1.0 Title
Blood Products – Prescription and Supply of Intravenous Immunoglobulin (IVIg) and Subcutaneous Immunoglobulin (SCIg)

2.0 Purpose
To ensure the appropriate use of IVIg as directed by The National Policy: Access to Government Funded Immunoglobulin Products in Australia, and to provide information for accessing immunoglobulins under the arrangements set out by the National Blood Authority (NBA), promoting safe, high quality management and use of blood related products.

3.0 Procedure
Immunoglobulin products are a precious high cost resource for which governments have determined the Criteria as the basis for access to government funded product. The aim of Criteria is to ensure that government funded immunoglobulin products are directed to patients most likely to benefit based on reliable evidence and where alternative therapies are limited. The Criteria undergoes progressive revision. See Criteria for Clinical Use of Immunoglobulin in Australia Version 3, or browse the Criteria for use Index.

Consent must be obtained for immunoglobulin administration. Consent remains valid for ongoing treatments, unless the patient withdraws consent or the patient’s circumstances change, as per 3.7 and 3.8 in the NC-NNSW-PRO-6892-13: Blood Products-Patient Consent. Specific consent is also required for the collection and use of personal information that is stored in BloodSTAR. See BloodSTAR Privacy Controls. The consent form and information for patients as to what details are recorded and why, is available in the privacy consent section when requesting an authorisation in BloodSTAR.

BloodSTAR is a national online system that governs the administration, management, prescribing, authorizing and dispensing of immunoglobulin products across all stakeholder groups. Dispensers of Immunoglobulin products will access BloodSTAR via a module in BloodNET.

A range of BloodSTAR support materials is available on the NBA website.
A request for authorization for Immunoglobulin is initiated by the treating clinician through BloodSTAR. Relevant patient and diagnosis details are required.

Prescribers of Immunoglobulin should register for access to BloodSTAR for each hospital where practising. Prescribers may request immunoglobulin for a patient at any time with provisional access to BloodSTAR. This provisional access expires after 14 days unless full access is approved by a facility administrator.

The system enables assessment of eligibility made against the Criteria. The Blood Service has the role of authorizer, and the prescriber is notified electronically of the decision by the authorizer.

During ‘Downtime’ emergency authorisation forms can be obtained from the Blood Service.

For emergency authorisation requests, contact the Blood Service.

The medical specialist must provide a patient review to the Blood Service by their predetermined treatment review date. Patient outcomes must be recorded along with any request for increased dosage. Failure to comply with review requirements will result in the patient no longer being able to access government funded immunoglobulin.

The prescriber must advise cessation of treatment where clinical benefit has not been achieved or when product is no longer required.


If the request is authorized, the requested dispensing facility will also be notified of the details through BloodSTAR.

The dispenser (pharmacy or pathology departments) will be responsible for product ordering, inventory and dispensing of the product through BloodNET. Dispensers will only issue immunoglobulin against requirements that are authorised in BloodSTAR.

For generic IVIg information, and specific IVIg product infusion rates, refer to Appendix 1.

SCIG is approved for patients with a medical condition where there is support for use cited in Criteria for the clinical use of immunoglobulin in Australia.

A hospital participating in the national SCIG program is required to establish their capability and capacity to manage a hospital based home administered SCIG program. The hospital must provide access to all resources and is accountable for management and use of product.

The hospital must monitor compliance for the management and use of SCIG in line with the National Safety and Quality Health Service (NSQHS) Standards: Clinical Governance and Blood Management.
The hospital must have an appropriate supervising specialist who considers patient suitability for self-management and administration of SC Ig in the home\textsuperscript{3}.

The SC Ig program must provide ongoing clinical oversight and support for participating patients\textsuperscript{3}.

The hospital based SC Ig program must ensure patients have access to all necessary equipment and consumables\textsuperscript{3}.

SC Ig programs must provide education and training for staff and patients, including transport, storage, and use of equipment and infusion techniques. A comprehensive Training Checklist supports staff training\textsuperscript{2}.

For authorisation of SC Ig, requesting clinicians are required to provide information to the Blood Service through BloodSTAR, to establish that the request meets criteria\textsuperscript{3}.

Orders for SC Ig product are made through BloodNet.

Stock supplied to the patient should not exceed two months treatment\textsuperscript{3}.

Unused, discarded or spoiled product shall be reported by the hospital through BloodNET, to assist the NBA with supply reconciliation and planning\textsuperscript{3}.

Regular review to assess clinical benefit of treatment shall be conducted at periods specified by the responsible clinician, in addition to and supportive of the patient review that is required by the Blood Service. Patients shall be encouraged to maintain their Patient receipt and use diary on product management and adverse reactions as an aid for the clinician at regular assessments\textsuperscript{3}.

Further details on SC Ig Governance can be found at Appendix B in the National Policy: Access to Government - Funded Immunoglobulin Products in Australia.

Patients should remain on the SC Ig product they commenced treatment on, unless there is an adverse event or patient choice.

Patient information on IVIg and SC Ig treatments can be found at Patient Fact Sheets and Resources.

4.0 Required Knowledge and Assessment to Perform this Procedure

Prescribing clinicians should be familiar with the consent process, requesting authorisation, prescription, review and reporting within BloodSTAR. Nursing staff administering IVIg should have knowledge of BloodSTAR processes, and refer to the NC-NNSW-PRO-6975-13 Blood Products – Administration.

Dispensers of Immunoglobulin product will have knowledge of BloodNet, to maintain inventory, receipt and dispense orders, ensure cold chain integrity, and record product fate.

Staff responsible for implementation and ongoing education of a SC Ig program will be Registered Nurses (RN) currently working in Cancer Care (CC) that shall have attended staff education sessions presented by the CC Clinical Nurse Consultant with the support of CSL Behring. Education shall
follow the NBA guidelines for SClg therapy. Required knowledge for RNs within the NNSW LHD is outlined in the learning objectives in Appendix 2.

5.0 Monitoring and Evaluation
Administration of IVlg and SClg in accordance with this procedure and national guidelines will be audited in the annual NNSW LHD Blood and Blood Products audit. Any IIMS relating to Immunoglobulins will be monitored by local transfusion committees with appropriate action planning. Review of this procedure shall be undertaken with NSW Health guidelines and NBA governance updates. BloodSTAR\(^2\) also acts as a national authorisation and outcomes database.

6.0 Definitions
Standards Australia and virtually all national standards bodies around the world including the American Association of Blood Banks are following the rules set down by the international standards body International Organisation for Standardisation (ISO) for the use of the terms 'shall', and 'should'.

- The term 'shall' indicates a mandatory requirement; however, this does not imply a mandatory legal requirement in an Australian standard.
- The term 'should' implies a recommendation where guidance is intended and does not preclude other acceptable practices.
- The term 'may' is used to indicate an acceptable alternative or addition to the prescribed practice.

7.0 References
8.0 Appendices

Appendix 1:  Generic Immunoglobulin Information and Specific IVIg Product Infusion Rates

Appendix 2:  Implementation of a Subcutaneous Immunoglobulin (SClg) therapy in the home: Care and Haematology Units – NNSW LHD Staff Training Summary.
Generic IVlg information

Warning: Infusion rates for IV Immunglobulins are NOT interchangeable.
Only use infusion rates specific to each IVlg product.

Storage
Flebogamma 5% and 10%: < 30°C or refrigerated in a monitored blood fridge.
Privigen 10%: < 25°C or refrigerated in a monitored blood fridge.
Intragam 10%: refrigerated between 2°C to 8°C in a monitored blood fridge\(^5\).
Do not freeze any IVlg product. Store protected from light. Do not use after expiry date\(^5\).
All IVlg products contain no antimicrobial preservatives. Use for 1 patient, on 1 occasion only.
Used bottles must be discarded in medical waste, not in recycling.
Contact product provider (pharmacy) regarding ‘Return to Stock’ for any unused bottles\(^4\).

Visual Inspection of Product
Immunoglobulins should be clear or slightly opalescent, colourless to pale yellow.
Do not use solutions that are cloudy or have deposits (sediments or particles)\(^4\).

Prior to Administration
Correct reversible risk factors for adverse reactions (dehydration) before infusion.
Ensure authorisation in BloodSTAR. Check informed consent documented as per NC-NNSW-PRO-6892-13 BloodProducts – Patient Consent.
Ensure IV access patent. Explain procedure to patient including symptoms of possible reactions. Take baseline observations (TPR & BP), general patient status including pre existing rashes\(^4\). Check resuscitation equipment is in working order. Allow product to reach room temperature\(^4\).

Right Patient – Right Product
Check prescription, infusion date, brand and concentration in BloodSTAR.
IV medication administration checks as per PD2013_043 Medication Handling in NSW Public Health Facilities.
Batch numbers are scanned in BloodNet at the time of dispensing\(^2\). Dispensing episodes are saved in BloodNet and dispense episode receipts can be printed\(^4\).

IV Line
A pump must be used to ensure constant delivery of accurate rates.
A Standard IV line (170 – 200 micron filter) may be used.
Glass bottles require a vented system.
Premedication may be prescribed as per the treating doctor.
Do not add medications or IV fluids to Immunoglobulin products. Use a separate IV line to administer separately from any medications or IV fluids other than 0.9% Sodium Chloride\(^5\).
The line can be cleared with 0.9% Sodium Chloride on completion of the infusion\(^4\).
Administration
Administer rates as per each Immunoglobulin product.
During an infusion, subsequent vials may commence at the same rate that the preceding vial finished.
Each bottle should be completed within 4 hours.
It is recommended that subsequent infusions be given according to the same protocol, unless there has been a change in health status or reaction to a previous infusion, in which case consult the treating doctor.

Reactions
Tend to be infusion related. Refer to the PI of product.
Signs and symptoms may include: dyspnoea, wheezing, chest tightness, coughing, blood pressure changes, tachycardia, flushing, fever, rigors, skin rash/urticaria, headache, vomiting, nausea, abdominal and back pain.
If a reaction occurs:
   Stop infusion immediately
   Assess vital signs
   Notify medical officer
   Administer emergency care as required
If a minor reaction occurs (commonly headache) the infusion can often be restarted cautiously at a slower rate after patient clinically improves.
Report adverse events to Immunoglobulin in the IIMS, and inform the product provider. A suspected adverse reaction report (SARS) should be filled out for appropriate drug.

Observations
Observation of general status should be monitored regularly throughout infusions.
TPR & BP:
   Baseline prior to commencing
   With each rate increase
   Hourly once maximum rate achieved
   On completion
   Any time the patient experiences new or increased symptoms.

Post infusion
Monitor for 1 hour after completion of the infusion for those who:
   Have not had IVIg before
   Switched from another product
   Have had a long interval since last infusion
   Have had significant deterioration in health
   Have had a reaction to current or previous infusion
Other patients should be observed for at least 20 minutes.
### Specific IVIg Product Infusion rates

#### INTRAGAM 10% Adults

Contraindicated in patients with true anaphylactic reaction to human immunoglobulins (especially in pts with antibodies against IgA) or to excipient glycine.<br><br>• 60 mL/hr for 15 mins (15 mLs)<br>• 120 mL/hr for 15 mins (30 mLs)<br>• 240 mL/hr until complete

#### INTRAGAM 10% Paediatric

Paediatric rates are not contained in the PI. Referenced from Lady Cilento Children’s Hospital, Qld.

**Note:** Rates for paediatric Intragam infusions are mL/kg/hr<br><br>• 0.5mL/kg/hr for 15 minutes (Maximum of 30mL/hr)<br>• 1.0mL/kg/hr for 15 minutes (Maximum of 60mL/hr)<br>• 2.0mL/kg/hr for 15 minutes (Maximum of 120mL/hr)<br>• 3.0mL/kg/hr thereafter (Maximum of 240mL/hr)

#### PRIVIGEN 10%

Contraindicated in patients with hyperprolinaemia or in those with known hypersensitivity to this product, (especially in patients with IgA deficiency where the pt has anti-IgA antibodies).<br><br>• 0.3 mL/kg/hr for 30 minutes*<br>• 0.6 mL/kg/hr for 30 minutes<br>• 1.2 mL/kg/hr for 30 minutes<br>• 2.4 mL/kg/hr for 30 minutes**<br>• 3.6 mL/kg/hr for 30 minutes<br>• 4.8 mL/kg/hr for 30 minutes***

*Initial rate in pts naïve to human immunoglobulin, switched from alternative IVIg or haven’t received IVIg for a long time.<br>**Step rate rises between 2.4mL/kg/hr and 4.8 mL/kg/hr are at the discretion of the healthcare professional and as tolerated by the patient.<br>***Maximum infusion rate: PID & CIDP - 4.8mL/kg/hr with exception of the first three infusions, where maximum rate is 2.4mL/kg/hr. ITP – 2.4mL/kg/hr.

#### FLEBOGAMMA 5%

Contraindicated in hypersensitivity to homologous immunoglobulins, especially in IgA deficiency, when the patient has antibodies against IgA. Fructose intolerance.<br><br>• 1 mL/kg/hr for 30 minutes*<br>• 2 mL/kg/hr for 30 minutes<br>• 4 mL/kg/hr for 30 minutes<br>• 6 mL/kg/hr for 30 minutes (Maximum 300mL/hr)

*For patients with Immune deficiencies, if no reaction to the first infusion, Flebogamma 5% can be infused at rate increases every 15 minutes. Maximum rate of 6mL/kg/hr not to exceed 500mL/hr.<br><br>#### FLEBOGAMMA 10%

Contraindications as for Flebogamma 5%<br>Hereditary fructose intolerance. In babies and young children hereditary fructose intolerance may not yet be diagnosed and may be fatal, thus, they should not receive this medicinal product.<br><br>• 0.6mL/kg/hr for 30 minutes<br>• 1.2mL/kg/hr for 30 minutes<br>• 2.4mL/kg/hr for 30 minutes**<br>• 3.6mL/kg/hr for 30 minutes<br>• 4.8mL/kg/hr for 30 minutes**

*If the patient tolerates the infusion well, additional increments of 1.2mL/kg/hr may be made at 30 minute intervals. For patients experiencing adverse reactions, reduce infusion rate in subsequent infusions and limit maximum rate to 2.4mL/kg/hr.<br>**Maximum rate 4.8 mL/kg/hr.

Lower maximum infusion rates of 200mL/hr, or 300mL/hr for Flebogamma 5%, are recommended in high risk patients e.g. >65 years of age, diabetics, obese, those with pre-existing or risk factors for cardiac disease, renal failure or arterial or venous thoromboembolism; those with hyperviscosity; paraprotein or dehydration. Consult treating doctor. Use ideal body weight to calculate infusion rates in obese patients.
Implementation of a Subcutaneous Immunoglobulin (SCIg) therapy in the home.
Cancer Care and Haematology Units – NNSW LHD
Staff Training Summary

Purpose:
To provide information, education and training for the subcutaneous immunoglobulins (SCIg) to registered nurses within the cancer care and haematology unit. These nurses will then be responsible for the training, education and ongoing support to the patients within the unit receiving SCIg.
The SCIg product for use is, but not limited to:
• Hizentra® 20% (CSL)
• Evogam® 16% (CSL)

Background:
In March 2013, the Jurisdictional Blood Committee (JBC) approved the introduction of subcutaneous immunoglobulin (SCIg) under the national blood arrangements, subject to certain requirements. Details of these requirements, products available and governing requirements for hospital based programs are available from the National Blood Authority website: Subcutaneous Immunoglobulin (SCIg).

SCIg is approved for patients with a medical condition where there is support for use cited in Criteria for the clinical use of immunoglobulin in Australia

Objective:
Participants will be able to understand the key elements associated with subcutaneous immunoglobulins (SCIg)
• Understand disease processes approved for SCIg use
• Understand procedures and processes for SCIg
• Understand what the treatment will achieve
• Understand administration methods and timeframes
• Identify risks and adverse events/side effects and how they are to be managed
• Understand key elements of education and self-administration, (teach patients/carers) support them with ongoing product and consumables
• Understanding ordering and supply of SCIg.
# NNSW LHD Clinical Procedure Cover Sheet

## COVER SHEET

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<td>NC-NNSW-PRO-6889-13, NC-AREA-POL-3297-08</td>
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<td>Sites/Services where compliance with this procedure is mandatory.</td>
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| Related Ministry of Health PDs, LHD Documents or Australian Standards: | • NC-NNSW-PRO-6892-13 Blood Products - Patient Consent  
• PD2013_043 Medication Handling in NSW Public Health Facilities  
• PD2013_049 Recognition and Management of Patients who are Clinically Deteriorating  
• NSW Health Risk Matrix  
• PD2018_042 Blood Management  
• IB2014_068 National Policy – access to Government Funded Immunoglobulin Products in Australia |
| Risk Management | Guided by the National Blood Agreement policy objectives, government funded immunoglobulin products are provided to patients according to clinical need and appropriate clinical practice. |
| Current Risk Rating | R – Minor/Possible |
| Targeted Risk Rating | W – Minimal/Possible |
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