

Subcutaneous immunoglobulin (SCIg)  
clinical practice guidance template

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## General information

Immunoglobulins (Ig), also known as antibodies, are a critical part of the body’s immune defence system. They are produced by particular types of white blood cell known as B cells and plasma cell and recognise and bind to particular antigens such as bacteria, viruses, toxins or other foreign substances, thereby aiding in the pathogen’s destruction.

Ig manufactured products are fractionated blood products made from pooled human plasma where the Ig has been purified for a specific purpose. Manufactured Ig can be supplied as intravenous (in a vein) Ig or subcutaneous Ig (SCIg)

Subcutaneous immunoglobulin (SCIg) is a treatment that is administered under the skin (subcutaneously) and is generally used for:

* replacement Ig therapy - providing additional Ig to patients who do not make enough of their own to aid in maintaining a healthy immune system. This is generally because of a genetic disorder, disease, or as a side effect of disease treatment; and
* immunomodulation Ig therapy – supporting patients with a range of auto-immune disorders by modulating their immune system (to prevent it attacking its own body).

## Purposes

To provide health services with the necessary information to implement a SCIg program.

To assist health services in the development of the necessary governance documents that will facilitate safe administration of SCIg according to the manufacturers’ instructions (product information).

This information is a guide only.

Health service policy/procedures based on this information should be implemented, and monitored for compliance with best practice, the manufacturer’s specific product information, safety guidelines and all other requirements specific to the products and the National Safety and Quality Health Service (NSQHS) Standards.

All health service policies/procedures should be developed in accordance with local governance requirements and approval processes.

## Approved access conditions for SCIg

The National Blood Authority (NBA) sets out the access conditions for patients to be approved to receive SCIg. To be eligible, patients must fulfil the eligibility requirements of the Criteria for the Clinical Use of Immunoglobulin in Australia (the Criteria) which is available online in [BloodSTAR](http://www.criteria.blood.gov.au) <https://www.criteria.blood.gov.au>

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, namely:

* Inborn errors of immunity (IEI) with antibody deficiency
* Specific antibody deficiency (SAD)
* Acquired hypogammaglobulinaemia secondary to haematological malignancies, or post-haemopoietic stem cell transplantation
* Secondary hypogammaglobulinaemia unrelated to haematological malignancies, or post-haemopoietic stem cell transplantation
* Chronic inflammatory demyelinating polyneuropathy (CIDP), (including IgG and IgA paraproteinaemic demyelinating neuropathies)

1. Being treated by a clinical specialist within a health service based SCIg program 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
2. Following a patient specific SCIg request submitted and approved in BloodSTAR.

## Governance requirements for a hospital based SCIg program

Prior to commencing a SCIg program the health service Chief Executive or Director of Clinical Services (or equivalent) must provide a signed acknowledgement of compliance with the governing requirements to the NBA.

The following information is outlined in the National Blood Authority Hospital Acknowledgement Form National Subcutaneous Immunoglobulin Program. To access the acknowledgement form, go to: [Subcutaneous immunoglobulin (SCIg) | National Blood Authority](https://www.blood.gov.au/blood-products/immunoglobulin-products/subcutaneous-immunoglobulin-scig) <https://www.blood.gov.au/blood-products/immunoglobulin-products/subcutaneous-immunoglobulin-scig>

The governance requirements are as follows:

#### 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 NSQHS Standards.

#### 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 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. 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.

#### Supply of product

Requests for SCIg for authorised patients must be managed via BloodSTAR. The amount of SCIg supplied to a patient should not exceed more than is required for treatment for two months. Supply and dispensing of SCIg product to patients must be in accordance with relevant state/territory legal requirements and the [National Policy: Access to Government Funded Immunoglobulin Products in Australia](https://www.blood.gov.au/supply-system/governance-immunoglobulin-products) <https://www.blood.gov.au/supply-system/governance-immunoglobulin-products>.

In exceptional cases alternative arrangements for supply of SCIg may be needed.

#### Reporting unused, discarded, spoilt/broken product

Patients supplied with SCIg will be expected to report details of unused, discarded or spoilt/broken product to the health service, to be recorded in-turn by the health service through BloodNet or alternative arrangement if necessary. This, and other information relevant for authorisation of requests collected by BloodSTAR will be reported to the NBA to assist with supply reconciliation and planning.

## Considerations for a successful SCIg program

The success of a SCIg program is dependent on appropriate resourcing such as:

* Dedicated registered nurse specialist/s for the SCIg program who undertake administrative tasks as well as patient education/care.
* Consultant medical specialist/s to refer patients to the program, conduct medical reviews and consent, prescribe the product and complete BloodSTAR requirements.
* A pharmacist to dispense SCIg as it is a Schedule 4 (S4) medication.
* Laboratory/blood bank scientists or pharmacist to order the product from Australian Red Cross Lifeblood (Lifeblood) and maintain traceability.
* Provisions of specialised equipment and consumables need to be provided for the patient.
* Availability of patient education and support resources.
* A location for patient education and SCIg program administration.
* Fulfilment of BloodSTAR requirements by participating clinicians.

## BloodSTAR

BloodSTAR is an online system used across Australia to manage access to government funded immunoglobulin products.

To register and create a BloodSTAR account go to [National Blood Authority](https://www.blood.gov.au) <https://www.blood.gov.au>. National Blood Authority also have [BloodSTAR user tips and support materials](https://www.blood.gov.au/bloodstar-user-tips-and-support-materials) <https://www.blood.gov.au/bloodstar-user-tips-and-support-materials>.

#### 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 patient lists in BloodSTAR. Staff are responsible for creating their own BloodSTAR log in account via the Blood Portal. Once created, the facility administrator can then approve access.

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

* Request for SCIg is created electronically by the Treating Medical Specialist (TMS) or delegated Medical Officer (MO) via BloodSTAR. The NBA [Requesting SCIg product tip sheet](https://www.blood.gov.au/bloodstar-user-tips-and-support-materials) can assist. <https://www.blood.gov.au/bloodstar-user-tips-and-support-materials>
* Once request has been submitted via BloodSTAR, Lifeblood reviews and approves the request if all the criteria are met.
* When the request has been approved by Lifeblood, the treating MO and TMS, are notified via BloodSTAR and the affiliated laboratory/pharmacy who issue/dispense the SCIg are notified via BloodNet.
* SCIg dose is then requested by the laboratory/pharmacy from Lifeblood and delivered to the requesting laboratory/pharmacy.

**NB:** AsSCIg is a S4 medication it must be prescribed by an authorised practitioner (e.g. a medical practitioner) and dispensed by a pharmacist for home administration.

#### Options for SCIg dispensing

1. The transfusion laboratory (pathology service) orders SCIg in BloodNet and it is traced via the laboratory information system (LIS). Lifeblood delivers SCIg to the transfusion laboratory and it is then transferred to the pharmacy for dispensing and collection by the patient.
2. The pharmacy orders SCIg in BloodNet and it is traced via the pharmacy system. Lifeblood delivers SCIg to the pharmacy for dispensing and collection by the patient.
3. Regional patients once competent to infuse at home may collect SCIg from a local pharmacy if required/more convenient. The NBA, Lifeblood customer service and Blood Matters Clinical Nurse Consultant (SCIg) can assist setting up this process if the pharmacy is new to the dispensing of SCIg.

## Patient selection criteria

Patients who are eligible for SCIg (or their carer) must be able to:

* Draw up and administer the SCIg as per patient competency (see appendix A).
* Understand the importance of correct storage, handling, and transport of SCIg.
* Understand safe disposal of medical waste.
* Be compliant with self-administration, documentation and attending for review.
* Understand the importance of reporting adverse effects or any concerns related to treatment.

SCIg may not be appropriate for patients with:

* Extensive skin conditions - psoriasis, eczema
* Cognitive impairment
* Poor manual dexterity, decreased hand grip, tremors, poor eyesight.
* Severe thrombocytopenia

## SCIg product comparison\*

#### \*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 required. Information current as of August 2025.

#### Presentation

All SCIg products are clear and colourless to a pale yellow or light brown solution. Do not use if particulate matter and/or discoloration is observed.

None of the SCIg products require reconstitution.

|  |  |  |  |
| --- | --- | --- | --- |
| Hizentra® AU (CSL Behring)  20% Ig solution | Hizentra® (CSL Behring)  20% Ig solution | Cuvitru® (Takeda)  20% Ig solution | Xembify® (Grifols)  20% Ig solution |
| Domestic plasma source  Solution; 1g (5mL), 4g (20mL) vials | Imported plasma source  Solution; 1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL) vials | Imported plasma source  Solution; 1g (5mL), 2g (10mL), 4g (20mL), 8g (40mL) vials | Imported plasma source  Solution; 1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL) vials |

#### Storage

Do not freeze, do not use if the solution has been frozen, protect from light, do not use after expiry date.

|  |  |  |  |
| --- | --- | --- | --- |
| Hizentra® AU | Hizentra® | Cuvitru® | Xembify® |
| Store below 25°C. | Store below 25°C. | Refrigerate at 2-8oC. | Refrigerate at 2-8oC.  May be stored ≤25°C for up to 6 months any time prior to expiry date. |

#### Stabiliser

|  |  |  |  |
| --- | --- | --- | --- |
| Hizentra® AU | Hizentra® | Cuvitru® | Xembify® |
| Proline | Proline | Glycine | Glycine |

#### Product dosing and infusion rates

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

Dosing varies based on indication. Check the manufacturers’ PI for specific dosing. 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). 1.

Please refer to each product information (PI) for dosing and infusion rates

[Lifeblood SCIg information](https://www.lifeblood.com.au/health-professionals/products/fractionated-plasma-products/immunoglobulins/SCIg) <https://www.lifeblood.com.au/health-professionals/products/fractionated-plasma-products/immunoglobulins/SCIg> also contains information and links to each available SCIg product.

#### IgA level

For IgA deficient patients, product with the lowest IgA level should be selected. The treating clinician should discuss IgA deficiency with the patient.

#### Contraindications

* Patients with a history of severe systemic hypersensitivity or anaphylactic reaction to the active substance or to any of its excipients.
* Hizentra® AU and Hizentra® are contraindicated in patients with hyperprolinemia type I or II.
* Cuvitru® and Xembify® are contraindicated in patients with severe IgA deficiency and a history of hypersensitivity to human immunoglobulin treatment.

#### Special warnings and precautions for use\*

For **subcutaneous** administration only and **must not** be administered intravenously.

If inadvertently administered into a blood vessel, patients could develop shock. In the case of shock, current medical standards for shock treatment should be implemented. Contact 000 immediately.

**\*For further information on special warnings and precautions for use refer to specific product information.**

Product information references:

[Hizentra AU](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2020-PI-01937-1&d=20231015172310101) <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2020-PI-01937-1&d=20231015172310101&d=202>

[Hizentra](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2025-PI-01243-1) <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2025-PI-01243-1>

[Cuvitru](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-01104-1&d=20250909172310101)

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-01104-1>

[Xembify](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-01660-1) <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-01660-1&d=20250505172310101>

## Equipment and consumables for SCIg administration

#### SCIg administration can require specific equipment and consumables (see appendix B)

* Infusion pump,
* Subcutaneous needles and tubing,
* Luer lock syringes(s) (must fit pump if used),
* Drawing up needles or vented dispensing pins,
* Alcohol swabs or skin prep,
* Surgical tape/dressing,
* Small band aid or gauze,
* Sharps container,
* Transport bag and ice brick if required (Cuvitru® and Xembify® are stored at 2-8°C),
* Patient treatment record/Infusion diary/product App,
* Antibacterial wipes or soapy water (to clean SCIg preparation area/placemat).

#### Types of pumps and infusion sets

The information below is an example of equipment and consumables available. Blood Matters do not endorse the use of any particular equipment and consumables. 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** – SCIg 60 pump, Versarate Plus rate controller and Soft-Glide needles. SAF-Q Needles: Number of lumens: 1, 2, 3, 4 Needle gauge: 24g, 27g Needle length: 6mm, 9mm, 12mm OPTFlow Needles: Number of lumens: 1, 2, 3, 4, 5, 6 Needle gauge: 26g Needle length: 4mm, 6mm, 9mm, 12mm, 14mm

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 VersaRate Plus rate controller allows the patient to easily control the rate of administration. The SAF-Q and OPTFlow needles are supplied with transparent dressings.

**Go Medical Industries**

**Springfuser® syringe infusion pump** – 10, 30 & 50 **Flow Control Tubing** – (FCT) constant 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. The FCT 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.

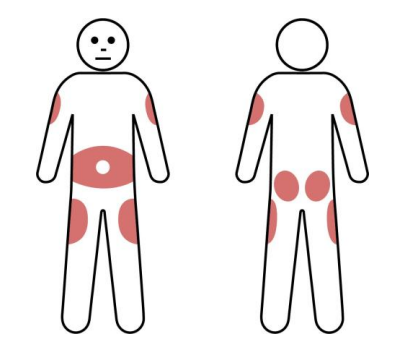
**Clinect**

**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) 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. Neria needles are supplied with transparent dressings.

## Infusion site selection

SCIg is administered subcutaneously. 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. [ASCIA PID Clinical Update](https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Clinical_Update_PID_2025.pdf) <https://www.allergy.org.au/images/stories/pospapers/ASCIA\_HP\_Clinical\_Update\_PID\_2025.pdf>

Figure 2: Infusion sites



## Product administration procedure

#### Infusion process: in the health service

**Prior to commencing the infusion check that:**

* The patient has consented to receive SCIg as per health service requirements.
* SCIg has been prescribed (product, dose, rate, route, and frequency).
* The correct SCIg product has been issued as some products have similar names.
* 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.
* The patient is well hydrated.

**Checking the patient, product and prescription:**

* 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.
* Document pre administration checks as per health service protocol.
* Check you have the right rate of infusion. Different SCIg products are given according to different infusion schedules and patient clinical need.
* Please be aware that infusion volumes per site/per infusion vary between products(refer to PI).
* 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.

#### Observations: in the 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
* post infusion observation – patients naïve to human normal immunoglobulin and patients switched from an alternative product or when there has been a long interval since the previous infusion should be monitored for the first hour after the first infusion. All other patients should be observed for at least 20 minutes post completion.
* Additional observations may be required based on patient’s clinical condition e.g. adverse event.
* Please be aware that local policies may require more frequent observations.

#### Administration instructions

* Wash hands and set out equipment and consumables on a clean surface.
* Remove the protective cap from the vial and wipe the rubber stopper with alcohol swab.
* Draw SCIg into infusion syringe using drawing up needle or vented dispensing pin.
* If using a drawing up needle, slowly inject air into the air space in the vial that is equivalent to the amount of SCIg to be withdrawn. Then withdraw the SCIg from the vial. If multiple vials are required to achieve the desired amount of SCIg, repeat this step.
* If using the vented dispensing pin, there is no need to inject air into the air space.
* Once required dose is withdrawn into the syringe attach the infusion set with the required number of needles.
* Prime the infusion set with the SCIg leaving approximately 2-5cm of air at the needle end.
* Clean the injection site/s with antiseptic solution.
* Grasp the skin between two fingers and insert the needle/s at a 90° angle into the subcutaneous tissue.
* **SCIg must not be injected into a blood vessel.** To test the needle/s are not located in a blood vessel, gently pull back on the syringe plunger and look to see if any blood is flowing back into the tubing. If you see blood, remove and discard the needle and tubing. Repeat priming and needle insertion steps using a new infusion set and a new infusion site.
* Secure the needle/s with tape or transparent dressing.
* Infuse SCIg slowly by push or pump at the specified administration rate.
* Infusion rate and site/s may be changed if required.
* Multiple injection sites can be used simultaneously. Injection sites should be at least 5cm apart and 5cm from the umbilicus.
* Remove the peel-off label from the SCIg vial and insert into the patient treatment record or diary or scan barcode into the product App.

#### Completion of infusion

* At completion of the infusion remove the syringe from the pump and leave the syringe attached to the infusion set.
* Remove the dressing and take the needle/s out of the skin.
* Cover injection site/s with band aid/gauze and apply light pressure to the injection site/s.
* Human immunoglobulins are a biohazard – equipment and vials cannot be disposed of in general household waste.
* The needle/s, infusion set, syringes and empty vials must be discarded in a sharps container.
* Once the sharps container is full return it to the health service for disposal.

## Adverse effects and management

Adverse effects most commonly tend to be infusion site related. Figure 3 shows a typical mild and moderate injection site reaction.

Figure 3: Mild and moderate injection site reactions

Mild injection site reaction Moderate injection site reaction

Table 3 and 4 outline possible adverse effects and management for SCIg related products. Please refer to individual PI for specific risk profiles.

Slower rate of infusion and increased monitoring may be considered for patients who receive SCIg:

* for the first time,
* when switched from an alternative product,
* when there has been a long interval since the previous infusion.

Table 3: Possible adverse effects for SCIg products

| Very common | Common | Rare |
| --- | --- | --- |
| Infusion site related  Headache  Fever/ feeling hot  Nausea  Vomiting  Diarrhoea  Sore throat (nasopharyngitis) | Chills  Back pain  Arthralgia  Hypotension  Dizziness  Urticaria | Allergic reactions  Anaphylactic shock  Thromboembolism  Renal complications  Haemolysis  Transmissible agents  Aseptic meningitis |

#### Troubleshooting

Table 4: ASCIA Management guide for SCIg infusion site reactions and problems

|  |  |  |
| --- | --- | --- |
| Site issue | Possible cause/s | Management options |
| Redness | Common reaction, which usually settles over 24-48 hours.  Excessive redness may be due to:   * an allergy or sensitivity to dressing/tape, * needle not inserted correctly, or needle too short. | If it does not cause discomfort, do nothing.  Warm or cold pack for short periods may help with discomfort.  Wrap warm/cold packs in a cloth - do not apply directly to the skin.  Slow the infusion rate if uncomfortable.  Try using an over-the-counter non-drowsy antihistamine.  Check correct needle placement/length with your nurse specialist.  Consider alternative tapes/dressings to secure needle/s with your nurse specialist. |
| Swelling | Common reaction, which usually settles over 24-48 hours. Swelling usually results from the amount of fluid being infused underneath the skin (amount of swelling should relate to the volume being infused). | If it does not cause discomfort, do nothing.  A warm pack for short periods may help with absorption.  A cold pack for short periods may help with discomfort, but delays absorption.  Wrap warm/cold packs in a cloth - do not apply directly to the skin.  Take a walk to help with absorption.  Check correct needle placement/length with your nurse specialist.  May need to decrease volume at the site, reduce the rate or change the infusion site. This should be discussed with your nurse specialist. |
| Itching or burning | Incorrect needle placement.  Incorrect needle length.  Irritation from tape.  Ig at needle tip, causing skin irritation. | Do not scratch or rub.  Check needle placement and length.  Try using an over-the-counter non-drowsy antihistamine.  Consider alternative tapes/ dressings to secure needle/s.  Apply cold pack for short periods - wrap pack in a cloth - do not apply directly to the skin.  Discuss dry priming with your nurse specialist. |
| Pain with infusions | Incorrect needle placement.  Incorrect needle length.  Infusion going too fast. | Check needle placement/length.  Apply cold pack for short periods - wrap pack in a cloth - do not apply directly to the skin.  Slow infusion rate.  Try simple pain medication (such as paracetamol) before starting the infusion.  Take a walk to provide a distraction.  Check tape placement for pulling on skin or body hair.  Discuss with your nurse specialist. |
| Blanching (whiteness) | Normal tightening of tissue that can occur as SCIg infuses into the fatty tissue under the skin. | Do nothing, usually goes away on its own when the fluid is absorbed.  Warm pack for short periods (may assist absorption) - wrap pack in a cloth - do not apply directly to the skin. |
| Leaking from the infusion site | Incorrect needle insertion.  Incorrect needle length.  Amount of volume infused at the site. | Check needle insertion.  May need to consider changes to volume, needle length or rate of infusion.  Speak to your nurse specialist or doctor. |

[Subcutaneous immunoglobulin (SCIg) therapy - general information - Australasian Society of Clinical Immunology and Allergy (ASCIA)](https://www.allergy.org.au/patients/immunodeficiencies/scig-therapy-general-information?highlight=WyJzY2lnIiwiZmFxIl0=)

<https://www.allergy.org.au/patients/immunodeficiencies/scig-therapy-general-information?highlight=WyJzY2lnIiwiZmFxIl0=>

#### Adverse effect reporting

Adverse effects should be reported using an in-house quality management system and to the relevant product manufacturer or the Therapeutic Goods Administration (TGA).

Adverse event forms are available directly from the product manufacturer:

CSL Behring email: [medicalinformation@cslbehring.com.au](mailto:medicalinformation@cslbehring.com.au)

Takeda email: [medinfoapac@takeda.com](mailto:medinfoapac@takeda.com)

Grifols email: [australia\_medinfo@grifols.com](mailto:australia_medinfo@grifols.com)

Or contact the Lifeblood transfusion nurses (TN) who will forward a copy. Lifeblood TN email: [vtatn@redcrossblood.org.au](mailto:vtatn@redcrossblood.org.au)

Where a change of product is required, this is done via BloodSTAR using a dose/product change authorisation request by the treating Medical Officer. NBA has a tipsheet to assist [Requesting a Dose/Product Change or an Additional Dose tip sheet](https://www.blood.gov.au/bloodstar-user-tips-and-support-materials) <https://www.blood.gov.au/bloodstar-user-tips-and-support-materials>

There is an option to create an alert in BloodSTAR to prevent further dispensing of the offending product. The alert can be added by the treating Medical Officer. The NBA has a tip sheet to assist [BloodSTAR Adding a Do Not Prescribe to a Patient Record](https://www.blood.gov.au/bloodstar-user-tips-and-support-materials) <https://www.blood.gov.au/bloodstar-user-tips-and-support-materials>

## Nurse competency

The nurse providing education to patients receiving SCIg should demonstrate an understanding and competency in regard 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 and rate, 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 troubleshooting
* Patient education requirements and resources available.

(Ozerovitch 2013, Younger et. al. 2015)

## Patient education

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 self-administer at home will 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).

Education may be undertaken in the health service by a SCIg Coordinator/Nurse, or through the CSL Cares, Cuvitru at Home or Grifols Connex patient support programs or other approved nursing service in the patient’s home.

#### Home treatment: patient education requirements

Participants must receive appropriate training and education prior to home self-administration. They must:

* Understand transport and storage requirements of the product prescribed.
* Be able to select appropriate infusion sites and care for the site.
* Describe equipment and consumables necessary to complete procedure.
* Demonstrate SCIg administration procedure and safe removal and disposal of needle, infusion set and vials.
* Understand how to use infusion device/pump, and what to do when not working.
* Understand ‘push’ method as an alternative if required.
* Understand how to check and prepare product.
* Demonstrate ability to prepare infusion site and draw up single or multiple vials and prime infusion set.
* Demonstrate insertion of subcutaneous needle/catheter.
* Draw back on syringe to check for blood and discuss actions to take if blood is present.
* Demonstrate appropriate aseptic technique.
* Understand potential adverse events/reactions that could result from the infusion and their management.
* Understand ordering and collection of product and consumables.
* Understand how to report wastage and return unused product.
* Document/record treatment in patient treatment record/diary/App.
* Document and report wastage.
* Patient to be informed of who to contact in an emergency.

#### Examples of patient training checklists templates and patient information

* Appendix A patient education template
* Example – NBA [Training Checklist for Home Administered Subcutaneous Immunoglobulin (SCIg) Infusion Treatment](https://www.blood.gov.au/blood-products/immunoglobulin-products/subcutaneous-immunoglobulin-scig) <https://www.blood.gov.au/blood-products/immunoglobulin-products/subcutaneous-immunoglobulin-scig>
* NBA patient information brochures [SCIg support materials](https://www.blood.gov.au/blood-products/immunoglobulin-products/subcutaneous-immunoglobulin-scig) <https://www.blood.gov.au/blood-products/immunoglobulin-products/subcutaneous-immunoglobulin-scig>
* ASCIA [Subcutaneous Immunoglobulin (SCIg) Nurse Competency and Patient Training Checklists](https://www.allergy.org.au/hp/papers/ascia-scig-competency-training-checklists) <https://www.allergy.org.au/hp/papers/ascia-scig-competency-training-checklists>
* Australian Primary Immunodeficiency Patient Support (AusPIPS) [About Immunoglobulin patient information brochure](https://www.auspips.org.au/files/2001377_AusPips%20Brochure_English_A4_v6.5.pdf) <https://www.auspips.org.au/files/2001377\_AusPips%20Brochure\_English\_A4\_v6.5.pdf>

CSL Behring, Takeda and Grifols have a large range of information, treatment record diaries and other resources available for both patients and health care providers:

* Contact CSL Behring at: [customerservice@cslbehring.com.au](mailto:customerservice@cslbehring.com.au) or for customer service enquiries for plasma-derived therapies within Australia phone: 1800 063 892
* Contact Takeda at: [medinfoapac@takeda.com](mailto:medinfoapac@takeda.com) or go to the [Takeda website](https://www.takeda.com/en-au/what-we-do/our-products/) for detailed instructions for administration <https://www.takeda.com/en-au/>
* Go to [Grifols Gateway](https://www.gatewayhcpportal.com.au/en/login) to access educational resources, patient brochures and product information <https://www.gatewayhcpportal.com.au/en/login>

## Documentation

The patient is required to record their treatment. This can be done using a patient treatment record (see Appendix C), or product providers treatment diary or App.

Information required:

* Product name
* Batch number and expiry date
* Dose
* Volume
* Infusion time
* Infusion site
* Infusion rate
* Symptoms/side effects.

## Product and consumable order and collection

Patients should liaise with the SCIg Coordinator/Nurse regarding product and consumable requirements.

* A maximum of two months’ supply of SCIg product can be dispensed.
* The equipment checklist (see Appendix B) can be used as an aid to ensure the patient has a sufficient supply of consumables.

## Follow up/review

Patients should be medically reviewed on a six-monthly basis or as directed by treating specialist. The review information is entered into BloodSTAR.

The SCIg Coordinator/Nurse should review the patient regularly and review the patient treatment record (Appendix C) and discuss any adverse events or issues.

## Transport recommendations

* All products need to be taken directly home and stored as directed (don’t stop to shop on the way home).
* Cuvitru® and Xembify® 2-8°C.
* Hizentra® AU and Hizentra® < 25°C.
* Don’t put products in the car boot for travel (too hot, too easily forgotten); it must be in the cabin of the car.
* If travelling by plane the product should be taken as carry-on luggage and stored as directed, never in checked luggage. Refer to [Blood Matters Travelling overseas with SCIg guide](https://www.health.vic.gov.au/patient-care/subcutaneous-immunoglobulin-scig-program-tools-and-resources) for further information on travelling with SCIg <https://www.health.vic.gov.au/patient-care/subcutaneous-immunoglobulin-scig-program-tools-and-resources>

## Wastage

* Expired or unused SCIg product vials must be returned to the health service/pharmacy and not discarded in household waste.
* Record all waste/unused SCIg product vials on the patient treatment record/treatment diary/App.
* The NBA has a tip sheet to assist [Managing broken vials](https://www.blood.gov.au/bloodstar-user-tips-and-support-materials) <https://www.blood.gov.au/bloodstar-user-tips-and-support-materials>

## Appendix A: Example of a patient education competency template

Affix Patient identification label here

Insert health service details……………………………………..

The person administering the SCIg must be assessed as competent by the clinician prior to transitioning to home-based self-administration.

The number of training sessions required are individualised for each patient.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Session 1**  Date:\_\_/\_\_/\_\_  Clinician Name:  Signature: | **Session 2**  Date:\_\_/\_\_/\_\_  Clinician Name:  Signature: | **Session 3**  Date:\_\_/\_\_/\_\_  Clinician Name:  Signature: |
| Competent (C)/Not yet competent (NYC) | **C/NYC** | **C/NYC** | **C/NYC** |
| Describes transportation & storage of SCIg |  |  |  |
| Describes SCIg administration & infusion site/s |  |  |  |
| Demonstrates infusion sites and appropriate selection |  |  |  |
| Understands equipment required |  |  |  |
| Understands use of infusion device/pump (*if infusion device/pump used)* |  |  |  |
| Demonstrates “push” method (patient must be aware even if infusion device pump is used) |  |  |  |
| Demonstrates SCIg product checking – type, dose, expiry, discolouration |  |  |  |
| Demonstrates drawing up SCIg from single or multiple vials (aseptic technique) |  |  |  |
| Demonstrates priming the giving set and pump set up (where pump used) |  |  |  |
| Demonstrates infusion site skin preparation |  |  |  |
| Demonstrates subcutaneous needle/catheter insertion - no touch (aseptic) technique |  |  |  |
| Demonstrates needle/catheter taping |  |  |  |
| Checks for blood return and understands process if blood is present |  |  |  |
| Demonstrates ability to remove and safely discard needle/s |  |  |  |
| Demonstrates ability to accurately record treatment in patient treatment record/diary/app |  |  |  |
| Understands how to report waste and return unused SCIg |  |  |  |
| Understandings adverse effects and how to manage them |  |  |  |

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

## Appendix B: Recommended consumable supply list template

Affix Patient identification label here

Insert health service details……………………………………..

A guide to equipment required by patient

|  |  |
| --- | --- |
| Consumable | Amount required |
| Small coolers – ice bricks if required. Cuvitru®/Xembify® stored 2-8OC  Utilise cooler in cases of extreme heat and long travel distance for Hizentra® AU and Hizentra® to ensure product remains below 25OC. | Provided by patient/ CSL Behring /Takeda/Grifols |
| Plastic container to store SCIg in refrigerator | Provided by patient |
| Infusion device/pump enter details of equipment selected if using this infusion method |  |
| Luer lock syringe 10mL, 20mL ,30mL, 50mL, other size if required |  |
| Drawing up needle or vented dispensing pin |  |
| Subcutaneous infusion set - add details of choice |  |
| VersaRate Plus rate controller if required |  |
| Transparent film dressing if required |  |
| Alcohol prep swabs |  |
| Antibacterial surface cleaner wipes |  |
| Surgical tape |  |
| Cotton wool balls |  |
| Band-aids |  |
| Sharps container (exchange when full) |  |
| Patient treatment record/diary/App |  |
| Topical anaesthetic cream if required e.g. EMLA cream |  |

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

## Appendix C: Patient treatment record template

*Affix Patient identification label here*

Insert health service details…………………………………….

**Healthcare team contact details**

Health service/Clinic name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Specialist name**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ email: (if applicable) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Nurse name**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ email: (if applicable) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

General Practitioner name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ phone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Product: (circle) Hizentra® AU, Hizentra®, Cuvitru®, Xembify®, Dose:\_\_\_g / \_\_\_\_mL, Frequency:\_\_\_\_\_\_\_\_\_

**Infusion Record**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Date/time |  |  |  |  |  |  |  |  |
| Volume |  |  |  |  |  |  |  |  |
| Site/s used |  |  |  |  |  |  |  |  |
| Infusion time |  |  |  |  |  |  |  |  |
| Infusion rate |  |  |  |  |  |  |  |  |
| Adverse event |  |  |  |  |  |  |  |  |
| Medications used (if relevant) |  |  |  |  |  |  |  |  |
| Batch numbers & expiry date (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 Hizentra® AU and Hizentra®. Takeda have a patient record booklet available for Cuvitru®. Grifols have a patient record booklet available for Xembify®.

## Reference list/recommended reading

### National Blood Authority

[Governance for immunoglobulin products](https://www.blood.gov.au/supply-system/governance-immunoglobulin-products) <https://www.blood.gov.au/supply-system/governance-immunoglobulin-products>

[Joining the national SCIg program - governing requirements](https://www.blood.gov.au/blood-products/immunoglobulin-products/subcutaneous-immunoglobulin-scig) <https://www.blood.gov.au/blood-products/immunoglobulin-products/subcutaneous-immunoglobulin-scig>

[BloodSTAR user tips and support materials](https://www.blood.gov.au/bloodstar-user-tips-and-support-materials) <https://www.blood.gov.au/bloodstar-user-tips-and-support-materials>

[Criteria for the clinical use of immunoglobulin in Australia ( the Criteria)](https://www.criteria.blood.gov.au/) <https://www.criteria.blood.gov.au/>

### Australian Red Cross Lifeblood

[Comparison of Subcutaneous Immunoglobulin Products Available under National Blood Supply Arrangements](https://www.lifeblood.com.au/health-professionals/learn/resource-library?query=Comparison%20of%20Subcutaneous%20Immunoglobulin%20Products%20available%20under%20%20National%20Blood%20Supply%20Arrangements&category=All&filetype=All&sort_bef_combine=changed_1_DESC)

<https://www.lifeblood.com.au/health-professionals/learn/resource-library?query=Comparison%20of%20Subcutaneous%20Immunoglobulin%20Pro>

[Australian Red Cross Lifeblood Subcutaneous Immunoglobulin (SCIg) fact sheet](https://www.lifeblood.com.au/health-professionals/products/fractionated-plasma-products/immunoglobulins/SCIg) <https://www.lifeblood.com.au/health-professionals/products/fractionated-plasma-products/immunoglobulins/SCIg>

### CSL Behring

[Hizentra AU consumer medicine information (CMI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2023-CMI-01369-1) <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2023-CMI-01369-1&d=20250505172310101>

[Hizentra AU product information (PI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2020-PI-01937-1&d=20231015172310101) <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2020-PI-01937-1&d=20231015172310101>

[Hizentra consumer medicine information (CMI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2015-CMI-01958-1) <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2015-CMI-01958-1>

[Hizentra product information (PI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2014-PI-03180-1) <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2014-PI-03180-1>

### Takeda

[Cuvitru consumer medicine information (CMI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2020-CMI-02577-1) <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2020-CMI-02577-1>

[Cuvitru product information (PI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-01104-1) <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-01104-1>

### Grifols

[Xembify consumer medicine information (CMI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-CMI-01658-1&d=20231015172310101) <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-CMI-01658-1&d=20231015172310101>

[Xembify product information (PI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-01660-1) <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-01660-1&d=20250505172310101>

### Other websites

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

[Immune Deficiencies Foundation Australia](https://www.idfa.org.au) < https://www.idfa.org.au>

[Australian Primary Immune Patient Support (AusPIPS)](https://www.auspips.org.au) < https://www.auspips.org.au>

## Journal Articles

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

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

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

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