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# 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. It could be used by health services when developing a program and/or creating/updating policy and procedures.

Health service policy/procedures based on this information 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.

The current SCIg products (2021) include/will include:

* Evogam® (CSL) a 16% concentrate, volume per dose [0.8g (5mL), 3.2g (20mL) vials]
* Hizentra® (CSL) a 20% concentrate, volume per dose [1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL) vials]
* Cuvitru ® (Takeda) a 20% concentrate [1g (5mL), 2g (10mL), 4g (20mL), 8g (40mL)]. Normal Immunoglobulin (human) contains at least 98% IgG.
* Hyqvia® (Takeda) a 10% concentrate - available vials sizes and implementation date to be confirmed. Volume per dose could include [2.5g (25mL), 5.0g (50mL), 10.0g (100mL), 20.0g (200mL) or 30.0g (300mL) of the active Normal Immunoglobulin (Human)]. Hyqvia is administered with Vorhyaluronidase alfa, a permeation enhancer. Hyqvia is comprised of two vials, Normal immunoglobulin and corresponding quantity of Vorhyaluronidase alfa.

**NB:** The subsidised SCIg treatment (product) prescribed is decided by the treating medical specialist in conjunction with the patient to determine the most suitable product for their individual situation.

Health services may choose to limit the number of products held in consultation with clinical staff.

# Organisational requirements to establish a SCIg program

## 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](http://www.criteria.blood.gov.au)

Acknowledgement form

Health services 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/SCIg> .

## Approved access conditions for SCIg as per the National Blood Authority (NBA)

SCIg is only available under national blood supply arrangements for patients with a medical condition:

1. Where there is support for use cited in the Criteria for the clinical use of immunoglobulin in Australia, namely:

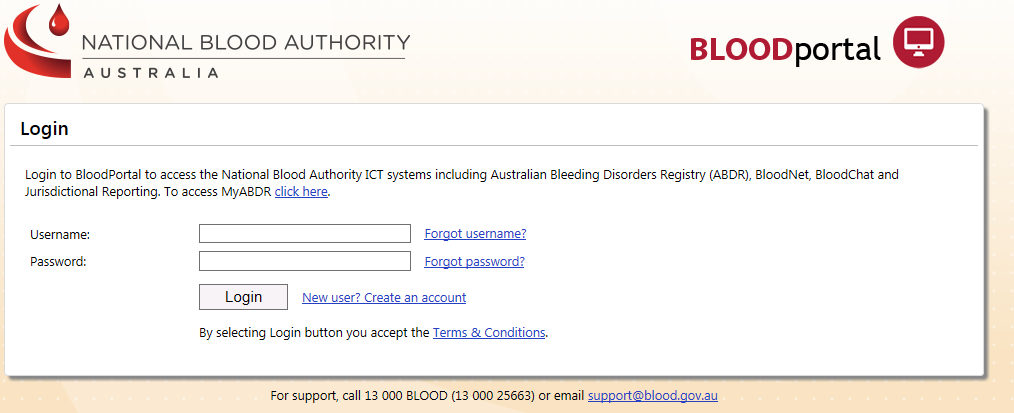
* primary immunodeficiency diseases with antibody deficiency
* specific antibody deficiency
* acquired hypogammaglobulinaemia secondary to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)
* secondary hypogammaglobulinaemia unrelated to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)
* Chronic inflammatory demyelinating polyneuropathy (CIDP), (including IgG and IgA paraproteinaemic demyelinating neuropathies)\*

\* SCIg is approved for use for the treatment of CIDP under the national blood arrangements pending the outcome of a current Health Technology Assessment (HTA) review evaluating the use of immunoglobulin in the treatment of CIDP. Further information is available <https://www.blood.gov.au/access-sub-cutaneous-immunoglobulin-scig-chronic-inflammatory-demyelinating-polyneuropathy-cidp>, and

1. Being treated by a clinical specialist within a hospital based SCIg program (see below), where the hospital 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
2. Following a patient-specific SCIg request submitted and approved in BloodSTAR.

To register and create a BloodSTAR account go to [www.blood.gov.au](http://www.blood.gov.au) select the Blood Portal tab, select New user? Create an account (Figure 1). Tip sheets for creating an account are located: <https://www.blood.gov.au/bloodportal>

Figure1: Login example



## Governing requirements for a hospital based SCIg program

The following information is outlined in the National Blood Authority Hospital Acknowledgement Form National Subcutaneous Immunoglobulin Program found at: <https://www.blood.gov.au/SCIg>

**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 Standards (NSQHS), the Clinical Governance Standard Standards (1) and the Blood Management Standard (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.

The health service based SCIg programs 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 the 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
* Laboratory/blood bank scientists
* Consumables
* Availability of patient education and support resources

## 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
* 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, handling, and transporting SCIg
* Patient monitoring including required pathology tests and frequency
* Adverse effect management and reporting
* Correct disposal of equipment
* Ordering and dispensing of SCIg and where dispensed
* BloodSTAR – login, planning, monitoring and trouble shooting
* Patient education requirements and resources available

(Ozerovitch 2013, 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 the participants (patient/carer’s) ability to:

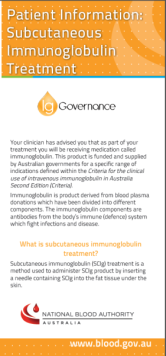
* Understand the importance of correct storage and handling of SCIg
* Understand correct equipment required to transport SCIg
* Draw up SCIg and manage consumables
* Perform the infusion and select correct infusion site/s
* Understand the infusion device/pump use and what to do when it not working or if the alarm sounds
* Understand the “push” method as an alternative or when the infusion device/pump is unavailable
* Understand safe disposal of sharps
* Understand and maintain the infusion regimen
* Be able to record treatment in patient diary/record/treatment App
* Understand the importance of reporting adverse effects or any concerns related to treatment
* Collect SCIg as scheduled
* Attend treatment training sessions and regular review by treating Medical Officer.

Contraindications of SCIg:

* Anaphylactic or severe systemic reactions to immunoglobulin (Ig) or known systemic hypersensitivity to any of the excipients
* Extensive skin conditions - psoriasis, eczema
* Cognitive impairment
* Poor manual dexterity, decreased hand grip, tremors, poor eyesight
* IgA deficiency – discuss with immunologist (Cuvitru® and Hyqvia® - patients with severe IgA deficiency)
* Hizentra® - patients with known hyperprolinemia (Type I or II)
* Evogam® - patients known reactions to glycine
* Hyqvia® - patients with known systemic hypersensitivity to hyaluronidase or Vorhyaluronidase alfa, or known systemic hypersensitivity to any of the excipients.

Successful SCIg therapy depends on the participants commitment to therapy and the education and support they receive. Participants 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. The time involved and the number of training sessions required for the individual to perform the procedure, feel comfortable and competent to home administer may vary and needs to be considered when commencing training. 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).

[](https://www.blood.gov.au/system/files/documents/scig-trifold-patient-information-brochure20160307.pdf)

Patient information brochures located on the NBA website – <https://www.blood.gov.au/system/files/documents/scig-trifold-patient-information-brochure20160307.pdf>.

CSL Behring also has a range of patient information, treatment diaries and educational material and is available by contacting Customer Service at: [customerservice@cslbehring.com.au](mailto:customerservice@cslbehring.com.au)

For customer service enquiries for plasma-derived therapies within Australia phone: 1800 063 892

Takeda patient information (consumer information (CI)) is available <https://www.takeda.com/en-au/what-we-do/our-products/>

## SCIg approval/dispensing process

All SCIg approved health services will have an allocated BloodSTAR 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 SCIg therapy the following process applies:

* Request for SCIg is created electronically by treating medical specialist or delegated Medical Officer (MO) via BloodSTAR. The NBA has a tip sheet to assist <https://www.blood.gov.au/system/files/FINAL-BloodSTAR-Requesting-SCIg-tipsheet.pdf> (This requires a BloodSTAR login - <https://www.blood.gov.au/system/files/BloodSTAR-User-Tip-Sheet-Registration%20-and-Role-Requests.pdf> )
* Once request has been submitted via BloodSTAR the Australian Red Cross Lifeblood (Lifeblood), 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 SCIg are notified electronically via BloodSTAR to BloodNet
* SCIg dose is then requested from Lifeblood and delivered to the requesting laboratory/pharmacy.

**NB:** SCIg is a Schedule 4 (S4) drug that is required to be prescribed by an authorised practitioner (e.g. a medical practitioner) and dispensed by a pharmacist in the lawful practice of their profession. Alternatively, the prescriber may also be authorised to supply S4 drugs, however, they must ensure that true and accurate records are made and that each container of a medicine is labelled in accordance with the specifications for ‘dispensed medicines’ contained in the Poisons Standard plus drugs and poisons legislation (where applicable). This responsibility cannot be delegated to another person. Health practitioners must also ensure adherence to traceability regulations for blood products. Further information regarding the regulatory requirements for health practitioners is located here**:** [**https://www2.health.vic.gov.au/public-health/drugs-and-poisons/health-practitioners**](https://www2.health.vic.gov.au/public-health/drugs-and-poisons/health-practitioners)

Traceability is required – further information can be found [add the link to the Blood Matters webpage document]

**Options for SCIg dispensing to ensure traceability**

1. SCIg is ordered and delivered to the transfusion laboratory (or pathology service) 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 Lifeblood customer service can assist with setting up this process if the pharmacy is new to the dispensing of SCIg. [www.blood.gov.au](http://www.blood.gov.au)

# N**ursing considerations**

## Infusion process: in the health service

**Prior to commencing the infusion check**:

* The patient has consented to receive SCIg as per health service requirements
* SCIg has been prescribed (dose, route and frequency)
* The correct SCIg presentation has been issued (check that the prescribed 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 the expiry date of the product – do not use if expired
* Check that the product meets the visual inspection criteria
* 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 Tables 1 & 2)

* Products/preparations are not interchangeable. Change only occurs if there is a clinical reason for change and a new authorisation and prescription has been obtained
* Administration techniques – may be via manual push or 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 as tolerance develop and this can help to reduce the amount of swelling and redness that can occur post infusion.

## Observations – in health service

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.

# Patient education

Patients should receive a personalised education programme. This may be undertaken in the health service by a clinical nurse specialist trained in how to administer SCIg therapy at home, or through the CSL Cares program or other approved nursing service.

**Home treatment: patient education requirements**

* Treatment must be documented/recorded by participants in patient treatment diary/record/App
* Participants must:
  + Receive appropriate training and education prior to home administration
  + Understand transportation and 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,
  + 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
  + Understand potential situations/reactions which could result from the infusion
  + Understand correct management of any reactions to treatment
  + Understand how to report wastage and return unused product
  + Understand ordering and collection of product and consumables

Specific steps to be assessed prior to participant considered competent for home administration. The number of training sessions should be individualised according to participants’ needs

(Wasserman 2008).

National Blood Authority website: <https://www.blood.gov.au/system/files/documents/scig-training-checklist-for-patients.pdf> - Training Checklist for Home Administered Subcutaneous Immunoglobulin (SCIg) Infusion Treatment – example template.

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](mailto:customerservice@cslbehring.com.au)

Takeda patient information (consumer information (CI)) is available <https://www.takeda.com/en-au/what-we-do/our-products/>

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](mailto:customerservice@cslbehring.com.au)

Takeda patient information (consumer information (CI)) is available <https://www.takeda.com/en-au/what-we-do/our-products/> incudes detailed instructions for administration.

# Dosing

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

Please check the manufacturers’ product information (PI) for specific dosing. As a guide, patients may 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 (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).

The treating medical specialist in conjunction with the patient determines the SCIg product most suitable for their individual situation. Health services may choose to limit the number of products held in consultation with clinical staff. Refer to Appendix A for further product information.

The current SCIg products (2021) include/will include:

* Evogam® (CSL) a 16% concentrate, volume per dose [0.8g (5mL), 3.2g (20mL) vials]
* Hizentra® (CSL) a 20% concentrate, volume per dose [1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL) vials]
* Cuvitru ® (Takeda) a 20% concentrate [1g (5mL), 2g (10mL), 4g (20mL), 8g (40mL)]. Normal Immunoglobulin (human) contains at least 98% IgG.
* Hyqvia® (Takeda) a 10% concentrate - available vials sizes and implementation date to be confirmed. Volume per dose could include [2.5g (25mL), 5.0g (50mL), 10.0g (100mL), 20.0g (200mL) or 30.0g (300mL) of the active Normal Immunoglobulin (Human)]. Hyqvia is administered with Vorhyaluronidase alfa, a permeation enhancer. Hyqvia is comprised of two vials, Normal immunoglobulin and corresponding quantity of Vorhyaluronidase alfa.

Table 1: Product dosing guide\*

|  |
| --- |
| **Evogam® (CSL)** dose and dosage interval must be individualised for 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 10mL/hr gradually increased to 20mL/hr as tolerated.  Maximum dose recommended is 40mL/hr.  If larger doses are given >20mL /site administration via multiple sites is recommended (CSL Behring Evogam® PI). |
| **Hizentra® (CSL**)  **Replacement therapy-** 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  **Immunomodulation therapy** - The recommended subcutaneous dose is 0.2 to 0.4 g/kg of body weight per week. The dose may need to be adapted to achieve the desired clinical response.  Infusion device/pump - 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.  If larger doses are given >25mLs /site administration via multiple sites is recommended (CSL Behring Hizentra® PI).  Manual push - the recommended initial infusion rate should not exceed 0.5 mL/min (30 mL/hour/site).  If well tolerated, the infusion rate can be increased up to 2.0 mL/min/site (120 mL/hour/site), based on the healthcare professional’s judgement and patient’s individual tolerability. |
| **Cuvitru ® (Takeda)** dose and dosage interval must be individualised for each patient based on serum IgG trough levels and clinical response. Table 2 is an extract Cuvitru ® PI for transition dosage. Further information regarding dosing available <http://www.guildlink.com.au/gc/ws/tk/pi.cfm?product=tkpcuvit11220> |
| **Hyqvia® (Takeda)** must be administered sequentially beginning with the Vorhyaluronidase alfa followed by Normal Immunoglobulin. The dose level may need to be individualised for each patient dependent on the pharmacokinetic and clinical response. Further information regarding dosing available http://www.guildlink.com.au/gc/ws/tk/pi.cfm?product=tkphyqui10719 |

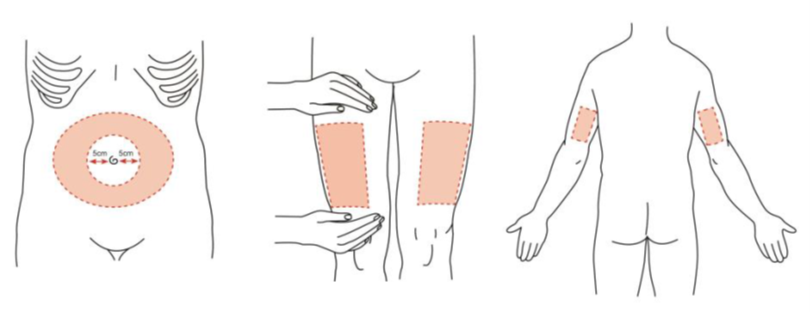
\*This information has been summarised using the manufacturer’s product information (PI) and has not been subject to manufacturer endorsement. When considering these products, review of the full PI is encouraged.

Table 2: Dosing for patients switching from other subcutaneous or intravenous immunoglobulin treatments

|  |  |  |  |
| --- | --- | --- | --- |
| **CUVITRU Dosing Frequency** | | | |
|  | **Weekly** | **Bi Weekly** | **Frequent dosing (2-7 times per week)** |
| **For patients switching from Immunoglobulin Subcutaneous (Human) treatment (SCIG):** | The weekly dose of CUVITRU (in grams) is recommended to be the same as the weekly dose of prior SCIG treatment (in grams) 1 | Biweekly dosing: Multiply the calculated weekly dose by 2 | Divide the calculated weekly dose by the desired number of times per week |
| **For patients switching from Immunoglobulin Intravenous (Human) treatment (IVIG):** | To calculate the initial weekly dose, divide the previous IVIG dose in grams by the number of weeks between intravenous doses1, 2 |
| 1 To convert the dose (in grams) to millilitres (mL), multiply the calculated dose (in grams) by 5.  2 Begin treatment with CUVITRU one week after the patient’s last IVIG. | | | |

# **Administration of SCIg**

## **Figure 2: Infusion sites**



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>

**NB:** It is not recommended to rotate infusion sites. 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 most commonly tend to be infusion site related. Table 2 and 3 outline possible effects and management. Please refer to individual product information for specific risk profiles.

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 3: Possible side effects for SCIg products

|  |  |  |
| --- | --- | --- |
| **Very Common** | **Common** | **Rare** |
| * Infusion site related * Headache * Fever * Nausea * Vomiting * Diarrhoea | * Chills * Back pain * Arthralgia * Hypotension * Dizziness | * Allergic reactions * Anaphylactic shock * Thromboembolism * Renal complications * Haemolysis * Transmissible agents Urticaria * Aseptic meningitis |

Table 4: Adverse effect management at home [Ensure to record all adverse effects in patient diary]

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

## Troubleshooting

Table 5 – Troubleshooting issues and actions

|  |  |
| --- | --- |
| **Troubleshooting Site reactions**  Injection-site reactions following SCIg therapy. Examples of injection-site reactions that were classified as mild and moderate are shown.**Mild** Injection-site reactions following SCIg therapy. Examples of injection-site reactions that were classified as mild and moderate are shown. **Moderate** | |
| **Injection site reactions**   * Blanching * Redness/rash * Itching * Discomfort * Swelling | Assess for tape allergy – change to paper/ hypoallergenic tape  Assess needle size – choose needle that is consistent with volume to be infused  Assess length of needle – may be too short and infusing into the intradermal layer  Assess site location – may be too close to muscle layer  Decrease rate of infusion or volume per site  Avoid tracking of Ig through the intradermal layer check needle tip is dry prior to insertion  Consider appropriateness of rotating infusion site  Consider use of topical anaesthetic cream |
| **Leaking at insertion site** | Assess needle – ensure fully inserted and fixed securely  Assess placement – is it in area of movement, consider alternative site  Assess length of needle – may be too short, change to longer needle  Assess infusion volume – decrease amount per site  Assess rate of infusion – slowing rate may help |
| **Extreme discomfort with needle** | Assess needle length ensure not too long and irritating abdominal wall  Assess needle is being inserted ‘dry’ to prevent tracking through intradermal layer  Consider using needleless indwelling subcutaneous catheter device  Consider using ice or topical anaesthetic cream prior to insertion |
| **Long infusion time** | Ensure SCIg ready to use at room temperature  Assess volume per site, rate of infusion, number of sites or adjust infusion regime  Check equipment for clamps/kinks, correct selection of needle size, tubing  If using a pump check function, battery power is not low |
| **Blood return observed** | Remove and discard needle with blood return and reinsert with new insertion needle and site |

<https://www.slideshare.net/DallasAllergyImmunology/immunoglobulin-replacement-therapy>

## Adverse effect reporting

Adverse effects should be reported using an in house quality management system and also reported to the supplier to notify the manufacturer and also to Lifeblood.

Manufacturer adverse event forms are available directly from the supplier or contact the Lifeblood transfusion nurses (TN) in your state/territory who will forward a copy. Lifeblood Victorian/Tasmanian TN email: [vtatn@redcrossblood.org.au](mailto:vtatn@redcrossblood.org.au)

CSL Behring email: [adverse.events.global@cslbehring.com](mailto:adverse.events.global@cslbehring.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\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **BRAND NAME** | **Evogam®** | **Hizentra®** | | **Cuvitru®** | | **Hyquvia®** (Implementation date to be confirmed) |
| Presentation | Solution; 0.8g (5mL), 3.2g (20mL) vials | Solution; 1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL) vials | | Solution; 1g (5mL), 2g (10mL), 4g (20mL), 8g (40mL) vials | | Hyqvia® is a dual vial unit consisting of one vial of Normal Immunoglobulin 10% (Human) and one vial of Vorhyaluronidase alfa.  Solution; Hyquvia® -2.5g (25mL), 5.0g (50mL), 10.0g (100mL), 20.0g (200mL) or 30.0g (300mL) not all sizes marketed. Vorhyaluronidase alfa - 200 units in 1.25mL, 400 units in 2.5mL, 800 units in 5mL, 1600 units in 10mL or 2400 units in 15mL of the active Vorhyaluronidase alfa [160 U/mL]. (Available vials sizes to be confirmed). |
| Concentration | 16% | 20% | | 20% | | 10% |
| Distributor | Australian Red Cross Lifeblood | Australian Red Cross Lifeblood | | Australian Red Cross Lifeblood | | Australian Red Cross Lifeblood |
| Plasma source | Local | Imported | | Imported | | Imported |
| Stabiliser/other constituents 1 | Glycine | Proline (non-essential amino acid) | | Glycine | | Hyqvia® – Glycine  Vorhyaluronidase alfa - Sodium phosphate, Dibasic dehydrate, Sodium hydroxide, Human albumin, Calcium chloride, Sodium chloride, Edetate disodium, Water for Inject. For proportions, refer to PI. |
| Storage Conditions – do not freeze, protect from light. | Refrigerate at 2-8oC for up to 2 years.  Once removed from refrigeration, store below 25oC and use within 2 weeks. | Store below 25oC for up to 30 months. | | Store below 25°C for 24 months from date of manufacture. Do not use after the expiry date printed on the carton and the label. | | Store in a refrigerator (2°C – 8°C) for 36 months.  Do not use beyond the expiration date printed on the vial or carton. |
| Need for Reconstitution | No | No | | No | | No - Must be administered following Vorhyaluronidase alfa |
| Approved therapeutic indications for use | Evogam® is indicated in adults and children for replacement therapy in:  • Primary Immunodeficiency Diseases (PID) and  • Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment. | Hizentra® is indicated for:  Replacement therapy in adults and children in:  • Primary Immunodeficiency Disease (PID) and  • Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment.  Immunomodulatory therapy in:  • Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) as maintenance therapy after stabilisation with IVIg. | | Cuvitru® is indicated as replacement therapy in adult and paediatric patients for:  • Primary immunodeficiency diseases (PID) and  • Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment. | | Hyqvia® is indicated for replacement therapy in adults in:  • Primary Immunodeficiency Disease (PID) and  • Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment. |
| IgA level 2 | < 0.025mg/mL | ≤ 0.05mg/mL (normally below 0.005mg/mL). | | Average IgA concentration is 0.08 mg/mL | | Not more than 0.14 mg/mL |
| Contraindications | Evogam® is contraindicated in patients who have had a true anaphylactic reaction to the active substance or to the excipient glycine | 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. | | Cuvitru® is contraindicated in:  Patients with known anaphylactic or severe hypersensitivity reactions to the subcutaneous administration of the active substance or any of the excipients.  Patients with severe IgA deficiency and a history of hypersensitivity to human immunoglobulin treatment. | | Hyqvia® is contraindicated in:  Patients who have had a history of anaphylactic or severe systemic reactions to the administration of IgG,  IgA deficient patients with antibodies to IgA and a history of hypersensitivity,  Patients with known systemic hypersensitivity to hyaluronidase or Vorhyaluronidase alfa, or known systemic hypersensitivity to any of the excipients. |
| Precautions | Evogam® or Hizentra® for **subcutaneous** administration only and **must not** 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. | | | Cuvitru® or Hyqvia® must be administered **subcutaneous** only and **must not** be administered intravenously or intramuscular. | | |
| Aseptic Meningitis Syndrome (AMS) | | |  | |  |
| 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. | | | | | |
| Hypersensitivity | | |  | |  |
| 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 immunoglobulin (normal). | | | True hypersensitivity reactions may occur. They can particularly occur in cases of IgA deficiency with anti-IgA antibodies and these patients should be treated with caution. Rarely, human normal immunoglobulin can induce a fall in blood pressure with anaphylactic reaction, even in patients who had tolerated previous treatment with human normal immunoglobulin. | | Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with human normal immunoglobulin. For further information refer to PI  **Hypersensitivity to Vorhyaluronidase alfa**  Any suspicion of allergic or anaphylactic like reactions following Vorhyaluronidase alfa administration requires immediate discontinuation of the infusion and standard medical treatment should be administered, if necessary. |
| Thromboembolism | | |  | |  |
| 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 patients with pre-existing risk factors for thrombotic events and with obese patients. Risks 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.  Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.  For patients at risk of thrombosis, minimum dose and infusion rate should be considered.  (See Product Information for further information) | | | | | |
| Acute renal failure | | |  | |  |
| Reports of renal dysfunction and acute renal failure in patients receiving immunoglobulin 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.  Caution using products containing sucrose, current formulations available in Australia do not contain sucrose.  SCIg should be administered at the minimum rate of infusion and dose practicable in patients at risk of acute renal failure.  (See Product Information for further information) | | | | | |
| Pathogen safety | Refer to Product information | | | 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. | | | Immunoglobulin administration may impair for a period of at least 6 weeks and up to 3 months the efficacy of live attenuated virus vaccines such as measles, rubella, mumps and varicella. After administration of these products, an interval of 3 months should elapse before vaccination with live attenuated virus vaccines. In the case of measles, this impairment may persist for up to 1 year. Therefore, patients receiving measles vaccine should have their antibody status checked.  Admixtures of Hyqvia® with other drugs and intravenous solutions have not been evaluated. It is recommended that HYQVIA be administered separately from other drugs or medications that the patient may be receiving. The product should not be mixed with immunoglobulin products from other manufacturers. | | |
| 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. | | The safety of Cuvitru® product for use in human pregnancy has not been established in controlled clinical trials and therefore it should only be given with caution to pregnant women. Immunoglobulin products have been shown to cross the placenta, increasingly during the third trimester.  Clinical experience with immunoglobulins suggests that no harmful effects on the pregnancy course or foetus/ neonate are to be expected. | | There are no adequate data from the use of Hyqvia® in pregnant women. Maternally administered immunoglobulins have been shown to cross the placenta, increasingly during the third trimester.  The effects of antibodies to the Vorhyaluronidase alpha component of Hyqvia® on the human embryo or on human foetal development are unknown. |
| Use in lactation | Immunoglobulins are excreted in breast milk and may contribute to the transfer of protective antibodies to the neonate. | | | During breast-feeding immunoglobulins are excreted into the milk and may contribute to the transfer of protective antibodies to the neonate.  Physicians should balance the potential risks and only prescribe Cuvitru®, if clearly needed. | | There are no adequate data from the use of Hyqvia® in lactating women. |
| 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. | | Cuvitru® contains a human plasma derived native protein, which is not anticipated to have an adverse effect on fertility. | | Currently data is not available for clinical safety on development of the reproductive system. |
| 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. | | Refer to Product information | | |
| Use in the elderly | Clinical studies of 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. | | Cuvitru® was evaluated in pivotal studies which included a total of 12 subjects of the age 65 years and older. No differences in safety or efficacy were observed for this group. | | Hyqvia® was evaluated in 7 subjects over age 65 in the clinical trial, and sufficient data is not available to determine whether safety of this product is different in this population. |
| Genotoxicity | No genotoxicity studies have been conducted | | | CUVITRU contains a human plasma derived native protein, which is not anticipated to possess genotoxic potential. | | Genotoxicity studies were not performed as the hyaluronidase is the recombinant form of a naturally occurring protein; as such it is not expected to interact with DNA or other chromosomal material, nor has it been shown to transform cells and promote the growth of normal or malignant cells. |
| Carcinogenicity | No carcinogenicity studies have been conducted | | | CUVITRU contains a human plasma derived native protein, which is not anticipated to possess carcinogenic potential. | | Carcinogenicity studies were not performed as the hyaluronidase is the recombinant form of a naturally occurring protein; as such it is not expected to interact with DNA or other chromosomal material, nor has it been shown to transform cells and promote the growth of normal or malignant cells. |
| 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 alloantibodies for example the antiglobulin test. | | | Refer to Product information | | |
| Adverse Effects – Specific  (Refer to relevant PI for detailed information) | Very Common  Infusion site reaction, Headache, Nausea, Vomiting, Diarrhoea, Abdominal pain, Fever, Pain in extremity. | | Common  Chills, Fatigue, Back pain, Arthralgia, Myalgia, Hypotension. | | Rare  Hypersensitivity, allergic reactions, anaphylactic shock, thromboembolic reactions, Aseptic Meningitis. | |
| 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  Patient education should include information and awareness of potential adverse events, management and reporting | | | | | |
| Administration | Should only be administered SUBCUTANEOUSLY. Must not be mixed with any other product.  Hyqvia® is a dual vial unit Normal Immunoglobulin 10% (Human) and one vial of Vorhyaluronidase alfa. Hyqvia® must be administered sequentially beginning with the Vorhyaluronidase alfa followed by Normal Immunoglobulin.  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. | | Cuvitru® is a clear and colourless to a pale yellow or light brown solution. | | Hyqvia® is a dual vial unit consisting of one vial of Normal Immunoglobulin 10% (Human) and one vial of Vorhyaluronidase alfa. Normal Immunoglobulin is a clear or slightly opalescent and colourless or pale yellow solution. Vorhyaluronidase alfa is a clear, colourless solution. |
| Infection Control | Evogam® Hizentra® Cuvitru® and Hyqvia® 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 10mL/hr gradually increased to 20mL/hr as tolerated.  Maximum dose recommended is 40mL/hr.  If larger doses are given >20mLs /site administration via multiple sites is recommended | Hizentra®  Replacement therapy - 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 patient’s clinical response and serum IgG trough levels  Immunomodulation therapy - The recommended subcutaneous dose is 0.2 to 0.4 g/kg of body weight per week. The dose may need to be adapted to achieve the desired clinical response.  Infusion device/pump - 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.  If larger doses are given >25mLs /site administration via multiple sites is recommended (CSL Behring Hizentra® PI).  Manual push - the recommended initial infusion rate should not exceed 0.5 mL/min (30 mL/hour/site).  If well-tolerated, the infusion rate can be increased up to 2.0 | | Refer to Product information | | |
| 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: \***This information has been summarised using the manufacturer’s product information (PI) and has not been subject to manufacturer endorsement. When considering these products, review of the full PI is encouraged and links are included below.

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

**References**:

<https://www.transfusion.com.au/blood_products/fractionated_plasma/SCIg>

<http://www.csl.com.au/s1/cs/auhq/1196562765747/Web_Product_C/1255931734133/ProductDetail.htm> Evogam® (CSL)

<http://www.csl.com.au/s1/cs/auhq/1217017237558/Web_Product_C/1252900931961/ProductDetail.htm> Hizentra® (CSL)

<http://www.guildlink.com.au/gc/ws/tk/pi.cfm?product=tkpcuvit11220> Cuvitru® (Takeda)

<http://www.guildlink.com.au/gc/ws/tk/pi.cfm?product=tkphyqui10719> Hyqvia® (Takeda)

# 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**

**SCIg 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 SCIg 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. 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 2400

Website: https://www.emedtc.com/products

**LTR Medical**

Distributors

**Springfuser® syringe infusion pump – 10, 30 & 50**

**Flow Control Tubing – (**FCT) constant intravenous (IV) or subcutaneous (SC) infusions in either a 10mL, 30mL or 50mL configuration at a variety of pre-set flow rates. Tubing sets include syringe. Needles are required to be purchased from other suppliers.

TheFCT has been tested with fluid less viscous than SCIg and as such, flow rates may vary.

NB: the Springfuser® is not validated specifically for SCIg use, which may lead to issues with procurement of this device for SCIg infusion.

**Contact details**

1800 319 419

[info@ltrmedical.com](mailto:info@ltrmedical.com)

Website: <http://ltrmedical.com/springfusor>

**CLINECT [Neria needles]**

Neria (steel cannula) - 27gauge needle – 1, 2 and 4 lumen (8mm and 10mm cannula length)

Neria (soft cannula) – 27gauge needle – 1 lumen (9mm)

Health Purchasing Victoria (HPV) approved – the Neria range is approved and listed on the HPV tender.

The 27G cannulas are small and therefore better to be used with pumps rather than the ‘push method’. Neria has a luer-lock connection and is compatible with all pumps.

Contact details:

Please contact Clinect on the email or phone number below for product support including insertion instruction videos and patient brochures.

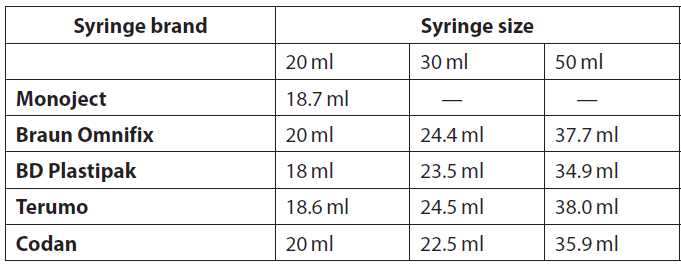
03 9918 5555

**Website:** [**www.clinect.com.au**](http://www.clinect.com.au) **Email:** [**info@clinect.com.au**](mailto:info@clinect.com.au)

**REM SYSTEMS**

Suppliers of BD BodyGuard™T syringe driver.

**BD BodyGuard™T** -Can hold syringes 2-50 mL – the maximum volume of the syringe is dependent on the syringe brand.



REM SYSTEMS has available both online training and face to face to ensure you are confident in the use of the BD BodyGuard™ T

**Contact details**

1800 737 222

[customerservice@REMsystems.com.au](mailto:customerservice@REMsystems.com.au)

Website: [www.remsystems.com.au](http://www.remsystems.com.au)

**MEDICAL DEVICES**

Suppliers ofSCIg validated infusion devices and needles.

**HigH-Flo needles™ -** available in 24 and 26 gauge with a variety of needle lengths (4-14mm depending on guage) and configurations from single to four needle sets for 24 gauge and single to six for 26 gauge.Use of multiple configurations with a Y-connector could increase the number of sites.

**FREEDOM60® syringe infusion system** (60mL syringe)

**FreedomEdge® syringe infusion system** (20-30mL syringes)

**Contact details**

1800 77 51 51

[support@medicaldevices.com.au](mailto:support@medicaldevices.com.au)

Website: <http://medicaldevices.com.au/syringe-infusion-systems/>

# Appendix C: Patient education competency template

*Affix Patient identification label here*

*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.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Patient Skills** | **Session 1**  Date:\_\_/\_\_/\_\_  Clinician Name:  Signature: | **Session 2**  Date:\_\_/\_\_/\_\_  Clinician Name:  Signature: | **Session 3**  Date:\_\_/\_\_/\_\_  Clinician Name:  Signature: | **Session 4**  Date:\_\_/\_\_/\_\_  Clinician Name:  Signature: | **Session 5**  Date:\_\_/\_\_/\_\_  Clinician Name:  Signature: |
| Competent (C)  Not yet competent (NYC)  (Please circle) | **C**  **NYC** | **C**  **NYC** | **C**  **NYC** | **C**  **NYC** | **C**  **NYC** |
| Describe transportation & storage of SCIg product |  |  |  |  |  |
| Define SCIg administration & location of infusion site/s |  |  |  |  |  |
| Demonstrates appropriate selection of infusion sites |  |  |  |  |  |
| Understands appropriate equipment required |  |  |  |  |  |
| Demonstrates understanding of infusion device/pump (*only required if infusion device/pump used)* |  |  |  |  |  |
| Demonstrates understanding of “push” method. *(pt must be aware even if infusion device pump is used)* |  |  |  |  |  |
| Demonstrates understanding of SCIg checking – type, dose, expiry, discolouration |  |  |  |  |  |
| Demonstrates understanding of how to draw up SCIg from single or multiple vials (aseptic technique) |  |  |  |  |  |
| Demonstrates ability to: -  - prime tubing and set up pump (where pump used ) |  |  |  |  |  |
| 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 |  |  |  |  |  |
| Demonstrate ability to remove and safely discard needle |  |  |  |  |  |
| Demonstrates ability to accurately record treatment in infusion diary and understands how to report waste and return unused SCIg |  |  |  |  |  |
| Demonstrates understanding of adverse effects and how to manage |  |  |  |  |  |

Created using NBA, Sunshine Health Service documents, Younger et. al. 2015

# Appendix D: Consumable supply list template

*Affix patient identification label here*

*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.

|  |  |
| --- | --- |
| **Patient supply** | **Number to be supplied each month** |
| SCIg Product vial size   |  |  |  |  | | --- | --- | --- | --- | | Hizentra® | Evogam®– | Cuvitru ® | Hyqvia® | | 1g (5mL) | 0.8g (5mL) | 1g (5mL) | 2.5g (25mL), | | 2g (10mL) | 3.2g (20mL) | 2g (10mL) | 5.0g (50mL), | | 4g (20mL) |  | 4g (20mL), | 10.0g (100mL | | 10g (50mL |  | 8g (40mL) | 20.0g (200mL) | |  |  |  | 30.0g (300mL) | | **NB:** Dose approved and frequency of infusion needs to be considered when requesting SCIg. Ensure vials requested match dose required to ensure no waste.  Hizentra® 1g\_\_\_\_\_\_\_\_\_\_\_\_2g\_\_\_\_\_\_\_\_\_\_\_  4g\_\_\_\_\_\_\_\_\_\_\_10g\_\_\_\_\_\_\_\_\_\_  Evogam® 0.8g\_\_\_\_\_\_\_\_\_3.2g\_\_\_\_\_\_\_\_\_\_  Cuvitru ® 1g\_\_\_\_\_\_\_\_\_\_\_2g\_\_\_\_\_\_\_\_\_\_\_  4g\_\_\_\_\_\_\_\_\_\_\_8g\_\_\_\_\_\_\_\_\_\_\_  Hyqvia® 2.5g\_\_\_\_\_\_\_\_\_\_5g\_\_\_\_\_\_\_\_\_\_\_  10g\_\_\_\_\_\_\_\_\_\_20g\_\_\_\_\_\_\_\_\_\_  30g\_\_\_\_\_\_\_\_\_\_ |
| Small coolers – ice bricks if required. Evogam® and Hyqvia® must be stored between 2-8 degrees Celsius.  Utilise cooler in cases of extreme heat and long travel distance for Hizentra® to ensure product remains below 25 degrees Celsius.  Plastic container to store SCIg in refrigerator. |  |
| Infusion device/pump *enter details of equipment selected if using this infusion method* |  |
| Leur lock syringe *10mL , 20mL ,30mL, other* size if required |  |
| Drawing up needle 19 gauge |  |
| Infusion needle/s/catheter of choice - *add details of choice* |  |
| Infusion extension set if required |  |
| Alcohol prep swabs |  |
| Surgical tape |  |
| Cotton wool balls |  |
| Sharps container (exchange when full) |  |
| Infusion diary |  |
| Topical anaesthetic cream if required e.g. EmLa cream |  |

Created using Sunshine Health Service, Duff et.. al. 2015, Younger et.. al. 2013.

# Appendix E: Patient record template

*Affix Patient identification label here*

*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®, Cuvitru®, Hyquvia® Dose:\_\_\_\_\_\_\_g / \_\_\_\_\_\_\_\_\_mL Frequency:\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Infusion Record**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| **Date and Time** |  |  |  |  |  |  |  |  |
| **Volume** |  |  |  |  |  |  |  |  |
| **Site/s used** |  |  |  |  |  |  |  |  |
| **Side effects** |  |  |  |  |  |  |  |  |
| **Medications used** |  |  |  |  |  |  |  |  |
| **Batch numbers** (affix label/s) |  |  |  |  |  |  |  |  |
| **Notes** |  |  |  |  |  |  |  |  |

**Next appointment date:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Created using CSL Behring ‘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

Consent

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

**National Blood Authority related**

<http://www.blood.gov.au/Ig-governance> Ig governance document

<https://www.blood.gov.au/system/files/documents/Governing%20requirements%20for%20a%20hospital%20based%20SCIg%20program.pdf> Governing requirements for a health service based SCIg program

<https://www.blood.gov.au/system/files/BloodSTAR-Tip-Sheet-SCIg-Nurses.pdf> SCIg planning tip sheet for Dispensing via BloodSTAR

<https://www.blood.gov.au/system/files/documents/p5.1_scig_poster_0.pdf>

<https://www.blood.gov.au/system/files/documents/NBA_IVIgCriteria_SecondEdition_Internals-WEB_updated_ref.pdf>

<https://www.blood.gov.au/system/files/Updated-IVIg-Comparison-table.pdf>

<https://www.blood.gov.au/system/files/documents/faqs-subcutaneous-immunoglobulin-changes-September2016.pdf>

**Transfusion.com.au**

<http://resources.transfusion.com.au/cdm/singleitem/collection/p16691coll1/id/869/rec/1> Shipper info

<http://resources.transfusion.com.au/cdm/singleitem/collection/p16691coll1/id/611/rec/6> Evogam® video

<http://resources.transfusion.com.au/cdm/singleitem/collection/p16691coll1/id/704/rec/9> SCIg fact sheet

**CSL Behring**

CSL Behring has a large range of patient information and other resources available for both patients and health care providers contact [customerservice@cslbehring.com.au](mailto:customerservice@cslbehring.com.au)

Evogam®, product information. CSL Behring (Australia) Pty Ltd. 2012 (revision 2020)

<http://www.csl.com.au/s1/cs/auhq/1196562765747/Web_Product_C/1255931734133/ProductDetail.htm>

Hizentra® product information. CSL Behring (Australia) Pty Ltd. 2014 (revison 2020

<http://www.csl.com.au/s1/cs/auhq/1217017237558/Web_Product_C/1252900931961/ProductDetail.htm>

**Takeda**

Takeda patient information (consumer information (CI)) is available <https://www.takeda.com/en-au/what-we-do/our-products/>

Cuvitru® product information <http://www.guildlink.com.au/gc/ws/tk/pi.cfm?product=tkpcuvit11220>

Hyqvia® product information <http://www.guildlink.com.au/gc/ws/tk/pi.cfm?product=tkphyqui10719>

# Other websites

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

<https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_SCIg_Position_Statement_2014.pdf>

<https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Clinical_Update_PID_2017.pdf>

# Journal Articles

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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

Haddad. E, Barnes. D, Kafal. A. 2012. Home therapy with subcutaneous immunoglobulins for patients with primary immunodeficiency diseases. *Transfusion and Apheresis Science ,*46 pp315-321

Jolles. S, Orange. J, Gardulf. A, Stein. M, Shapiro. R, Borte. M, Berger. M. 2014. Current treatment options with immunoglobulin G for the individualization of care in patients with primary immunodeficiency disease. *Clinical and Experimental Immunology*, 179: pp146-160

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Streu, E. 2016. Subcutaneous Immunoglobulin in Oncology Clinical Practice. *Clinical Journal of Oncology Nursing*, Vol 20. No 4. pp437-439

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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

Wasserman. R. 2008. Common infusion-related reactions to subcutaneous immunoglobulin therapy: Managing patient expectations. *Patient Preference and Adherence* 2 163-166

Windegger. T, Lambooy. C, Hollis. L, Morwood. K, Weston. H, Lin Fung. Y. 2017. Subcutaneous Immunoglobulin Therapy for Hypogammaglobulinaemia Secondary to Malignancy or Related to Drug Therapy. *Transfusion Medicine Reviews* 31. pp 45-50.

Krishnarajah. G, Lehmann. J, Ellman. B, Bhak. R, DerSarkissian. M, Leader. D,Bullinger. A, Sheng Duh. M. 2016. Evaluating Dose Ratio of Subcutaneous to Intravenous Immunoglobulin Therapy Among Patients With Primary Immunodeficiency Disease Switching to 20% Subcutaneous Immunoglobulin Therapy*. Am J Manag Care*. 22:S475-S481, Vol 22 No 15. <http://www.ajmc.com/journals/supplement/2016/subcutaneous-immunoglobulin-therapy/subcutaneous-immunoglobulin-therapy-article/P-3>

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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>