## Purpose

The purpose of this proposal is to seek approval for the development of/expansion of the Subcutaneous Immunoglobulin (SCIg) Program at [insert health service].

## Background

While there is currently a SCIg program available to some patients at [insert health service] there is interest from clinicians to make this treatment choice more widely available.

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.
* Enables flexibility in day-stay bed capacity, and National Weighted Activity Unit (NWAU) funding model.
* 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.
* Maximising opportunities to manage patients in primary care or in their own home.
* Reducing the requirements for hospital admission.
* 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.

The Australasian Society of Clinical Immunology and Allergy (ASCIA) Position Statement – Subcutaneous Immunoglobulin (SCIg) identifies a number of 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 conditions

SCIg is only available under national blood supply arrangements for patients with a medical condition:

1. where there is support for use cited in the Criteria for the clinical use of immunoglobulin in Australia, namely:
	* + Primary immunodeficiency diseases with antibody deficiency
		+ Specific antibody deficiency
		+ Acquired hypogammaglobulinaemia secondary to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)
		+ Secondary hypogammaglobulinaemia unrelated to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)
		+ Chronic inflammatory demyelinating polyneuropathy (CIDP)
2. being 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
3. following a patient specific SCIg request submitted in BloodSTAR.

## Patient selection

[Insert health service] data:

The National Blood Authority (NBA) BloodSTAR data can identify numbers 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 dependant on long term, if not lifelong support of Ig therapy to maintain wellness.

While we know not all of these patients would be suitable, or wish to transition to SCIg, the ideal would be that systems exist whereby those deemed eligible were provided with the choice.

Eligibility assessment is essential and includes:

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

## Programs available to support SCIg accessibility for patients:

**Victorian Department of Health (DH) SCIg Access Program support**

The Victorian DH SCIg Access Program is currently (correct as July 2023) supporting public health services for patients administering SCIg with a payment of $680/patient/quarter. $600.00/patient/quarter paid to the administering facility ($2,400.00/patient/year) and $80/patient/quarter paid to non-private dispensing pharmacies ($320.00/patient/year). Data used to determine payments to health services and pharmacies, is through BloodSTAR.

Costs:

|  |  |  |
| --- | --- | --- |
|  | Each | Per year |
| Equipment; EMED pump SCIg 60. This is the pump currently used at [insert health service]. It has a guarantee for 3 years. It has been found to be simple to use and handle, and it works well. To date those using it at [insert health service] have not had issues with it. |  | $390.00 (once only) |
| Consumables:* EMED SCIg needle set – double lumen. (May vary depending on lumens used).
* Syringe
* Needles
* Alcohol wipes
* Micropore
* Spot band aide
* Sharps bin
* Rate controller (optional)
 | $14.20$0.43$0.11$0.01$0.29$0.09$1.43$10.40 | $738.40$22.36$5.72$2.60$1.16$9.36$37.18$540.80 |
| Product: Fractionated blood product incurs nil direct cost to health service or patient. Requires dispensing from a pharmacy as it is a classified S4 medication (some health services are funding a dispensing fee of this amount)  | $80.00/quarter | $320.00 |

**CSL Behring, CARES patient support program**

This service is available to all patients administering Hizentra®, Evogam®° and Hizentra® AU, free of charge and includes nursing support for patients in the home with SCIg training, periodic check in support and access to a telephone support service. There are several Victorian health services accessing this to support their SCIg programs.

Utilising this service will free up the nurse resource requirements.

° Evogam® will be discontinued and replaced with Hizentra® AU in 2023

**Takeda, Cuvitru atHome patient support program**

This service is available to all patients administering Cuvitru®, free of charge and includes nursing support for patients in the home with SCIg training, periodiccheck in support and access to a telephone support service. There are several Victorian health services accessing this to support their SCIg programs.

Utilising this service will free up the nurse resource requirements.

## Proposed Model

(Per health service)

## References

1. Australasian Society of Clinical Immunology and Allergy (ASCIA). Position Statement Subcutaneous Immunoglobulin (SCIg). Available at <http://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_SCIg_Position_Statement_2014.pdf> Accessed July 2023.

2. National Blood Authority. Subcutaneous Immunoglobulin (SCIg). Available at <https://www.blood.gov.au/SCIg> Accessed July 2023.

3. Asia Pacific Immunoglobulins in Immunology Expert Group (APIIEG) Consensus Recommendations for the use of Immunoglobulin Replacement Therapy in Immune Deficiency. Edition 2, July 2009. <http://www.apiieg.org/files/1/APIIEG%20Consensus%20Recommendations%20Edition%201%20June%202008.pdf> Accessed July 2023.

4. Berger M. Subcutaneous immunoglobulin replacement in primary Immunodeficiencies. *Clin Immunol* 2004;112:1-7.

5. Wasserman RL et al. Pharmacokinetics of subcutaneous IgPro20 in patients with primary immunodeficiency. *Clin Pharmacokinet* 2011; 50 (6): 1–10.

6. Misbah SA. Effective dosing strategies for therapeutic immunoglobulin: managing wear-off effects in antibody replacement to immunomodulation. *Clin Exp Immunol* 2014 Dec; 178(Suppl 1): 70–71.

7. Gardulf A et al. Children and adults with primary antibody deficiencies gain quality of life by subcutaneous IgG self-infusions at home. *J Allergy Clin Immunol* 2004;114(4):936–42.

8. Haddad E et al. Home therapy with subcutaneous immunoglobulins for patients with primary immunodeficiency diseases. *Transfus Apher Sci* 2012;46(3):315-21.

9. Chapel HM et al. The comparison of the efficacy and safety of intravenous versus subcutaneous immunoglobulin replacement therapy. *J Clin Immunol* 2000; 20(2):94-100.

10. Ochs HD et al. Safety and efficacy of self-administered subcutaneous immunoglobulin in patients with primary immunodeficiency diseases. *J Clin Immunol* 2006; 26 (3): 265-273.

11. Jolles S, Sleasman JW. Subcutaneous Immunoglobulin Replacement Therapy with Hizentra, the First 20% SCIG Preparation: a Practical Approach. *Adv Ther* 2011; 28(7):521-533.

12. Stein MR et al. Safety and Efficacy of Privigen, a Novel 10% Liquid Immunoglobulin Preparation for Intravenous Use, in Patients with Primary Immunodeficiencies. *J Clin Immunol* 2009; 29:137–144.

13. Berger M. Subcutaneous immunoglobulin replacement in primary immunodeficiencies. *Clin Immunol* 2004;112:1–7.

14. Bonilla FA. Pharmacokinetics of immunoglobulin administered via intravenous or subcutaneous routes. *Immunol Allergy Clin North Am* 2008;28, 803–819.

15. Gardulf A et al. Rapid subcutaneous immunoglobulin replacement therapy is effective and safe in children and adults with primary immunodeficiencies – a prospective, multi-national study. *J Clin Immunol* 2006;26(2):177–85.

16. Hoffman F et al. Home-based subcutaneous immunoglobulin G replacement therapy under real-life conditions in children and adults with antibody deficiency. *Eur J Med Res* 2010; 15(6): 238–245.

17. Kobrynski L. Subcutaneous immunoglobulin therapy: a new option for patients with primary immunodeficiency diseases. Biologics 2012; 6: 277–287.

18. Nicolay U et al. Health-related quality of life and treatment satisfaction in North American patients with primary immunodeficiency diseases receiving subcutaneous IgG self-infusions at home. *J Clin Immunol* 2006;26(1):65-72.

|  |
| --- |
| To receive this document in another format, phone 03 9694 0102, using the National Relay Service 13 36 77 if required, or email Blood Matters <bloodmatters@redcrossblood.org.au>.Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.© State of Victoria, Australia, Department of Health, July 2023.**ISBN** 978-1-76131-198-7 **(pdf/online/MS word)**Available at [Blood Matters Program](https://www.health.vic.gov.au/patient-care/blood-matters-program) <https://www.health.vic.gov.au/patient-care/blood-matters-program> |