

Hospital Acknowledgement Form

National Subcutaneous Immunoglobulin Program

Purpose of this form

This form sets out the governing requirements for hospitals for ordering and providing subcutaneous immunoglobulin (SCIg) products under the national blood arrangements within a hospital based SCIg program. To see the list of established hospital based SCIg programs please visit the NBA website at <https://www.blood.gov.au/blood-products/immunoglobulin-products/subcutaneous-immunoglobulin-sci-g>.

Hospitals participating in the national SCIg program are required to provide an acknowledgement of these requirements by the Chief Executive or Director of Clinical Services (or equivalent) prior to ordering and providing SCIg products to their patients. In South Australia and Western Australia, the state health departments will confirm hospital participation. In NSW these requirements are being managed by the NSW Ministry of Health through communication with Local Health District and Specialty Health Network Chief Executives, and this form is not required.

Approved access conditions

SCIg is only approved under the national blood arrangements for patients:

- > with a medical condition where there is support for use cited in *the Criteria for the clinical use of immunoglobulin in Australia (the Criteria)*, namely:
 1. primary immunodeficiency diseases with antibody deficiency
 2. specific antibody deficiency
 3. acquired hypogammaglobulinaemia secondary to haematological malignancies (chronic lymphocytic leukaemia, multiple myeloma, non-Hodgkin lymphoma and other relevant malignancies, and post-haemopoietic stem cell transplantation)
 4. secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency)
 5. chronic inflammatory demyelinating polyneuropathy (CIDP), (including IgG and IgA paraproteinaemic demyelinating neuropathies)*, and
- > being treated by a clinical specialist within a hospital-based SCIg program (see below), where the hospital provides access to all resources and takes full accountability for the management and use of the SCIg product, at no additional cost to patients, and
- > following a patient-specific SCIg request submitted and authorised in BloodSTAR.

* SCIg is approved for use for the treatment of CIDP under the national blood arrangements pending the outcome of a current Health Technology Assessment (HTA) review evaluating the use of immunoglobulin in the treatment of CIDP. For more information please visit [here](#).

Governing requirements for a hospital based SCIg program

Quality Assurance

The hospital must have in place policies and procedures that provide quality assurance and monitor compliance for the management and use of SCIg in line with the National Safety and Quality Health Service (NSQHS) Standards, particularly Standards 1 and 7.

Clinical oversight

The hospital must have a treatment program for the management and use of immunoglobulin for the relevant indications, including an appropriate supervising specialist.

The hospital 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 hospital 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 hospital 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 product as an aid for the clinician at the assessment.

Supply of product

Requests for SCIg for authorised patients must be managed via BloodSTAR, or alternative arrangements if necessary. 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](#).

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 hospital, to be recorded in-turn by the hospital 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.

SCIg program hospital details

Item	Details
Hospital name:	
Address:	
SCIg program contact person/s:	
Contact person's title	
Contact person's phone number	
Contact person's email address	

Note: the above information will be published on the NBA website to assist patients to locate a local SCIg program.

Chief Executive / Director of Clinical Services acknowledgement

I acknowledge the governing requirements for the appropriate supply and use of SCIg products, funded under the national blood arrangements, and confirm that the management of this hospital based SCIg program is in accordance with these requirements.

Signed:

Name:

Position:

Date:

South Australia and Western Australia

State Health Department endorsement

I confirm that the above mentioned hospital has approval from this State Health Department to participate in the National SCIg Program.

Signed:

Name:

Position:

Date:

Lodgement of form

Please forward the completed form to the National Blood Authority at

Fax: (02) 6151 5235 (Attention: Ig Governance)

Email: iggovernance@blood.gov.au

The National Blood Authority will confirm the hospital's participation in the SCIg Program via the contact person's email address provided on the form.

If you have enquiries please contact the National Blood Authority on 13 000 BLOOD (13 000 25663) or (02) 6151 5000 or at iggovernance@blood.gov.au.