Guideline

Establishing a Subcutaneous Immunoglobulin Hospital Program

Summary This Guideline provides information on the establishment of a subcutaneous immunoglobulin hospital program - principles and procedures.

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Audience All Staff of NSW Health

Secretary, NSW Health

ESTABLISHING A SUBCUTANEOUS IMMUNOGLOBULIN (SCIG) HOSPITAL PROGRAM

GUIDELINE SUMMARY

NSW Health's commitment to providing world class clinical services, enhancing the quality of life of its patients and empowering patients to be partners in their care underpin the matter covered in this Guideline.

This Guideline outlines the principles for establishing a SCIg hospital program to train and support suitable, SCIg-eligible patients to treat themselves at home in familiar surroundings and at a time that suits them. Trained patients will not have to travel to hospital for regular intravenous infusions of immunoglobulin and will be able to pick up their treatment product as close to their home as possible.

KEY PRINCIPLES

This Guideline applies to all NSW Health staff involved in the establishment and running of a SCIg hospital program.

Local Health Districts (Districts) involved in the planning of a SCIg hospital program are encouraged to promote the collaboration of clinical specialty areas to ensure equity of patient access to the program. In addition, consideration should be given to patients being able to access training and product as close to their homes as possible.

The hospital General Manager must approve the provision and resourcing of SCIg clinical services by facilities in their hospital.

SCIg may be managed (ordered, receipted, stored and released for dispensing) by a facility's pathology/transfusion medicine laboratory or by the facility's pharmacy department. The unit/facility that manages SCIg must be registered as an Approved Health Provider (AHP). If the unit/facility that manages SCIg is different from the unit/ facility that normally manages blood and blood products, a second AHP registration will be required.

The NSW Ministry of Health's Office of the Chief Health Officer must be advised of the following by the hospital General Manager:

1. approval has been given to commence providing subcutaneous immunoglobulin therapy at the health facility;
2. health facility has all the necessary processes and resources in place to support service provision; and
3. in the event that a second AHP has been arranged, provide confirmation that the Local Health District Blood Management Committee and Drug and Therapeutics Committee (or their equivalents) will be responsible for oversighting the governance of SCIg in the facility.

BloodSTAR must be used by treating clinicians to obtain authorisation for patients to receive government-funded subcutaneous immunoglobulin. Before entering patient

details into BloodSTAR the treating clinician must obtain the patient's consent to do so. In addition, patient consent is required before the patient is treated with SCIg.

BloodNet must be used to order SCIg, to replenish SCIg imprest, to receipt the product and to record SCIg dispensing episodes.

There is no prescriptive dispensing arrangement for SCIg but the product must be dispensed by a pharmacist and recorded by them in iPharmacy. The dispensing arrangement that a facility proposes to adopt must be endorsed by the District Drug and Therapeutics Committee and the Blood Management Committee (or their equivalents) and approved by the District Director of Pharmacy (or equivalent).

It is NSW Health policy that hospital pharmacies can charge a dispensing fee for SCIg in line with the Pharmaceutical Benefits Scheme (PBS) fee. Chief Executives may waive the fee either by a local directive or on a case-by-case basis. If patients are charged a dispensing fee for SCIg they must be charged a single fee, regardless of the duration of supply and the number of different vial sizes and doses prescribed.

Public hospitals can dispense SCIg to a community patient who has a prescription from a private authorised prescriber.

REVISION HISTORY

Version	Approved by	Amendment notes
November-2020 (GL2020_024)	Deputy Secretary, Population & Public Health	Initial Document

ATTACHMENTS

1. Establishing a subcutaneous immunoglobulin hospital program: Guideline

CONTENTS

1 BACKGROUND

In Australia, immunoglobulins are used to treat a wide variety of neurological, haematological, immunological and a small number of miscellaneous conditions[1]. Since 2013 government-funded subcutaneous immunoglobulin (SCIg) has been available to treat patients with specific medical conditions where support for its use is cited in the Criteria for the clinical use of immunoglobulin in Australia, version 3 (the Criteria).

Administration of immunoglobulin subcutaneously, as opposed to intravenously, enables suitable, appropriately trained and supported patients to self-administer SCIg treatment at home. Trained patients do not have to travel to hospital for regular intravenous transfusions of immunoglobulin.

The National Blood Authority National SCIg Program outlines the minimum requirements to establish a hospital based SCIg program.

Participating hospitals may be:

1. SCIg managing hospitals that both train the patients and dispense SCIg; or
2. SCIg dispensing-only hospitals.

1.1 About this document

This Guideline provides NSW public hospitals with a set of overarching principles and procedures to promote a consistent approach to the design and implementation of SCIg programs. It is intended to support staff in those facilities that wish to act either as a SCIg managing hospital, or as a SCIg dispensing-only hospital.

It provides guidance in relation to:

1. initial administrative steps to be undertaken;
2. IT systems to be used for
    a. obtaining authorisation for patients to receive government funded SCIg and
    b. accessing SCIg;
3. dispensing arrangements for SCIg.

1.2 Key definitions

Approved Health Provider (AHP)

An AHP is a unit/facility (for example, a hospital pathology/transfusion laboratory) that is registered to hold blood and blood products. In order to be registered the unit/facility has to demonstrate that it is able to meet the expectations of Health Ministers, as outlined in the Australian Health Ministers' Statement on National Stewardship Expectations for the Supply of Blood and Blood products issued on 12 November 2010.

[1] See Criteria for the clinical use of immunoglobulin in Australia (Version 3)

This requires that the unit/facitlity has processes and procedures in place to ensure the safe storage and handling of blood and blood products and that there is a governance structure in place to oversight the use of blood and blood products in that facility.

Authorisation

Approval for a patient to receive one or more doses of immunoglobulin until the end of the authorised period. An authorisation also sets out the requirement for the review of the patient prior to the end of the authorisation period.

BloodNet

BloodNet is a web-based system that allows staff in health facilities across Australia to order blood and blood products from Australian Red Cross Lifeblood, manage their inventory and document receipting and wastage.

BloodSTAR

An online system used across Australia to manage access to the supply of government-funded immunoglobulin products.

Dispense

In the case of SCIg, dispense means the acts of

- Checking against the prescription;
- Appropriately labelling and, if necessary, packaging; and
- Carrying out final check

Imprest

Non-patient labelled stock of subcutaneous immunoglobulin held in either the pharmacy or pathology / transfusion laboratory, depending on the local arrangement in place.

2 STEPS FOR ESTABLISHING A SCIG PROGRAM

2.1 Obtain the approval of the hospital General Manager

Hospitals proposing to set up as a SCIg managing hospital must first obtain the approval of their General Manager for the following:

- approval to deliver the services;
- approval for resourcing the services;
- approval for the facility to be listed as a managing hospital on the National Blood Authority website.

Resourcing the services includes:

1. resourcing of relevant staff to run the program and train the patients;
2. funding for equipment and consumables including but not limited to syringe drivers/pumps, syringes, needles, sharps bins, alcohol swabs, gauze, dressings and flow control tubing.

For information about setting up a SCIg hospital program, local health districts should contact the Blood Watch team at: CEC-BloodWatch@health.nsw.gov.au

2.2 Applying for a second Authorised Health Provider (AHP) registration *(if needed)*

The hospital unit /facility that will manage SCIg (i.e. order, store, release SCIg for dispensing and record dispensing episodes) must be registered as an AHP.

This document assumes that the hospital transfusion/pathology laboratory of any NSW public hospital that wants to establish a SCIg program will already be registered as an AHP to hold blood and blood products.

A managing hospital that intends to hold blood and blood products in its pathology/transfusion laboratory and manage SCIg in its pharmacy department will need to have two AHP registration numbers; one for the pathology/transfusion laboratory, and one for the pharmacy. If there are not already two AHPs in place, the hospital will need to apply for a second AHP registration by contacting the Australian Red Cross Lifeblood Transfusion Scientist on (**02) 9234 2442** to make an application. The application will then be referred to the National Blood Authority.

2.3 Advising the NSW Ministry of Health

The hospital General Manager is to email the Office of Chief Health Officer at the NSW Ministry of Health (MOH-OCHO@health.nsw.gov.au) to advise that:

- Approval has been given to commence providing subcutaneous immunoglobulin therapy at the health facility.
- The health facility has all the necessary processes and resources in place to support service provision.
- Where a second AHP has been arranged, confirmation that the Local Health District Blood Management Committee and Drug and Therapeutics Committee (or their equivalents) will be responsible for oversighting the governance of SCIg in the facility.

The Office of Chief Health Officer will provide the National Blood Authority with the details of the managing hospitals for inclusion in the list of SCIg managing hospitals on the National Blood Authority's website at blood.gov.au/SCIg

3 INFORMATION TECHNOLOGY

3.1 BloodSTAR

BloodSTAR standardises and manages access to the supply of immunoglobulin products for the treatment of conditions identified in the Criteria for the clinical use of immunoglobulin in Australia.

Treating clinicians must use BloodSTAR to:

- determine whether their patient is authorised to receive government-funded SCIg

- organise patient reviews
- request SCIg dose changes.

BloodSTAR can also be used to nominate the dispensing facility where the patient will pick up their SCIg if it is not the patient's SCIg managing hospital.

Facilities and clinicians must be registered to use BloodSTAR. Facilities must nominate at least two facility administrators to grant access to relevant staff in the facility. Further information about BloodSTAR, facility registration and user registration is available at www.blood.gov.au/bloodstar.

The National Blood Authority's Blood Operations Centre can also be contacted via:

- Telephone: **1300 025 663**
- Email: support@blood.gov.au

3.2 BloodNet

BloodNet must be used by a facility's pathology/transfusion laboratory or pharmacy department, depending on which unit / facility has the responsibility for managing SCIg.

If the unit / facility that takes responsibility for managing SCIg does not currently use BloodNet they are to contact the National Blood Authority Health Provider Engagement Team via:

- Telephone: **1300 025 663**
- Email: support@blood.gov.au

Further information about BloodNet is available at: https://www.blood.gov.au/BloodNet

4 INVENTORY MANAGEMENT

SCIg must be ordered from Lifeblood using BloodNet. For privacy reasons (*Commonwealth Privacy Act),* the product cannot be ordered on a named patient basis. Instead, facilities are required to establish an imprest system with the size of the imprest varying according to the number of patients being treated with SCIg and the doses of SCIg they require.

SCIg should be ordered to replace product issued to patients from the imprest. This arrangement means that inventory levels need to be carefully monitored, with replacement stock being ordered once product has been dispensed.

Metropolitan health facilities are to hold a maximum imprest stock of one week's supply of SCIg for their patients. Rural health facilities are to hold a maximum imprest stock of one month's supply.

Further information about managing SCIg inventory is available in the National Blood Authority's *Module 2: Managing Intravenous and Subcutaneous Immunoglobulin Inventory*

5 PATIENT CONSENT

5.1 Consent to enter patient data into BloodSTAR

Prior to entering any patient data into BloodSTAR, the treating clinician must obtain the patient's consent to do so. A privacy statement and notice information sheet to give to patients is available from https://www.blood.gov.au/bloodstar-privacy-controls

5.2 Patient consent to be treated with SCIg

Clinicians must obtain informed patient consent prior to treating them with SCIg. The processes for obtaining patient consent are documented in the NSW Health *Consent to Medical & Healthcare Treatment Manual 2020* and NSW Health Policy Directive *Blood Management* (PD2018_042).

If the treatment requires multiple doses of SCIg, consent is only required once, before the first dose. For patients requiring long-term treatment, reviewing and obtaining consent at regular intervals of at least 1 year (but no greater than 2) is considered best practice.

A new consent must be obtained if:

- an alternative SCIg product is to be used; or
- new risks associated with the treatment are identified.

Consent must be noted in the patient's medical record.

6 DISPENSING OF SCIG

6.1 Dispensing arrangements

SCIg is a Schedule 4 medication that is provided directly to eligible patients on the presentation of a valid prescription and must be dispensed by a pharmacist. Only doses authorised by BloodSTAR are to be dispensed.

There are at least three possible dispensing arrangements for SCIg:

1. SCIg may be managed and dispensed by a hospital's pharmacy department;
2. SCIg may be managed by the hospital's pathology departments and taken to the hospital's pharmacy department to be dispensed to the patient; or
3. SCIg may be managed by the facility's pathology/ transfusion laboratory with an arrangement in place for the facility's pharmacist to attend to dispense the product for the patient ready for the patient to pick up from the transfusion laboratory.

Individual hospitals can determine the dispensing arrangement for SCIg that best suits them, ensuring that they have the correct AHP registration(s). Prior to implementation, the dispensing arrangement must be:

1. endorsed by the District's Drug and Therapeutics Committee and Blood Management Committee (or equivalents); AND
2. approved by the Director of Pharmacy (or equivalent), who has overall oversight of dispensing of SCIg endorsed and approved.

Dispensing of SCIg must be recorded in the relevant pharmacy system (iPharmacy) AND in BloodNet. Depending on the dispensing arrangement in place the dispensing episode will be recorded in BloodNet by the pharmacy staff or the pathology/transfusion laboratory staff.

6.1.1 Community patients with a prescription from a private authorised prescriber

As an exception to section 5.4.3 of the NSW Health Policy Directive *Medication Handling in NSW Public Health Facilities* (PD2013_043) (or equivalent provision in any subsequent version of the Policy Directive), NSW public hospitals can dispense SCIg to a community patient who has a prescription from a private authorised prescriber. In this situation, the hospital will need to follow patient registration procedures to facilitate dispensing from iPharmacy.

Community patients with a prescription from a private medical prescriber must liaise with the dispensing hospital prior to collecting their product to facilitate timely dispensing.

6.2 Prescription charges

NSW public hospital pharmacies can charge a dispensing fee for SCIg in line with the PBS fee. The fee may be waived by the Chief Executive by a local directive, or on a case-by-case basis.

If patients are charged a dispensing fee for SCIg, they must be charged a single fee, regardless of the duration of supply and the number of different vial sizes and doses prescribed. The dispensing fee can be collected using local protocols such as through cashiers or via billing processes

6.3 Provision of SCIg and ongoing consumables

Patients who live near the managing hospital where they have been trained should pick up their SCIg and ongoing consumables (e.g. syringes) from that hospital.

If a patient lives some distance from their managing hospital, which may be in another local health district, the managing hospital must arrange for the patient to pick up their product from a dispensing hospital closest to the patient's home.

The patient's 'home' district is responsible for the ongoing provision of SCIg and consumables for that patient. Prior agreement must be obtained from the dispensing hospital and, once obtained, the patient's treating clinician must enter the details of the nominated dispensing hospital into BloodSTAR.

In rural areas, the closest hospital to the patient's home may not have a pharmacist on site. In this scenario, arrangements may be made for the patient's product to be dispensed at a hospital that does have a pharmacist on site and for it to be transported to the hospital closest to the patient's home for them to pick up.

Alternatively, districts may make arrangements with local general practitioners or medical centres for patients to pick up their SCIg and ongoing consumables from them, noting that the GP or medical centre must be an AHP.

7 REFERENCES

- Criteria for the clinical use of immunoglobulin in Australia (Version3) https://www.criteria.blood.gov.au
- National Policy: Access to Government Funded Immunoglobulin Products in Australia
- *Poisons and Therapeutic Goods Act 1966 (NSW)*
- *Poisons & Therapeutic Goods (Poison List) Proclamation 2016 (NSW)*
- *Poisons and Therapeutic Goods Regulation 2008 (NSW)*
- *Privacy Act 1988 (Cth)*
- Standards for the Uniform Scheduling of Medicines and Poisons