## Subcutaneous immunoglobulin (SCIg) business case template

## Purpose

The purpose of this proposal is to seek approval for the commencement of a subcutaneous immunoglobulin (SCIg) program at [insert health service].

## Background

SCIg:

* Is an alternative option to intravenous immunoglobulin (IVIg) for eligible patients according to the Criteria for the clinical use of immunoglobulin in Australia (the Criteria).
* Is a subcutaneous infusion, self/carer administered in the home at own convenience.
* Negates need for day admission for IVIg infusion.
* Well tolerated with favourable safety profile.
* Often administered weekly/fortnightly providing stable IgG levels, potentially promoting wellness, by avoiding peaks and troughs in immunoglobulin (Ig) levels that occur with IVIg therapy.
* Potentially reducing the need for antibiotic therapy and/or inpatient admission.

## Potential benefits of a SCIg Program:

* Protects some of our most vulnerable patients from hospital presentations.
* Maximises opportunities to manage patients in primary care or in their own home.
* Improvement in patient’s quality of life; home-based treatment.
* Reduced incidence of systemic adverse events with SCIg infusion compared with IVIg; therefore, reduced treatment costs in managing these events.
* Reduces the requirements for hospital admission and frees up day-stay bed capacity.
* Aligns with National Safety and Quality Health Service (NSQHS) Standards, including NSQHS Standard 2: Partnering with consumers which describes patient participation and involvement in the delivery of their care.

The Australasian Society of Clinical Immunology and Allergy (ASCIA) Position Statement – Subcutaneous immunoglobulin (SCIg) identifies several SCIg benefits including1:

* Home based therapy
* IV access not required (suitable for patients with IV access difficulties)
* Few systemic side effects
* Can be used for patients with previous systemic reactions to IVIg
* More consistent IgG levels with no wear off effects related to IgG trough levels
* Improved quality of life (QOL) of patient and family with flexibility, independence and empowerment (less travel time, opportunity for personal travel)
* Reduced hospital costs

In its Position Paper on Subcutaneous Immunoglobulins, ASCIA states that1:

“*SCIg infusions for immunoglobulin replacement therapy (IRT) are efficacious, well tolerated, have a favourable safety profile and should be available to all patients where clinically appropriate, with relevant education and follow up care.”*

## SCIg approved conditions2

SCIg is available under the national blood arrangements for these 5 specific medical conditions, in circumstances that meet the National Blood Authority (NBA) criteria:

* + - inborn errors of immunity (IEI) with antibody deficiency
		- specific antibody deficiency
		- acquired hypogammaglobulinaemia secondary to haematological malignancies or post-haemopoietic stem cell transplantation
		- secondary hypogammaglobulinaemia unrelated to haematological malignancies or post-haemopoietic stem cell transplantation
		- chronic inflammatory demyelinating polyneuropathy (including IgG and IgA paraproteinaemic demyelinating neuropathies).

In addition, patients must be 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 the SCIg must be applied for, approved and managed through the national online system, BloodSTAR.

## Patient selection

[Insert health service] data:

NBA BloodSTAR data can identify the number of patients who would be eligible for SCIg per medical diagnosis (Blood Matters can provide data for Victorian health services)

Immunology patients - xx

Neurology patients – xx

Haematology patients – xx

These patients are dependent on long term, if not lifelong support of Ig therapy to maintain wellness.

While not all these patients would be suitable, or wish to transition to SCIg, a program should exist whereby eligible patients are provided with the choice.

Eligibility assessment is essential and includes:

* Ensuring patient’s skin integrity is suitable. Patients cannot have significant skin lesions which prevent safe and regular SCIg administrations.
* The patient or their carer must also have the dexterity/care to handle and manage the infusions appropriately.

## Funding available to support SCIg accessibility for patients:

SCIg is funded through the Tier 2 Non-Admitted Services Classification 10.22 Subcutaneous immunoglobulin (SCIg) infusion therapy – home delivered.

SCIg is a fractionated blood product which incurs no direct cost to the health service or patient. It requires dispensing from a pharmacy as it is a classified S4 medication.

**Table 1: Costs per patient based on one infusion each week using a double lumen needle set.**

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| --- | --- | --- |
|  | Each | Per year |
| Equipment; EMED pump SCIg 60. This is the pump currently used at many health services and has a 3-year guarantee. It has been found to be simple to use and handle, and it works well.  |  | $595.00 (once only)˚ |
| Consumables:* EMED SCIg needle set – double lumen. (Cost will vary depending on the number of lumens used).
* Syringe (BD 50mL luer-lock)
* Drawing up needle
* Alcohol wipes
* Spot bandaid
* Sharps bin
* BBraun Mini Spike 2 (optional)
* VersaRate Plus adjustable flow controller (optional)
 | $17.60˚$0.43\*$0.02\*$0.01\*$0.09\*$7.46\*$4.76\*$11.60˚ | $915.20˚$22.36\*$1.04\*$1.56\*$9.36\*$29.84\*$247.52\*$603.20˚ |

˚Price correct September 2025

\*Approximate cost.

**Patient support programs**

Patient support programs are offered by the SCIg manufacturing companies and provide some infusion related consumables and decrease the nurse resource requirements of health services. These programs are available free of charge for patients using their products and include nursing support for patients in the home with SCIg administration training, periodic check in support and access to a telephone support service.

These are the programs currently available:

* CSL Behring, CARES patient support program
* Takeda, Cuvitru at Home patient support program
* Grifols, Connex patient support program

## Proposed Model

(Per health service)

## References

1. Australasian Society of Clinical Immunology and Allergy (ASCIA). Position Statement Subcutaneous Immunoglobulin (SCIg). Available at <https://www.allergy.org.au/hp/papers/scig> Accessed August 2025.

2. National Blood Authority. Subcutaneous Immunoglobulin (SCIg). Available at <https://www.blood.gov.au/blood-products/immunoglobulin-products/subcutaneous-immunoglobulin-scig> Accessed August 2025.

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