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

Restrictions:

Governing requirements

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

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Scope / Criteria

SCIg is only approved for patients with a medical condition:
1. where there is support for use cited in the *Criteria for the clinical use of 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)*
2. being treated by a clinical specialist within a hospital based SCIg program, 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
3. following a patient-specific SCIg request submitted in BloodSTAR.

Patient eligibility

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

Note

*Patients with Chronic inflammatory demyelinating polyneuropathy (CIDP), (including IgG and IgA paraproteinaemic demyelinating neuropathies) **must first be stabilised on IVIg before switching to SCIg**

Contra-indications of SCIg:

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

Safety considerations

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

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

Nurse competency

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

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

Patient identification process

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

Specialist review

Once identified patients to see specialist/treating team to discuss with specialist transition to or commencement on SCIg.
Need to be enrolled in a program refer pg. 5

- Specialist to review/order IG levels via Dorevitch result CC to trak if none recent.
- Current inpatients nurse to contact specialist re urgent appointment if patient having difficulty making appointment.
- If transitioning to commence within 1-2 weeks of last IVIg dose if monthly / 1 week if fortnightly IVIg (CIDP patients to commence 1 week after last IVIg dose).

Presentation

- Hizentra® which is a 20% concentrate comes [1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL) vials].
- *Evogam® is a 16% concentrate so has a larger volume per dose [0.8g (5mL), 3.2g (20mL) vials].*
- Cuvitru ® (Takeda) a 20% concentrate [1g (5mL), 2g (10mL), 4g (20mL), 8g (40mL)]. Normal Immunoglobulin (human) contains at least 98% IgG.

Dosing

The treating medical specialist will ultimately determine the dose of SCIg to be provided for each patient.
As a guide patients will receive a dose 0.4g/kg** in total per 4 week period The dose can be divided into 4 weekly doses of 0.1g/kg or more depending on the volume per infusion site, dose and frequency as decided by clinician and as tolerated or decided by the patient

- **Example 1** patient weight =80kgs, 0.4g/kg = 32g, weekly dose of 0.1g/kg = 8g
- **Example 2** Patient is currently on 36 g IVIG every four weeks
    - The equivalent weekly SCIg = 9g / week
    - Calculation for Hizentra
        - 9g / 0.2 g/ml = 45 ml of SCIG Hizentra per week.
    - *Calculation for Evogam:*
        - *Volume in ml of SCIG that is needed for each dose would be:*
        - *SCIG dose (ml) = 9 g of SCIG / 0.160 g/ml = 56.25 ml of Evogam*
        - *This could be supplied by 55 ml of Evogam every week*

****CIDP patients** The therapy with Hizentra® is initiated 1 week after the last IVIg infusion. The recommended subcutaneous dose is 0.2 to 0.4 g/kg body weight per week. The weekly dose can be divided into smaller doses and administered by the desired number of times per week. For dosing every two weeks, double the weekly Hizentra® dose.https://www.cslbehring.com.au/-/media/cslb-australia/documents/aus-pis-and-cmis/hizentra-au-product-information-900.pdf?la=en-us&hash=A19A062CE3F5D20597A0E266266C4B3C752EA8E4

- Vials are available in different sizes and doses should be rounded to the nearest vial size.

- Patients may require a loading dose of IVIg 1-2 weeks prior to the commencement of SCIg to ensure adequate trough serum IgG level.
- Different patients will require different IgG levels to remain clinically well and free from infections and different dosing regimens to achieve and maintain appropriate trough IgG levels
- The choice of SCIg product is determined by the treating medical specialist in conjunction with the patient.
- Refer to product guides for further information
  - https://www.cslbehring.com.au/-/media/cslb-australia/documents/aus-pis-and-cmis/evogam-au-pi-800.pdf?la=en-us&hash=2FECE8E47F85B328F10996442028EC8F31F833DD Evogam®
  - https://www.cslbehring.com.au/-/media/cslb-australia/documents/aus-pis-and-cmis/hizentra-au-product-information-800.pdf?la=en-us&hash=852F1A8C1BA08F755B6BE1FE7209193EF0489F40 Hizentra®
  - https://www.takeda.com/en-au/what-we-do/our-products/ Civitru®

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

*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 doses [1, 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.			

SCIg approval / dispense process

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

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

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

SUBCUTANEOUS IMMUNOGLOBULIN (SCIG) PROGRAM

Initial Authorisation Request submitted in BloodSTAR including Privacy Consent (www.blood.gov.au)
Initial Prescription forwarded to pharmacy.
Patient enrolled in company programs see below
Day procedure notified.

- Cuvitru – training undertaken at home by Cuvitru at HOME program
- Hizentra / Evogam Patients are trained in day procedure

Enrolment

Cuvitru

Prescriber completes CUVITRU PSP Patient enrolment and consent form INTERACTIVE

- **Email to** support@cuvitruathome.com.au; OR
- **Fax to** 1800 329 054; OR
- **Mail to** Cuvitru atHOME, Reply Paid 85298, NORTH SYDNEY NSW 2060
- **Or For online patient enrolment** www.cuvitruathome.com.au

Hizentra / Evogam Patients

- Prescriber - Completes **SCIg - CSL Cares Nurse Care Patient Enrolment form**
  - Assess level of support required - at a minimum all patients to be enrolled in Level 3 so they can access phone support. Most patients would benefit from Level 1, with a coaching visit when first administering at home.

Email form to support@cslbehringcares.com.au or fax the form to 1800 734 989

Subcutaneous Immunoglobulin (SCIg) Program Treatment Flowchart

Selection of Patients:

- Primary immunodeficiency with antibody deficiency
- Specific antibody deficiency
- Acquired hypogammaglobulinaemia secondary to haematological malignancy
- Secondary hypogammaglobulinaemia

Treating Consultant:

- Patient identified & accepted into program by Haematologist.
- Initial Authorisation Request submitted in BloodSTAR including Privacy Consent (www.blood.gov.au)
- Prescription of product
- Notification of Day procedure
- Medication chart if having doses in day procedure during training- Hizentra/ Evogam only
- Enrolment into company program -

Treatment co-ordination:

Notification to SCIg program co-ordinator (Day stay ward)

- Communication with patient re: SCIg program, products, infusion methods, training timeframe.
- **Current Ig Patient must agree to transfer to inclusion in the SCIg Program – personnel choice**

Ordering of Product:- (1 week prior to treatment)·

- Order via BloodSTAR Pharmacy to order product in Blood Net. ·
- Once Pt is stable ordering can be undertaken each 2 months.
- Pt. to notify pharmacy 1 week in advance of need for new supplies

Patient training

Cuvitru – training undertaken at home by Cuvitru at HOME program

Hizentra / Evogam Patients traning undertaken in Day procedure, reviews as required individualised to the patient requirements

Collection of supplies - Organised by day procedure collected from pharmacy when picking up prescriptions

Home treatment: Patient education requirements

<u>Cuvitru – training undertaken at home by Cuvitru at HOME program</u>

<u>Hizentra / Evogam Patients</u> to receive a personalised education program in day procedure by a clinical nurse specialist trained in how to administer SCIg therapy at home.

Patients must:

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

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Initial training for self-administration at home

<u>Cuvitru – training undertaken at home by Cuvitru at HOME program</u>

<u>Hizentra / Evogam Patients</u>

Specific steps to be assessed prior to patient/carer considered competent to self-administer medication in a home setting.

The number of training sessions should be individualised according to patient's/carer's needs, as a guide patient training weekly 2-4 weeks.

- The first education session is usually a minimum of 2hrs but can be up to 3hrs to be undertaken in Day Procedure.
- The subsequent sessions tend to be shorter 1 – 2hrs in Day procedure
  - Demonstrate at first visit
  - Support and assist at second visit
- Patient information utilised
  - **SCIg- Doing your own Subcutaneous Immunoglobulin (SCIg) Infusion** https://www.youtube.com/watch?v=LOEQz165jtU emed
  - https://www.youtube.com/watch?v=nP4LGk-I5Ds Hizentre CSL
  - CSL Patient packs and support program brochure.
  - Patient Education competency record is completed (Appendix 2).
- Future Visits are booked in Day Procedure.

Documentation / responsibilities

Patient / carer	**All** Patient to notify pharmacy 1 week in advance of need for new supplies Treatment must be documented /recorded in patient treatment diary (booklet)/ **Hizentra only** - My Hizentra app, SWH only code for setup 4949 https://www.hizentra.com/patient-infusion-app.
Specialist	BloodSTAR authorization & Annual blood product consent **All -** Prescriptions for each 1 or 2 month supply of product for home administration • **Hizentra / Evogam -** Medication order on medication chart for training sessions Complete enrolment form see above.
Nurse	**All patients** - Organize consumables and have available at pharmacy for pick up ***Hizentra / Evogam Patients*** • Education competency (Appendix 2) • Consumables supplied. (Appendix 3) • Treatment record / care plan (Appendix 5) • Patient assessment form (Appendix 6) at each review / or entry in clinical notes
Pharmacy	BloodSTAR/ BloodNet request dose etc. Dispense as prescribed, ensure patients are also given consumables supplied from Day procedure.
Support program	Reports from support program forward to Day procedure and to be include in Patients medical record.

Patient reviews

Cuvitru –undertaken at home by Cuvitru at HOME program

Hizentra / Evogam Patients Once patient is independent for administration of SCIg they may required regular review and will require supply of product and equipment.

- Frequency of review is dependent on the independence of the patient, most will only require review by haematologist as per their clinical condition indicates.
  Suggested nursing review program if required - Monthly for the first 3 months of treatment approx. 30 min – 1hour depending if there are any issues that need to be addressed, if deemed independent enough can have 8 weekly reviews Or 8 weekly with CSL support visit
- Once patient is stable (nil adverse effects/issues) collection may be extended to 2 monthly.
- If requiring ongoing reviews the Nurse will review
  - the adequacy of replacement, resulting in serum IgG level > 7 g/L,
  - the Patient Treatment Diary,
  - Clinical indicators of effective IgG replacement that include, but are not limited to, clinical infections or antibiotic prescriptions and
  - Reinforce what to do in case of adverse effects.
- As a guide IgG blood test is to be undertaken Pre, 2nd monthly for first 6mths then as directed by Medical Officer.
- Complete **Patient Assessment** form (Appendix 6) at each nursing review. Address all identified issues and if required discuss with MO.
- **ON collection of product** the patient is supplied with the required consumables as required on the Consumable Supply List (Appendix 3) and document consumables given (file in Infusion folder).
- **Document** nursing reviews in patient clinical record on patient assessment form /clinical notes

- Nursing review treatment record / care plan (Appendix 5) and update if needed (file in Infusion folder, if updated old form filed in medical record with date superseded).
- Make next review booking with patient if required.
- The Nurse may consider ceasing the SCIg and returning the patient to IVIg if there are concerns regarding patient ability to safely administer or the patient is unable to meet the required schedule.
- If patient has any further questions, they can also contact the 'CSL support program' outside review appointments.

Pharmacy

- Medication order on medication chart required for dispensing for training sessions.
- **Prescription** required for each 1 or 2 month supply of product for home administration.
- **Patient to Collect** SCIg product from pharmacy. Hizentra must be stored below 25 degrees Celsius (fridge) Evogam, Cuvitru refer product info.
- Pack product in patient supplied esky with ice bricks and instruct patient to go directly home and place in fridge
- Ensure patients are also given consumables supplied from Day procedure
- Follow-up that authorisation (BloodSTAR) and prescriptions are organised for next review.
- Reminder to specialist if more paperwork required. ,

Patient education

Refer **SUBCUTANEOUS IMMUNOGLOBULIN (SCIG) – ADMINISTRATION**

Key align policies

MEDICATION Administration

Key align documents

CUVITRU atHOME Supporting your experience booklet
CUVITRU PSP Patient enrolment and consent form INTERACTIVE
SUBCUTANEOUS IMMUNOGLOBULIN (SCIG) – ADMINISTRATION
SCIg - CSL Cares Nurse Care Patient Enrolment form
SCIg- Doing your own Subcutaneous Immunoglobulin (SCIg) Infusion

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Legislation, standards & best practice

POISONS CONTROL PLAN (PCP)

References

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

Contributors

	Name First initial. Surname	Position I.e. AUM Intensive care	Involved in			
			Development / review	Ratification	Implementation	Compliance
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Contributors:	M Bell	Unit manager Day procedure	X			
	L Spence	Director of Pharmacy	X			
Committee/s:	Medication safety committee Clinical governance committee			X X		
Consumer input						
Executive sponsor	K McConnon	Exec Director of Medical Services				

Implementation & communication Monthly memo from CEO Office
Education program

Compliance Riskman

Appendix 1: Patient information - How to administer *refer*

SCIg- Doing your own Subcutaneous Immunoglobulin (SCIg) Infusion

Appendix 2: Patient education competency

Affix Patient identification label here

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:
Competent (C) Not yet competent (NYC) (Please circle)	**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				
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.				
Changes or problems (record in clinical notes)	☐	☐	☐	☐
Satisfactory to self-administer Yes /No				
Patient acknowledgment.				
Rebook to Day Procedure if more education needed	☐	☐	☐	☐

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

Appendix 3: Consumable supply list

South West Healthcare

Affix patient identification label here

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

Product and supplies		**Number supplied each review**								
Patient supply										
Small Esky & ice brick/s frozen if required *Make sure patient knows to bring to each review.*										
Preparation area mat *Supplied by CSL with startup kit*										
Infusion pump – *EMED SCIg 60* if required Supplied on setup										
Band-Aids to apply post infusion										
Hospital supply	Supply No	E.g. Per week								
Leur lock syringes BD 50mL if using EMED syringe driver ☐ Other if using different method _____ ☐		1								
Drawing up needle - Micropin for Hizentra		2								
Infusion needle/s – *SAF Q* _____		1								
Infusion extension set if required		?1								
Rate controller if using EMED syringe driver may only be required initially		1								
Occlusive dressing i.e. Tegaderm to anchor needle while infusion in progress *comes with EMED*		?2								
Pressure pad (if on blood thinners) otherwise pt. supplies own Band-Aid		?2								
Alcohol prep swabs.		3								
Sharps container (exchange when full)		? 1								
Infusion diary / sheets / using app https://www.hizentra.com/patient-infusion-app	Pg. 11									
SCIg Product Number to be supplied each month Hizentra® – vial size 1g (5mL) ☐ 2g (10mL) ☐ 4g (20mL) ☐, 10g (50mL)☐ Evogam®– vial size 0.8g (5mL) ☐ 3.2g	Pharmacy									
Staff initials										
Date supplied										

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

Appendix 4: Patient treatment diary

NB: CSL Behring have patient record booklets available for both Evogam® and Hizentra® which can be used instead.
or My Hizentra app https://www.hizentra.com/patient-infusion-app
____ SWH set up code 4949

Affix Patient identification label here

Healthcare team contact details

Hospital /Clinic name:_____

Specialist name:_____

Phone:_____email: (if applicable)_____

Nurse name:_____

Phone:_____email: (if applicable)_____

General Practitioner name:_____phone:_____

Product: (circle) Evogam®Hizentra® Dose:_____g /_____mL Frequency:_____

Infusion Record

	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.

Appendix 5 Subcutaneous immunoglobulin program

Treatment record / care plan

Affix Patient identification label here

Commence new treatment record sheet if changes to dose, treatment hospital or unit.

Please keep as a record in unit based infusion folders for reference by nursing staff

Patient Weight _____(kg)

Product Name: (please circle) Evogam Hizentra

Total Dose: Monthly _____(g) Weekly _____(g)

Total Volume: Monthly _____(mL) Weekly_____(mL)

Number of Infusions each week: (please circle) 1 Other (please state)**:** _____

Number of Injection Sites: 1 2 3 4 **Volume Infused each site:** _____

Vial Size each weekly dose:

Evogam: 5mL (0.8g) no. of vials _____ 20mL (3.2g) no. of vials _____

Hizentra: 5mL (1g) no. of vials _____ 10mL (2.g) no. of vials _____

20mL (4g) no. of vials _____ 50mL (10g) no. of vials _____

S/C Needle

EMED Size ___G x ___mm number of lumens_____

Other _____

Luer Lock Syringe Size and number:

50 mL BD Luer Lock Number _____

Other _____

Comments: _____

Nurse signature **Date** **Time**

Date superseded

Appendix 6 SUBCUTANEOUS IMMUNOGLOBULIN PROGRAM

Patient Assessment form

Affix Patient identification label here

Assessment to be undertaken at each training session / product collection booking/ review

IgG blood test is to be undertaken Pre, 2nd monthly for first 6mths then as directed by Medical officer

Date Infused / product collected Date range --/-- /--- to --/-- /--- Assessor	**Patient Assessment** **IgG result** _____Date of collection_____ Lab **Site reaction**: no yes size (cm) *(please circle)* redness swelling itchy other Other reactions: _____ _____ _____ *Since the last patient review / assessment:* **Has the patient had any recent infections** No…..Yes.. If yes: Type _____Duration_____ _____ _____ Did the infection require the patient to attend a GP No Yes Did the patient commence on antibiotics No Yes If yes, Name _____Dose_____ Duration_____ Did the patient require admission into hospital No Yes If yes, how many days Hospital Name **Other issues** (please comment): _____ _____ _____ _____ _____ _____