer check needle tip is</td>
</tr>
<tr>
<td></td>
<td>dry prior to insertion</td>
<td>dry prior to insertion</td>
</tr>
<tr>
<td></td>
<td>Consider appropriateness of rotating infusion site</td>
<td>Consider appropriateness of rotating infusion site</td>
</tr>
<tr>
<td></td>
<td>Consider use of topical anaesthetic cream</td>
<td>Consider use of topical anaesthetic cream</td>
</tr>
</tbody>
</table>

| Leaking at insertion site      | Assess needle - ensure fully inserted and fixed securely             | Assess needle - ensure fully inserted and fixed securely               |
|                                | Assess placement – is it in area of movement, consider alternative site | Assess placement – is it in area of movement, consider alternative site |
|                                | Assess length of needle – may be too short, change to longer needle | Assess length of needle – may be too short, change to longer needle    |
|                                | Assess infusion volume – decrease amount per site                    | Assess infusion volume – decrease amount per site                      |
|                                | Assess rate of infusion – slowing rate may help                      | Assess rate of infusion – slowing rate may help                        |

| Extreme discomfort with needle | Assess needle length ensure no too long and irritating abdominal wall | Assess needle length ensure no too long and irritating abdominal wall    |
|                                | Assess needle is being inserted “dry” to prevent tracking through   | Assess needle is being inserted “dry” to prevent tracking through       |
|                                | intradermal layer                                                  | intradermal layer                                                     |
|                                | Consider using needless indwelling subcutaneous catheter device     | Consider using needless indwelling subcutaneous catheter device        |
|                                | Consider using ice or topical anaesthetic cream prior to insertion  | Consider using ice or topical anaesthetic cream prior to insertion     |

| Long infusion time            | Ensure SCIg ready to use at room temperature                        | Ensure SCIg ready to use at room temperature                           |
|                                | Assess volume per site, rate of infusion, number of sites or adjust infusion | Assess volume per site, rate of infusion, number of sites or adjust infusion |
|                                | regime                                                              | regime                                                                  |
|                                | Check equipment for clamps/kinks, correct selection of needle size, tubing. | Check equipment for clamps/kinks, correct selection of needle size, tubing. |
|                                | If using a pump check function, battery not low                     | If using a pump check function, battery not low                        |

| Blood return observed         | Remove and discard needle with blood return and reinset with new     | Remove and discard needle with blood return and reinset with new        |
|                                | insertion needle and site                                           | insertion needle and site                                              |

https://www.slideshare.net/DallasAllergyImmunology/immunoglobulin-replacement-therapy
Adverse effect reporting

Adverse effects should be reported using in house quality management system and also reported to both the supplier and the Blood Service.

Supplier adverse event forms are available directly from the supplier or contact the Blood Service transfusion nurses (TN) who will forward a copy. Blood Service TN email: vtatn@redcrossblood.org.au  
CSL Behring email: adverse.events.global@csibehring.com

Where a change of product is required, this is done via BloodSTAR using a dose change request / initial authorisation request by the treating Medical Officer. There is also the option of creating an alert on BloodSTAR to prevent dispensing of the offending product. The alert can be added by the treating Medical Officer.
### Appendix A: Product description

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>Evogam®</th>
<th>Hizentra®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation</td>
<td>Solution; 0.8g (5mL), 3.2g (20mL) vials</td>
<td>Solution; 1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL) vials</td>
</tr>
<tr>
<td>Concentration</td>
<td>16%</td>
<td>20%</td>
</tr>
<tr>
<td>Distributor</td>
<td>Australian Red Cross Blood Service</td>
<td>Australian Red Cross Blood Service</td>
</tr>
<tr>
<td>Stabiliser ¹</td>
<td>Glycine</td>
<td>Proline (non-essential amino acid)</td>
</tr>
<tr>
<td>Storage Conditions</td>
<td>Refrigerate at 2-8°C for up to 2 years. Do not freeze. Once removed from refrigeration, store below 25°C and use within 2 weeks. Protect from light.</td>
<td>Store below 25°C for up to 30 months. Do not freeze. Protect from light.</td>
</tr>
<tr>
<td>Need for Reconstitution</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>IgA level ²</td>
<td>&lt; 0.025mg/mL</td>
<td>≤ 0.05mg/mL (normally below 0.005mg/mL).</td>
</tr>
<tr>
<td>Contraindications</td>
<td>Evogam® ® is contraindicated in patients who have had a true anaphylactic reaction to the active substance or to the excipient glycine</td>
<td>Hizentra® ® is contraindicated in patients with a history of severe systemic hypersensitivity or anaphylactic reactions/anaphylaxis to the active substance of Hizentra® ® or to any of its excipients. Hizentra® ® must not be used if any of the following listed conditions is existent: • Hyperprolinemia type I or II.</td>
</tr>
<tr>
<td>Precautions</td>
<td>Evogam® ® or Hizentra® ® for <strong>Subcutaneous</strong> administration only and <strong>must not</strong> be administered intravenously. They have not been studied for intravenous or intramuscular use. If Evogam® ® or Hizentra® ® is inadvertently administered into a blood vessel, patients could develop shock. In the case of shock, current medical standards for shock treatment should be implemented. <strong>Aseptic Meningitis Syndrome (AMS)</strong> Aseptic meningitis syndrome has been reported to occur in association with SCIg treatment. Discontinuation of SCIg treatment has resulted in remission of AMS within several days without sequelae. <strong>Hypersensitivity</strong> True hypersensitivity reactions are rare. They can occur in the very seldom cases of IgA deficiency with anti-IgA antibodies. Rarely, SCIg can induce a fall in blood pressure with anaphylactic reaction, even in patients who have tolerated previous treatment with human normal immunoglobulin. <strong>Thromboembolism</strong> There is clinical evidence of an association between Immunoglobulin administration and thromboembolic events such as myocardial infarction, stroke, pulmonary embolism and deep vein thromboses. Caution should be exercised in prescribing and infusing SCIg in obese patients and in patients with pre-existing risk factors for thrombotic events (such as advanced age, hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilisation, severely hypovolemic patients, and patients with diseases which increase blood viscosity). Patients should be sufficiently hydrated prior to the use of immunoglobulins</td>
<td></td>
</tr>
</tbody>
</table>
### Acute renal failure

There have been occasional reports of renal dysfunction and acute renal failure in patients receiving IVIG products. Patients at increased risk are those with pre-existing renal insufficiency, diabetes mellitus, age greater than 65 years, volume depletion, sepsis and paraproteinaemia, and those taking concomitant nephrotoxic drugs.

SC Ig should be administered at the minimum rate of infusion and dose practicable in patients at risk of acute renal failure.

### Pathogen safety

Refer to Product information

### Drug interactions - specific

The interaction of SCIg preparations with other medicines has not been established in appropriate studies. Immunoglobulin infusion may impair the efficacy of live attenuated virus vaccines such as measles, rubella, mumps and varicella for a period of at least six weeks and up to three months. After infusion of SCIg an interval of three months should elapse before vaccination with live attenuated virus vaccines. In the case of measles, this impairment may persist for up to one year. Therefore patients receiving measles vaccine should have their antibody status checked. Additionally, immunoglobulins should not be administered for at least two weeks after these vaccines are given.

### Use in pregnancy – General

The safety of this product for use in human pregnancy has not been established in controlled clinical studies. Evogam®® should be given to pregnant women only if clearly needed. Hizentra®® should only be given with caution to pregnant women and breast-feeding mothers. Clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus or the neonate are to be expected.

### Use in lactation

Immunoglobulins are excreted in breast milk and may contribute to the transfer of protective antibodies to the neonate.

### Effects on Fertility

No reproductive toxicity studies have been conducted with Evogam®®. Based on clinical experience with immunoglobulins it is suggested that no harmful effects on fertility are to be expected.

### Paediatric use

There were no apparent differences in the safety and efficacy profiles as compared to adults. No paediatric-specific dose adjustments were necessary to achieve the desired serum IgG levels. The safety and efficacy of Evogam®® was not studied in the paediatric population under five years of age. Clinical trials with Hizentra®® showed a similar safety profile in paediatric and adult patients. The safety and efficacy of Hizentra®® has not been formally studied in paediatric patients under two years of age.

### Use in the elderly

Clinical trials with Evogam®® did not include sufficient numbers of patients aged 65 years and over to determine whether safety of this product is different in this population. Limited information available in clinical trials showed no difference in safety profile in patients ≥65 years of age than in younger patients.

### Genotoxicity

No genotoxicity studies have been conducted

### Carcinogenicity

No carcinogenicity studies have been conducted

### Adverse Effects – General

After infusion of immunoglobulin the transitory rise of various passively transferred antibodies in the patient’s blood may result in misleading positive results in serological testing. Passive transmission of antibodies to erythrocyte antigens e.g. A, B, D may interfere with some serological tests for red cell allo-antibodies for example the antiglobulin test.

<table>
<thead>
<tr>
<th>Adverse Effects – Specific</th>
<th>Very Common</th>
<th>Common</th>
<th>Rare</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Refer to relevant PI for detailed information)</td>
<td>Infusion site reaction, Headache, Nausea, Vomiting, Diarrhoea, Abdominal pain, Fever, Pain in extremity</td>
<td>Chills, Fatigue, Back pain, Arthralgia, Myalgia, Hypotension</td>
<td>Hypersensitivity, allergic reactions, anaphylactic shock, thromboembolic reactions, Aseptic Meningitis.</td>
</tr>
</tbody>
</table>
Subcutaneous immunoglobulin (SCIg) Clinical Practice Guidance Principles


| Monitoring | In health service use only - Baseline set of vital signs. Closely monitor patient for any adverse events during infusion and for at least 20 minutes post infusion. Slowing or stopping the infusion usually allows the symptoms to subside. Assess vital signs, notify the medical officer, and provide emergency care as required. Minor reactions: the infusion may be resumed at a slower rate or rate that does not result in recurrence of the symptoms once the patient is stable and has clinically improved. Severe reactions stop infusion, Notify Medical Officer. Initiate appropriate treatment. Report Adverse reaction as per health service policy and procedure and to the relevant company (CSL/Grifols)

The following patients may experience a higher frequency of adverse events, including those of a minor nature when receiving SCIg:
- those receiving SCIg for the first time
- when there has been a long interval since the previous infusion or
- in rare cases, when the human normal immunoglobulin product is switched

| Administration | Should only be administered SUBCUTANEOUSLY. Must not be mixed with any other product. Should be brought to room temperature before use.

| Appearance | Evogam® solution is clear and colourless or pale-yellow or light brown. If Evogam® appears to be turbid or to contain sediment, it must not be used. Do not use if the solution has been frozen. Hizentra® is normally clear and pale-yellow or light-brown. If it appears to be cloudy or contains particulate matter, do not use. Do not use if the solution has been frozen.

| Infection Control | Evogam® and Hizentra® contain no antimicrobial preservative. They must, therefore be used immediately after opening the bottle. Use in one patient on one occasion only. Any unused portion should be discarded appropriately.

| Traceability | The name and batch number of every SCIg bottle administered to a patient must be recorded for traceability purposes.

| Equipment | Alcohol cleansing wipe, subcutaneous needle/s, extension tubing set, leur lock syringe/s, sterile dressing, adhesive tape, EMLa cream if required (paediatric use), cotton balls, sharps container, subcutaneous infusion pump if required (pumps must be used in compliance with manufacturer’s instructions. Patient record sheet/diary

| Dosage and rate of infusion | 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 15mL/hr. If well tolerated infusion rate can be gradually increased to 25mL/hr/site. If larger doses are given >25mLs/site administration via multiple sites is recommended

| Considerations | Where a patient is appropriate for home administration of SCIg, the patient or caregiver must be instructed in: subcutaneous administration techniques; the keeping of a treatment diary; recognition of adverse reactions and measures to take in the case of adverse reactions.

Notes: Although the majority of renal adverse events have occurred with sucrose containing IVIg products, caution is also advised during administration of any SCIg product(1). For IgA deficient patients, product with the lowest IgA level should be selected(2).

References:

Version 9 – February 2019
Appendix B: Infusion equipment

NB: The information below is an example of equipment and devices available. Blood Matters do not endorse the use of any particular equipment/resources. Health services should clarify the information with the suppliers independently and source equipment available and purchase equipment appropriate to their patient needs.

EMED Technologies

**SC lg 60 infusion system** – pump, rate control dial and needles (24 & 27 gauge – 1, 2, 3, 4 lumens – 4, 6, 9 & 12mm length).
The 24 gauge needles are the most appropriate for “push” administration as it allows the viscous SC lg to be administered with less force by the patient. The smaller the lumen the more difficult it is to push.
The multiple lumens allow for faster total administration as the recommended rate of SC lg is 25mL/hour/site. If patients’ dose is greater than 25mL in volume, it is advisable to administer in multiple sites.
This pump is an option for patients who have dexterity issues, as it does not require force to operate, and the rate control dial allows the patient to easily control the rate of administration.

**Contact details**
02 9450 0844
Website: [http://emedicaldevices.com/infusion-pumps.shtml](http://emedicaldevices.com/infusion-pumps.shtml)

LTR Medical

**Springfuser** – pump and rate control tubing (30mL in 5 minute is the preferred rate control tubing used by health services with 27 gauge needles – it does not run this fast for SC lg as the rate control tubing is designed for intravenous administration of fluid). The rate control tubing is not adjustable so does not allow the patient to adjust the rate during the infusion; however, they can stop at any time by removing the syringe or clamping the line. 1 x 35mL syringe is supplied with the rate control tubing.

NB: the springfuser is not validated specifically for SC lg use which may lead to issues with procurement of this device for SC lg infusion

**Contact details**
1800 319 419
info@ltrmedical.com
Website [http://ltrmedical.com/springfusor](http://ltrmedical.com/springfusor)

CLINECT

**Neria** - needles 27gauge – 1 & 2 lumen.
Caution: commonly used with a pump. They are too small for the viscosity of SC lg if using “push method”.

**Contact details**
03 9918 5555
www.clinect.com.au
Subcutaneous immunoglobulin (SCIg) Clinical Practice Guidance Principles

REM Systems
NIKI T 34 (30mL syringe/24mL volume) & T34L pumps (60mL syringe) - pump
Contact details
1800 737 222
Website: Niki T34 (takes up to 30mL syringe with 24mL volume) http://www.cme-infusion.com/syringe-pumps
NIKI T34L (takes a 60mL syringe and 60mL volume) http://www.cme-infusion.com/syringe-pumps

MEDICAL DEVICES
Hi-FLO (needles 27guage) and Freedom 60 infuser – pump
SCIg validated infusion device and needles. For further information
Contact details
1800 77 51 51
sales@medicaldevices.com.au
Website: http://www.rmsmedicalproducts.com/products/
Appendix C: Patient education competency template

Insert health service details

Steps must be assessed by the clinician prior to patient/carer being competent to self-administer SCIg. The number of training sessions required are individualised for each patient.

<table>
<thead>
<tr>
<th>Patient Skills</th>
<th>Session 1</th>
<th>Session 2</th>
<th>Session 3</th>
<th>Session 4</th>
<th>Session 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Date:<strong>/</strong>/__</td>
<td>Date:<strong>/</strong>/__</td>
<td>Date:<strong>/</strong>/__</td>
<td>Date:<strong>/</strong>/__</td>
<td>Date:<strong>/</strong>/__</td>
</tr>
<tr>
<td></td>
<td>Clinician Name:</td>
<td>Clinician Name:</td>
<td>Clinician Name:</td>
<td>Clinician Name:</td>
<td>Clinician Name:</td>
</tr>
<tr>
<td></td>
<td>Signature:</td>
<td>Signature:</td>
<td>Signature:</td>
<td>Signature:</td>
<td>Signature:</td>
</tr>
<tr>
<td>Competent (C)</td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Not yet competent (NYC)</td>
<td>NYC</td>
<td>NYC</td>
<td>NYC</td>
<td>NYC</td>
<td>NYC</td>
</tr>
<tr>
<td>(Please circle)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Describe transportation &amp; storage of SCIg product</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Define SCIg administration &amp; location of infusion site/s</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrates appropriate selection of infusion sites</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Understands appropriate equipment required</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrates understanding of infusion device/pump (only required if infusion device/pump used)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrates understanding of “push” method. (pt must be aware even if infusion device/pump is used)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrates understanding of SCIg checking – type, dose, expiry, discolouration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrates understanding of how to draw up SCIg from single or multiple vials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrates ability to: - prime tubing and set up pump (where pump used)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrate ability to - prepare skin for infusion site -insert s/c needle/catheter using no touch (aseptic) technique -secure needle/catheter check for blood return</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrate ability to remove and safely discard needle</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrates ability to accurately record treatment in infusion diary and understands how to report waste and return unused SCIg</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrates understanding of adverse effects and how to manage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Created using NBA, Sunshine Health Service documents, Younger et. al. 2015
Appendix D: Consumable supply list template

*Insert hospital details*

Use as a guide to equipment required by patient to home administer SCIg.

Modify depending on infusion method and consumables available within your hospital.

<table>
<thead>
<tr>
<th>Patient supply</th>
<th>Number to be supplied each month</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SClg Product</strong></td>
<td></td>
</tr>
<tr>
<td>Hizentra® – vial size</td>
<td></td>
</tr>
<tr>
<td>1g (5mL)</td>
<td></td>
</tr>
<tr>
<td>2g (10mL)</td>
<td></td>
</tr>
<tr>
<td>4g (20mL)</td>
<td></td>
</tr>
<tr>
<td>10g (50mL)</td>
<td></td>
</tr>
<tr>
<td>Evogam® – vial size</td>
<td></td>
</tr>
<tr>
<td>0.8g (5mL)</td>
<td></td>
</tr>
<tr>
<td>3.2g (20mL)</td>
<td></td>
</tr>
<tr>
<td><strong>NB:</strong> Dose approved and frequency of infusion needs to be considered when requesting SClg. Ensure vials requested match dose required to ensure no waste.</td>
<td></td>
</tr>
<tr>
<td>Hizentra® : 1g___________</td>
<td>2g___________</td>
</tr>
<tr>
<td>4g___________</td>
<td>10g__________</td>
</tr>
<tr>
<td>Evogam® : 0.8g___________</td>
<td>3.2g___________________________</td>
</tr>
<tr>
<td><strong>Small Esky – ice bricks if required Evogam® must be stored between 2-8 degrees Celsius. Utilise esky in cases of extreme heat and long travel distance for Hizentra® to ensure product remains below 25 degrees Celsius</strong></td>
<td></td>
</tr>
<tr>
<td>Plastic container to store SClg in refrigerator</td>
<td></td>
</tr>
<tr>
<td><strong>Infusion pump enter details of equipment selected if using this infusion method</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Leur lock syringe 10mL , 20mL, 30mL, other size if required</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Drawing up needle 19 gauge</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Infusion needle/s /catheter of choice - add details of choice</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Infusion extension set if required</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Alcohol prep swabs</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Surgical tape</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Cotton wool balls</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Sharps container (exchange when full)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Infusion diary</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Topical anaesthetic cream if required e.g. EmLa cream</strong></td>
<td></td>
</tr>
</tbody>
</table>

Created using Sunshine Health Service, Duff et. al. 2015, Younger et. al. 2013.
### Appendix E: Patient record template

*Insert hospital details*

**Healthcare team contact details**

Hospital /Clinic name:________________________________________________________________________

Specialist name:____________________________________________________________________________

Phone:________________________________ email: (if applicable)_____________________________________

Nurse name:________________________________________________________________________________

Phone:________________________________ email: (if applicable)_____________________________________

General Practitioner name:______________________________________phone:_________________________

Product: (circle) Evogam® Hizentra® Dose:_______g / _____________mL Frequency:____________________

**Infusion Record**

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date and Time</td>
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<tr>
<td>Volume</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site/s used</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Side effects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medications used</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Batch numbers</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>(affix label/s)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notes</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Next appointment date:________________________________________________________

Created using CSL Behring’s ‘Hizentra®’, Sunshine Health Service, Duff et. al. 2015, Younger et. al. 2013. NB: CSL Behring have patient record booklets available for both Evogam® and Hizentra®
Appendix F: Suggested headings for Clinical Practice Template.

Overview of available SCIg products

Indications

Precautions

Contraindications

Adverse effects

SCIg presentation

Storage and transport conditions

Infusion site selection

Administration techniques

Equipment/consumables

Patient selection criteria

Patient education checklist

Administration procedure

Waste disposal

Record keeping - recording infusion/reporting waste

SCIg ordering

Collection of SCIg supply

Follow up/review requirements
Reference list/recommended reading

NBA related


Transfusion.com.au


CSL Behring

CSL Behring has a large range of patient information and other resources available for both patients and health care providers contact customerservice@cslbhering.com.au

Evogam®, product information. CSL Behring (Australia) Pty Ltd. 2015


Hizentra®, product information. CSL Behring (Australia) Pty Ltd. 2014


Other websites

Australasian Society of Clinical Immunology and allergy (ASCIA)  https://www.allergy.org.au


Journal Articles

Duff, C., Ochoa, D., Riley, P., Murphy, E., Zampelli, A. 2013 Importance of Ancillary supplies for Subcutaneous Immunoglobulin Infusion. *Journal of Infusion Nursing* pp384-390

Gerth, W., Betschel, D., Zbrozek, A. 2004 Implications to payers of switch from hospital-based immunoglobulin to home-based subcutaneous immunoglobulin therapy in patients with primary and secondary immunodeficiencies in Canada. *Allergy, Asthma & Clinical Immunology*, 10:23 http://www.aacijournal.com/content/10/1/23 accessed June 8 2017


Younger, E., Blouin, W., Duff, C., Buehler, K., Murphy, E. 2015 Subcutaneous Immunoglobulin Replacement Therapy: Ensuring Success. *Journal of Infusion Nursing* pp70-79.

Younger, M., Blouin, W., Duff, C., Epland, K., Murphy, E., Sediak, D. 2013 Nursing Guidelines for Administration of Immunoglobulin Replacement Therapy. *Journal of infusion Nursing* pp58-68


Acknowledgements

Blood Matters would like to acknowledge the Victorian Transfusion Nurse Team of the Australian Red Cross Blood Service for their contributions to this document.

Sunshine Coast Hospital and Health Service for allowing their SCIG related documents to be accessed and used.

Other examples are available at Blood Matters website and are available for use with appropriate acknowledgments /permission https://www2.health.vic.gov.au/hospitals-and-health-services/patient-care/speciality-diagnostics-therapeutics/blood-matters