NATIONAL BLOOD AUTHORITY AUSTRALIA

National Subcutaneous Immunoglobulin Program Governance Requirements Acknowledgement Form

1. Purpose

The purpose of this form is to obtain a formal acknowledgement of, and commitment to comply with, the governance requirements for a healthcare facility to participate in the National Subcutaneous Immunoglobulin (SCIg) Program.

In VIC, QLD, NT, TAS and ACT, this form must be completed and signed by the person responsible for clinical governance within the facility and then submitted to the National Blood Authority (NBA). The NBA will ensure the form has been completed appropriately and then enable the healthcare facility to be recognised as a SCIg facility in BloodSTAR. This must occur prior to the provision of SCIg products to patients.

In SA and WA, this form must be completed and signed by the person responsible for clinical governance within the healthcare facility, submitted to the state health department for approval, then sent to the NBA. The NBA will ensure the form has been completed appropriately and then enable the healthcare facility to be recognised as a SCIg facility in BloodSTAR. This must occur prior to the provision of SCIg products to patients.

In NSW, these requirements are managed by the NSW Ministry of Health through communication with Local Health District and Specialty Health Network Chief Executives, and therefore this form is not required.

Please complete and submit this form to the NBA Immunoglobulin (Ig) Governance team at: iggovernance@blood.gov.au.

2. Background

National Policy

Australian governments have agreed to provide Ig under the National Blood Agreement when the prescription, use and management of Ig abide with the following principles:

- an Ig product is prescribed according to clinical need, appropriate clinical practice and in accordance with the *Criteria for the clinical use of Ig in Australia* (Criteria) and an approved authorisation in BloodSTAR
- an Ig product is dispensed for a patient assessed as eligible against the Criteria and with an approved authorisation in BloodSTAR
- the prescription, use and management of Ig products is consistent with processes described in the *National Policy: access to government–funded Ig products in Australia* (National Policy) and
- policies and procedures are developed to support compliance with the National Policy, relevant legislation, privacy, guidelines and the National Safety and Quality Health Service (NSQHS) standards.

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National SCIg Program

In addition to the above principles, access to SCIg products under the National Blood Agreement is provided through an assurance framework for the quality use of the product. SCIg may be supplied under the National Blood Agreement only for patients:

- with a medical condition where there is support for use cited in the Criteria. A list of the medical conditions currently supported, as well as a list of healthcare facilities with existing SCIg programs, is provided at www.blood.gov.au/blood-products/ immunoglobulin-products/subcutaneous-immunoglobulin-scig; and
- under the care of a medical specialist within a healthcare facility participating in the National SCIg Program.

The NBA established the National SCIg Program to ensure quality use and management of government funded SCIg. Healthcare facilities participating in the National SCIg Program must demonstrate their capability and capacity to safely and effectively manage a SCIg Program. This includes adhering to the National SCIg Program governance requirements.

3. National SCIg Program Governance Requirements

3.1 Ongoing patient care and support obligations

The healthcare facility must have the capability and capacity to safely and effectively manage a SCIg Program to support patients throughout their SCIg treatment. The healthcare facility must ensure that the SCIg Program has the mechanisms in place to provide ongoing clinical oversight and support for participating patients. This includes:

- the regular review of the patient's suitability to self-administer SCIg from both a physical and psychological perspective. Considerations include a patient's dexterity and desire to continue to self-infuse.
- the regular review of the patient's ongoing competency to ensure the safe and effective SCIg infusion at home. For example, if it is evident that a process is not being followed correctly, such as checking medications prior to administration, the patient may need to repeat training and competency assessment.
- policies and procedures to ensure the patient has access to a representative of the SCIg Program or a connection with the SCIg Program (such as a connected community care provider) for out of hours enquiries or support, including both routine and emergency support.

3.2 Training, equipment and consumables

The healthcare facility must ensure patients have access to all necessary training, equipment and consumables required to support the safe administration of SCIg at home, at no additional cost to patients. Where certain equipment or resources are considered optional, the healthcare facility may seek to apply a fee for the provision of that resource. However, to support equitable access while still supporting patient choice, these resources are provided at no additional cost to the patient. The necessary training, equipment and consumables which all patients must be provided access to include:

- the initial training and competency assessment of the patient and/or their carer to ensure safe SCIg infusions at home, including for transport, storage, use of equipment and infusion techniques. All competency assessments must be completed to a level of competence to ensure a safe and effective self-administration of SCIg treatment. The number of education sessions to ensure a safe level of competence will depend on the patient's individual circumstances. Where additional education support services are available (such as through

product suppliers) to provide the above educational requirements, overall patient management responsibilities remain with the SCIg program staff.

- the equipment necessary to ensure safe SCIg infusions at home. Where certain equipment is considered optional, the healthcare facility may seek to apply a fee for the provision of that resource. An example may be the availability of different pump options for SCIg infusions; however, where a patient chooses to use a pump, one pump should be funded by the healthcare facility. Where additional costs to patients may arise, such as the purchase of extra batteries for infusion pumps, these costs should be minimised to avoid creating barriers to equitable access while still supporting patient choice
- the consumables necessary to ensure safe SCIg infusions at home such as infusion sets, syringes, pumps and sharps containers.

3.3 Product ordering and supply management

Healthcare facilities participating in the National SCIg Program should be aware of the National Policy requirements in relation to ordering and supplying SCIg products to patients. Healthcare facilities must ensure:

- all requests for SCIg for authorised patients are managed via BloodSTAR
- supply and dispensing of a SCIg product to a patient is in accordance with relevant state/territory legal requirements and the *National Policy: Access to Government-Funded Immunoglobulin Products in Australia*
- the amount of SCIg supplied to a patient does not exceed more than is required for treatment for 2 months
- policies and procedures are developed for providing a SCIg product for up to 2 months, either directly to the patient or via a prescription with instructions of where to obtain their product
- policies and procedures are developed for notifications and actioning of unused or damaged products along with Adverse Event Reporting (AER) and should include the Therapeutic Goods Administration (TGA), the Blood Service and the product supplier, as appropriate.

3.4 Clinical governance

The healthcare facility must have policies and procedures that provide overarching clinical governance for the management and use of SCIg in line with the National Policy, the SCIg governance requirements, NSQHS Standards, particularly the *Clinical Governance Standard* and the *Blood Management Standard* and any other relevant guidelines and policies.

The healthcare facility must have a treatment program for the management and use of Ig for the relevant indications, including an appropriate supervising specialist. 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 product as an aid for the clinician at the assessment.

3.5 Compliance monitoring and continuous program improvement

The healthcare facility must have processes in place to drive quality use of SCIg and improvements to the facility SCIg program. Healthcare facilities must provide education and ongoing training for health professionals associated with a SCIg program, for example education for nurses on new equipment, to ensure patients are receiving the most up-to-date support.

The healthcare facility must have processes in place for compliance monitoring. This includes data capture, reporting, analysis and policies and processes for reporting unused, discarded, and spoilt/broken products for both clinical staff and patients. Unused, discarded or spoilt/broken product should be recorded in BloodNet. The processes should ensure that patients report incidents back to the SCIg program coordinator and feed back into ongoing review and improvement.

The healthcare facility must have the mechanisms to undertake regular self-audits of the SCIg program to ensure compliance with the National SCIg Program governance requirements.

4. SCIg Program contact details and Acknowledgement

To be completed by the healthcare facility.

SCIg Program Details
Name of the healthcare facility where the SCIg program operates:
Address of the healthcare facility:
SCIg Program Management Please nominate the operational lead position responsible for day-to-day SCIg governance, communication, and coordination at the healthcare facility. Please use generic details instead of a person's individual contacts to assist with the ongoing monitoring of the role. This information will be published on the NBA website to assist in locating a SCIg Program. Where the SCIg program contact details change, please provide an updated form to the NBA.
Position (e.g.: nurse coordinator or equivalent):
Email (e.g.: SCIgProgram@healthfacility.gov.au):
Phone number:

Acknowledgement

To be signed by the person responsible for clinical governance within the facility, ideally a Chief Executive or Director of Clinical Services

I acknowledge the governance requirements for the appropriate supply and use of SCIg products, funded under the national blood arrangements, and confirm that the management of the SCIg Program at the above facility is in accordance with these requirements. I acknowledge the healthcare facility personnel involved in the prescription, use and management of Ig have read, understood and commit to adhering to the *National Policy: Access to Government-Funded Ig Products in Australia* (see National Policy) that sets out the rules and requirements for accessing Ig products in Australia. Signed: Name: Position: Date:

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5. State Health Department Endorsement (SA and WA only)

I confirm that the above-mentioned healthcare facility has approval from this State Health Department to participate in the National SCIg Program.
Signed:
Name:
Position:
Department:
Date:

6. Lodgement of form

Please submit the completed form to the NBA at: iggovernance@blood.gov.au

The National Blood Authority will confirm the healthcare facility's participation in the SCIg Program via the SCIg Program Manager email address provided on this form.

If you have inquiries, please contact the Ig Governance team at: iggovernance@blood.gov.au