National Blood Authority

Evaluate and Develop Options to Improve Access to Subcutaneous Immunoglobulin (SCIg)

Final Report

19 May 2023

HealthConsult
Better thinking
Better advice

Acknowledgements

HealthConsult would like to acknowledge the broad range of stakeholders across Australia that have provided input and advice to this project, which are listed in Appendix E. This includes NBA staff, members of NBA's Immunoglobulin Governance Committees, jurisdictional health services (including the Australian Government Department of Health and Aged Care), peak bodies, patient advocacy groups, SCIg suppliers, clinicians, patients, health services community pharmacies and pathology providers.

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ABF	Activity-Based Funding
ASCIA	Australasian Society for Clinical Immunology and Allergy
COAG	Council of Australian Governments
GBS	Guillian-Barre Syndrome
HSANZ	Haematology Society of Australia and New Zealand
IDFA	Immune Deficiencies Foundation of Australia
IHACPA	Independent Health and Aged Care Pricing Authority
JBC	Jurisdictional Blood Committee
JIIG	Jurisdictional Immunoglobulin Interest Groups
JIPI	Jurisdictional Immunoglobulin Performance Improvement
MBS	Medicare Benefits Schedule
NBA	National Blood Authority
NHRA	National Health Reform Agreement
NIGAC	National Immunoglobulin Governance Advisory Committee
NSW	New South Wales
PHI	Private health insurers
PWG	Project Working Group
SWG	Specialist working groups
TMS	Treating Medical Specialist
WA	Western Australia

Executive Summary

On 17 March 2022, the National Blood Authority (NBA) engaged HealthConsult to:

"develop and evaluate options to achieve the optimal uptake of subcutaneous immunoglobulin (SCIg)."

Eligibility for patient access to publicly funded Immunoglobulin (Ig) is administered by the NBA through the National Immunoglobulin Governance Program ('the Program'). The supply of Ig products such as Intravenous Ig (IVIg) and SCIg is managed by the NBA and funded under the National Blood Agreement, at no cost to patients.

Widespread evidence exists of SCIg supporting patient-centred quality of life benefits as well as cost savings for health systems compared to IVIg. [1,2,3,4,5,6,7,8,] A survey of patients and carers conducted for this project showed that 95.2% of patients who have tried SCIg and IVIg believe that SCIg is the better treatment option. However, SCIg usage in Australia (as a proportion of eligible Ig patients) is around 16%, compared to around 25% in countries such as the United Kingdom, Canada, France, and Italy.[9] **Therefore, opportunities exist to optimise the uptake of SCIg in Australia** and increase access for patients, health services and the health system to SCIg (where appropriate).

The scope of HealthConsult's engagement included:

- **identifying barriers to the optimal uptake of SCIg** because of the current service model
- **developing options to optimise access to SCIg.** The identified options aim to develop a service model that is adaptable to changing conditions in a clinical setting and promotes sustainability in the National SCIg Program to support eligible patients

[1] Gardulf A et al. Subcutaneous immunoglobulin replacement in patients with primary antibody deficiencies: safety and costs. Lancet. 1995;345(8946)
[2] Gardulf A et al. Children and adults with primary antibody deficiencies gain quality of life by subcutaneous IgG self-infusions at home. J All Clin Immunol. 2004;114(4):936–42
[3]; Högy B, Keinecke HO & Borte M. Pharmacoeconomic evaluation of immunoglobulin treatment in patients with antibody deficiencies from the perspective of the German statutory health insurance. Eur J Health Econ. 2005;6:24–9
[4] Beauté J et al. Economic evaluation of immunoglobulin replacement in patients with primary antibody deficiencies. Clin Exp Immunol. 2010;160(2):240–5
[5] Martin A et al. Economic benefits of subcutaneous rapid push versus intravenous immunoglobulin infusion therapy in adult patients with primary immune deficiency. Transfus Med. 2013;23(1):55–60
[6] Gerth WC, Betschel SD & Zbrozek AS. Implications to payers of switch from hospital-based intravenous immunoglobulin (IVIg) to home-based subcutaneous immunoglobulin (SCIg) therapy in patients with primary immunodeficiencies (PID) and secondary immunodeficiencies (SID) in Canada. All Asth Clin Immun. 2014;10:A42
[7] Perraudin C et al. Home-based subcutaneous immunoglobulin for chronic inflammatory demyelinating polyneuropathy patients: A Swiss cost-minimization analysis. PLOS ONE. 2020;15(11):e0242630
[8] 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;26:65–72
[9] Based on information provided in a written submission by a global SCIg supplier

- **providing recommendations** on options to overcome barriers to optimal SCIg uptake and inform the future direction of the National SCIg Program.

This document reports on the outcome of the options evaluation process and presents an implementation plan for the recommended options. It should be read in conjunction with Attachment A - HealthConsult NBA SCIg service model implementation plan, which is a separate document.

Barriers to optimising SCIg uptake

The issues and barriers to optimising the uptake of SCIg vary in their nature and impact. Broadly, the issues impacting SCIg uptake relate to challenges in:

- **funding and resourcing** the equipment, labour and services needed to operate the SCIg service model. Challenges in funding and resourcing are the biggest barrier to optimise access to SCIg in the current service model – particularly in the private health sector. Addressing barriers to funding and resourcing for SCIg would make substantial improvements to how almost all parts of the SCIg service model operates
- **clinician and hospital preferences.** Doctors and nurses in hospitals are a key gateway for patients to access SCIg, but some clinicians are hesitant to transition patients to use SCIg
- **low awareness of SCIg and its benefits**, which influences clinician and hospital preferences and limits the ability of some patients to advocate to trial usage of SCIg
- **dispensing and supply arrangements**, which are considered resource-intensive by pharmacy and pathology providers, and limits ease of access to SCIg
- **access**, patients therefore have to pay out-of-pocket costs to purchase consumables and equipment that are needed to use SCIg. Limited access to SCIg programs in some regional and rural areas also creates access challenges for patients.

Recommendations to optimise SCIg uptake

Stakeholder consultations and desktop research established 16 options that were assessed against five criteria to identify recommended options to optimise SCIg uptake in Australia. A project-specific Working Group provided further advice and feedback on the proposed options to inform which should be recommended, and why. A description of the options and recommendations (in priority order) are summarised in Table 1.

Table 1: Summary of options and recommendations to optimise SCIg uptake in Australia

Option	Rationale for recommendation
Options recommended for implementation	
Option 1: Establish position statement(s) on when SCIg should be considered for initiation of Ig treatment	• Strongly supported by Project Working Group and rated highly on impact, necessity and implementation feasibility, with low expected cost impacts.
Option 2: Review, update and enhance the National Policy	• Rated highest on all options for necessity. • Strongly supported by jurisdictional health departments. • The work to review, update and enhance the National Policy can be implemented at low cost.
Option 3: Develop a national statement on the benefits of SCIg to improve education and awareness	• Expected to positively impact SCIg uptake via clinician awareness and understanding of the benefits of SCIg. • Expected to be strongly supported by most key stakeholder groups and would require a low overall level of effort to implement.
Option 4: Nationally consistent guiding documents to support National Policy	• Expected to have a moderate impact on SCIg uptake at a low implementation cost. • Expected to be broadly supported by key stakeholders to enhance the National Policy.
Option 5: Improve reporting on SCIg use to jurisdictional health departments	• Could be implemented at low cost and low effort to improve visibility of information on SCIg usage across Australia to inform targeted action where low levels of uptake are identified.
Option 6: Disposal of sharps containers	• Very strongly supported by patient advocacy groups as a solution to address an issue that may impact patient willingness to use SCIg. • However, this option would be expected to have a low overall impact on improving SCIg uptake.
Option 7: Fund SCIg as a hospital substitution treatment through private health insurers *Note this option only applies to providers in the private sector*	• Considered necessary to address a significant disparity in SCIg usage in the public and private sector. • However, it is expected that this option would be highly challenging to implement. Significant effort would likely be needed to agree arrangements with private health insurers, although experience in Victoria has demonstrated that this is possible.
Option 8a: Establish a bundled or capitation funding model for SCIg through IHACPA's work on 'future funding models' *Note this option only applies to providers in the public sector*	• Rated highest of all options on estimated impact on improving SCIg uptake. • Was strongly supported by jurisdictional health departments and considered highly necessary. • Has recently been examined by IHACPA.
Option 8b: Including SCIg in the national non-admitted activity-based funding model *Note this option only applies to providers in the public sector*	• Has a high level of support from states, territories and patient groups and rated highly on impact on SCIg uptake but would require significant coordination to implement.
Option 8c: National funding for hospital-based SCIg services, equipment and consumables under the National	• Rated highly on impact on SCIg uptake and necessity for implementation.

Option	Rationale for recommendation
Blood Arrangements *Note this option only applies to providers in the public and private sectors*	• Was strongly supported but would require further scoping and coordination across jurisdictional health departments and the NBA to implement.
Option 8d: Bundling consumables and equipment into the SCIg unit price *Note this option only applies to providers in the public and private sectors*	• Precedent exists for NBA to bundle consumables into the unit price of blood products, however, impact on SCIg uptake would be less than many other options.
Options not recommended for implementation	
Option 9: Establish MBS item numbers for SCIg	• Leadership (and therefore implementation feasibility) for this option is un-tested. There is currently no clear sense of what organisation or individual would lead this option. Implementation likely to be challenging. • Highly necessary, but impact on SCIg uptake would depend on extent of new MBS items that may be approved, and level at which benefits are set.
Option 10: Obtain agreement for broader distribution of SCIg via community pharmacies	• Expected to have a high impact on SCIg uptake but would be extremely challenging to obtain agreement for implementation. • Cost impacts to implement this option are expected to be high, with potential cost impacts on patients.
Option 11: Extend SCIg services to clinic or private nursing services	• Rated as having a moderate impact and moderate necessity. • However, would likely be very costly and challenging to implement.
Option 12: Change to state/territory regulatory arrangements to allow non-pharmacy supply of SCIg	• Not broadly supported and expected to be highly challenging to implement.
Option 13: Enhance jurisdictional SCIg service planning and coordination	• Very little support among key stakeholders and a very low expected impact on SCIg uptake.
Option 14: Home delivery of SCIg by suppliers	• Dependent on changes to state/territory regulatory arrangements (Option 12), which were deemed infeasible. • Low level of support among key stakeholders and expected to be difficult to implement.
Option 15: Home delivery of SCIg by hospitals	• Perceived to be unnecessary and unlikely to be supported by hospitals or jurisdictional health departments.
Option 16: Establish jurisdictional state-wide SCIg coordinators	• Perceived to be a waste of money to achieve negligible impact on SCIg uptake.
Option 17: Establishing dedicated funding for SCIg in each jurisdiction, similar to the model operated by Victoria	• Not supported by most jurisdictional health departments, costly and deemed unnecessary by most members of the PWG.

Conclusions

Improving awareness of SCIg, enhancing the National Policy and establishing a nationally consistent funding approach for SCIg services are key directions to optimise the uptake of SCIg across Australia. Although establishing a new, national funding approach for SCIg is likely to require significant coordination and implementation effort, it holds the potential to address many of the key barriers that are impacting the optimal uptake of SCIg and should be a key focus area for the NBA and its stakeholders in the medium-term.

In the meantime, a range of 'quick wins' can be achieved by improving documentation supporting implementation of SCIg and the National Policy and developing a national statement on the benefits of SCIg, to drive increased clinician and patient awareness. Most of these quick wins can be achieved with moderate levels of implementation effort by leveraging the significant support that exists for these initiatives across key stakeholders.

1. Project context and background

On 17 March 2022, the NBA engaged HealthConsult to:

"develop and evaluate options to achieve the optimal uptake of subcutaneous immunoglobulin (SCIg)."

1.1. Context

Immunoglobulin (Ig) is a human plasma-derived product that is produced from donors. Ig products offer considerable therapeutic benefits for those with medical conditions where an immune replacement or immune modulation therapy is required. Three types of immunoglobulin products are provided under the National Blood Arrangements:

(1) Intravenous immunoglobulin (IVIg)

(2) Subcutaneous immunoglobulin (SCIg)

(3) Normal Human Immunoglobulin (NHIg).

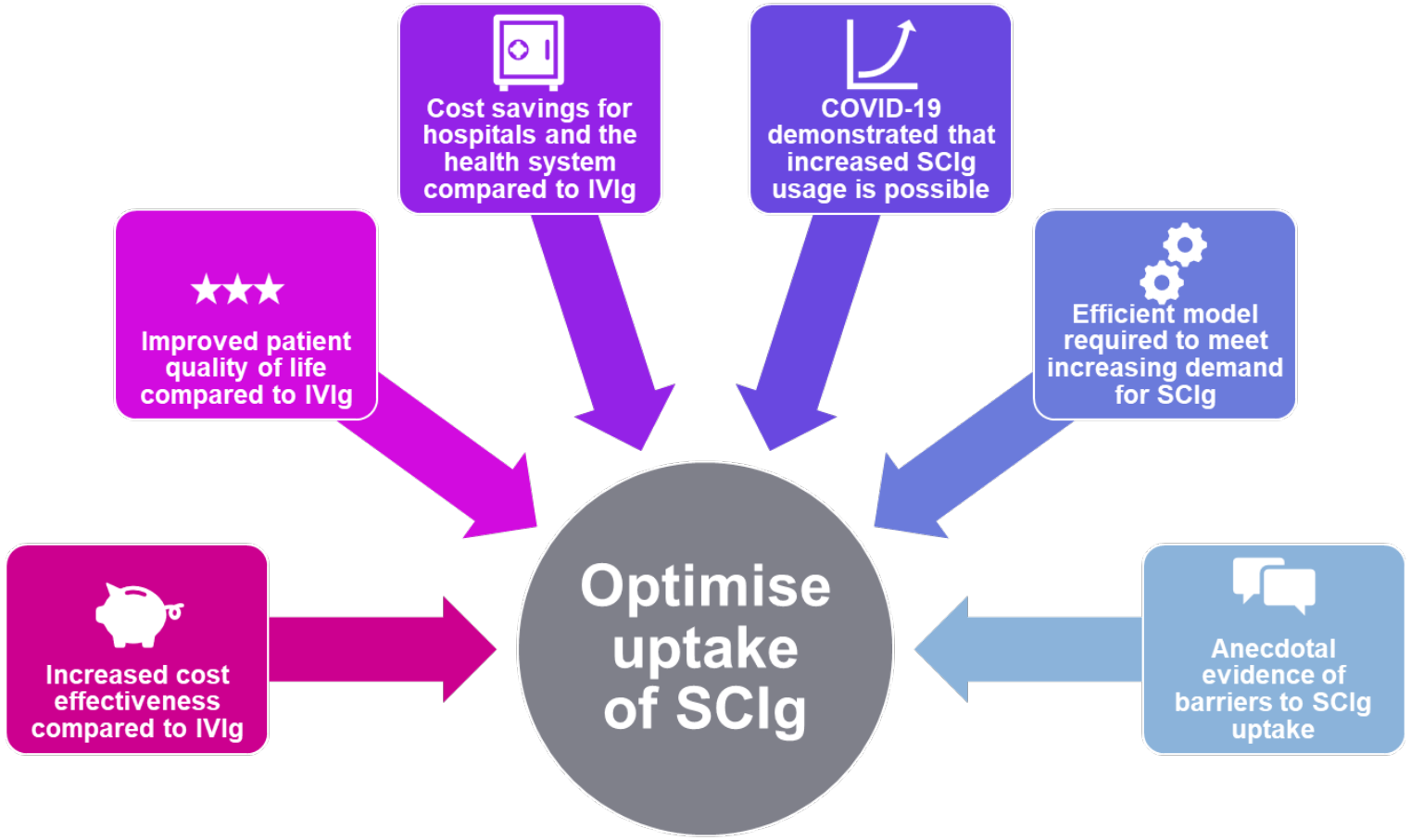
Widespread evidence exists of SCIg providing patient-centred quality of life benefits as well as cost savings for health systems compared to IVIg.[10,11,12,13,14,15,16,17,18,19] Currently, around 16% of eligible Australian patients using Ig are treated with SCIg. While this proportion is comparable to countries such as Germany, the USA and the Netherlands, other countries such as the United Kingdom, Canada, France and Italy have achieved SCIg usage rates of around 25% of eligible Ig patients.[20] Given the documented benefits of SCIg for patients and savings for health systems, this

[10] Gardulf A et al. Subcutaneous immunoglobulin replacement in patients with primary antibody deficiencies: safety and costs. Lancet. 1995;345(8946)
[11] Gardulf A et al. Children and adults with primary antibody deficiencies gain quality of life by subcutaneous IgG self-infusions at home. J All Clin Immunol. 2004;114(4):936–42
[12]; Högy B, Keinecke HO & Borte M. Pharmacoeconomic evaluation of immunoglobulin treatment in patients with antibody deficiencies from the perspective of the German statutory health insurance. Eur J Health Econ. 2005;6:24–9
[13] Beauté J et al. Economic evaluation of immunoglobulin replacement in patients with primary antibody deficiencies. Clin Exp Immunol. 2010;160(2):240–5
[14] Martin A et al. Economic benefits of subcutaneous rapid push versus intravenous immunoglobulin infusion therapy in adult patients with primary immune deficiency. Transfus Med. 2013;23(1):55–60
[15] Gerth WC, Betschel SD & Zbrozek AS. Implications to payers of switch from hospital-based intravenous immunoglobulin (IVIg) to home-based subcutaneous immunoglobulin (SCIg) therapy in patients with primary immunodeficiencies (PID) and secondary immunodeficiencies (SID) in Canada. All Asth Clin Immun. 2014;10:A42
[16] Perraudin C et al. Home-based subcutaneous immunoglobulin for chronic inflammatory demyelinating polyneuropathy patients: A Swiss cost-minimization analysis. PLOS ONE. 2020;15(11):e0242630
[17] 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;26:65–72
[18] Gardulf A et al. Prognostic factors for health-related quality of life in adults and children with primary antibody deficiencies receiving SCIg home therapy. Clin Immun. 2008;126(1):81–8
[19] Anterasian C et al. Quality of Life Differences for Primary Immunodeficiency Patients on Home SCIg versus IVIg. J Clin Immunol. 2019;39(8):814–22
[20] Based on information provided in a written submission by a global SCIg supplier

suggests that SCIg usage (and hence, the associated benefits) in Australia are not currently optimised. Optimising uptake will ensure that Australian Ig patients, health services and the health system overall can realise the benefits that have been widely demonstrated as being associated with SCIg.

Figure 1 summarises the key factors influencing the need to increase the uptake of SCIg. These represent the key drivers for undertaking this project.

Figure 1: Drivers for optimising the SCIg service model



1.2. What does an optimal uptake of SCIg 'look like'?

Feedback from the NBA, patients, suppliers, jurisdictional health departments and other stakeholders identified several characteristics of what the optimal uptake of SCIg could look like, to inform future service model redesign. These characteristics include:

- **awareness** - eligible patients are aware of and able to make decisions about whether they wish to access SCIg
- **there are no barriers to access** - eligible patients who want to try SCIg and are suitable to access it can do so
- **role clarity** - everyone involved in the service model understands their roles and responsibilities and complies with them
- **the model is patient-centred -** patients can access SCIg without incurring additional costs[21], they can infuse at a time/place that is convenient for them and they have access to advice and services where and when they need it
- **access to SCIg is seamless** and is not impacted by where patients live, whether patients are travelling or arrangements for transitioning from IVIg to SCIg.

These factors have been used as reference points for assessing the extent to which options to improve the SCIg service model can optimise uptake and address other barriers that were identified in the service model.

1.3. Project scope

The NBA engaged HealthConsult to:

- identify barriers to the optimal uptake of SCIg as a result of the current service model
- develop options through stakeholder consultation that support development of a service model adaptable to changing conditions in the clinical setting and promote sustainability within the National SCIg Program to support eligible patients to access SCIg into the future
- evaluate the options
- report on the outcome of the options evaluation process.

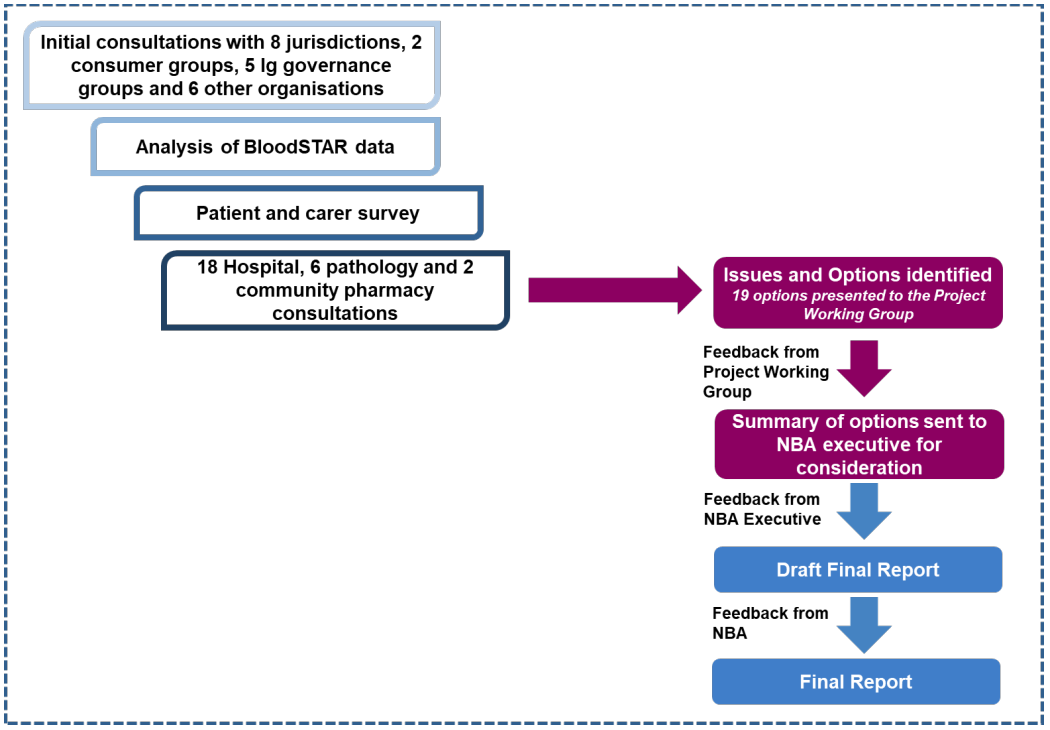
[21] National Blood Authority Australia. Immunoglobulin Governance- National Policy: Access to Government-Funded Immunoglobulin Products in Australia. 2019 July, pg. 7. Available from: https://www.blood.gov.au/system/files/documents/2019-immunoglobulin-governance-national-policy-V8FINAL.pdf

1.4. Project methodology

Initial consultations were completed with eight jurisdictional health departments, two patient groups, five Ig governance groups and six other organisations[22] to understand the current SCIg model and issues relating to the uptake of SCIg (Figure 2). Appendix E provides a list of organisations that were consulted during the project.

SCIg usage data was sourced from BloodSTAR and analysed to understand SCIg usage and trends across Australia and by jurisdiction, hospital and clinician. A survey of patients and carers was also conducted, along with consultations with 18 hospitals, six pathologies and two community pharmacies, to understand clinical and patient-related barriers and opportunities to improve the current SCIg service model. The results of these findings are detailed in Chapter 2 of this report.

Figure 2: Project methodology overview



[22] Other organisations include Victoria Blood Matters, ASCIA, Australian Red Cross Lifeblood (Lifeblood), Commonwealth Department of Health, and suppliers Takeda and CSL Behring

A summary of the issues and options was presented on 6 October 2022 to a Project Working Group (PWG) that was formed to provide advice to the project. The PWG is comprised of 23 members that were drawn from jurisdictional health departments, specialist working groups, clinicians, and patient representative groups across Australia.

Feedback on the options was obtained at the workshop and through an online survey that was conducted from 20 October 2022 to 10 November 2022. The survey asked PWG members to rate each of the 19 options on a scale of 1 to 5 (where 1 = strongly disagree and 5 = strongly agree) against the following criteria:

- do you think the implementation of this option will have an **impact on SCIg usage**?
- if this option is progressed, **would it be implementable** by a health service?
- do you think this change is **likely to be supported** by the proposed lead organisation?
- could this option be **implemented with a reasonable amount of work** by the proposed lead organisation?
- could any **barriers to the implementation** of this option be easily overcome?
- is this option **necessary**?

A summary of the feedback obtained from the PWG at the workshop and through the survey is provided in Appendix C. This feedback has informed the options evaluation process presented in this report, which has also considered feedback on the issues and options provided by the NBA and the two rounds of consultations conducted during the project.

1.5. Options evaluation methodology

To complete the evaluation of the options, each option was rated against each criterion on a three-point scale (high, medium and low). These ratings were assigned by HealthConsult by drawing on the feedback obtained through stakeholder consultations, the patient and carer survey, and the PWG. Options that were deemed impactful, necessary or would likely be supported by the lead organisation were given higher points. Conversely, the rating scale was reversed for criteria relating to implementation effort cost impacts, so that higher ratings (indicating high levels of implementation effort or high-cost impacts) were given lower points. Points were then added across all criteria to achieve a total overall score for each option out of 15.

Table 2 summarises the grading system applied to each criterion and how it has been applied to determine the total score for each option.

Table 2: Grading system applied to each criterion

Criterion	High	Medium	Low
Impact on SCIg uptake	This option is expected to have a significant impact on optimising the number of patients using SCIg across Australia by fully addressing one or more barriers to usage, as determined from PWG survey results and stakeholder consultations.	This option would have a moderate impact on the number of SCIg patients across Australia by partially addressing one or more barriers to usage, as determined from PWG survey results and stakeholder consultations.	This option is unlikely to have a significant impact on increasing SCIg uptake, as determined from PWG survey results and stakeholder consultations. Any barriers this option would address in SCIg the current service model would not be related directly to SCIg uptake.
Necessity	There was widespread support from most stakeholders and PWG members that implementation of this option is essential to optimise SCIg uptake.	There was general support or mixed views from stakeholders and PWG members that the implementation of this option is needed to optimise SCIg uptake.	There was a low level of support for this option from stakeholders and PWG members or a view that this option is not necessary to optimise SCIg uptake.
Likely support by lead organisation	Support from the lead organisation(s) already exists, or is probable, as the process to implement this option is unlikely to be costly or time-consuming.	It may be difficult to obtain support from the lead organisation(s). Further conversations would be required with the lead organisation to establish buy-in before implementation could proceed.	It is unlikely that support from the lead organisation would be obtained due to the option being costly, time-consuming and/or would require significant effort to complete.
Barriers to implementation	A significant level of effort, coordination and planning is required to implement this option. This includes buy-in from multiple stakeholder groups and/or substantial coordination for the option to proceed which will be difficult to achieve.	A moderate level of effort, planning and coordination is required to implement this option, but this effort is likely to be achievable (or is already supported) based on feedback from stakeholders and PWG members.	A low level of effort, planning and coordination would be required to implement this option. Relationships and/or buy-in from stakeholders already exist, which would expedite the implementation process. There is clarity on roles and responsibilities for implementation and buy-in to execute them.
Cost impacts	Costs incurred to implement the option are estimated to be greater than $5 million.	Costs incurred to implement the option are estimated to be between $1 million and $3 million.	Costs incurred to implement the option are estimated to be less than $1 million.

A threshold of 10 points has been chosen as the basis for distinguishing whether or not an option is recommended. A score of 10 was chosen due to both a natural break in the outcome of the evaluation of the options and because the options not recommended have a high implementation effort and medium to high impact on cost for only a low to medium impact on SCIg uptake. It is vital that the NBA and governments instead focuses their efforts, resourcing and funding on options that are achievable and likely to produce an impact on SCIg uptake.

The detailed results and rationale from the options evaluation process for each of the 20 options are presented in Appendix C. The survey results from the 19 options that were presented to the PWG[23] are provided in Appendix D.

[23] Option 9 was added as a new option after initial options were presented to the PWG. Although 20 options were evaluated in total, only 19 were presented to the PWG.

1.6. Purpose and objectives of this paper

This project has reviewed the issues impacting the uptake of SCIg and proposed options to optimise the provision of SCIg in line with the National Ig Governance Program and the objectives of the National Blood Agreement.

This report synthesises the information-gathering, consultation and analysis undertaken throughout the project to date to describe:

- the key issues and opportunities in the current SCIg service model, and recommended options to address them (Chapter 2)
- options to improve funding and resourcing for SCIg (Chapter 3)
- options to influence clinical and hospital preferences for SCIg (Chapter 4)
- options to improve SCIg dispensing and supply arrangements (Chapter 5)
- options to improve awareness of SCIg and its benefits (Chapter 6)
- options to improve access to SCIg (Chapter 7)
- options to improve guidelines, documents and data (Chapter 8)
- other options (Chapter 9)
- conclusions (Chapter 10)
- the project methodology (Appendix A)
- a summary of recommended options to optimise the SCIg service model, by rating (Appendix B)
- the outcomes of the detailed evaluation process for each option (Appendix C)
- the outcomes of the survey of PWG members on the proposed options (Appendix D)
- the stakeholders that were consulted throughout the project (Appendix E).

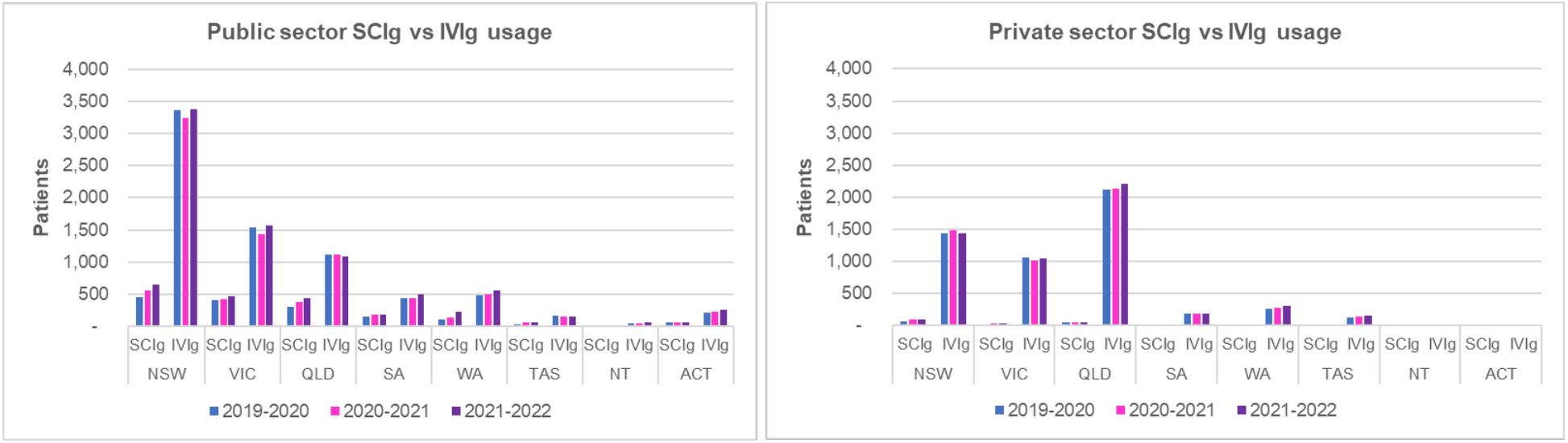
2. Key findings, options and recommendations

This Chapter describes the findings, issues and barriers that were identified through the project as impacting SCIg uptake; the options that were developed to address the issues/barriers; and the outcomes of the evaluation process to recommend improvements to the SCIg service model.

2.1. SCIg usage and trends

Whilst there has been an overall increase in usage of both IVIg and SCIg since 2019, currently, around 16% of eligible Australian patients using Ig are treated with SCIg. Figure 3 shows the number of eligible patients receiving both IVIg and SCIg from 2019-20 to 2021-22, by jurisdiction. This highlights that IVIg usage is substantially higher in both the public and private sectors across all jurisdictions. Private IVIg usage Is particularly high in Queensland, and is growing, whereas public IVIg treatment in Queensland is has decreased since 2019.

Figure 3: SCIg versus IVIg usage in the public and private sectors, by jurisdiction



Source: NBA BloodSTAR data

The National Policy states that hospitals participating in the National SCIg Program are required to comply with governing requirements, which relate to quality assurance, clinical oversight, equipment and facilities, and education and training. However, **analysis of SCIg usage across jurisdictions shows substantial variation in how the SCIg product and associated consumables and equipment are funded and provided to patients**. Table 3 highlights the differences in the provision of hospital SCIg programs across the different jurisdictions.

Table 3: Hospital SCIg program delivery, by state/territory

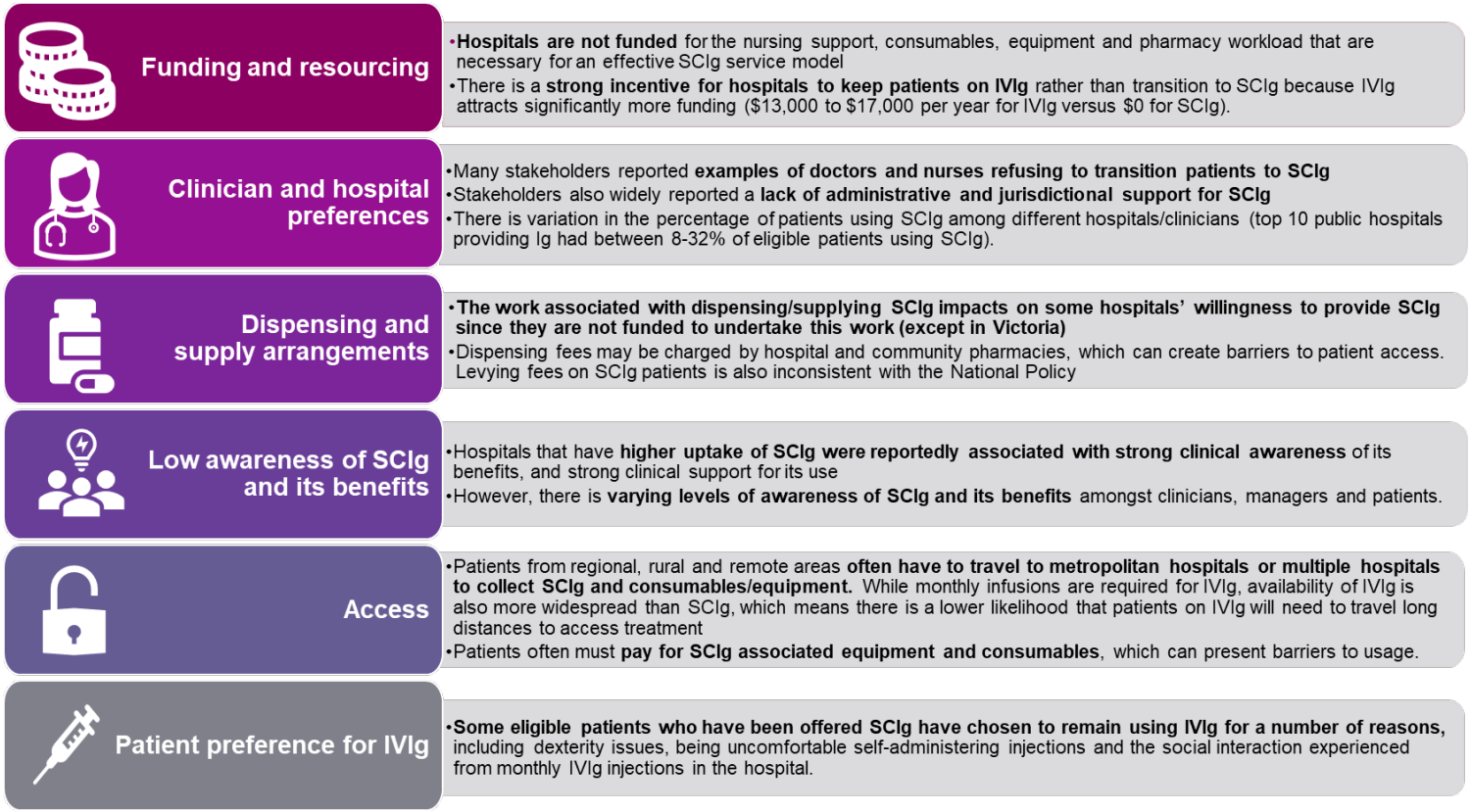
State / Territory	Funding for the provision of clinical oversight and regular review	Provision of consumables and equipment	Education and training for staff and patients	Pharmacy/pathology workload and dispensing fees
NSW	No funding	The consumables and equipment provided to patients varies between hospitals within each jurisdiction. Costs to obtain consumables and equipment are occasionally incurred by patients	Varies between hospitals within the jurisdiction, with some hospitals choosing to use training provided by SCIg suppliers (CSL Behring and Takeda)	The dispenser (and potential associated dispensing fees) varies between hospitals within the jurisdiction
VIC	The Victorian Department of Health provides funding of $680 per patient per quarter to public hospitals that deliver the SCIg Program. Of this amount, $600 is provided to the 'Administering Facility' and $80 to the 'Dispensing Facility'			
QLD	No funding			
SA	No funding			
WA	In the process of establishing arrangements in their metropolitan tertiary referral hospitals to receive non-admitted funding through senior nurse interventions with SCIg patients under Tier 2 clinic codes 40.39 (Neurology) and 40.48 (Haematology and Immunology)			
TAS	No funding			
ACT	No funding			
NT	No funding		Ad-hoc basis, as SCIg program is not formally provided in NT	Dispensed via pathology on an ad-hoc basis, with no dispensing fees

Source: Adapted from stakeholder consultations with jurisdictions and hospitals participating in the SCIg program

2.2. Barriers and issues in SCIg uptake

Figure 4 summarises the key issues and barriers that were identified as impacting SCIg uptake and how they affect the current SCIg service model.

Figure 4: Summary of key barriers to SCIg uptake



2.2.1. Funding and resourcing

Limitations in funding and resourcing were consistently identified as the main impediment to SCIg uptake in both the public and private hospital sectors. Key issues include that:

- although SCIg product is funded for eligible patients under the National Blood Agreement, jurisdictions and hospitals are responsible for funding the nursing resources, equipment, consumables, and pharmacy/pathology time that are necessary for home-based administration of SCIg. In most jurisdictions (except Victoria), there is no specific funding stream for these resources
- current funding models provide a strong incentive for health services/jurisdictions to maintain patients on IVIg – approximately $13,000 to $15,000 per patient
- the absence of an approach to fund SCIg is also likely to be a driver of very low usage of SCIg in private hospitals. Although 36.5% of eligible Australian Ig patients were treated privately in 2021-22, only 3.4% of privately treated Ig patients used SCIg (compared to 28% of Ig patients in public hospitals).

A national funding approach for SCIg would be optimal to achieve consistency and predictability for health service providers. A national approach would also bridge the significant gap in funding that hospitals receive for IVIg, compared to SCIg.

2.2.2. Clinician and hospital preferences

Analysis of BloodSTAR data shows that clinician preferences (for SCIg or IVIg) are a key driver of usage. The 10 clinicians with the highest number of SCIg patients in Australia account for 16.9% of total SCIg users nationwide. These 10 clinicians represent less than 2% of the 578 total prescribers of SCIg across Australia in 2021-22. 29% of the 'top 100' SCIg prescribers have more than 50% of patients under their management on SCIg. This suggests that **increasing clinician and hospital 'buy in' to the benefits of SCIg has significant potential to optimise SCIg uptake**.

2.2.3. Dispensing and supply arrangements

Like IVIg, SCIg is a Schedule 4 medication under the Poisons Standard and should be available from a pharmacist on prescription, except where jurisdictional legislation has been amended to include pathology to supply SCIg. However, **dispensing arrangements for SCIg were widely identified as being a key challenge to the ability of hospitals to provide SCIg efficiently, effectively and at no additional cost to patients** because of:

- workload associated with dispensing SCIg via pharmacy and pathology
- inconsistent application of patient dispensing fees to patients, which can create barriers to access for patients with low income
- limited community pharmacies dispensing SCIg as a result of the high workload and absence of reimbursement for providing SCIg.

2.2.4. Awareness of SCIg and its benefits

Opportunities exist to improve uptake of SCIg by improving awareness of its availability, indications and benefits to clinicians, hospitals and consumers. Consultations revealed varying levels of awareness of SCIg and its benefits among specialists, nursing staff, hospital managers and among patients receiving Ig therapy. Feedback received through the project indicated that "the general knowledge base for SCIg amongst consultants is low."

Work has recently been undertaken by NPS Medicinewise, the NBA and the Australasian Society for Clinical Immunology and Allergy (ASCIA) to improve awareness of SCIg through a *Value in Prescribing Program* grant of $2.4 million that ended in June 2022. However, the feedback received from consumers and some clinicians suggests that there is more work to do to improve awareness of SCIg and its benefits. Given the importance of clinician preferences noted above**, it is possible that increasing awareness of SCIg and its benefits could produce meaningful improvements in uptake and opportunities to offer it to their patients.**

2.2.5. Access

Regionality and cost were consistently reported as challenges by consumers in their ability to access SCIg. Access emerged as an area where stakeholders identified inequities between patients receiving IVIg and patients receiving SCIg, since the availability of IVIg is more widespread than SCIg. Some patients who use SCIg are also unable to work full-time (some are unable to work at all), which means they face additional challenges to using SCIg where they are required to pay for consumables or equipment. This also represents a key difference to IVIg, where patients receiving treatment in public facilities do not incur these costs. **Since many challenges in access are related directly to funding and costs, improving funding arrangements for SCIg is likely to address many barriers to access**.

2.2.6. Patient preference for IVIg

Both stakeholder consultations and patient survey feedback indicated a range of reasons why patients may choose not to use SCIg. In some cases, these reasons relate to IVIg providing more suitable clinical management; other patients may not be suitable for SCIg treatment due to dexterity or body composition (e.g. low levels of subcutaneous fatty tissue can make SCIg difficult to administer); while other patients experience adverse reactions from SCIg that are not experienced on IVIg. Patient preferences for IVIg represent a legitimate issue that is ultimately unlikely to be influenced by options to improve the SCIg service model and were therefore assessed as having a low impact on SCIg uptake.

2.3. Recommended options to address barriers and issues impacting SCIg uptake

To address these barriers and issues, 20 options were developed through stakeholder consultation and have been evaluated in this report. Although most options will impact more than one of the barriers described in Figure 4, Table 4 categorises each option according to its focus or the main issue it seeks to address. Table 4 also summarises the outcome of the evaluation scoring process and indicates which options have been recommended in order of total evaluation scores. 11 options are recommended in total. However, only one of options 8a, 8b, 8c and 8d would ultimately be implemented as they all relate to the development of a national funding model. The proposed implementation approach seeks to prioritise these four options and assess their feasibility to be implemented in turn.

Table 4: Summary of options evaluation outcome, ordered by total evaluation score

Option	Option focus area(s)	Impact on SCIg uptake	Necessity	Likely support by lead organisation	Implementation effort/ feasibility	Cost impacts	Total score	Implementation timeframe
Options recommended for implementation								
Option 1: Establish position statement(s) on when SCIg should be considered for initiation of Ig treatment	Low awareness of SCIg	High	High	Medium	Low	Low	**14**	Tactical (1-3 years)
Option 2: Review, update and enhance the National Policy	Guidelines, documents and data	Medium	High	High	Medium	Low	**13**	Quick win (less than 1 year)
Option 3: Develop a national statement on the benefits of SCIg to improve education and awareness	Low awareness of SCIg	Medium	Medium	High	Low	Low	**13**	Quick win (less than 1 year)
Option 4: Nationally consistent guiding documents to support National Policy	Guidelines, documents and data	Medium	Medium	Medium	Medium	Low	**11**	Quick win (less than 1 year)
Option 5: Improve reporting on SCIg use to jurisdictional health departments	Guidelines, documents and data	Low	Medium	Medium	Low	Low	**11**	Quick win (less than 1 year)
Option 6: Disposal of sharps containers	Access	Low	Medium	High	Medium	Low	**11**	Tactical (1-3 years)
Option 7: Fund SCIg as a hospital substitution treatment through private health insurers	Funding and resourcing Access	High	High	Medium	Medium	High	**11**	Strategic (3 years or more)
Option 8a: Establish a bundled or capitation funding model for SCIg through IHACPA's work on 'future funding models'	Funding and resourcing Access	High	High	Medium	High	High	**10**	Strategic (3 years or more)
Option 8b: Including SCIg in the national non-admitted activity-based funding model	Funding and resourcing Access	High	High	Medium	High	High	**10**	Strategic (3 years or more)
Option 8c: National funding for hospital-based SCIg services, equipment and consumables under the National Blood Arrangements	Funding and resourcing Access	High	High	Medium	High	High	**10**	Strategic (3 years or more)

Option	Option focus area(s)	Impact on SCIg uptake	Necessity	Likely support by lead organisation	Implementation effort/ feasibility	Cost impacts	Total score	Implementation timeframe
Option 8d: Bundling consumables and equipment into the SCIg unit price	Funding and resourcing Access	Medium	Medium	High	Medium	Low	**10**	Strategic (3 years or more)
Options that are <u>not</u> recommended for implementation								
Option 9: Establish MBS item numbers for SCIg	Funding and resourcing Access	Medium	High	Low	Low	Medium	9	N/A – not recommended
Option 10: Obtain agreement for broader distribution of SCIg via community pharmacies	Dispensing and supply	High	Medium	Medium	High	High	9	N/A – not recommended
Option 11: Extend SCIg services to clinic or private nursing services	Access	Medium	Medium	Medium	High	High	**8**	N/A – not recommended
Option 12: Change to state/territory regulatory arrangements to allow non-pharmacy supply of SCIg	Dispensing and supply	Low	Medium	Low	High	Low	**8**	N/A – not recommended
Option 13: Enhance jurisdictional SCIg service planning and coordination	Access	Low	Low	Low	High	Low	**7**	N/A – not recommended
Option 14: Home delivery of SCIg by suppliers	Access	Medium	Low	Low	High	Medium	**7**	N/A – not recommended
Option 15: Home delivery of SCIg by hospitals	Access	Medium	Low	Low	High	Medium	**7**	N/A – not recommended
Option 16: Establish jurisdictional state-wide SCIg coordinators	Access	Medium	Low	Low	High	Medium	**7**	N/A – not recommended
Option 17: Establish dedicated funding for SCIg in each jurisdiction, similar to the model operated by Victoria	Funding and resourcing	Medium	Low	Low	High	High	**6**	N/A – not recommended

The following sections describe the outcome of the options evaluation process for each option focus area (i.e. funding and resourcing, clinical and hospital preferences, dispensing and supply arrangements, low awareness of SCIg and its benefits, access and guidelines, documents and data).

3. Options to improve funding and resourcing for SCIg

Funding and resourcing constraints were the most commonly identified barrier to SCIg uptake during stakeholder consultations. Although SCIg product is funded for eligible patients under the National Blood Agreement:

- **in the public sector**, hospitals and jurisdictional health departments are responsible for funding the nursing resources, equipment, consumables and pharmacy/pathology time that are necessary for home-based administration of SCIg. Funding is provided via activity-based funding (ABF) in line with the provisions of the National Health Reform Agreement. Currently, no mechanism exists under the public ABF funding model to reimburse hospitals for patient interactions or pharmacy/pathology costs related to SCIg. Patient interactions with medical specialists in outpatient settings would normally be funded under the national, non-admitted Tier 2 clinic structure. However, there is no clinic code under which interactions related to SCIg can be paid. The public ABF model also does not provide dedicated funding for the nursing time associated with patient education and follow-up, or time and resources spent by pharmacy or pathology to manage and dispense SCIg.
- **in the private sector**, funding is provided by one or a combination of:
  - private health insurers (although there is currently no provision to fund SCIg in the vast majority of private health insurance policies). Patients with private health insurance can also elect to be treated as a private patient in a public hospital
  - the Medicare Benefits Schedule (MBS), which provides some government funded reimbursement for specific services or procedures. The benefit paid is typically a proportion of the total cost, which varies between hospitals and service providers. There are currently no MBS items related to SCIg
  - patients, which pay out of pocket costs for treatment (after reimbursement via the MBS and private health insurers). In most cases, patients using SCIg in the private sector are required to pay out of pocket costs. Rare exceptions were identified through this project where private clinicians will opt to pay for some equipment, consumables and nursing support for SCIg patients.

In most jurisdictions (except Victoria), **hospitals are not funded specifically for the nursing support, consumables, equipment and pharmacy workload that are necessary for an effective SCIg service model.** There is also a **strong incentive for hospitals to keep patients on IVIg rather than transition to SCIg** as hospitals lose funding for patients who transition from IVIg (approximately $13,000 to $17,000 per year for IVIg to $0 per treatment for SCIg[24]). **A lack of funding incentives for using SCIg is also likely to be a driver of very low usage of SCIg in private hospitals.** 36.5% of eligible Ig patients were treated privately in 2021, but only 3.4% used SCIg.

As a result of these funding and resourcing constraints, the SCIg service model:

- **is fragmented and implemented differently** across jurisdictions, hospitals and clinical units within hospitals

[24] In Victoria, hospitals are provided with funding of $2,720 per patient per year

- **is often not resourced or funded within hospitals**, which impacts their ability to support the ongoing achievement of the additional assurance requirements for SCIg that have been set by the NBA under the *National Policy on Access to Government-Funded Immunoglobulin Products in Australia* (the 'National Policy')
- **provides limited (or no) incentives** for clinicians and hospitals to treat eligible patients on SCIg (compared to IVIg).
- **can result in patients incurring additional out-of-pocket costs**, which is inconsistent with the National Policy and provides a disincentive to use SCIg compared to IVIg.

Seven options were considered to address issues related to funding and resourcing in the SCIg service model.

Five options are recommended for implementation. These are:

- **Option 7:** Fund SCIg as a hospital substitution treatment through private health insurers
- **Option 8a:** Establish a bundled or capitation funding model for SCIg through IHACPA's work on 'future funding models'
- **Option 8b:** Including SCIg in the national non-admitted activity-based funding model
- **Option 8c:** National funding for hospital-based SCIg services, equipment and consumables under the National Blood Arrangements
- **Option 8d**: Bundle consumables and equipment into the SCIg unit price.

Options 9 and 17 are not recommended because:

- The appetite for an organisation or individual to lead Option 9 (Establish MBS item numbers for SCIg) has not been tested. Implementation is likely to be complex and time-consuming. The success of implementation would depend on identifying an individual or organisation with the skills and expertise to navigate the MSAC application process.
- Option 17 (Dedicated jurisdictional SCIg funding) would not be suitable to establish a sustainable, nationally consistent approach to funding SCIg. Most stakeholders believe that other funding options would have a greater impact on SCIg usage and are deemed more necessary.

It was clear from feedback during stakeholder consultations and from the PWG that **a nationally consistent approach to funding SCIg services is essential to optimise SCIg uptake in Australia**. A funding model that consistently and appropriately allocates funding to service providers for all elements of the SCIg service model across the public and private sectors is required. A comprehensive funding approach would reimburse service providers for both the SCIg product and 'wrap around' services such as labour costs associated with nursing, pharmacy/pathology staff responsible for dispensing, and the equipment and consumables that are needed to self-administer SCIg.

Implementation of a nationally consistent service funding model would address many of the current barriers to SCIg uptake (including access). National funding for SCIg across both the public and private sectors therefore warrants detailed and focused effort to overcome many of the current challenges in the existing SCIg service model. As a result, the three options that provide a universal public funding strategy for SCIg were rated highly by stakeholders, and all of these options emerged with the same overall score of 10 out of 15 on the evaluation criteria.

Bundling of consumables and equipment into the SCIg unit price could also provide a nationally consistent approach for one element of the SCIg service model and could be considered a lower priority if options that provide a universal funding approach for SCIg are not pursued.

It is important to note that recommended options related to funding (i.e. Options 7, 8a, 8b, 8c and 8d) have been ranked at the lower end of recommended options overall due to the expected high levels of effort that will be needed to implement them. Notwithstanding their lower overall score compared to some other options, **achieving a sustainable funding approach for SCIg represents the most important change that should be pursued to optimise uptake in the future**.

Option 7 (Fund SCIg as a hospital substitution treatment through private health insurers) is the preferred approach to improve funding and resourcing for SCIg in the private sector. It is currently being trialled in Victoria with promising results, and should be pursued alongside options for improving funding and resourcing in the public sector (i.e. Options 8a or 8b).

Given that only one approach to national funding for SCIg is required in the public sector, the recommended funding and resourcing options for the public sector have been prioritised to focus implementation effort. In priority order, the following funding and resourcing options should be explored:

(1) Option 8a: Establish a bundled or capitation funding model for SCIg through IHACPA's work on 'future funding models'

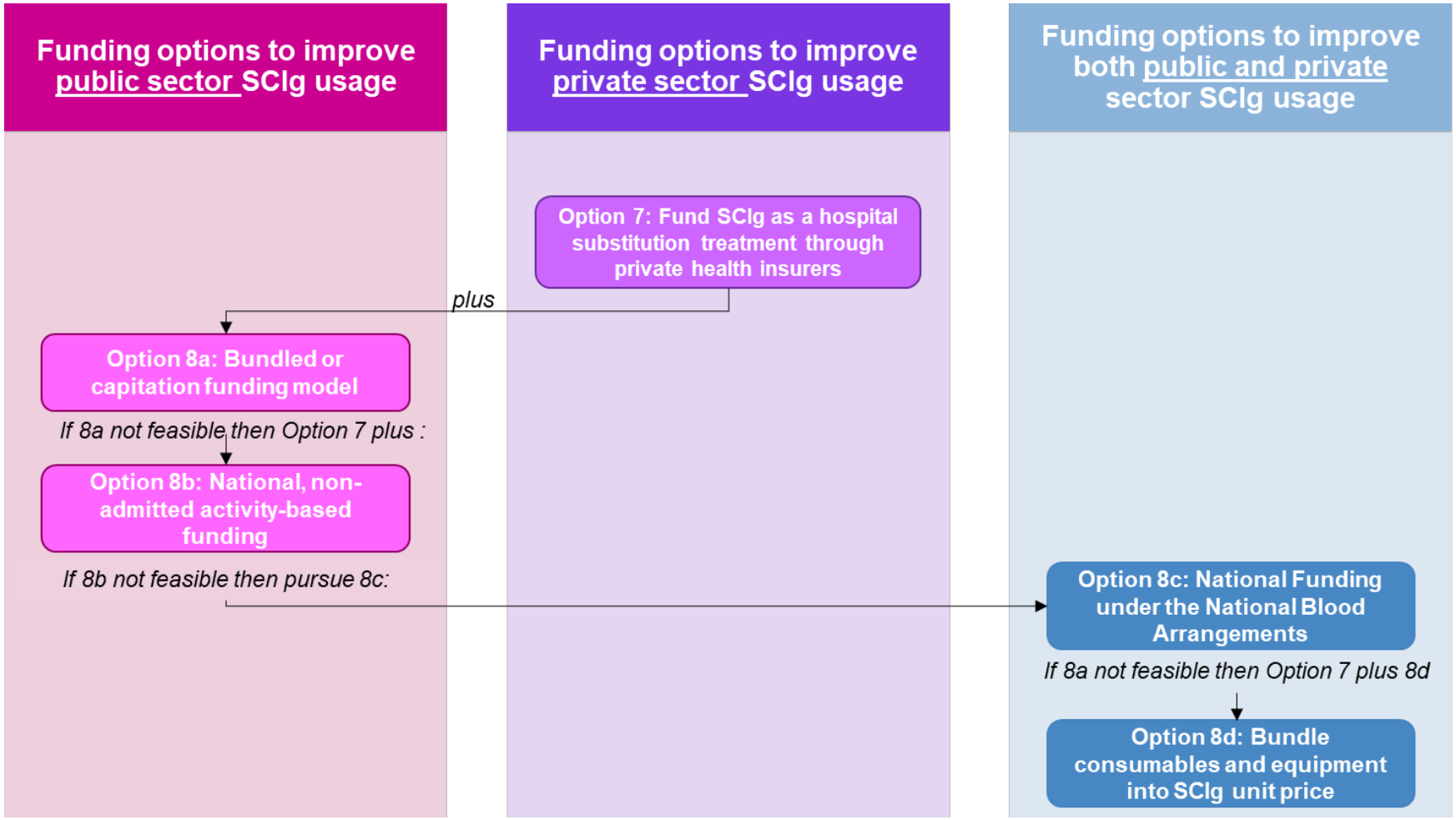
(2) Option 8b: Including SCIg in the national non-admitted activity-based funding model

(3) Option 8c: National funding for hospital-based SCIg services, equipment and consumables under the National Blood Arrangements (this option could apply to both the public and private sector)

(4) Option 8d: Bundle consumables and equipment into SCIg unit price (this option could apply to both the public and private sector).

A summary of these prioritised options for improving SCIg funding and resourcing, and reasons why they are recommended are depicted in Figure 5.

Figure 5: Prioritised funding and resourcing options



An overview of the five recommended funding and resourcing options, including high level implementation roles, responsibilities and costs is detailed in subsections 3.1 to 3.5.

3.1. Option 7: Fund SCIg as a hospital substitution treatment through private health insurers

Table 5: Proposal to Fund SCIg as a hospital substitution treatment through private health insurers

Question	Rationale
Why has this option been recommended?	• This option is recommended to improve the very low usage of SCIg in the private sector. • Experience in Victoria suggests that implementation is possible (albeit resource-intensive), and is generating interest among clinicians and private health insurers
What is it?	• This option proposes that work is undertaken by the Australian and state/territory governments to build on the approach that has been started by Victoria to ensure more eligible patients can be reimbursed for private SCIg treatment by their health insurer. • Seeking private health insurer approval for reimbursement of SCIg treatment for eligible patients as a hospital substitution treatment would support greater SCIg uptake among privately insured patients. Currently, approximately 3.4% of private patients receiving Ig treatment use SCIg • Over time, as more SCIg patients are accepted as a hospital substitution basis, SCIg could become a standard benefit in a broader range of private health insurance consumer policies.
How would it work?	Work would be required by the Australian Department of Health and Aged Care (or jurisdictional health departments), to: • Liaise with the National Home Nursing Service (NHNS) (or a similar nursing provider) and non-hospital pharmacies to agree to arrangements for dispensing to SCIg patients. The NHNS has been confirmed as a hospital authorised to deliver the SCIg Program by the Victorian Government, in accordance with NBA policy), so these arrangements would need to be expanded to cover other jurisdictions. • Initially, the Australian or state/territory governments would need to work closely with private health insurers and private sector clinicians to identify and seek approval from private health insurers for suitable patients to be reimbursed on the basis that SCIg represents a hospital substitution treatment. • Governments would also need to engage with representatives from private hospitals and insurers to build an understanding of SCIg as a hospital substitution treatment, and identify barriers and the feasibility of this option. Communicating the evidence about the cost savings associated with SCIg (and the ability to free up chairs in private hospitals for other patients that may attract a higher benefit payment) may be useful to achieve this.

3.2. Option 8a: Establish a bundled or capitation funding model for SCIg through IHACPA's work on 'future funding models'

Table 6: Proposal to pilot SCIg as a future funding model

Question	Rationale
Why has this option been recommended?	• This option would provide a nationally consistent funding solution for essential supports for SCIg delivery in public hospitals such as nurse coordination and pharmacy/pathology SCIg handling and dispensing costs. • The establishment of SCIg as a future funding model was investigated by IHACPA to inform its Pricing Framework for Australian Public Hospital Services 2023-24.[25] This work has placed the development of a bundled or capitation payment model for SCIg 'on the radar' for IHACPA and jurisdictional health departments, which could be leveraged to expedite the implementation of this option in the future.
What is it?	• Although the development of a 'future funding model' for SCIg will not be pursued by IHACPA in 2023-24, the Pricing Framework stated that IHACPA "will engage with the National Health Reform Agreement Reform Implementation Group (NHRA RIG) and jurisdictional health departments to facilitate SCIg guidelines for considering trial future funding model proposals under bilateral agreements with the Commonwealth".[26] The NBA, jurisdictional health departments and patient groups should maintain engagement with IHACPA to progress discussions regarding these bilateral agreements. • The NBA (joint lead organisation) would work with jurisdictional health departments to develop submissions to the IHACPA to request SCIg is piloted under a 'future funding model', such as bundled or capitation payment, where: – bundled payments are made to health providers for a clinically defined episode or bundle of related health care services, or – capitation payments are for the care of a patient over a defined period, where the provider is accountable for services consumed by the patient during that period. • Implementation of the funding model would be completed by IHACPA (joint lead organisation).
How would it work?	• Implementation of Option 8a would require moderate-to-high effort by the NBA, IHACPA, jurisdictional health departments and health services. – IHACPA would need to engage with jurisdictional health departments and health services to design the classification, costing and pricing framework for this model. – Jurisdictional health departments would need to collaborate to lobby IHACPA for the establishment of national ABF funding. They would also need to participate in costing studies to collect data needed to understand the quantum and type of costs to be captured in the ABF model. – Health services would need to establish data collection mechanisms to support the recording of activity to claim funding. This would require close engagement between health services and jurisdictional health departments. • This option would cost at least $6.4 million per year to implement.[27] Additionally, costs associated with conducting the costing study ($100,000-$200,000) would be incurred by IHACPA.

[25] IHACPA. Pricing Framework for Australian Public Hospital Services 2023-24. Consultation Report. 2022 Dec. Available from: https://www.ihacpa.gov.au/sites/default/files/2022-12/Pricing%20Framework%20for%20Australian%20Public%20Hospital%20Services%202023-24%20-%20Consultation%20Report%20-%20Final.PDF
[26] IHACPA. Pricing Framework for Australian Public Hospital Services 2023-24. Consultation Report. 2022 Dec. Available from: https://www.ihacpa.gov.au/sites/default/files/2022-12/Pricing%20Framework%20for%20Australian%20Public%20Hospital%20Services%202023-24%20-%20Consultation%20Report%20-%20Final.PDF
[27] This costing assumes that funding provided is $680 per patient per quarter and 25% of all eligible public SCIg patients across Australia would receive SCIg

Question	Rationale
	• If implemented, this option would mean states, territories and the Australian Government would jointly meet the costs required to support SCIg. Current cost-sharing arrangements under the NHRA mean that states/territories meet 55% of costs, with 45% of costs met by the Australian Government.

3.3. Option 8b: National non-admitted activity-based funding

Table 7: Proposal to fund SCIg under the national non-admitted activity-based funding model

Question	Rationale
Why has this option been recommended?	• If Option 8a does not proceed, it is recommended that Option 8b be pursued as the next priority. • This option would positively impact SCIg uptake as it would provide a nationally consistent approach to funding public hospital SCIg programs. • It rated the highest of all funding options for support from the lead organisations and rated highly on impact and ability to be implemented by a health service. This option has a high level of support from states, territories and patient groups. • Work is also currently underway in Western Australia (WA) to trial the development of a funding model to attract national, non-admitted ABF for SCIg in this jurisdiction. Progress of this work could be monitored to assess whether the approach being adopted in WA could be scaled-up to a national level.
What is it?	• The NBA (joint lead organisation) would coordinate advocacy among patient groups, clinicians and jurisdictional health departments for the establishment of a dedicated clinic code under the national, non-admitted Tier 2 ABF model. Implementation of the funding model would then be completed by IHACPA (joint lead organisation). The funding model would ideally capture all elements of staff time required to deliver SCIg services in hospitals (including time associated with providing nursing support to patients, pharmacy/pathology workload) and consumables/equipment that need to be provided to patients. • Two Non-Admitted Tier 2 clinics related to clinical interactions provided by allied health and/or senior nurse to patients could be appropriate to fund SCIg services. These include Neurology, Haematology and Immunology clinics. • Funding for SCIg-related service events provided by medical specialists could also be eligible for non-admitted ABF funding under the Tier 2 clinics related to Neurology, Immunology or Haematology.
How would it work?	• If the work being undertaken in WA proves to be successful (and if Option 8a cannot be implemented within two to three years), the NBA and jurisdictional health departments should advocate to IHACPA for SCIg to be recognised under the national, non-admitted ABF model. • Implementation of Option 8b would require moderate effort by IHACPA, jurisdictional health departments and health services, and low effort by the NBA. – IHACPA would need to engage with jurisdictional health departments and health services to design the classification, costing and pricing framework for this model. – Jurisdictional health departments would need to collaborate to lobby IHACPA for the establishment of national ABF funding. They would also need to participate in costing studies to collect data needed to understand the quantum and type of costs to be captured in the ABF model. – Health services would need to establish data collection mechanisms to support the recording of activity to claim funding. This would require close engagement between health services and jurisdictional health departments.

Question	Rationale
	• This option would cost at least $6.4 million per year to implement.[28] Additionally, costs associated with conducting the costing study ($100,000-$200,000) would be incurred by IHACPA. • If implemented, this option would mean states, territories and the Australian Government would jointly meet all the costs required to support SCIg. Current cost-sharing arrangements under the National Health Reform Agreement will require that states/territories meet 55% of costs, with the remaining 45% of costs met by the Australian Government.

3.4. Option 8c: National funding for hospital-based SCIg services, equipment and consumables under the National Blood Arrangements

Table 8: Proposal to fund SCIg under the National Blood Arrangements

Question	Rationale
Why has this option been recommended?	• It is recommended that Option 8c be pursued if Option 8a and 8b do not proceed. • This option would deliver a universal, nationally consistent approach to funding SCIg programs in both the public and private sectors and would therefore provide the most comprehensive approach to funding SCIg across Australia. • This option could also address the significant challenge posed by the absence of a system-wide approach to funding SCIg in the private sector that remains unresolved. At present, these challenges significantly restrict SCIg uptake in the private system.
What is it?	• The NBA (lead organisation) would work with jurisdictional health departments to seek agreement on the national funding of SCIg services under the National Blood Arrangements. • Funding would involve each health service obtaining a defined amount of money under the National Blood Arrangements for SCIg products, consumables/equipment and services needed to operate hospital-based SCIg programs, for both public and private hospitals. • Ideally, the funding model would capture all elements of staff time required to deliver SCIg services in hospitals (including time associated with providing nursing support to patients, pharmacy/pathology workload) and consumables/equipment that need to be provided to patients. Adjustments in funding may need to be assessed to account for differences in public and private hospitals, or different geographic locations (e.g major cities versus regional/rural/remote areas).
How would it work?	• Implementation of Option 8c would require a significant level of effort by the NBA. It is expected that this option would take two to three years to implement. • Overall, funding for this option would be part of National Supply Plan and Budget which is paid for by jurisdictions with a funding split of 63% Commonwealth; 37% states and territories

[28] This costing assumes that funding provided is $680 per patient per quarter and 25% of all eligible public SCIg patients across Australia would receive SCIg

Question	Rationale
	• Funding services (such as time associated with pathology, pharmacy and nursing staff in hospitals to manage SCIg) nursing time via the National Blood Arrangements would also be a new approach for the NBA, which currently only funds blood products. Substantial planning and changes to the National Blood Arrangements would be therefore needed to operationalise this option. This option would require: – work to design the funding approach and the quantum of funds to be provided to each hospital. This would likely involve a costing study – changes to the National Blood Agreement and National Policy to reflect the payment scheme from this option – the creation of a business case proposal, which would need to be endorsed by all jurisdictional health departments – new investment in the NBA workforce to manage the funding and acquittal process. • In total, this option would cost at least $10.2 million per year to implement[29]. This estimate assumes that the funding provided is consistent with the Victorian model and 25% of all eligible SCIg patients across Australia (public and private) would receive SCIg. Additionally, costs associated with conducting the costing study ($100,000-$200,000) and managing the funding Program would be incurred by the NBA.

3.5. Option 8d: Bundle consumables and equipment into SCIg unit price

Table 9: Proposal to bundle consumables and equipment into SCIg unit price

Question	Rationale
Why has this option been recommended?	• It is recommended that this option be pursued only if Options 8a, 8b and 8c do not proceed or are determined to be unviable. • Although this option would only fund selected components of the SCIg service model (consumables and equipment), doing so would provide a nationally consistent approach to funding part of the SCIg service model that would alleviate some of the cost impacts that health services currently incur to support SCIg patients. • Unlike options 8a, 8b and 8c, this option would not rely on coordination across multiple different stakeholder groups and could be implemented if sufficient appetite exists within the NBA. • This option was perceived as having a high level of support by the PWG and could be implemented effectively. Precedents already exist for the NBA to bundle consumables into the unit price of blood products, since this already occurs for Haemophilia patients. This experience would likely mean that barriers to implementation for this option could be addressed.
What is it?	• This option proposes that the NBA negotiates upcoming contracts with suppliers to provide consumables and equipment within the SCIg unit price. This option could address variability across equipment (pumps), consumables used and the level of financial contribution that patients can be required to make to use SCIg. • This change could ensure patients and hospitals can access the consumables and equipment they need to use SCIg effectively without incurring costs to do so, which was identified as a key barrier to SCIg uptake by both hospitals and patients.

[29] $680 per patient per quarter, for 3759 eligible public and private patients (based on NBA BloodSTAR data)

Question	Rationale
How would it work?	• Implementation of this option would require moderate effort by the NBA, who would need to engage with patient groups and clinicians to develop approved lists of equipment and consumables to be provided to patients to ensure a consistent supply of equipment that meets minimum standards and varying patient needs. The approved list of equipment and consumables would then need to be registered by the TGA as an 'ancillary kit.' The NBA would then need to negotiate SCIg supply to include consumables and equipment within the unit price for future contracts. • Overall, funding for this option would be part of National Supply Plan and Budget which is paid for by jurisdictions with a funding split of 63% Commonwealth; 37% states and territories • Once contracts are negotiated, SCIg suppliers would supply both SCIg products and consumables/equipment to health services, for patients to pick up. • Although costs would need to be tested with suppliers to estimate cost impacts precisely, if consumables and equipment cost approximately $220 to $450 per patient per year[30], this option would cost between $492,800 to $1 million per year.[31] This cost may increase due to the need of the TGA to register the consumables and equipment as an ancillary kit. • Currently, states, territories (and in some cases, patients) are required to meet costs associated with SCIg consumables and equipment. Implementation of this option would result in a net shift in costs from jurisdictional health departments to the NBA.

[30] Based on feedback from the SCIg patient and carer survey
[31] Based on 2,240 patients that currently access SCIg, per BloodStar data.

4. Options to influence clinical and hospital preferences for SCIg

Dedicated hospital staff that are passionate about SCIg and its benefits were often highlighted as a key reason why SCIg programs are established in hospitals. Hospitals that have the most patients using SCIg are typically those that employ a dedicated SCIg nurse co-ordinator to identify, transition, train, and manage SCIg patients. In contrast, many hospitals allocate a fraction of a nursing resource from another area such as chemotherapy to the SCIg coordination role, which reportedly creates capacity challenges in fulfilling all of the responsibilities required to transition patients onto SCIg and support their ongoing management. **Decisions about whether hospitals provide SCIg are often influenced by funding and capacity constraints.** A lack of funding was consistently identified as impacting on a hospital's willingness to provide dedicated resources to support a SCIg Program.

Treating medical specialists and nursing staff in hospitals is a key gateway for patients to access SCIg through their roles in identifying and consenting suitable patients to transition to SCIg. The influence of dedicated and passionate staff resources on SCIg uptake is reflected in Table 10, which shows the top 10 clinicians by the number of patients on SCIg. These **top 10 clinicians account for 1.9% of the 515 SCIg prescribers in 2021-22 but treated 16.9% of total eligible SCIg patients across Australia**. Many of the clinicians with the highest number of SCIg patients have more than 50% of their eligible patients on SCIg. Some of these clinicians were consulted during the project. They strongly advocated SCIg's benefits and are committed to ensuring their patients can realise them.

Table 10: Top 10 clinicians by number of patients on SCIg, 2021-22

Treating Medical Specialist (TMS)	State	Number of eligible SCIg patients 2021-22	% of total eligible Aust. SCIg patients 2021-22	Cumulative total % on SCIg	% of eligible TMS patients using SCIg	% of eligible TMS patients using IVIg
Clinician 1	VIC	61	2.6%	2.6%	38%	62%
Clinician 2	QLD	59	2.5%	5.1%	39%	61%
Clinician 3	NSW	39	1.6%	6.7%	52%	48%
Clinician 4	QLD	38	1.6%	8.3%	63%	37%
Clinician 5	QLD	37	1.6%	9.9%	62%	38%
Clinician 6	VIC	37	1.6%	11.5%	51%	49%
Clinician 7	VIC	33	1.4%	12.9%	62%	38%
Clinician 8	VIC	33	1.4%	14.2%	62%	38%

Treating Medical Specialist (TMS)	State	Number of eligible SCIg patients 2021-22	% of total eligible Aust. SCIg patients 2021-22	Cumulative total % on SCIg	% of eligible TMS patients using SCIg	% of eligible TMS patients using IVIg
Clinician 9	NSW	32	1.4%	15.6%	27%	73%
Clinician 10	QLD	31	1.3%	16.9%	31%	69%

Source: NBA BloodSTAR data

Stakeholders also widely reported a lack of administrative and jurisdictional support for SCIg, and that hospital managers don't understand its benefits. It was suggested that lack of funding is a key reason why managers are reluctant to support SCIg programs. In some cases, this lack of support means that only some clinical departments within hospitals provide the SCIg Program, which results in some eligible patients not having the opportunity to use SCIg in these hospitals.

Stakeholders often reflected that barriers to SCIg uptake that are related to clinician and hospital preferences are often underpinned by issues in funding and resourcing, (Chapter 3) or low levels of awareness about SCIg and its benefits (Chapter 6). For example, implementation of a national funding model for SCIg (Options 8a, 8b, 8c and 8d) would likely reduce the reluctance of hospitals to fully resource SCIg programs due to the absence of a dedicated funding stream for SCIg. Likewise, better awareness of the benefits of SCIg (Options 1 and 3) could influence the preference of clinicians, patients and hospital administrators to advocate more strongly for the expansion of SCIg programs. As a result, this section recognises clinician and hospital preferences as an issue to be resolved but proposes that options to address these issues are more appropriately presented in Chapters 3 and 6.

5. Options to improve SCIg dispensing and supply arrangements

SCIg (like IVIg) is a Schedule 4 medication under the Poisons Standard, and should be available from a pharmacist on prescription, except where state or territory regulatory arrangements have been amended to include pathology to supply SCIg. [32] Queensland and Western Australia have updated regulatory arrangements in their jurisdictions to permit dispensing of SCIg via pathology. However, in most jurisdictions, SCIg is supplied via pathology without this regulatory change.

There is a significant workload associated with dispensing SCIg from both pathology and pharmacy. **The work associated with dispensing/supplying SCIg impacts some hospitals' willingness to provide SCIg since they are not funded to undertake this work** (except in Victoria). Pathologies also currently absorb the cost of couriering SCIg to smaller hospitals, which was viewed as being unsustainable into the future.

Given the workload that was reported to manage SCIg, some hospital pharmacies currently seek to recover costs by charging dispensing fees, although levying out-of-pocket charges on patients is not consistent with the National Policy. There was variability in the application of dispensing fees among health services that were consulted, with fees at the discretion of the individual pharmacy. Typically, dispensing fees varied between $6.80 for concession card holders to $42.50 for patients without a concession. Patient groups raised that those who have comorbid conditions or are unable to work due to their diagnoses may not be able to afford out-of-pocket charges for SCIg. This may mean they will use IVIg instead.

Dispensing by community pharmacies was broadly considered an 'ideal model' from a patient perspective. **However, the workload and costs for individual community pharmacies to manage and dispense SCIg are currently prohibitive. Only two community pharmacies (both in NSW) currently dispense SCIg.** These pharmacies only provide the product, with consumables provided by the treating hospital. Strong communication and coordination between the treating hospital and the pharmacy were identified as being key to this model, as well as the ability to contact a patient's TMS when required. These elements would need to be embedded into any future operating model involving community pharmacies.

Two options (Options 10 and 12) were considered to address issues related to dispensing and supply arrangements in the SCIg service model.

Both Options 10 and 12 are not recommended because:

- Option 10 (Obtain agreement for broader distribution of SCIg via community pharmacies) would require substantial implementation effort by the NBA, the Pharmacy Guild of Australia and community pharmacies. Cost impacts associated with this option (including appropriate education,

[32] The Poisons Standard February 2022, accessed from https://www.legislation.gov.au/Details/F2022L00074

training and equipment) would be high and are likely to be passed on to patients by community pharmacies through dispensing fees unless nationally funded.

- Option 12 (Changes to state/territory regulatory arrangements to allow non-pharmacy supply of SCIg) was considered by multiple PWG members as being a complex and logistically difficult process that would require significant time and resources to complete. This option is unlikely to be supported by all jurisdictions which would not provide a nationally consistent approach to accessing SCIg.

6. Options to improve awareness of SCIg and its benefits

Hospitals that have higher uptake of SCIg were reportedly associated with a strong awareness of its benefits, and strong clinical support for its use. Clinicians (both doctors and nurses) that can 'champion the process' to transition patients from IVIg were identified during consultations as a key characteristic of hospitals where there is high uptake of SCIg. The BloodSTAR data presented in Table 6 also shows that many of the specialists that are highly engaged in the provision of SCIg appear as the clinicians with the greatest number of SCIg patients. Dedicated SCIg nursing coordinators were also considered pivotal to achieve high levels of awareness and uptake of SCIg within hospitals.

However, **consultations revealed varying levels of awareness of SCIg and its benefits among specialists, nursing staff and hospital managers. Furthermore, not all patients are given information on SCIg or understand its benefits.** Four survey respondents stated that education about SCIg would need to improve for them to transition from IVIg to SCIg. Increasing awareness of SCIg among both clinicians and patients was highlighted as a key opportunity to enhance uptake.

Two options were considered to address issues related to low awareness of SCIg and its benefits. These are:

- **Option 1:** Establish position statements on when SCIg should be considered for initiation of Ig treatment.
- **Option 3:** Develop a national statement on the benefits of SCIg to improve education and awareness

Both options are recommended for implementation.

It was clear from stakeholder feedback that there are opportunities to improve awareness about the benefits of SCIg among both patients and clinicians to optimise uptake. The research undertaken through this project has highlighted that commencing Ig treatment with a SCIg product (rather than an IVIg product) can be undertaken safely and is practised overseas and in certain hospitals across Australia.

Including patient characteristics and circumstances in which initiation of SCIg is clinically safe as part of a national statement could also be an important mechanism to optimise SCIg uptake by ensuring that suitable patients can access SCIg treatment earlier. Initiation of suitable patients on SCIg would also mitigate the effort nursing staff often need to expend to identify and transition suitable patients from IVIg, which was reported to be a significant resource impost on these staff.

An overview of the two recommended options relating to SCIg awareness, including high level implementation roles, responsibilities and costs is detailed in subsections 6.1 and 6.2.

6.1. Option 1: Establish position statements on when SCIg should be considered for initiation of Ig treatment

Table 11: Proposal to establish position statements on when SCIg should be considered for initiation of Ig treatment

Question	Rationale
Why has this option been recommended?	• Research indicates that initiation of Ig therapy using SCIg is possible[33] and is a standard clinical practice in Sweden, Denmark, Norway and Germany. Two Australian hospitals that were consulted have implemented SCIg as the default treatment for relevant conditions. Only patients not suitable for SCIg are treated via IVIg at these hospitals. • Several PWG members believe that a position statement on the initiation of Ig therapy using SCIg would have a high impact on SCIg usage without being costly to implement. • This option was seen as necessary by stakeholders, would be easy to implement, and could be a 'tactical initiative' to increase the uptake of SCIg.
What is it?	• This option proposes a review of the circumstances and patient characteristics under which SCIg can be used for the initiation of Ig treatment and the development of a position statement(s) that describes when the initiation of treatment on SCIg may be suitable. Separate position statements may be required for immunology, haematology and neurology patients, and this would need to be established through clinical consultation.
How would it work?	• Several approaches were suggested to develop position statements on the initiation of SCIg treatment. These avenues could be pursued individually or in combination: – the NBA (through its SWGs) could work with the clinical professional groups (ASCIA and HSANZ) to develop targeted correspondence aimed at providing a clear statement about the benefits of use/access to SCIg and advising on the circumstances when SCIg can be a clinically suitable option at the initiation of Ig therapy. Procedures and policies would then be published by clinical professional groups and promoted to clinicians to improve awareness of which patients are suitable for initiation on SCIg as a first-line Ig therapy, and how this should occur. – "SCIg champions" could be promoted in health services to highlight the benefits of SCIg to clinical peers to promote uptake. – updates to BloodSTAR could potentially be used as a reminder tool for clinicians to check if a patient is suitable for SCIg when initiating Ig. • Cost impacts associated with this option are expected to be low overall. Upfront costs in creating the position statement and ongoing costs to periodically update the document could be met within the existing resources and funding envelope of the NBA, clinical professional groups and patient groups.

[33] Koterba, A. and Stein, M. (2015). 'Initiation of immunoglobulin therapy by subcutaneous administration in immunodeficiency patients naive to replacement therapy', Allergy Asthma Clin Immunol. 2015; 11(1): 63.

6.2. Option 3: Develop a national statement on the benefits of SCIg to improve education and awareness

Table 12: Proposal to develop a national statement on the benefits of SCIg to improve education and awareness

Question	Rationale
Why has this option been recommended?	• This option would provide a national statement on the clinical, patient and cost-effectiveness benefits of SCIg. This was seen by one PWG member to be "vital to optimise the uptake and resources for SCIg programs" and received broad support from other PWG members. • Education to patients and clinicians on the benefits of SCIg was considered a weak strategy on its own, however, a national statement from an authoritative source, backed by clinical and research evidence, published broadly on a forum such as the websites of the NBA and clinical professional groups, was viewed as providing a strong statement that could promote a broader understanding of SCIg. In doing so, it could provide a platform to enhance future education campaigns targeted at patients or clinicians. • Stakeholder feedback suggests that this option is likely to be supported by the lead organisation (the NBA), is implementable without being costly and could be a 'quick win' to increase SCIg uptake.
What is it?	• This option proposes that the NBA, via its specialist working groups (SWGs) develops a statement on the clinical, patient and cost-effectiveness benefits of SCIg compared to IVIg. The national statement could also set out patient characteristics and circumstances where initiation of Ig treatment on SCIg may be clinically suitable, to optimise uptake (see Option 1). • The national statement would collate and summarise the published evidence on these elements of SCIg usage to promote a more widespread understanding of the benefits of using SCIg for patients, clinicians and the health system overall. It would present evidence about cost savings to the health system, patient convenience benefits and quality of life improvements for patients that have transitioned to SCIg and provide links to more information for patients or clinicians. • The national statement would be published on the websites of the NBA and relevant clinical peak bodies such as Australasian Society for Clinical Immunology and Allergy (ASCIA) and Haematology Society of Australia and New Zealand (HSANZ). Its release could be promoted through regular communication channels in each of these organisations. • The national statement could then be used as a resource by SCIg service providers to advocate for resources and funding through links to the national statement or to improve education and awareness for SCIg amongst both hospitals and patients on an ongoing basis.
How would it work?	• This option would be led by the NBA, who, through its haematology, immunology and neurology SWGs, would develop and publish the national statement. • Clinicians, patient advocacy groups and clinical professional groups should be consulted to assist with developing the statement. Hospitals that currently initiate Ig treatment using SCIg for certain patient groups could also be engaged to provide advice. • Ongoing resources would be required to update the national statement with new evidence and information over time as required. • Cost impacts associated with this option are expected to be low overall. Upfront costs in creating the document and ongoing costs to periodically update the document could be met within the existing resources and funding envelope of the NBA, clinical professional groups and patient groups.

7. Options to improve access to SCIg

Various barriers to accessing SCIg were identified as impacting SCIg uptake in both stakeholder consultations and the patient and carer survey that was conducted as part of this project. In addition to challenges in access due to limited clinical or patient awareness of SCIg (which are discussed in Chapters 2.2 and 2.4), barriers in patient access to SCIg products, equipment and consumables were reported due to:

- **Regionality.** A key objective in increasing SCIg uptake is that every patient who is eligible for SCIg treatment should have access to the Program, no matter where they reside in Australia. However, limitations in the availability of SCIg programs at regional, rural and remote hospitals mean that patients often have to travel to metropolitan hospitals or multiple hospitals to collect SCIg and consumables/equipment. While monthly infusions are required for IVIg, the availability of IVIg is also more widespread than SCIg, which means there is a lower likelihood that patients on IVIg will need to travel long distances to access treatment. Patients in remote areas also do not always have access to SCIg training and support services provided by either hospitals or SCIg suppliers, with one patient stating that *"trying to organise assistance [for SCIg] was a logistical nightmare"*
- **Cost.** Some patients who use SCIg are unable to work full-time due to their ongoing immunodeficiency and other comorbidities. Some are unable to work at all. Patients who are unable to work full-time often find it difficult to meet costs for equipment, consumables and dispensing fees, which can create barriers to access. This represents a key difference to IVIg, where patients receiving treatment in public facilities do not incur these costs. Four out of 12 respondents to the patient and carer survey stated that costs for SCIg-associated equipment/consumables would need to be reduced for them to consider transitioning from IVIg.

Five options were considered to address issues related to access to SCIg. None of these options passed the threshold for being recommended. However, as the biggest barrier to access is funding and resourcing (as been described in Chapter 2.1), **it is likely that establishment of a nationally-consistent funding approach (Option 8a, 8b, 8c or 8d) will address many barriers to access. Establishing a funding model for SCIg should therefore be a key priority for the NBA in the future.**

Options 11, 13, 14, 15 and 16 are not recommended because:

- Option 11 (Extend SCIg services to a clinic or private nursing services) may cause fragmentation of care between hospital-based clinicians who prescribe SCIg and clinic/private nursing services. It would require a significant level of implementation effort from the NBA and would likely involve additional costs being incurred by patients to access private nurse-led SCIg services in the community. This is not consistent with the access requirements set out in the National Policy.
- Option 13 (Enhance jurisdictional SCIg service planning and coordination) is perceived to have a low impact on SCIg uptake and was not deemed necessary by most PWG members. While in theory this option would be straightforward to implement, it is unlikely to be feasible due to a perception among jurisdictional health departments that there would be little value in establishing such positions, and hence a low likelihood that they would be funded.

- Option 14 (Home delivery of SCIg by suppliers) was perceived to cause potential fragmentation of care by disrupting arrangements for patients to access integrated treatment and follow-up with hospital-based healthcare providers for other comorbidities. It would also require substantial effort to achieve regulatory change in each jurisdiction to allow for non-pharmacy dispensing of SCIg, which was considered unlikely to be achievable. This option would also be dependent on the implementation of Option 12 (changes to state/territory regulations to allow non-pharmacy dispensing of SCIg), which is not recommended (see Chapter 5).
- Option 15 (Home delivery of SCIg by hospitals) would require significant coordination between hospital staff and transport companies to ensure cold chain requirements are met, and access to home delivery can occur efficiently in rural and regional areas. This would be costly and may take SCIg nursing resources away from core clinical duties.
- Option 16 (Establish jurisdictional state-wide SCIg coordinators) would require all jurisdictions to support this option. Feedback suggests that this would be difficult to obtain due to a low level of support for this option among jurisdictions and a low likelihood that a nationally consistent approach could be achieved. Key issues included:
  - how to define the role of a state-wide SCIg co-ordinator consistently across jurisdictions
  - how many positions would be required per population of SCIg patients
  - how such positions would be funded by jurisdictional health departments, and
  - how coordinators would work with health services to optimise SCIg uptake.

Although none of the options that are specifically focused on addressing are recommended for implementation, significant improvements to access would be achieved if a viable approach to national funding and resourcing of SCIg (i.e. Option 8a, 8b, 8c or 8d) are implemented. Establishment of a national finding approach for SCIg therefore represents a key future direction for the NBA to support the optimal uptake of SCIg across Australia.

8. Options to improve guidelines, documents and data

While not necessarily a barrier to SCIg uptake, stakeholders identified the importance of having a robust set of guidelines, documents and data to support SCIg programs across the country.

Currently, governance arrangements for Ig products exist primarily through the National Policy. The National Policy sets out the roles and responsibilities of individuals involved in the use and management of Ig products. It also sets out additional assurance requirements for hospitals that deliver the SCIg Program.

Stakeholder feedback suggests that in practice, there is substantial variation in the extent to which requirements set out in the National Policy are being met. These variations exist across jurisdictions, within jurisdictions and in some cases, within hospitals that are approved to deliver the SCIg Program. Furthermore, some stakeholders expressed a need for other documentation to support the National Policy, such as updated best practice guidance, processes and advice for hospitals on how to establish and operate a SCIg Program, process flowcharts and guidance for patients on infusion.

Jurisdictional health departments also highlighted that they are currently reliant on the NBA to provide data on SCIg usage. Updated and timely data reports could be used to implement targeted initiatives to optimise SCIg uptake in specific hospitals. These reports could also be used to identify SCIg clinical champions who could communicate the benefits of SCIg to their peers to optimise uptake.

Three options were considered to improve guidelines, documents and data relating to SCIg. All three options are recommended for implementation. An overview of the three recommended options, including high level implementation roles, responsibilities and costs is detailed in subsections 8.1 to 8.3.

8.1. Option 2: Review, update and enhance the National Policy

Table 13: Proposal to review, update and enhance the National Policy

Question	Rationale
Why has this option been recommended?	• A desire for a more nationally consistent approach to delivering SCIg was a key theme to emerge from both stakeholder consultations and PWG feedback. The National Policy is considered a key mechanism to drive this better national consistency in oversight and delivery of the SCIg Program. • This option is seen to be essential by most stakeholders, as this option rated the highest in the PWG survey out of the 19 options that were presented overall, and was the highest rated option for "necessity".
What is it?	• This option proposes that the NBA reviews and updates the National Policy to provide more clarity to providers and improve consistency in how SCIg is delivered across Australia. Updates would also be made to support the implementation and communication of other changes that are recommended in this report. • Proposed changes include: – clarifying the status of Ig under the Poisons Standard – broadening terminology to recognise SCIg can be provided in settings other than hospitals – ensuring that Chapter 4 of the National Policy includes specific reference to processes associated with access to SCIg – re-considering how requirements are framed for hospitals to deliver initial education and training to SCIg patients (as some hospitals use the training provided by suppliers). • Proposed changes that would be required to implement recommendations made in this report include: – updating responsibilities for funding and resourcing SCIg programs (if Options 8a, 8b, 8c or 8d are implemented) – considering whether minimum requirements for pumps, consumables and equipment would need to be referenced in the National Policy (Option 8d) – updating approved access requirements for SCIg to reflect any changes arising from Option 1. • Requirements for SCIg patients not to incur out-of-pocket costs to access SCIg should also be retained with minor updates to improve clarity.
How would it work?	• Implementation of this option would be led by the NBA, which would coordinate the process to review and update the National Policy. • A working group would be created with representation from both health professionals (medical/nursing/transfusion scientist /pharmacist representation) and jurisdictions to provide feedback on proposed changes to the National Policy. • Cost impacts associated with reviewing the National Policy are expected to be low and would mostly relate to the time of existing staff within the NBA to coordinate stakeholder engagement processes and propose updates to the policy. Ongoing costs would be incurred to periodically update and refresh the document in the future. These costs could probably be met within the existing resources and funding envelope of the NBA. Alternatively, a dedicated external review of the National Policy could be commissioned, which could cost up to $100,000.

8.2. Option 4: Nationally consistent guiding documents to support National Policy

Table 14: Proposal to develop and publish nationally consistent guidance documentation to optimise the SCIg service model

Question	Rationale
Why has this option been recommended?	• At present, guidelines for establishing and operating SCIg programs are published separately by jurisdictions and hospitals. This includes material such as promotional posters, conversation starters, business case templates, process flowcharts, letters, clinical practice guidance, ordering requirements, patient assessment forms and patient infusion guides. • There is an opportunity for the NBA to identify the most effective guidance materials that exist across Australia and to develop a consistent resource set that could be published on the NBA's website. Development of the resource set could also involve developing new materials where gaps exist. • This option would not be costly to implement and could be a 'quick win' to increasing the uptake of SCIg.
What is it?	• This option proposes that the NBA works with jurisdictional health departments and hospitals to develop a suite of updated, guidance material that aims to promote a more nationally consistent approach to delivering SCIg services. This material can support and enhance the National Policy. • Materials could include: – best practice guidance, processes and advice for hospitals on how to establish and operate a SCIg Program – specifying minimum requirements for pumps, consumables and equipment – providing clinical practice guidelines for how the SCIg service model should operate, including the nature and frequency of touch points between clinicians (doctors and nursing staff) and patients – promotional materials to clinicians and patients – process flowcharts which could be published as part of an updated National Policy – guidance for patients on infusion, accessing SCIg while travelling and sharps disposal arrangements.
How would it work?	• Implementation of this option would be led by the NBA, who would coordinate the process to review and update documentation on SCIg. • A working group would be created with representation from both health professionals (medical/nursing/transfusion scientist /pharmacist representation) and jurisdictional health departments. The working group would identify and prioritise what guidance documentation is required, collate current guidance documentation available in the public domain and identify what represents 'best practice', and review/approve draft documents that would be adapted by the NBA. • Minimal costs would be incurred by the NBA to implement this option, which could likely be implemented within its existing staffing resources and funding envelope. Ongoing costs (mostly associated with NBA staff time) would be incurred to periodically update and refresh these documents. • Alternatively, an external review of documentation available in the public domain could be commissioned to identify and develop a national resource set. This project could cost up to $50,000.

8.3. Option 5: Improve reporting on SCIg use to jurisdictional health departments

Table 15: Proposal to improve reporting on SCIg use to jurisdictional health departments

Question	Rationale
Why has this option been recommended?	• Jurisdictional Reports are currently provided to NBA's Jurisdictional Blood Committee (JBC) representatives and their nominees. These reports provide information on the Ig dispensed/supplied for each state and territory. However, jurisdictional representatives consulted through the project highlighted that the value of this information is limited. The analysis undertaken in this project has shown that BloodSTAR data is a potentially rich data source that could be used to drive meaningful improvements in SCIg uptake if it is presented differently. • This option could provide necessary ongoing review of SCIg programs, which is not currently consistent across Australia. It could also support the implementation of targeted initiatives to optimise SCIg uptake in specific health services where SCIg uptake (as a proportion of eligible IVIg usage) is below average, or below another benchmark that could be established using BloodSTAR data. • This option would be easy to implement, would not be costly and could be a 'quick win' to increase SCIg uptake.
What is it?	• This option proposes that the NBA develops more detailed annual reports (or 'league tables') at the jurisdiction and hospital level on SCIg usage. Benchmarks could be developed (such as the number of SCIg patients as a percentage of eligible Ig patients across Australia) and used to compare SCIg uptake by jurisdiction, hospital or clinician in reports that are provided to NBA governance groups and jurisdictional health departments. • These reports could then inform targeted discussion and action within jurisdictional health departments to optimise SCIg uptake in jurisdictions or hospitals that are below the benchmark level.
How would it work?	• This option would ideally involve the reinstation of Jurisdictional Immunoglobulin Interest Groups (JIIG) meetings, to identify what information and data would need to be incorporated into an updated reporting suite. Reports could be discussed at regular meetings • The NBA would then use existing BloodSTAR data to develop more granular hospital and clinician-level reports on SCIg usage for dissemination to jurisdictional health departments. This would include reports such as: – SCIg patients as a proportion of eligible Ig patients, by jurisdiction/hospital – number of hospitals in each jurisdiction with SCIg usage rates below the average % of eligible SCIg patients across Australia (currently 15%) – top 10 hospitals across Australia (and in each jurisdiction) by % of eligible patients using SCIg (versus IVIg). • Jurisdictional health departments could then use the data in these reports to implement targeted initiatives to optimise SCIg uptake in specific hospitals • Minimal costs would be incurred by the NBA to review the current reports provided by BloodSTAR, and ongoing costs would be incurred to periodically update and refresh these reports. These costs could probably be met within the existing resources and funding envelope of the NBA.

9. Other options

Whilst not necessarily a barrier to SCIg uptake, patients identified the importance of having a nationally consistent approach to the disposal of sharps containers. The disposal of sharps containers has been viewed by many patients as being a negative experience, and has led to some patients being reluctant to use SCIg.

Although this option may not have a significant impact on optimising SCIg uptake, it may address an important inconvenience associated with using SCIg, and therefore is recommended for implementation. An overview of the three recommended options, including high level implementation roles, responsibilities and costs is detailed in subsections 9.1.

9.1. Option 6: Disposal of sharps containers

Table 16: Proposal to dispose of sharps containers for SCIg patients

Question	Rationale
Why has this option been recommended?	• The disposal of sharps containers has been highlighted as a substantial area of concern by patient groups. It is commonly raised on patient forums as a negative experience, as often community pharmacies will refuse to dispose of full sharps containers due to the cost of disposal. • Existing council-led needle and syringe programs focus primarily on harm minimisation for intravenous drug users. Not all programs focus on the disposal of medical waste. SCIg patients may feel uncomfortable disposing of their sharps containers through these programs. • Several patients identified challenges associated with disposing of full sharps containers that store used needles and empty SCIg vials. The process of disposal of sharps containers was reported to be “humiliating,” “discriminating” and “shameful” for multiple patients. This can lead to SCIg patients feeling judged about their condition and has led to some patients being reluctant to continue on SCIg. • Although this option may not have a substantial impact on SCIg uptake, it would elevate this issue for SCIg patients and address a key inconvenience associated with using SCIg.
What is it?	• This option proposes that the NBA would support and coordinate patient advocacy groups to approach the Pharmacy Guild of Australia to seek agreement for community pharmacies to accept full sharps containers from SCIg patients. Support for the implementation of this option has not yet been tested with the Pharmacy Guild. • If a suitable approach could be agreed upon, the NBA, patient advocacy groups and Pharmacy Guild would communicate agreed changes to health services, patients and pharmacies across Australia. • Alternatively, the NBA could contract with environmental protection agencies (as some local councils have done) to collect and dispose of sharps containers safely, since many local councils already offer sharps disposal services to residents in their area.
How would it work?	• The NBA, in conjunction with patient advocacy groups, would approach the Pharmacy Guild of Australia to obtain an agreement for community pharmacies to accept full sharps containers from SCIg patients.

Question	Rationale
	• It is expected that support from the Pharmacy Guild of Australia would be dependent on securing funding for equipment to dispose of medical waste appropriately. To overcome funding issues for community pharmacies, this option could potentially be incorporated into Option 8d (the bundling of consumables and equipment into the SCIg unit price). This may be similar to clotting factor models which supply sharps containers with their products (however these models have different disposal options depending on local councils). • Upfront and ongoing costs would be incurred by the NBA to ensure community pharmacies have the equipment in place to dispose of medical waste appropriately. The cost impacts associated with this option are expected to be low overall (below $1 million per year).

10. Conclusion

Stakeholder consultations and desktop research highlighted that creating nationally consistent funding approach for SCIg services, improving awareness of SCIg and enhancing the National Policy will assist in optimising the uptake of SCIg across Australia.

This report recommends that 11 options are considered by the NBA for implementation to optimise uptake of SCIg. Options 1 to 6 scored highest in the evaluation process due to low levels of cost impacts and high implementation feasibility, compared to other recommended options.

- Option 1: Establish position statement(s) on when SCIg should be considered for initiation of Ig treatment
- Option 2: Review, update and enhance the National Policy
- Option 3: Develop a national statement on the benefits of SCIg to improve education and awareness
- Option 4: Nationally consistent guiding documents to support National Policy
- Option 5: Improve reporting on SCIg use to jurisdictional health departments
- Option 6: Disposal of sharps containers
- Option 7: Fund SCIg as a hospital substitution treatment through private health insurers (applicable to providers in the private sector only)
- Option 8a: Establish a bundled or capitation funding model for SCIg through IHACPA's work on 'future funding models' (applicable to providers in the public sector only)
- Option 8b: Including SCIg in the national non-admitted activity-based funding model (applicable to providers in the public sector only)
- Option 8c: National funding for hospital-based SCIg services, equipment and consumables under the National Blood Arrangements (applicable to providers in both the private and public sector)
- Option 8d: Bundling consumables and equipment into the SCIg unit price (applicable to providers in both the private and public sector).

Although they obtained a lower evaluation score due to higher levels of implementation effort/complexity, recommendations related to funding and resourcing (Options 7, 8a, 8b, 8c and 8d) would have the greatest impact on optimising SCIg uptake and should be a key focus area for the NBA and its stakeholders.

A proposed implementation plan for the recommended options is detailed in the document titled *Evaluate and Develop Options to Improve Access to SCIg: Attachment A to draft final report: Implementation plan summary*. The implementation plan further segments each recommended option into one of three categories (quick wins, tactical initiatives and strategic initiatives) to reflect roles and responsibilities and timeframe associated with implementation.

Appendix A: Project methodology overview

This project has been delivered over five stages between March 2022 and January 2023. The key stages and tasks that were undertaken are summarised in Figure 6.

We conducted extensive stakeholder consultations, an analysis of BloodSTAR data from 2019-20 and a survey of patients and carers of patients who use SCIg, to identify the issues impacting the uptake of SCIg and potential options to optimise the provision of SCIg in line with the National Ig Governance Program and the objectives of the National Blood Agreement.

To complete the evaluation, each option was rated against five criteria that were developed by HealthConsult and tested with the Project Working Group and the NBA. The criteria are:

(1) **impact** on increasing SCIg uptake

(2) the perceived **necessity** to address key issues or barriers in the SCIg service model

(3) whether the suggested change is **likely to be supported** by the proposed lead organisation

(4) if this option is progressed, what level of **barriers to implementation** would need to be overcome

(5) likely **cost impacts** because of the option, including whether cost shifting is likely.

Each criterion was rated by HealthConsult on a three-point scale (high, medium and low) by drawing on the feedback obtained through stakeholder consultations, the patient and carer survey, and the PWG.

Figure 6: Project methodology overview

Evaluate and develop options to improve access to Subcutaneous Immunoglobin (SCIg)	Stage 1: Project initiation and planning	Stage 2: Information gathering, analysis and initial consultation	Stage 3: Detailed stakeholder consultation	Stage 4: Develop and evaluate options	Stage 5: Reporting
Timeframe	**March 2022**	**April to June 2022**	**May to September 2022**	**September to November 2022**	**December 2022 to April 2023**
Key tasks	• Project initiation meeting • Refine stakeholder consultation strategy • Identify and obtain relevant documents and data • Prepare a risk management plan • Prepare project plan • Ongoing project management	• Review relevant documentation and reports • Analyse data provided by the NBA • Develop interview guides for policy and strategy-focused consultations • Present to NIGAC about project aims and objectives • Schedule and conduct strategy and policy-focused consultations • Design patient survey • Obtain ethics approval for patient survey • Consult with NBA Ig governance network of committees • Disseminate, collect and analyse patient and carer survey	• Develop interview guides for jurisdictional, supplier and hospital consultations • Seek nominations for jurisdictional and hospital consultations from JIIG members • Schedule and conduct jurisdictional and supplier consultations • Schedule and conduct hospital consultations	• Develop issues and options paper • Engage with Project Working Group to present, test and refine options and evaluation criteria • Internal options evaluation workshop	• Prepare first draft final report • Workshop with NBA Project Team • Refine and update the first draft report • Incorporate NBA feedback to prepare draft of the final report • Present to the NBA
	Ongoing fortnightly project management and update reporting				
Deliverables / outputs	**1.1 Project Plan (including risk management and consultation plans)** **1.2 Fortnightly written status reports**	**2.1 Design patient survey** **2.2 Ethics application** **2.3 Policy and strategy-focused consultations** **2.4 Patient and carer survey**	**3.1 Jurisdictional, supplier, dispenser and hospital consultations**	**4.1 Issues and options paper**	**5.1 First draft Final Report** **5.2 Second draft Final Report** **5.3 Final Report**

Appendix B: Summary of recommended options to optimise the SCIg service model, by rating

Table 17: Summary of recommended options to optimise the SCIg service model[34]

Option	Option focus area(s)	Impact on SCIg uptake	Necessity	Likely support by lead organisation	Barriers to implementation	Cost impacts	Total score
Option 1: Establish position statement(s) on when SCIg should be considered for initiation of Ig treatment	Low awareness of SCIg	High Score: 3	High Score: 3	Medium Score: 2	Low Score: 3	Low Score: 3	**14**
Option 2: Review, update and enhance the National Policy	Guidelines, documents and data	Medium Score: 2	High Score: 3	High Score: 3	Medium Score: 2	Low Score: 3	**13**
Option 3: Develop a national statement on the benefits of SCIg to improve education and awareness	Low awareness of SCIg	Medium Score: 2	Medium Score: 2	High Score: 3	Low Score: 3	Low Score: 3	**13**
Option 4: Nationally consistent guiding documents to support National Policy	Guidelines, documents and data	Medium Score: 2	Medium Score: 2	Medium Score: 2	Medium Score: 2	Low Score: 3	**11**
Option 5: Improve reporting on SCIg use to jurisdictional health departments	Guidelines, documents and data	Low Score: 1	Medium Score: 2	Medium Score: 2	Low Score: 3	Low Score: 3	**11**
Option 6: Disposal of sharps containers	Other	Low Score: 1	Medium Score: 2	High Score: 3	Medium Score: 2	Low Score: 3	**11**
Option 7: Fund SCIg as a hospital substitution treatment through private health insurers	Funding and resourcing Access	High Score: 3	High Score: 3	Medium Score: 2	Medium Score: 2	High Score: 1	**11**
Option 8a: Establish a bundled or capitation funding model for SCIg through IHACPA's work on 'future funding models'	Funding and resourcing Access	High Score: 3	High Score: 3	Medium Score: 2	High Score: 1	High Score: 1	**10**

[34] Scoring for Impact, necessity, likely support is based on a three point scale where (Low = 1; Medium = 2 and High = 3) because higher scores on these criteria would suggest a given option should be implemented. For the implementation effort/feasibility and cost impact criteria, the scale is reversed because high implementation effort / cost impacts create challenges that do not favour implementation of a given option.

Option	Option focus area(s)	Impact on SCIg uptake	Necessity	Likely support by lead organisation	Barriers to implementation	Cost impacts	Total score
Option 8b: Including SCIg in the national non-admitted activity-based funding model	Funding and resourcing Access	High Score: 3	High Score: 3	Medium Score: 2	High Score: 1	High Score: 1	**10**
Option 8c: National funding for hospital-based SCIg services, equipment and consumables under the National Blood Arrangements	Funding and resourcing Access	High Score: 3	High Score: 3	Medium Score: 2	High Score: 1	High Score: 1	**10**
Option 8d: Bundling consumables and equipment into the SCIg unit price	Funding and resourcing Access	Medium Score: 2	Medium Score: 2	High Score: 3	Medium Score: 2	Low Score: 3	**10**

Appendix C: Detailed options evaluation results

This appendix presents the evaluation of options for optimising SCIg uptake and addressing reported barriers and issues in the SCIg service model. It prioritises the proposed options and identifies considerations that would need to be addressed by the organisation(s) responsible for implementing them.

Assessment of each option against the evaluation criteria has been colour-coded to indicate whether each rating is positive or negative. Favourable evaluation outcomes are shaded dark green and rated three points, whereas unfavourable evaluation outcomes are shaded light green and rated one point.

This colour coding scheme has been developed to provide a quick reference to what evaluation outcomes favour the implementation of each option, and which evaluation outcomes do not favour implementation. This is because, for some criteria, the same rating will mean different things. For example:

- a rating of ‘high’ on the ‘Impact on SCIg uptake’ criterion is a favourable response that would suggest the option should be pursued
- however, a rating of ‘high’ on the ‘cost impacts’ criterion would suggest the option would need to achieve substantial benefits before its costs can be justified.

C.1. Funding and resourcing

Seven options were proposed to address issues in funding and resourcing:

(1) Fund SCIg as a hospital substitution treatment through private health insurers (Option 7)

(2) Piloting SCIg as a future funding model using a bundled or capitation payment methodology (Option 8a)

(3) Including SCIg in the national non-admitted activity-based funding model (Option 8b)

(4) Providing funding for SCIg and the services that 'wrap around' it under the National Blood Arrangements (Option 8c)

(5) Bundling consumables and equipment into the SCIg unit price (Option 8d),

(6) Establish MBS item numbers for SCIg (Option 9), and

(7) Establishing dedicated funding for SCIg in each jurisdiction, similar to the model operated by Victoria (Option 17).

The following sections present a detailed evaluation of these options and the rationale for how each has been rated.

C.1.1. Option 7: Fund SCIg as a hospital substitution treatment through private health insurers

This option proposes that the Australian Department of Health and Aged Care (DoHAC) or jurisdictional health departments work with private hospital provider groups, private health insurers (PHIs) and the NHNS to request SCIg is funded as a hospital substitution treatment to improve access to SCIg in the private sector. This would rely on demonstrating that SCIg treatment is more cost-effective while providing high-quality clinical outcomes for patients. Having a funding source coupled with increased education and awareness could result in increased access for SCIg patients being treated privately.

Implementation of this option would be led by the DoHAC or jurisdictional health departments, which would engage with representatives from the private health sector and insurers to negotiate for SCIg to be considered as a hospital substitution treatment and funded accordingly. Victorian Blood Matters has been working with two private health insurers and the NHNS to seek case-by-case approval for privately insured patients that require Ig to have SCIg consumables, equipment, nursing education/support and dispensing fees. Anecdotally, private health insurers are keen to further explore development of this option because of likely overall cost savings.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**High (3)**	• A very low proportion of eligible patients that are treated in the private sector (around 3.4%) currently access SCIg in the private sector, compared to 28% of eligible patients in the public sector. Improving funding for the private sector provision of SCIg could therefore have a significant impact on SCIg uptake. • **This option rated 8th out of the 19 options for impact on SCIg uptake in the PWG survey**, with a score of 4.06 out of 5. This suggests that the perceived impact on SCIg uptake would be better than most options.
Necessity *Is the option necessary?*	**High (3)**	• Feedback from the PWG suggested that **private hospitals are currently an 'untapped area' for optimising SCIg uptake**, and that broadening usage of SCIg in the private sector could make a big impact SCIg uptake if a viable approach can be identified. • One patient in the PWG described private hospitals as a "SCIg wasteland", and that **initiatives to optimise SCIg uptake in private hospitals would be futile without a dedicated funding source**. Improving funding for the private provision of SCIg would therefore be a prerequisite to achieving change in other elements of the private sector SCIg service model. • **There is a well-accepted need to develop a sustainable approach to incentivising the private sector provision of SCIg**. The PWG noted that patients are often switched from the private system to the public system when initiating SCIg treatment to gain access to SCIg programs (as SCIg programs in private settings are currently rare). • **This option rated 10th out of the 19 options for necessity in the PWG survey**, with a score of 3.88 out of 5. It has therefore been rated as 'medium' on this criterion.
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Medium (2)**	• Stakeholders expressed concern as to whether this option would be supported by the Australian Department of Health and Aged Care, due to high implementation effort, funding requirements and extensive timeframe to establish this option. • However, Victorian Blood Matters has been working productively with some private health insurers to support several patients to be reimbursed through their private health over for SCIg consumables, equipment, nursing education/support and dispensing fees. The Victorian experience indicates that this approach is achievable, but the appetite of other jurisdictions to adopt the same approach has not been tested.

Criterion	Rating	Rationale
		• **Survey feedback from the PWG rated this option 12th out of the 19 options for support from the lead organisation in the PWG survey,** with a score of 3.56 out of 5. There is uncertainty about whether this option would be supported.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**Medium (2)**	• **Implementation of Option 7 would require a significant level of implementation effort.** However, once greater interest and awareness of this option is achieved with clinicians and private health insurers the effort may lessen over time. • Work would be required by the Australian Department of Health and Aged Care (or jurisdictional health departments), which would need to: – engage with representatives from private hospitals and insurers to build an understanding of SCIg as a hospital substitution treatment, and identify barriers and the feasibility of this option. – overcome potential resistance to private hospitals needing to negotiate health fund contracts with PHIs to include funding for SCIg. Communicating the evidence about the cost savings associated with SCIg (and the ability to free up chairs in private hospitals for other patients that may attract a higher benefit payment) may be useful to achieve this. – consider holding targeted information sessions and/or developing materials specifically for PHIs to promote the clinical and economics benefits of SCIg. – liaise with the NHNS (or a similar nursing provider) and non-hospital pharmacies to agree arrangements for dispensing to SCIg patients. • **The experience of Victorian Blood Matters suggests that intensive work and resourcing is currently required to implement this approach.** However, once broader awareness and interest is achieved among private health insurers, clinicians and patients the implementation effort may decrease over time.
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**High (1)**	• **Cost impacts associated with this option are expected to be high overall.** This includes the investment of time and resources to negotiate SCIg payments with PHIs, as well as the resources required to establish a SCIg Program. • Additional cost impacts would be incurred once the funding model is operational. **If 25% of all eligible patients treated in the private sector (5,526 patients) could be transitioned to SCIg, this would cost $3.76 million.**
Total score	**11**	• **This option is recommended** to improve the very low usage of SCIg in the private sector. Experience in Victoria suggests that implementation is possible (albeit resource-intensive), and is generating interest among clinicians and private health insurers.

C.1.2. Option 8a: Establish a bundled or capitation funding model for SCIg through IHACPA's work on 'future funding models'

Option 8a proposes that the NBA works with jurisdictional health departments to develop a submission to the IHACPA to request SCIg is piloted under a 'future funding model', such as bundled or capitation payment. As per Option 8b, the funding model would ideally capture all elements of staff time required to deliver SCIg services in hospitals (including time associated with providing nursing support to patients, pharmacy/pathology workload) and consumables/equipment that need to be provided to patients. If the pilot is successful, this approach could then be translated into the national pricing model.

IHACPA has recently requested submissions to establish SCIg as a future funding model as a result of the work undertaken through this project. IHACPA's Pricing Framework for Australian Public Hospital Services 2023-24[35], refers to SCIg and states that IHACPA will engage with the National Health Reform Agreement Reform Implementation Group and jurisdictional health departments to facilitate guidelines for considering trial future funding model proposals under bilateral agreements with the Commonwealth.

Implementation of this option would be most effective if coordinated nationally by the NBA and IHACPA, with participation from state/territory health departments and patient groups.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**High (3)**	• Feedback from the PWG and stakeholder consultations suggested **that this option would have a high impact on optimising SCIg uptake**, as it would provide a nationally consistent approach for all hospitals providing SCIg, regardless of their size or location. **This option rated the highest out of the 19 options on impact, with a score of 4.35/5.** • This option would ensure that health services are funded to provide the resources, nursing support, pathology/pharmacy time and equipment that is necessary to operate a SCIg service model effectively. **It would also help to bridge the gap in public funding between IVIg and SCIg**.
Necessity *Is the option necessary?*	**High (3)**	• **Both stakeholder consultations and input from the PWG endorsed a nationally consistent funding approach for SCIg** as being necessary to optimise SCIg uptake. This option would provide national funding consistency.
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Medium (2)**	• Three jurisdictional health authorities and one patient advocacy group provided submissions for SCIg to be considered for a future funding model pilot to IHACPA. **This indicates that support already exists among many stakeholders involved in the SCIg service model.** • The recent release of IHACPA's 'Pricing Framework for Australian Public Hospital Services 2023-24' states that IHACPA will engage with the National Health Reform Agreement Reform Implementation Group and jurisdictional health departments to facilitate guidelines for considering trial future funding model proposals under bilateral agreements with the Commonwealth. • However, **support from all jurisdictions would be required for this option to proceed**. This option scored low (3.67 out of 5) in the PWG survey in the likelihood for it to be supported by the lead organisations (NBA and IHACPA).

[35] IHACPA. Pricing Framework for Australian Public Hospital Services 2023-24. Consultation Report. 2022 Dec. Available from: https://www.ihacpa.gov.au/sites/default/files/2022-12/Pricing%20Framework%20for%20Australian%20Public%20Hospital%20Services%202023-24%20-%20Consultation%20Report%20-%20Final.PDF

Criterion	Rating	Rationale
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**High (1)**	• **Implementation of Option 8a would require a moderate-to-high level of implementation effort by the NBA, IHACPA, jurisdictional health departments and health services**. As a 'future' funding model, this option would likely be more complex than establishing SCIg under the national ABF model (Option 1) since bundled and capitation-based funding models are not common in Australia and would require tailored design. A low level of implementation effort would be required by the NBA. – **IHACPA** would need to engage with jurisdictions and health services to design the funding model and how it would operate. This may take between one to three years to complete. – **Jurisdictional health authorities** would need to collaborate to lobby IHACPA for the establishment of SCIg as a future funding model. They would also need to participate in the design and delivery of the pilot study/ies needed to evaluate the funding model. – **Health services** would need to establish data collection mechanisms to support the recording of activity to claim funding. This was expected to require 'significant work' by several members of the PWG and would require close engagement between health services and jurisdictional health departments. • **Implementation of Option 8a would require a significant level of implementation effort by IHACPA and jurisdictional health departments** and may take up to three years to be implemented. The NBA would ideally leverage the work done so far and coordinate advocacy for this funding. • **This option was seen by PWG members as being complex**, as it would need cross-jurisdictional support, flexibility in the funding model to consider different clinical speciality requirements (e.g., needles for neurological conditions are likely to be more expensive than ones needed for immunological conditions, and neurology patients may need more frequent infusions) and a costing study to assess the impact of these differences.
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**High (1)**	• **Cost impacts associated with this option are expected to be high overall**. • In total, **this option would cost at least $6.4 million per year to implement**, assuming that the funding provided is similar to that of the Victorian model ($680 per patient per quarter) and 25% of all eligible public SCIg patients across Australia would receive SCIg (i.e. 2,378 patients).[36] In addition to these costs: – upfront costs would be incurred by jurisdictional health departments and health services associated with lobbying and conducting the pilot study/ies to establish the model. These costs would mostly be related to staff time but may also require some infrastructure investment. The nature and quantum of costs would depend on the pilot design. – one-off costs would be incurred by health services to update systems and processes to capture and report on activity associated with SCIg service delivery. Some additional capital costs may be required, but these will vary by hospital and cannot be reliably estimated. • **Costs associated with conducting the pilot study/ies would be incurred by IHACPA**. This may be between $100,000 to $200,000. Additional costs may be required if IHACPA provides funding to reimburse health services for the resources and time required to participate in the pilot.

[36] Based on NBA BloodSTAR data

Criterion	Rating	Rationale
		– Ongoing costs would be required by health services to collect the data required to support the model. • **The only cost shifting impact associated with Option 8a would be that Victoria would assume a lower share of costs than it is currently** since it funds 100% of the cost associated with SCIg service delivery and equipment in hospitals. This would reduce to 55% if Option 8b is implemented.
Total score	**10**	• **This option is recommended** as it would provide a nationally consistent funding solution for essential supports for SCIg delivery in public hospitals such as nurse coordination and pharmacy/pathology SCIg handling and dispensing costs. • The establishment of SCIg as a future funding model was investigated by IHACPA to inform its Pricing Framework for Australian Public Hospital Services 2023-24.[37] This work has placed the development of a bundled or capitation payment model for SCIg 'on the radar' for IHACPA and jurisdictions, which could be leveraged to expedite the implementation of this option in the future.

C.1.3. Option 8b: National non-admitted activity-based funding

Option 8b proposes that the NBA coordinates advocacy among patient groups, clinicians and jurisdictions for the establishment of a nationally consistent approach to funding SCIg services and equipment for public patients under the national, non-admitted Tier 2 ABF model. Ideally, the funding model would capture all elements of staff time required to deliver SCIg services in hospitals (including time associated with providing nursing support to patients, pharmacy/pathology workload) and consumables/equipment that need to be provided to patients.

One jurisdiction (Western Australia) is currently exploring this option. This jurisdiction is in the process of establishing arrangements in their metropolitan tertiary referral hospitals to receive non-admitted funding through nurse specialist interventions with SCIg patients under Tier 2 clinic codes 40.39 (Neurology) and 40.48 (Haematology and Immunology). Existing Tier 2 clinics could be used for this purpose, or advocacy could focus on the creation of a dedicated Tier 2 clinic code, such as those that exist for home-based dialysis, home parenteral and enteral nutrition and ventilation.

Implementation of this option would be led by the NBA (joint lead organisation, responsible for advocacy) and IHACPA (joint lead organisation, responsible for implementation) with participation from state/territory health departments and patient groups. If successful, further work would be required by IHACPA, state and territory health departments and health services across Australia to establish the funding model.

Criterion	Rating (score)	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**High (3)**	• Feedback from the PWG and stakeholder consultations suggested that this option would have a high impact on optimising SCIg uptake. This is because **this option would provide a nationally consistent approach to funding the resources all hospitals require to provide SCIg, regardless of their size or location**.

[37] IHACPA. Pricing Framework for Australian Public Hospital Services 2023-24. Consultation Report. 2022 Dec. Available from: https://www.ihacpa.gov.au/sites/default/files/2022-12/Pricing%20Framework%20for%20Australian%20Public%20Hospital%20Services%202023-24%20-%20Consultation%20Report%20-%20Final.PDF

Criterion	Rating (score)	Rationale
		• This option **could provide funding for supports that most stakeholders believed are necessary to optimise SCIg uptake**, such as nurse coordination and pharmacy/pathology SCIg handling and dispensing costs. • However, **some stakeholders were sceptical about whether ABF funding provided to hospitals would flow through to SCIg programs**. This scepticism was a limiting factor in this option having an impact on SCIg uptake.
Necessity *Is the option necessary?*	**High (3)**	• **Both stakeholder consultations and input from the PWG endorsed a nationally consistent funding approach for SCIg** as being necessary to optimise SCIg uptake. This option would provide national funding consistency. • One patient group stated that *"this would go a long way to address problems surrounding SCIg, I'd say **this is one of the best things that could be done to help make this shift**."*
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Medium (2)**	• **Advocacy of this option would be optimised if led by the NBA**, which could coordinate a nationally-endorsed submission to IHACPA by states and territories. However, the NBA's support for playing this role is currently untested. • **Implementation of this option would be ideally led by IHACPA**, who would be able to establish a national funding model. • Feedback from stakeholder consultations and the PWG indicated that **this option would have a high level of support among states, territories and patient groups,** which would be willing to liaise with the NBA and write submissions to pursue this option.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**High (1)**	• **Implementation of Option 8b would require a moderate level of implementation effort by IHACPA, jurisdictional health departments and health services**. A low level of implementation effort would be required by the NBA. – **IHACPA** would need to engage with jurisdictional health departments and health services to design the classification, costing and pricing framework that would need to underpin the model. This may take between one to three years to complete. – **Jurisdictional health authorities** would need to collaborate to lobby IHACPA for the establishment of national ABF funding. They would also need to participate in costing studies to collect data needed to understand the quantum and type of costs to be captured in the ABF model. – **Health services** would need to establish data collection mechanisms to support the recording of activity to claim funding. This was expected to require 'significant work' by several members of the PWG and would require close engagement between health services and jurisdictional health departments.
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**High (1)**	• **Cost impacts associated with this option are expected to be high overall**. • In total, **this option would cost at least $6.4 million per year to implement**, assuming that the funding provided is similar to that of the Victorian model ($680 per patient per quarter) and 25% of all eligible public SCIg patients across Australia would receive SCIg (i.e. 2378 patients)[38]. In addition to these costs: – upfront costs would be incurred by jurisdictional health departments and health services associated with lobbying and conducting costing studies to establish the model. These costs would mostly be related to staff time.

[38] Based on NBA BloodSTAR data

Criterion	Rating (score)	Rationale
		– one-off costs would be incurred by health services to update systems and processes to capture and report on activity associated with SCIg service delivery. Some additional capital costs may be required, but these will vary by hospital and cannot be reliably estimated. • **Costs associated with conducting the costing study would be incurred by IHACPA**. This may be between $100,000 to $200,000. Additional costs may be required if IHACPA provides funding to reimburse health services for the resources and time required to participate in the pilot. – Ongoing costs would be required by health services to collect the data required to support the model. • If implemented, this option would mean **states, territories and the Australian Government would jointly meet all meet the costs required to support SCIg**. Current cost-sharing arrangements under the National Health Reform Agreement will require that states/territories meet 55% of costs, with the remaining 45% of costs met by the Australian Government. • **The only cost shifting impact associated with Option 8b would be that Victoria would assume a lower share of costs than it is currently** since it funds 100% of the cost associated with SCIg service delivery and equipment in hospitals. This would reduce to 55% if Option 8b is implemented.
Total score	**10**	• **If Option 8a does not proceed, it is recommended that Option 8b be pursued as the next priority**. This option would positively impact SCIg uptake as it would provide a nationally consistent approach to funding hospital SCIg programs. It rated the highest of all funding options for support from the lead organisation and rated highly on impact and ability to be implemented by a health service. This option has a high level of support from states, territories and patient groups. • Work is also currently underway in Western Australia to trial the development of a funding model to attract national, non-admitted ABF funding for SCIg in this jurisdiction. Progress of this work could be monitored to assess whether the approach being adopted in WA could be scaled-up to a national level.

C.1.4. Option 8c: National funding under the National Blood Arrangements

This option proposes that NBA works with jurisdictional health departments to seek agreement on national funding of SCIg services under the National Blood Arrangements. Ideally, the funding model would capture all elements of staff time required to deliver SCIg services in hospitals (including time associated with providing nursing support to patients, pharmacy/pathology workload) and consumables/equipment that need to be provided to patients.

Unlike Options 8a and 8b, which would only apply to public hospitals, Option 8c could apply to both public and private hospitals. Payments could be made to the service provider directly and could be based on a per-patient model similar to the one operated by the Victorian Department of Health.

Implementation of this option would be led by the NBA, with participation from state/territory health departments to establish and endorse the operation of this option.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**High (3)**	• Feedback from the PWG and stakeholder consultations suggested **that this option would have a high impact on optimising SCIg uptake**, as it would provide a nationally consistent funding approach for SCIg programs in both the public and private sectors. • **This option rated 3rd out of the 19 options on impact in the PWG survey, with a score of 4.27 out of 5.**
Necessity *Is the option necessary?*	**High (3)**	• **Both stakeholder consultations and input from the PWG endorsed a nationally consistent funding approach for SCIg** as being necessary to optimise SCIg uptake. This option would provide national funding consistency. • **This option rated equal 4th out of the 19 options on necessity in the PWG survey**, with a score of 4.00 out of 5.
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Medium (2)**	• **This option was suggested by the NBA, so the NBA would likely support it**, however, this has not yet been tested. • **Support from states, territories and service providers would also be required for this option to proceed**. There was concern from PWG members that the NBA has historically been difficult in communicating and collaborating effectively with clinicians, which may impede the success of this option.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**High (1)**	• **Implementation of Option 8c would require a significant level of implementation effort by the NBA**, which would be responsible for funding SCIg programs in both the public and private sectors. This option would require: – changes to the National Blood Agreement and National Policy to reflect the payment scheme from this option – the creation of a business case proposal, which would need to be endorsed by all jurisdictions – new investment in the NBA workforce to manage the funding and acquittal process – a costing study to determine the price paid per patient. • Based on these activities, it would take between 2-3 years to implement this option. • **Despite these challenges for the NBA, feedback from the PWG suggested that barriers to this option could be overcome**, since this option ranked 5th out of the 19 options in the ability to overcome barriers to implementation, with a score of 3.53 out of 5.
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**High (1)**	• **Cost impacts associated with this option are expected to be high overall** since this option would deliver universal national funding for all SCIg patients (public and private). • In total, **this option would cost at least $10.2 million per year to implement**, assuming that the funding provided is consistent with the Victorian model ($680 per patient per quarter) and 25% of all eligible SCIg patients across Australia (public and private) would receive SCIg (i.e. 3,759 patients). In addition to these costs: – upfront workforce costs would be incurred by the NBA and jurisdictional health departments to establish the model and update the National Blood Agreement and National Policy to reflect the payment scheme. – a costing study should be conducted to ensure funding provided reflects the true costs of delivering SCIg in different types of hospitals. Costs associated with conducting the costing study would be incurred by the NBA. This may be between $100,000 to $200,000. Additional costs may be required if the NBA provides funding to reimburse health services for the resources and time required to participate in the study. – ongoing costs would be incurred by the NBA to manage the funding Program and distribute payments to service providers each year.
Total score	**10**	• **It is recommended that Option 8c be pursued if Option 8a and 8b do not proceed.**

Criterion	Rating	Rationale
		• This option would deliver a universal, nationally consistent approach to funding SCIg programs in both the public and private sectors, and would therefore provide the most comprehensive approach to funding SCIg across Australia. • This option could also address the significant challenge posed by the absence of a system-wide approach to funding SCIg in the private sector that remains unresolved. At present, these challenges significantly restrict SCIg uptake in the private system.

C.1.5. Option 8d: Bundle consumables and equipment into SCIg unit price

This option proposes that the NBA negotiates upcoming contracts with suppliers to provide consumables and equipment within the SCIg unit price. This option could address variability across equipment (pumps), consumables used and the level of financial contribution that patients can be required to make to use SCIg.

This option would require discussion to establish what consumables and equipment would be appropriate to bundle into the unit price to ensure that legitimate variations in the patient's need for consumables and equipment could be catered to. This option could address variability across equipment (pumps), consumables used and the level of financial contribution that patients can be required to make to use SCIg.

Implementation of this option would be led by the NBA, with advice from patient advocacy groups and clinical peak bodies.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**Medium (2)**	• Feedback from the PWG and stakeholder consultations suggested **that this option would have a moderate impact on optimising SCIg uptake.** • **This option rated 11th out of the 19 options on impact, with a score of 3.94 out of 5.** While it would provide a nationally consistent funding approach for SCIg, other funding options were rated higher for impact on SCIg usage.
Necessity *Is the option necessary?*	**Medium (2)**	• Feedback from stakeholder consultations and the PWG endorsed **a nationally consistent funding approach for SCIg** as being necessary to optimise SCIg uptake. • **This option was considered to have good support from jurisdictions** and may free up "valuable nursing time that is currently consumed in the supply and coordination of consumables." • **While this option could provide a nationally consistent approach for one element of the SCIg service model, it would not address other issues that were perceived to be more fundamental barriers to SCIg uptake**, such as time required by hospital-based nursing staff, pharmacies or pathology departments to manage patients and SCIg product. • This was reflected in other funding and resourcing options being rated more highly for necessity, **with this option only rating 11th out of the 19 options in the PWG survey**, with a score of 3.73 out of 5.
Likely support by lead organisation(s) *Will the proposed lead*	**High (3)**	• **Precedents exist for the NBA to bundle consumables into the unit price of blood products** since this already occurs for Haemophilia patients.

Criterion	Rating	Rationale
organisation implement the option?		• **This option was perceived to have a high likelihood of support by the NBA in the PWG survey**, as it rated 2nd out of the 19 options on support by the lead organisation, with a score of 4.07 out of 5.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**Medium (2)**	• **Implementation of Option 8d would require a moderate level of implementation effort by the NBA**, which would need to engage with many different stakeholders to develop and implement this option, including: – working with patient groups and clinicians to develop approved lists of equipment and consumables to be provided to patients to ensure a consistent supply of equipment that meets minimum standards/patient needs. Different patients will have different needs for consumables and equipment, which will need to be considered. The approved list of equipment and consumables would then need to be registered by the TGA as an 'ancillary kit.' – negotiating upcoming contracts with suppliers to agree on the scope and type of consumables and equipment that could be bundled into the unit price of SCIg – updating the National Policy to reflect new arrangements for the provision of consumables and equipment within the 'roles and responsibilities' section of the Policy – communicating changes in how equipment and consumables are provided to hospitals, clinicians and patients. • The bundling of consumables and equipment within the haemophilia unit price suggests that **barriers to bundling consumables and equipment for SCIg could be overcome by the NBA**. • **Discussions with suppliers indicated they would be open to making changes to upcoming contracts**, to allow for consumables and equipment as part of the price paid for SCIg.
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**Low (1)**	• **Cost impacts associated with this option would be borne entirely by the NBA.** • Although **costs would need to be tested with suppliers to estimate cost impacts precisely**, if consumables and equipment cost approximately $220 to $450 per patient per year[39], **this option would cost between $492,800 to $1 million per year[40]. This cost may increase due to the need of the TGA to register the consumables and equipment as an ancillary kit.** • Responsibility for meeting costs associated with SCIg consumables and equipment would result in **a net shift in costs from jurisdictions to the NBA/Australian Government** (which is funded 33% by states and territories and 67% by the Australian Government). Currently, states, territories (and in some cases patients) are required to meet costs associated with SCIg consumables and equipment.
Total score	**10**	• **It is recommended that this option be pursued only if Options 8a, 8b and 8c do not proceed or are determined to be unviable.** • Although this option would only fund selected components of the SCIg service model (consumables and equipment), doing so would provide a nationally consistent approach to funding part of the SCIg service model that would alleviate some of the cost impacts that health services currently incur to support SCIg patients.

[39] Based on feedback from the SCIg patient and carer survey
[40] Based on 2,240 patients that currently access SCIg, per BloodStar data.

Criterion	Rating	Rationale
		• Unlike options 8a, 8b and 8c, this option would not rely on coordination across multiple different stakeholder groups and could be implemented if sufficient appetite exists within the NBA. • This option was perceived as having a high level of support by the PWG and could be implemented effectively. Precedents already exist for the NBA to bundle consumables into the unit price of blood products, since this already occurs for Haemophilia patients. This experience would likely mean that barriers to implementation for this option could be addressed.

C.1.6. Option 9: Establish MBS item numbers for SCIg

This option aims to improve the willingness of clinicians in the private sector to encourage SCIg usage among private patients by establishing a new item(s) under the Medicare Benefits Schedule relating to SCIg treatment. Work would be required by a lead organisation (ideally a collective of jurisdictional health departments and clinicians) to develop a submission to the DoHAC's Medical Services Advisory Committee (MSAC) to seek approval for establishment of new MBS item numbers for SCIg.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**Medium (2)**	• Given the low uptake of SCIg in the private sector, **establishment of a dedicated MBS Item number(s) would likely provide a greater incentive for private clinicians to encourage SCIg usage**. • **However, the extent of any impact on SCIg usage would depend on what costs are approved by MSAC and the level at which benefits are set**. These could only be determined after MSAC has reviewed the evidence relating to SCIg and data relating to costs.
Necessity *Is the option necessary?*	**High (3)**	• Feedback from the PWG suggested that **private hospitals are currently an 'untapped area' for optimising SCIg uptake**, and that broadening usage of SCIg in the private sector could make a big impact SCIg uptake if a viable approach can be identified. • Feedback from the PWG suggested that **initiatives to optimise SCIg uptake in private hospitals would be futile without a dedicated funding source**. Improving funding for the private provision of SCIg would therefore be a prerequisite to achieving change in other elements of the private sector SCIg service model. • **There is a well-accepted need to develop a sustainable approach to incentivising the private sector provision of SCIg**. The PWG noted that patients are often switched from the private system to the public system when initiating on SCIg to gain access to SCIg programs (as SCIg programs in private settings are currently rare).
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Low (1)**	• **The requirements to develop a submission to MSAC are quite onerous** and involve a detailed review of published evidence relating to the proposed service/technology. Application pathways vary but involve the development of detailed documentation and evidence that sets out the case for public funding under the MBS. • Applications can be made by the medical profession, medical industry and others with an interest in seeking Australian government funding for a new medical service or change to an existing service. **It is unlikely that clinicians would have the time available to compile the evidence and meet submission requirements on their own**. A medical college or other peak body may be better-placed to develop a submission, but this has not been tested.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**Low (1)**	• Although there is extensive published evidence on the cost-effectiveness of SCIg compared to IVIg and its clinical efficacy, **the main barrier to implementation for this option is likely to be finding an individual or organisation that has the time and resources to develop an application and work through the MSAC application process**.
Cost impacts *What costs would be required to implement the option? Who would bear*	**Medium (2)**	• **Cost impacts are difficult to estimate** because they would depend on the level at which any MBS benefits are set, the scope of services/patients that may be approved for new MBS items and the update of any new MBS items by patients and clinicians. • Additional costs would most likely be incurred by the Australian government if new MBS items are created, but there may be some offsetting impacts if some patients currently being treated in the public sector instead opt for private treatment if MBS items are

Criterion	Rating	Rationale
them? Would there be cost shifting impacts?		established. In this case, government funding treatment in the public sector would instead be directed to the private sector. The nature of any offsets could only be determined once any MBS fees related to SCIg are determined.
Total score	**9**	• **This option is not recommended** due to likely challenges in the work required by jurisdictional health departments, clinicians or other groups to develop the required evidence to submit a request to MSAC to include SCIg on the MBS.

C.1.7. Option 17: Establish dedicated funding for SCIg in each jurisdiction, similar to the model operated by Victoria

If a national funding model for public hospital provision of SCIg is not successful, this option proposes that each jurisdictional health department establishes a dedicated SCIg funding stream. This funding stream could be based on the Victorian model, where a quarterly payment for each SCIg patient (currently $680 per patient, per quarter in Victoria) is made to each treating health service.

Implementation of this option would be led by jurisdictional health departments, who would each be required to establish a dedicated SCIg funding stream.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**Medium (2)**	• BloodSTAR data shows that Victoria has the second-lowest number of SCIg patients per-capita of any state or territory in Australia.[41] This suggests that the **implementation of a dedicated jurisdictional funding stream has not had a significant impact on optimising g SCIg uptake in this jurisdiction**. • **This option rated equal 12th out of the 19 options on impact in the PWG survey, with a score of 3.79 out of 5.**
Necessity *Is the option necessary?*	**Low (1)**	• **This option was not deemed necessary by most PWG members**, who believed that other funding options would have a greater impact on SCIg usage. This was reflected in feedback obtained through the PWG survey, where the option rated 16th out of the 19 options on the necessity with a score of 3.43 out of 5.
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Low (1)**	• While a dedicated funding model would optimise SCIg uptake, **multiple PWG members believed that this option would not be suitable** to establish a sustainable, nationally consistent approach to funding SCIg. • PWG members believed that **significant work would be required for the proposed lead organisations (jurisdictional health departments), which would make this option unpalatable**. • During consultations, **some state/territory health departments noted that they had sought approval to implement a similar funding approach in their jurisdiction, but had been refused**, which suggests this option is unlikely to be supported in most jurisdictions. • **The low level of support for this option was reflected in the PWG survey**, where it rated 18th out of the 19 options on support by the lead organisation, with a score of 3.15 out of 5.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**High (1)**	• PWG members believed that **significant work barriers to implementation exist for this option**, as almost all work associated with delivering it rests with state and territory health departments. While implementation could be achievable (as evidenced by the Victorian model), the limited appetite for this option would mean it is ultimately not feasible. • **There was widespread concern that this model would not be successful in overcoming barriers to implementation** in the PWG survey, with a rating of 3.08 out of 5 (equal 14th out of the 19 options for the ability to overcome barriers).

[41] Refer to Section 3.2.1 of the Issues and Options Paper (September 2022) for this analysis.

Criterion	Rating	Rationale
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**High (1)**	• Based on the number of SCIg patients across Australia (2,240), funded at the current level of the Victorian funding model **this option would cost a total of $6.1 million per year across all jurisdictions** combined. • **All costs associated with SCIg (except SCIg products) would be shifted to states and territories**.
Total score	**6**	• **This option is not recommended** as it would not be suitable for establishing a sustainable, nationally consistent approach to funding SCIg. • Most stakeholders believe that other funding options would have a greater impact on SCIg usage and are deemed more necessary.

C.2. Dispensing and supply arrangements

Two options were proposed to address issues relating to dispensing and supply arrangements:

(1) Obtain agreement for broader distribution of SCIg via community pharmacies (Option 10)

(2) Pursue changes to state/territory regulatory arrangements to allow a broader non-pharmacy supply of SCIg (Option 12)

The following sections present a detailed evaluation of these options and the rationale for how each has been rated.

C.2.1. Option 10: Obtain agreement for broader distribution of SCIg via community pharmacies

This option proposes that the NBA engages with the Pharmacy Guild of Australia to explore requirements for broader dispensing of SCIg through community pharmacies. Community pharmacies were viewed as 'an ideal delivery model' by some stakeholders, especially for people living in rural areas, or not able to easily get to their treating hospital, which would make SCIg more accessible for patients.

However, there are challenges associated with funding community pharmacies for the workload associated with managing SCIg. Currently, there are only a small number of community pharmacies across Australia that dispense SCIg. Consultations with these pharmacies identified the key issues for consideration including funding for the service and establishment of good communication channels with the treating facility for coordination of authorisations and prescriptions for the patients. SCIg is a non-PBS item and is therefore dispensed under a private prescription, which means that a process to 'control' the amount charged as a dispensing fee would need to be considered. Most other stakeholders have identified that the cost and resources associated with managing / dispensing SCIg would mean regular dispensing via community pharmacy would be prohibitive. Such challenges would need to be addressed for this option to be viable.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**High (3)**	• Feedback from the PWG and stakeholder consultations suggested that **implementation of this option would have a high impact on optimising SCIg uptake**, as it would allow patients to collect SCIg locally, and at the same time and place as other medications, This may provide an incentive for some patients to switch from treatment on IVIg to SCIg. • **This option may be particularly useful to optimise access to SCIg in rural and remote areas**, where it may be difficult to obtain SCIg from a local hospital.
Necessity *Is the option necessary?*	**Medium (2)**	• This option was supported by both PWG and the NBA as an ideal delivery option. On that basis, it is considered necessary for optimising access to SCIg. • **Feedback from the PWG survey rated this option in the top 50% for necessity**, as it ranked 7th out of the 19 options that were presented.
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Medium (2)**	• Given that this option relates to the supply of blood products, implementation of this option would be led by the NBA, which could actively engage **the Pharmacy Guild of Australia** to promote, design and implement this option. NBA support to lead the implementation of this option has not yet been tested. • If this option is supported by the NBA, **there may be opposition from other stakeholders (such as patient advocacy groups) that would need to be addressed**. This was illustrated by one patient group, which proposed that "absolutely no new costs should be passed onto patients who do SCIg, in the same way, no costs are passed onto patients doing IVIg as it would inhibit access." • NBA's work to design the operating model for this option would need to include the development of nationally consistent guidelines regarding caps on dispensing fees that community pharmacies could levy, to avoid creating barriers to access for patients who choose to pick up SCIg products from their local community pharmacy. However, **more widespread application of dispensing fees may result in opposition to this option by patient advocacy groups**. • Support from **local community pharmacies** would depend on if adequate funding arrangements were established to support education, training, staff workload and acquisition of appropriate equipment.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**High (1)**	**Implementation of Option 10 would require a significant level of implementation effort by the NBA, the Pharmacy Guild of Australia and community pharmacies**: • **The NBA would need to work with the Pharmacy Guild of Australia and patient advocacy groups** to develop guidelines (or updates to the National Policy) regarding dispensing fees to ensure inequity does not occur between different community pharmacies, or between patients who collect SCIg from the community versus hospital pharmacies. • **Community pharmacies** would need to work together with SCIg nurses and prescribing doctors to ensure communication channels are open and that the quantity and vials dispensed are appropriate for patients.
Cost impacts *What costs would be required to implement the option? Who would bear*	**High (1)**	• **Cost impacts associated with this option are expected to be high overall**. The costs mainly relate to upfront costs incurred for: – education and training for pharmacy staff on registering and dispensing through BloodSTAR – potential for the dispensing fee to be nationally funded (at a standard rate) to alleviate the financial burden for patients. This is expected to cost at least $672,000[42]

[42] Based on a $30 dispensing fee x 2,240 patients for 10 dispensings of SCIg per year

Criterion	Rating	Rationale
them? Would there be cost shifting impacts?		– equipment (including access to adequate refrigeration space) to allow for the storage of SCIg and provision to local patients. This is expected to cost at least $2,850,000[43] • Ongoing costs related to subsidising for extra workload required to dispense SCIg may be incurred. These costs would be borne by the NBA. • Any additional costs incurred by community pharmacies would likely be passed on to patients through dispensing fees. Although negotiating with the Pharmacy Guild would be required to agree on pricing parameters for any dispensing fee, **this would involve shifting some costs associated with pharmacy/pathology workload from jurisdictional health departments to patients**.
Total score	**9**	• **This option was not recommended** as it would require substantial implementation effort by the NBA, the Pharmacy Guild of Australia and community pharmacies. Cost impacts associated with this option (including appropriate education, training and equipment) would be high and are likely to be passed on to patients by community pharmacies through dispensing fees unless nationally funded.

C.2.2. Option 12: Pursue changes to state/territory regulatory arrangements to allow a broader non-pharmacy supply of SCIg

This option proposes that jurisdictional health departments follow the approaches of Queensland and Western Australia to pursue changes to regulatory arrangements to allow SCIg to be supplied by pathology (rather than requiring SCIg to be dispensed via pharmacy). Implementation of this option could optimise SCIg access for patients and open the possibility of home delivery of SCIg, equipment and consumables to patients by suppliers if all jurisdictions were to make this change. This option was initially suggested as a prerequisite for implementing home delivery of SCIg by suppliers, which was primarily aimed at addressing barriers to SCIg access.

Implementation of this option would need to be led by each jurisdiction, which would each pursue amendments to their state/territory regulations. If updated, jurisdictions would also need to make consequential updates to policies and procedures to reflect a choice between pharmacy and non-pharmacy supply of SCIg.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**Low (1)**	• Feedback from the PWG suggested that this option would have a low impact on optimising SCIg uptake, and should not be pursued because it would not provide a nationally consistent solution to optimise access to SCIg. • **This option rated low on the perceived impact on SCIg uptake in the PWG survey**, and ranked 15th out of 19 options for impact, with a rating of 3.64 out of 5.
Necessity *Is the option necessary?*	**Medium (2)**	• **There were mixed views about the necessity of this option**, with:

[43] Based on half of the pharmacies across Australia (total pharmacies: 5,700 x 0.5 = 2,850) require a second fridge costing $1,000

Criterion	Rating	Rationale
		– one PWG member expressed particular concern about this option, as SCIg (a Schedule 4 medication) "has been scheduled according to defined and consistent risk assessments, and should not be descheduled to account for shortcomings in distribution models" – another PWG member stated that some jurisdictions could unilaterally initiate their own investigations into the Western Australian and Queensland models for SCIg supply and potential ways to amend their own regulatory arrangements if they wish to do so. • Overall, this option scored equal 8th out of 19 for necessity in the PWG survey, which suggests it may offer some benefit if implemented, while also not being a critical impediment to how the SCIg service model functions.
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Low (1)**	• **This option is unlikely to be supported by jurisdictions** as significant legislative changes and resources would be required to undertake this option. • Many PWG members stated that **it would be logistically difficult and the process would be extremely time-consuming**.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**High (1)**	• Although Queensland and Western Australia provide precedents for implementing changes to state/territory regulatory arrangements, **this option was considered by multiple PWG members as being a complex and logistically difficult process** that would require substantial time and resources to complete. • **Jurisdictions would each need to pursue changes to relevant regulations** to allow non-pharmacy dispensing of SCIg. The approaches used by Queensland or Western Australia to allow pathology to supply SCIg could be explored as 'templates' for making the required changes. • **If updated supply arrangements are agreed upon, jurisdictions would then need to make consequential updates to policies and procedures** to reflect a choice between dispensing SCIg via pharmacy or supply via pathology. This includes potential changes to labelling arrangements for SCIg where it is supplied via pathology to ensure proper handling, storage and management. • **Feedback from the PWG suggests that implementation of this option would be very difficult**, with the option ranking 14th out of 19 for overcoming barriers to implementation in the PWG survey.
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**Low (3)**	• **Cost impacts associated with this option are expected to be low overall**. – Upfront costs would be incurred by jurisdictional health departments for the workforce associated with pursuing changes to state/territory regulatory arrangements. It is not clear how much this may cost, however, any changes could likely be managed without needing to invest in new staff. • **No cost shifting impacts would be expected** from the implementation of this option.
Total score	**8**	• **This option was not recommended** as it was considered by multiple PWG members as being a complex and logistically difficult process that would require significant time and resources to complete. • This option is unlikely to be supported by all jurisdictions which would not provide a nationally consistent approach to accessing SCIg.

C.3. Options relating to awareness of SCIg and its benefits

Two options were proposed to address issues in awareness:

(1) Establish position statement(s) on when SCIg should be considered for initiation of Ig treatment (Option 1)

(2) Develop a national statement on the benefits of SCIg to improve education and awareness (Option 3)

The following sections present a detailed evaluation of these options and the rationale for how each has been rated.

C.3.1. Option 1: Establish position statements on when SCIg should be considered for initiation of Ig treatment

This option proposes a review of the circumstances (and patient characteristics) under which SCIg can be used for the initiation of Ig treatment. The NBA and/or clinical professional groups would then publish updated position statements on SCIg usage (similar to the SCIg Position Statement published by the Australian Society for Clinical Immunology and Allergy) that describes when the initiation of treatment on SCIg may be suitable.

Implementation of this option would be led by the NBA, who, through its SWGs, could engage with patients and clinical professional groups in immunology, haematology and neurology to provide recommendations on when SCIg should be considered for initiation of Ig treatment. Procedures and policies would then be published by clinical professional groups and promoted to clinicians to improve awareness of which patients are suitable for initiation on SCIg as a first-line Ig therapy, and how this should occur.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**High (3)**	• **Feedback from the PWG expressed strong support for the establishment of position statements** to raise awareness of SCIg and when it may be suitable for a patient to be initiated on SCIg treatment. Although initiation of Ig treatment on SCIg is not common practice in Australia, several PWG members believed that this should be considered and would have an impact on SCIg usage if implemented. • One PWG member commented that "providing a consensus statement from a professional body on when it is safe to initiate a patient on SCIg and how to do this **will raise awareness and get patients onto SCIg faster**." • **This option rated equal 3rd out of the 19 options on impact in the PWG survey, with a score of 4.21 out of 5.**
Necessity *Is the option necessary?*	**High (3)**	• Most stakeholders and PWG members stated that this option is necessary. This was reinforced by feedback from the PWG survey, where **this option rated 2nd out of the 19 options on necessity, with a score of 4.23 out of 5.**
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Medium (2)**	• **Support for the NBA to lead this option has not been tested**, however, the process to implement this option is unlikely to be costly or time-consuming. • Stakeholder feedback suggests that **it is likely this option would be supported by clinicians and jurisdictions,** as long as flexibility for patient and provider choice remains regarding which type of Ig therapy best suits their needs. • **This option was rated in the top third (7th out of the 19) on perceived support by the lead organisation in the PWG survey**, with a score of 3.85 out of 5.

Criterion	Rating	Rationale
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**Low (3)**	• **A low amount of effort would be required to implement this option**, as most effort involves engagement between the NBA, clinical professional groups, clinicians and patients. Relationships between all these parties already exist, which could expedite the implementation process. • Several approaches were suggested to develop position statements. These avenues could be pursued individually or in combination: - the NBA could work with the clinical professional groups (ASCIA and HSANZ) to develop targeted correspondence aimed at providing a clear statement about the benefits of use/access to SCIg and advising on the circumstances when SCIg can be a clinically suitable option at the initiation of Ig therapy. - "SCIg champions" could be promoted in health services to highlight the benefits of SCIg to clinical peers to promote uptake. - updates to BloodSTAR could potentially be used as a reminder tool for clinicians to check if a patient is suitable for SCIg when initiating Ig. • **This option rated equal highest out of the 19 options for the ability to overcome barriers easily in the PWG survey, with a score of 4 out of 5.**
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**Low (3)**	• **Cost impacts associated with this option would be low overall, with a possibility that no new funding would be required.** – Upfront costs would be incurred by the NBA for resources and time to conduct clinical engagement and development of position statements. These costs could probably be met within the existing resources and funding envelope of the NBA, clinical professional groups and patient advocacy groups. – Ongoing costs would be incurred to invest in promotion and awareness campaigns to support the earlier transition of suitable patients to SCIg. However, these would also likely be achieved without new investment. – Some minor costs may be incurred by the NBA if BloodSTAR is updated to include a built-in prompt to check whether a patient may be suitable for initiation on SCIg. It is unlikely that these could exceed $100,000. • **No cost shifting impacts would be expected** from the implementation of this option.
Total score	**14**	• **This option has been recommended, as several PWG members believe that a position statement on the initiation of Ig therapy using SCIg would have a high impact on SCIg usage without being costly to implement.** • Research indicates that initiation of Ig therapy using SCIg is possible and is a standard clinical practice in Sweden, Denmark, Norway and Germany. Two Australian hospitals that were consulted have implemented SCIg as the default treatment for relevant conditions. Only patients not suitable for SCIg are treated via IVIg at these hospitals. • This option was seen as necessary by stakeholders, would be easy to implement, and could be a 'tactical initiative' to increase the uptake of SCIg.

C.3.2. Option 3: Develop a national statement on the benefits of SCIg to improve education and awareness

This option proposes that the NBA, via its SWGs develops a national statement on the clinical and cost benefits of SCIg compared to IVIg that is published on the websites of the NBA and relevant clinical peak bodies such as ASCIA and HSANZ. This national statement could then be used by SCIg service providers to advocate for resources and funding.

Implementation of this option would be led by the NBA, with advice from clinicians, clinical professional groups (such as ASCIA) and patient advocacy groups such as AusPIPS and IDFA.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**Medium (2)**	• This option was generally well-received by PWG members and stakeholders, with **one PWG member stating that "a national statement on the clinical and cost benefits of SCIg is vital to optimise uptake** and resources for SCIg programs." • Broadly, improving **education and awareness was seen to be "weak as a stand-alone strategy"** by some, and that education and awareness will only have an uptake on SCIg uptake if adequate resources for the department or hospital-based SCIg services are already in place (otherwise the impact on SCIg uptake could lose momentum). • **This option rated 7th out of the 19 options on impact in the PWG survey**, which suggests that it could help to optimise SCIg uptake, but should be considered as a lower priority than some other options**.**
Necessity *Is the option necessary?*	**Medium (2)**	• **Most stakeholders and PWG members stated that a national statement on the benefits of SCIg can** increase the awareness of SCIg among both hospitals and patients. • However, **some stakeholders felt that many clinicians are already well-aware of SCIg and its benefits but are prevented from advocating for treatment due to a lack of resources**, service availability and funding. Funding was therefore considered a higher priority to address by some members. • **This option was perceived as being highly necessary in the PWG survey**, as it rated 3rd out of the 19 options on necessity with a score of 4.07 out of 5.
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**High (3)**	• **Support for the NBA to lead this option has not been tested**, however, the process to implement this option is unlikely to be costly or time-consuming. • Discussion at the PWG workshop raised that options relating to education and awareness would receive more support from clinicians and jurisdictional health departments if a national statement on the clinical and cost benefits of SCIg compared to IVIg was created. • **This option was perceived as being likely to be supported by the NBA**, as it rated 3rd out of the 19 options on support by the lead organisation in the PWG survey, with a score of 4 out of 5.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**Low (3)**	• **A low amount of effort would be required to implement this option**. • The NBA, through its haematology, immunology and neurology SWGs, would create the national statement. Clinicians, patient advocacy groups and clinical professional groups will be consulted and can help in assisting with developing the statement • Ongoing resources would be required to update the national statement with new evidence and information.

Criterion	Rating	Rationale
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**Low (3)**	• **Cost impacts associated with this option are expected to be low overall, with a possibility that no new funding would be required.** – Upfront costs would be incurred by the NBA for workforce resources to develop the national statement. These costs could probably be met within the existing resources and funding envelope of the NBA, clinical professional groups and patient advocacy groups. – Ongoing costs would be incurred to manage, update or refresh the national statement periodically with new evidence or information. However, this could also be accommodated without additional investment by the NBA. – **No cost shifting impacts would be expected** from the implementation of this option.
Total score	**13**	• **This option is recommended as it would provide a national statement on the clinical, patient and cost-effectiveness benefits of SCIg.** This was seen by one PWG member to be "vital to optimise the uptake and resources for SCIg programs" and received broad support from other PWG members. • Education to patients and clinicians on the benefits of SCIg was considered a weak strategy on its own, however, a national statement from an authoritative source, backed by clinical and research evidence, published broadly on a forum such as the websites of the NBA and clinical professional groups, was viewed as providing a strong statement that could promote a broader understanding of SCIg. In doing so, it could provide a platform to enhance future education campaigns targeted at patients or clinicians. • Stakeholder feedback suggests that this option is likely to be supported by the lead organisation (the NBA), is implementable without being costly and could be a 'quick win' to increase SCIg uptake.

C.4. Options relating to access

Five options were proposed to address issues in access:

(1) Extend the SCIg Program to clinic or private nursing services (Option 11)

(2) Enhance jurisdictional SCIg planning and coordination (Option 13)

(3) Home delivery of SCIg by suppliers (Option 14)

(4) Home delivery of SCIg by hospitals (Option 15)

(5) Establish jurisdictional state-wide SCIg coordinators (Option 16)

The following sections present a detailed evaluation of these options and the rationale for how each has been rated.

C.4.1. Option 11: Extend the SCIg Program to clinic or private nursing services

This option would involve the SCIg Program being delivered through privately run, nurse-led clinics. SCIg is already provided through treating medical specialists based in clinics, however, this is a very small cohort of SCIg providers and is constrained by challenges in funding and resourcing of these clinics. Stakeholder feedback strongly suggested that the infrastructure and costs associated with establishing and operating a SCIg service through clinics or private nursing providers represent barriers to this as a viable option. This was highlighted by frequent observations that public hospitals often struggle to resource the SCIg Program. These challenges would need to be overcome for this option to be implemented more broadly. Implementation of this option would therefore likely be dependent on the establishment of dedicated funding arrangements for SCIg in the private sector as a hospital substitution treatment (see Option 7).

Implementation of this option would be led by the NBA, who would firstly need to update the National Policy to broaden eligibility to deliver SCIg programs beyond hospitals. The NBA would then engage with clinical champions operating in the private sector and nursing clinical peak bodies, to promote the establishment of SCIg clinics to their peers.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**Medium (2)**	• **Additional capacity to service SCIg demand in the private sector could optimise uptake in what is currently a largely 'un-serviced' market for SCIg**. However, the extent of private patient uptake of this model would depend on funding and access arrangements, which would need to be developed. • **This option rated 9th out of the 19 options for impact on SCIg uptake in the PWG survey**, with a score of 4 out of 5.
Necessity *Is the option necessary?*	**Medium (2)**	• Feedback from the PWG suggested that **private patients are currently an 'untapped area' for optimising SCIg uptake**, and there is an opportunity to broaden the usage of SCIg programs in the private sector. • **Clinic services were seen as an option to 'free up' valuable hospital resources** and may be more accessible for SCIg patients. • However, some PWG members believe that **extending funding and awareness of SCIg into private clinics may cause fragmentation of care** between hospital-based clinicians who prescribe SCIg and clinic/private nursing services. • **This option rated 7th out of the 19 options for necessity in the PWG survey**, with a score of 3.92 out of 5.
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Medium (2)**	• There are mixed views as to whether this option would be supported by NBA due to the significant amount of work and engagement that would be involved in establishing this option. **Support from the NBA to lead the implementation of this option has not been tested**. • **Support for the NBA to lead this option was perceived by the PWG to be moderate**, as this option rated equal 7th out of the 19 options for support from the lead organisation in the PWG survey**.**
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**High (1)**	• **Implementation of this option would require a significant level of implementation effort by the NBA**, which would need to consider: – funding and resources, to ensure the sustainable establishment of clinic or private nursing services – establishment of a robust clinical governance structure to ensure communication and continuity of care between hospitals and nurse-led clinics

Criterion	Rating	Rationale
		– specifying what types of senior nursing staff are suitably qualified to deliver the service and their proposed scope of practice. – updates to the National Policy, to: ▪ explicitly recognise that SCIg can be provided outside of hospital settings ▪ changes to BloodSTAR/BloodNet to allow clinic staff to use these systems ▪ outline proposed clinical governance arrangements between nursing services and hospitals where prescribers are based. • **The high level of implementation effort for this option was perceived as a key barrier by the PWG**, which ranked this option low on the ability to overcome barriers to implementation (13th out of 19 options) in the PWG survey,
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**High (1)**	• **Cost impacts associated with this option are expected to be high overall.** Costs would be borne by: – the NBA to establish and oversee the service model – the Australian and state/territory governments to establish a dedicated funding source for private practices(Option 6) – patients, who would need to pay to access private nurse-led clinics – practices, which would likely incur costs to provide the infrastructure, support and ongoing clinical oversight required to deliver the SCIg Program. • **This option would involve additional costs being incurred by patients** to access private, nurse-led SCIg services in the community.
Total score	**8**	• **This option is not recommended** as it may cause fragmentation of care between hospital-based clinicians who prescribe SCIg and clinic/private nursing services. • It would require a significant level of implementation effort from the NBA and would likely involve additional costs being incurred by patients to access private nurse-led SCIg services in the community. This is not consistent with the access requirements set out in the National Policy.

C.4.2. Option 13: Enhance jurisdictional SCIg planning and coordination

This option proposes that jurisdictional health departments develop annual, jurisdiction-wide SCIg service plans to improve the effectiveness and efficiency of how SCIg is delivered. By doing so, SCIg service plans could support the intent of the National Policy and guide standardised implementation of the SCIg Program within each jurisdiction, more equitable patient access to SCIg and improved alignment to the National Policy. This would involve each jurisdiction developing a service plan outlining which hospitals would provide SCIg, what the service model would look like, how equity issues would be addressed, and how consistent policies and procedures would be developed and implemented to maximise SCIg uptake.

Implementation of this option would be led by jurisdictional health departments (ideally by the state-wide SCIg coordinators suggested in Option 16). They would be responsible for developing annual service plans for the delivery of SCIg in their state or territory. Jurisdictional health departments would then present and discuss their annual service plan at JBC meetings.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**Low (1)**	• **There was generally negative feedback to this option impacting SCIg uptake**. Most stakeholders believed this option would not provide a nationally consistent approach to SCIg programs, and hence impact on uptake would differ between different jurisdictions. • **This negative perception was reflected in PWG survey results,** where this option rated 17th out of the 19 options on impact.
Necessity *Is the option necessary?*	**Low (1)**	• Stakeholder consultations identified **opportunities to improve the effectiveness and efficiency of SCIg delivery within states and territories** by better service planning and coordination of SCIg delivery at a jurisdictional level. • **However, this option was not deemed necessary by most PWG members**. It was highlighted that in some jurisdictions there is already state-wide oversight of policies and implementation. Where state-wide oversight is in place, this is reportedly hampered by a lack of funding and resources to manage SCIg programs at the local level. Addressing funding and resourcing challenges was therefore perceived to be a higher priority than this option. • **This option rated 14th out of the 19 options on necessity in the PWG survey**, with a score of 3.62 out of 5**.**
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Low (1)**	• PWG members believed that **support from jurisdictional health departments for this option would be difficult to obtain**. • **Investment in more nursing staff within health services was perceived to be more valuable**, so jurisdictional health departments are unlikely to dedicate resources to a state-wide coordination role. • **This option rated 15th out of the 19 options on support by the lead organisation in the PWG survey**, which suggests a low likelihood of implementation support**.**
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**High (1)**	• **In theory, this option could be relatively straightforward to establish and implement**, as most work required would be associated with jurisdictional health departments (and potentially the NBA) establishing guidelines on service planning requirements to support consistency across Australia. • However, in practice, **the PWG was sceptical that this option would be feasible due to the perceived low value of implementing such positions.** • **Perceived barriers to implementation were very high in the PWG survey**, where this option rated 17th out of 19 options for the ability to overcome barriers.

Criterion	Rating	Rationale
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**Low (3)**	• **Costs associated with this option would all be incurred by state and territory health departments and are expected to be low overall.** – Upfront costs would be associated with staffing and resources to create and roll out the initial service plan. It has been assumed that service plans would be developed from within existing state or territory health department resources (or through existing state-wide SCIg coordinators, where they exist). As a result, these costs could be met from within existing funding allocations. – Ongoing costs would be related to establishing a dedicated funding source to support the delivery of the ongoing service model. • **No cost shifting impacts would be expected** from the implementation of this option.
Total score	**7**	• **This option is not recommended** as it is perceived to have a low impact on SCIg uptake and was not deemed necessary by most PWG members. • While in theory this option would be straightforward to implement, it is unlikely to be feasible due to a perception among jurisdictional health departments that there would be little value in establishing such positions, and hence a low likelihood that they would be funded.

C.4.3. Option 14: Home delivery of SCIg by suppliers

This option proposes that upcoming NBA contracts with SCIg suppliers are negotiated to provide home delivery of SCIg products, equipment and consumables. This would be dependent on each jurisdiction obtaining approval for non-pharmacy dispensing of SCIg across all jurisdictions (Option 12).

Implementation of this option would be led by the NBA, who would renegotiate existing supplier agreements to deliver SCIg products and associated consumables to patients.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**Medium (2)**	• **Feedback from the PWG suggested that this option would have a low impact on optimising SCIg uptake.** This was reflected in feedback provided through the PWG survey, where this option ranked 16th out of 19 for impact on SCIg usage. • However, stakeholder consultations and survey feedback suggested that removing barriers associated with the collection of SCIg and consumables may increase the uptake of SCIg.
Necessity *Is the option necessary?*	**Low (1)**	• **Most members of the PWG believed that this option was not necessary**, as home delivery by suppliers may cause fragmentation of care and would not encourage integrated treatment and follow-up with hospital-based healthcare providers for other comorbidities. • **Stakeholder consultations suggested that widespread support exists for home delivery of SCIg products to patients** to remove barriers associated with patients travelling to hospitals to pick up SCIg products. Home delivery was also considered to be valuable to incentivise patients to transfer from IVIg to SCIg.

Criterion	Rating	Rationale
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Low (1)**	• **Initial discussions with suppliers highlighted support for this option**, subject to state and territory regulations being amended to allow for non-pharmacy dispensing of SCIg. However, it was acknowledged that this may be a lengthy process. • **It is unlikely that this option would be supported by the NBA**, even if jurisdictions can implement changes to regulatory arrangements to facilitate this option. Furthermore, it has been noted by NBA staff that any renegotiation of contracts is not likely to occur before 1 Jan 2026 (the end of existing arrangements).
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**High (1)**	• **Implementation of Option 14 would require a significant level of effort and planning**, including: – significant coordination to achieve regulatory change in each jurisdiction to allow non-pharmacy dispensing of SCIg (Option 12) – coordination of dispensing. There would need to be communication between SCIg nurses and suppliers to ensure correct vial sizes are dispensed – logistics with delivery, including meeting cold chain requirements (which may be difficult with regular major weather events), and access to home delivery in rural and regional areas – additional funding to suppliers for transport and delivery costs. • **Feedback from the PWG suggests that implementation of this option would be very difficult**, with the option scoring 18th out of 19 for overcoming barriers to implementation in the PWG survey.
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**Medium (2)**	• **Cost impacts associated with this option are expected to be medium**. – The largest component of costs would relate to additional costs to the NBA for the coordination of home delivery to patients. Although negotiation with suppliers would be required to estimate these costs accurately, if over 2,000 patients receive SCIg deliveries 10 to 12 times per year, delivery would cost at least $1 million per year[44] – Upfront costs would also be incurred by the NBA for the renegotiation of contracts with suppliers to include delivery of the product and associated consumables in the unit price • **This option would result in some cost shifting from jurisdictions (who are currently responsible for supplying SCIg to patients) to the NBA**. Some costs would be offset by not having to distribute SCIg products via Lifeblood to hospitals, however, the quantum of these costs is not known.
Total score	**7**	• **This option was not recommended**, as it was perceived to cause potential fragmentation of care by disrupting arrangements for patients to access integrated treatment and follow-up with hospital-based healthcare providers for other comorbidities. • It would also require substantial effort to achieve regulatory change in each jurisdiction to allow for non-pharmacy dispensing of SCIg, which was considered unlikely to be achievable. • This option would also be dependent on the implementation of Option 12 (changes to state/territory regulations to allow non-pharmacy dispensing of SCIg), which is not recommended.

[44] This cost assumes 2,000 patients access 10x home deliveries per year at an additional cost of $50 per delivery.

C.4.4. Option 15: Home delivery of SCIg by hospitals

This option proposes that the NBA, jurisdictional health departments and hospitals develop arrangements for home delivery of SCIg by hospitals. The success of this option would be contingent on capturing costs associated with home delivery as part of updated national or jurisdictional funding models for SCIg delivery. It could provide an alternative to home delivery by suppliers (Option 14) if all jurisdictions are unable to amend their regulations to allow non-pharmacy dispensing of SCIg.

Implementation of this option would be led by the NBA and jurisdictional health departments, who would need to establish arrangements with health services and to deliver SCIg products, consumables and equipment to patients.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**Medium (2)**	• **Feedback from the PWG suggested that this option would have a very low impact on optimising SCIg uptake**, as it ranked 18th out of 19 options for impact in the PWG survey. • However, stakeholder consultations and survey feedback suggested that removing barriers associated with the collection of SCIg and consumables may increase the uptake of SCIg.
Necessity *Is the option necessary?*	**Low (1)**	• **Most stakeholders believed that this option was not necessary**, as home delivery by hospitals may cause fragmentation of care and not encourage integrated treatment and follow-up with hospital-based healthcare providers for other comorbidities. • **This option scored lowest for necessity in the PWG survey**, with a rating of 2.85 out of 5**.**
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Low (1)**	• **It is unlikely that this option would be supported by the NBA**. Significant changes would need to occur to coordinate home delivery, and it is unlikely to impact on SCIg uptake and is not seen to be necessary. • **This option also scored lowest on likelihood to be supported by the lead organisation in the PWG survey**, with a score of 2.85 out of 5.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**High (1)**	• **Implementation of Option 15 would require a significant level of effort and planning**, including: – additional funding for staff resources in hospitals to manage home delivery – the additional workload for pharmacy assistants/pathologists/ SCIg nurses to package the product – logistics with delivery, including arrangements for coordination between hospital staff and transport companies to ensure cold chain requirements would are met, and access to home delivery in rural and regional areas – discussion around how smaller hospitals that provide SCIg would be able to implement home delivery. • **Feedback from the PWG suggests that implementation of this option would be very difficult**, with the option scoring lowest for overcoming barriers to implementation in the PWG survey.
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**Medium (2)**	• **Cost impacts associated with this option are expected to be high**. Securing funding to offset additional delivery and SCIg management costs for hospitals would be an essential prerequisite to this option being feasible. – Upfront costs would be incurred for additional funding of staff resources and equipment to coordinate home delivery – Ongoing costs for packaging of the product, transport and delivery would be incurred. • **It is suggested that this option should not be considered until nationally consistent funding arrangements for SCIg are established**

Criterion	Rating	Rationale
		• **This option would result in all costs for SCIg supply/dispensing being incurred by jurisdictions**. Unlike Option 10, no costs would be offset, as Lifeblood would still need to provide SCIg to hospitals.
Total score	**7**	• **This option was not recommended, as it** would require significant coordination between hospital staff and transport companies to ensure cold chain requirements are met, and access to home delivery can occur efficiently in rural and regional areas. This would be costly and may take SCIg nursing resources away from core clinical duties.

C.4.5. Option 16: Establish jurisdictional state-wide SCIg coordinators

This option proposes that state and territory health departments each establish and fund state-wide SCIg co-ordinator roles. These roles would support the planning and implementation of the SCIg Program in health services, increase awareness of SCIg and better support both patients and SCIg nurses.

Implementation of this option would be led by jurisdictions, who would employ state-wide SCIg coordinators to optimise uptake of SCIg in each jurisdiction and work towards a more nationally consistent approach to SCIg delivery.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**Medium (2)**	• There were mixed views about the impact of this option on SCIg uptake, but **on balance, this option was not expected to have a significant positive impact**: – one PWG member believed that state-wide SCIg coordinators would "provide an excellent basis for networking across the sector and assist in promulgating important and relevant information out to each SCIg Program." Another member highlighted that state-wide SCIg coordinators "could help the coordination of smaller SCIg programs or health services that are unable to provide this service" – however, one PWG member expressed concern that this option would adversely impact SCIg uptake, stating "state-wide coordination of SCIg support services may detract from the care supplied by the local primary service of the patient." • **These views were reflected in a low overall rating for impact in the PWG survey**, as it rated is option rated 14th out of the 19 options with a score of 3.79 out of 5.
Necessity *Is the option necessary?*	**Low (1)**	• **Stakeholder consultations identified that where state-wide SCIg coordinators exist that they are highly valued**. State-level SCIg coordinators have been told by other SCIg nurses that "they would love to have a state-wide SCIg co-ordinator role in their jurisdiction" to manage the coordination and communication between different hospitals. • **However, this option was not deemed necessary by most PWG members**, who believed that other options would have a greater impact on optimising SCIg usage. • **This option was rated low on necessity in the PWG survey** as it ranked 15th out of the 19 options presented.
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Low (1)**	• **PWG members believed that support from jurisdictional health departments for this option would be difficult to obtain**. This option would require defining the roles of a state-wide SCIg co-ordinator, how many positions are required per population of SCIg patients, and how they aim to work with health services. This may be difficult as different jurisdictions will have differing views on these issues. • These views were reflected in the PWG survey, where **this option rated 15th out of the 19 options on support by the lead organisation**.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**High (1)**	• Overall, **the PWG was sceptical that this option would be viable** due to: – perceived high levels of implementation effort to define the roles of a state-wide SCIg co-ordinator, including how they will interact with health services – challenges securing resourcing and funding for these positions by jurisdictional health departments.

Criterion	Rating	Rationale
		• **This option rated 15th out of 19 options for the ability to overcome barriers to implementation in the PWG survey.**
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**Medium (2)**	• Fractional appointment of senior nurse resources is likely to cost in the order of $70,000 to $90,000 per position, per year (**$560,000 to $720,000 across Australia per year**). • **Consideration could also be given to having a Nurse Practitioner play the role of state-wide SCIg co-ordinator**, due to the extra responsibilities and training required. Nurse Practitioner resources are likely to cost in the order of $125,000 to $135,000 per position, per year ($1,000,000 to $1,080,000 across Australia per year). • **No cost shifting impacts would be expected** from the implementation of this option.
Total score	**7**	• **This option was not recommended**, as it would require all jurisdictional health departments to support this option. Feedback suggests that this would be difficult to obtain due to a low level of support for this option among jurisdictions and a low likelihood that a nationally consistent approach could be achieved.

C.5. Options relating to guidelines, documents and data

Three options were proposed to address issues in guidelines, documents and data:

(1) Review, update and enhance the National Policy (Option 2)

(2) Develop nationally consistent guiding documentation on SCIg delivery (Option 4)

(3) Improve reporting on SCIg use to jurisdictional health departments (Option 5).

C.5.1. Option 2: Review, update and enhance the National Policy

This option proposes that the NBA reviews and updates the National Policy to provide more clarity to providers and improve consistency in how SCIg is delivered across Australia. Suggested changes include:

- **clarifying the status of Ig under the Poisons Standard** to ensure that hospitals are aware of their regulatory requirements for managing and dispensing/supplying Ig products. Several jurisdictional health departments and hospitals identified that they were not aware of this requirement, and it is not currently recognised in the National Policy and hospital responsibilities. Section 5.1 of the current policy could be updated to include specific references to the Poisons Standard where the policy references "any other applicable state or territory legislative requirements."
- **broadening terminology to recognise SCIg can be provided in settings other than hospitals**. Provision of SCIg outside of hospital settings currently occurs to a limited extent but was viewed as a potential constraint on the expansion of SCIg programs into non-hospital settings such as clinics. Suggested updates should include:
  - changing references to "hospital-based SCIg programs" and "hospitals participating in the SCIg Program" to reference "service providers" in Chapter 3.2 of the National Policy
  - re-naming terminology the *Hospital Acknowledgement Form for the National Subcutaneous Immunoglobulin Program* to refer to the "Service Provider Acknowledgement Form"
  - harmonising requirements for what organisation is responsible for completing the acknowledgment form across all jurisdictions. Currently, different arrangements for completing the form apply across jurisdictions, which does not support a nationally consistent approach to management and oversight of the SCIg Program
- **ensuring that Chapter 4 of the National Policy includes specific reference to processes associated with access to SCIg** across initial authorisation, ordering and dispensing/supplying, dose change/additional dosing and review and continuing treatment processes. Currently, only some processes associated with SCIg are included in this information.
- **re-considering how requirements are framed for hospitals to deliver initial education and training to SCIg patients** (as some hospitals use the training provided by suppliers).

Several other updates would also need to be made to the National Policy if the recommendations made in this report are accepted. These include:

- **updating responsibilities for funding and resourcing SCIg programs** if national funding arrangements under options 1, 2, 3 or 12 are implemented
- **considering whether minimum requirements for pumps, consumables and equipment would need to be referenced in the National Policy** (Option 2) to ensure broad understanding and consistency with the Policy

- **updating approved access requirements for SCIg to reflect any changes arising from Option 1** to promote the initiation of treatment using SCIg where clinically safe and appropriate to do so. Processes for access to SCIg in Section 4 of the National Policy would also need to be updated to reflect these changes.

Based on the feedback from jurisdictional health departments and patient groups throughout this project, **is recommended that the following requirements for SCIg patients not to incur out-of-pocket costs should be retained**, in:

- section 3.2 of the National Policy (i.e. "Hospitals participating in the National SCIg Program are required to…take full accountability for the management and use of the product within defined governing requirements, *and at no additional cost to patients*").
  - however, the NBA should consider updating wording in Section 3.2 to clarify that patients should not incur any out-of-pocket costs by removing the word "additional", i.e. "Hospitals participating in the National SCIg Program are required to…take full accountability for the management and use of the product within defined governing requirements, *and at no cost to patients*")
- the "Education and training" section of the Hospital Acknowledgement Form for the National Subcutaneous Immunoglobulin Program (i.e. "Service providers delivering the SCIg Program must ensure that patients have access to all necessary equipment and consumables to administer the product, at no cost")
- **the Tools and Resources in Section 6 of the National Policy** to reflect links to the suite of updated resources that are recommended in Option 4. In the interim, documents considered 'best practice' that is published by states, territories or individual health services could be referenced in this Section.

Implementation of this option would be led by the NBA, which has responsibility for the National Policy. Stakeholder feedback suggested that a working group with representation from both health professionals (medical/nursing/transfusion scientist /pharmacist representation) and jurisdictional health departments could help review the existing National Policy to ensure all required changes are identified and any changes are clear, align with contemporary clinical practice and promotes a more nationally consistent approach to oversight and delivery of the SCIg Program.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**Medium (2)**	• **The PWG perceived that changes to the National Policy would have a high impact on SCIg uptake**, as this option scored 2nd out of 19 for impact in the PWG survey. • One PWG member highlighted that there are weaknesses and misinterpretations of the current National Policy and that addressing them would help to optimise SCIg uptake. However, the overall impact on uptake would depend on the nature of changes that are processed and how they are operationalised.
Necessity *Is the option necessary?*	**High (3)**	• **A desire for a more nationally consistent approach to delivering SCIg was a key theme to emerge from both stakeholder consultations and PWG feedback**. The National Policy is considered a key mechanism to drive this outcome. • **Many health services identified that they were unaware that the National Policy existed, or that they were unable to find what they needed in the current National Policy** (e.g. more detailed explanations as to how to establish a SCIg Program in their health service).

Criterion	Rating	Rationale
		• **There was a strong view among most stakeholders that updates to the National Policy are essential** as they would provide more clarity to clinicians and improve the consistency in how service providers maintain SCIg programs across Australia. • **Feedback from the PWG also reflected a clear desire for changes to the National Policy**, as this option rated highest out of the 19 options for necessity in the PWG survey.
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**High (3)**	• **This option is expected to be supported by the NBA**, as changes to the National Policy are likely to be a key driver of improved national consistency in how SCIg is delivered. • A nationally consistent approach to delivering SCIg was a key theme to emerge from consultations with clinicians and jurisdictional health departments, and **there is high support among most stakeholders** for changes to the National Policy. • **The strong support for this option was reflected by the PWG survey**, where this option rated the highest of all 19 options for support from the lead organisation.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**Medium (2)**	• **Implementation of this option would require a moderate amount of effort. Most effort would be required by the NBA**, which would lead the process to engage its stakeholders and make updates to the Policy. However, a wide variety of stakeholder groups will need to have input into the process: – the NBA would need to lead the process to agree on what changes need to be made, and to seek feedback from its stakeholder groups on how such changes could be made to improve the National Policy and any impacts on these stakeholder groups – a working group with representation from both health professionals (medical/nursing/transfusion scientist /pharmacist representation) and jurisdictions were suggested as a mechanism to provide feedback on proposed changes. However, existing NBA governance groups could be used for this purpose – the NBA would need to communicate agreed changes and new policies to the blood sector, and ideally, directly to hospitals participating in the National SCIg Program.
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**Low (3)**	• **Cost impacts associated with this option for the NBA and other stakeholders are expected to be low**. • **Costs would be incurred by the NBA** for its staff to review and update the existing National Policy, although these could likely be accommodated within the NBA's existing funding envelope. • **Other stakeholder groups would incur costs to engage in the process to provide feedback and advice** on proposed updates, although new funding would not be required for this purpose. • **No cost shifting impacts would occur** if this option is implemented.
Total score	**13**	• **This option is recommended**, as a desire for a more nationally consistent approach to delivering SCIg was a key theme to emerge from both stakeholder consultations and PWG feedback. The National Policy is considered a key mechanism to drive this outcome. • This option is seen to be necessary by stakeholders, would be supported by the NBA and would not be costly to implement. This option was rated the highest in the PWG survey out of the 19 options that were presented.

C.5.2. Option 4: Develop and publish nationally consistent guidance documentation to optimise the SCIg service model

This option proposes that the NBA works with jurisdictional health departments and hospitals to develop a suite of updated guidance material that aims to promote a more nationally consistent approach to delivering SCIg services. At present, guidelines for establishing and operating SCIg programs are published separately by jurisdictional health departments and hospitals. This includes material such as promotional posters, conversation starters, business case templates, process flowcharts, letters, clinical practice guidelines, ordering requirements, patient assessment forms and patient infusion guides.

Several stakeholders suggested opportunities exist for the NBA to identify the most effective guidance, identify gaps, develop materials that address any gaps and publish required materials to support a more nationally consistent approach to SCIg delivery. These could potentially be useful resource sets that could be published on the NBA's website. Some of the suggested documents that the NBA could consider compiling and publishing on its website may include:

- best practice guidance, processes and advice for hospitals on how to establish and operate a SCIg Program
- specifying minimum requirements for pumps, consumables and equipment
- providing clinical practice guidelines for how the SCIg service model should operate, including the nature and frequency of touch points between clinicians (doctors and nursing staff) and patients
- promotional materials to clinicians and patients
- process flowcharts which could be published as part of an updated National Policy
- guidance for patients on infusion, accessing SCIg while travelling and on sharps disposal arrangements.

Implementation of this option would be led by the NBA, who would coordinate the process to review and update documentation on SCIg. NBA would also coordinate input from a working group with representation from both health professionals (medical/nursing/transfusion scientist /pharmacist representation) and jurisdictional health departments - either from within its existing committee structure or as a special purpose advisory group.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**Medium (2)**	• **Most PWG members suggested that this option would optimise SCIg uptake** by working towards a more nationally consistent approach to maintaining SCIg programs in health services. This option scored equal 8th out of 19 options for impact in the PWG survey. • **However, this view was not widespread**. One PWG member stated that "until there is a unified process to access SCIg/methods, it is hard to think that a unified guiding document(s) will have much impact".
Necessity *Is the option necessary?*	**Medium (2)**	• **There was a strong view that nationally consistent guidelines on SCIg are required** because current guidelines vary between states and hospitals. Developing a suite of updated guidance material could also help to reinforce messages in the National Policy.

Criterion	Rating	Rationale
		• **However, other options (mainly those related to funding) rated more highly on this criterion** in feedback obtained through the PWG survey. This option rated 7th out of 19 options for necessity.
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Medium (2)**	• Although **support for this option has not specifically been tested with the NBA, it is expected that it would likely be supported**. • **Stakeholder feedback suggests that this option would be supported by jurisdictional health departments and hospitals**, who expressed a strong desire for more national consistency in guidance on establishing and maintaining a SCIg Program. • However, it was highlighted by one PWG member that guiding documents and positions would need to be backed up by appropriate funding models, which are likely to represent a higher priority overall.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**Medium (2)**	• Implementation of Option 4 would require a moderate amount of effort by the NBA, which would lead the process to identify and adapt existing guidance material in consultation with state and territory health departments and individual health services that have published guidance material. Key activities would include the NBA, jurisdictional health departments and patient groups working together to: – prioritise the guidance documentation that is required – identify and collate existing guidance material related to agreed priority areas – agree how existing materials could be adapted (where required) to meet key needs – develop new supporting documentation where gaps exist in the current documentation – publishing the suite of documentation for comment and feedback before seeking endorsement from relevant NBA governance groups – uploading the documents to a central repository of SCIg resources that are publicly accessible on the NBA website.
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**Low (3)**	• **Cost impacts associated with this option for the NBA and other stakeholders are expected to be low**. • **Costs would be incurred by the NBA** for its staff to review and update existing documentation, although these could likely be accommodated within the NBA's existing funding envelope. • **Other stakeholder groups would incur costs to engage in the process to provide feedback and advice** on proposed updates, although new funding would not be required for this purpose. • **No cost shifting impacts would occur** if this option is implemented.
Total score	**11**	• **This option is recommended**. There is an opportunity for the NBA to identify the most effective guidance materials that exist across Australia and to develop a consistent resource set that could be published on the NBA's website. Development of the resource set could also involve developing new materials where gaps exist. • This option would not be costly to implement and could be a 'quick win' to increasing the uptake of SCIg.

C.5.3. Option 5: Improve reporting on SCIg use to jurisdictional health departments

This option proposes that the NBA develops more detailed annual reports (or 'league tables') at the jurisdiction and hospital level on SCIg usage. Jurisdictional Reports are currently provided to NBA's JBC representatives and their nominees. These reports provide information on the Ig dispensed/supplied for each state and territory. However, the granular data collected through BloodSTAR could allow the development of more detailed annual reports (or potentially, 'league tables'). These reports would benchmark hospitals or clinicians against average proportions of SCIg usage as a proportion of total eligible patients and be provided to NBA governance groups and jurisdictional health departments to inform targeted action to optimise SCIg uptake.

Implementation of this option would be led by the NBA, which would review and improve the data that is provided by BloodSTAR to jurisdictional health departments.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**Low (1)**	• **Feedback from the PWG suggested that this option would have a low impact** on optimising SCIg uptake unless funding and resourcing models for SCIg are improved. • **The low perceived impact of this option was reflected in the PWG survey**, where it scored equal 12th out of 19 options for impact.
Necessity *Is the option necessary?*	**Medium (2)**	• **There were mixed views about the necessity of this option**, with: – stakeholder feedback indicating that there are substantial opportunities to improve the reporting jurisdictional health departments receive from the NBA – however, several PWG members expressed a low level of confidence in the data provided by BloodSTAR to jurisdictional health departments, which means there is scepticism about the value of data-driven initiatives. • **The necessity of this option was perceived to be low by the PWG**, as it ranked 13th out of 19 options for necessity in the PWG survey.
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**Medium (2)**	• **Support for this option has not been tested with the NBA**. For this reason, it has been allocated a 'medium' rating on this criterion.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**Low (3)**	• **Implementation of this option would require minor changes to the current process for the NBA and its governance groups, which are unlikely to present significant barriers to implementation**. Key changes would include: – NBA using existing BloodSTAR data collections to develop more granular hospital and clinician-level reports on SCIg usage for dissemination to jurisdictional health departments. This process would benefit from engagement with state and territory health departments to ensure that reports provided to hospitals and jurisdictional health departments are useful, consistent and timely – jurisdictional representatives could then use the data in these reports to implement targeted initiatives to optimise SCIg uptake in specific hospitals. Jurisdictional health departments would need to allocate resources and establish/leverage ongoing communication channels with health services to ensure discussion with specific hospitals as required

Criterion	Rating	Rationale
		• **Several PWG members suggested that for this option to be workable, the JIPI Group meetings would need to be reinstated.** This group hasn't met for over 12 months.
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**Low (3)**	• **Cost impacts associated with this option are expected to be low**, as it leverages existing data and reporting arrangements. – Initial costs would be incurred by the NBA to review and update the current reports provided by BloodSTAR, however, any changes could likely be made within existing resources and without needing to implement significant changes to reporting systems. • **Staff time within state and territory health departments would also be required** to provide input to the process to develop the new suite of reports, however, these would also be accommodated within existing resources. • **No cost shifting impacts would occur** if this option is implemented.
Total score	**11**	• **This option is recommended.** It could provide necessary ongoing review of SCIg programs, which is not currently consistent across jurisdictional health departments. It could also support the implementation of targeted initiatives to optimise SCIg uptake in specific health services where SCIg uptake (as a proportion of eligible IVIg usage) is below average, or below another benchmark that could be established using BloodSTAR data. • This option would be easy to implement, would not be costly and could be a 'quick win' to increase SCIg uptake.

C.6. Other

One option was proposed in this section:

(1) Disposal of sharps containers (Option 6)

C.6.1. Option 6: Disposal of sharps containers

This option proposes that the NBA, in conjunction with patient advocacy groups, approaches the Pharmacy Guild of Australia to obtain an agreement for community pharmacies to accept full sharps containers from SCIg patients.

Implementation of this option would be led jointly by the NBA and patient advocacy groups, who would work together to negotiate with the Pharmacy Guild of Australia to identify a funded approach to the disposal of medical waste from SCIg treatment through community or hospital pharmacies.

Criterion	Rating	Rationale
Impact on SCIg uptake *Will the option increase SCIg uptake?*	**Low (1)**	• While a nationally consistent disposal agreement via community pharmacies would address significant challenges for patients, **this option would have a low impact on optimising SCIg uptake**. • **This option scored the lowest out of the 19 options for impact in the PWG survey**.
Necessity *Is the option necessary?*	**Medium (2)**	• **The disposal of sharps containers is a significant issue for SCIg patients** and has been highlighted as a substantial area of concern by patient groups. The disposal of sharps containers is commonly raised on patient forums as a significant challenge. From this perspective, this is a necessary change. • **Many local councils offer sharps disposal services**, so this option may not be necessary for SCIg patients in all locations. • However, this option was not seen as impactful and necessary for SCIg uptake as other options (e.g. funding options). **Overall, this option scored equal 11th out of 19 options for necessity in the PWG survey.**
Likely support by lead organisation(s) *Will the proposed lead organisation implement the option?*	**High (3)**	• **This option is likely to be supported by the NBA and would be strongly supported by patient advocacy groups.** • Although the Pharmacy Guild was not consulted during this project, it is expected that support from the Pharmacy Guild of Australia would be dependent on securing funding for equipment to dispose of medical waste appropriately.
Implementation effort/feasibility *What barriers to implementation are likely? Can they be overcome?*	**Medium (2)**	• Implementation effort for this option is medium and would require significant advocacy and engagement by SCIg patient groups (AUsPIPS, IDFA and GBS Association), who would lead advocacy efforts with the NBA playing a coordinating role. – The NBA and patient advocacy groups (AusPIPS, IDFA and the GBS Association) would approach the Pharmacy Guild to seek accordance for community pharmacies to accept full sharps containers from SCIg patients. The Pharmacy Guild would need to be in agreeance with this option for it to proceed (this is currently untested) – If a suitable approach could be agreed upon, the NBA, patient advocacy groups and Pharmacy Guild would communicate agreed changes to health services, patients and pharmacies across Australia – Funding for this option would be provided by the NBA

Criterion	Rating	Rationale
		• **Alternatively, the NBA could contract with environmental protection agencies** (as some local councils have done) to collect and dispose of sharps containers safely. • **Supports (particularly funding) would need to be in place for this option to be viable**. To overcome funding issues for community pharmacies, this option could potentially be incorporated into Option 8d (the bundling of consumables and equipment into the SCIg unit price). This may be similar to clotting factor models which supply sharps containers with their products (however these models have different disposal options depending on local councils).
Cost impacts *What costs would be required to implement the option? Who would bear them? Would there be cost shifting impacts?*	**Low (3)**	• **Cost impacts associated with this option are expected to be low overall (below $1 million per year)**. – Upfront and ongoing costs would be incurred by the NBA to ensure community pharmacies have the equipment in place to dispose of medical waste appropriately. • **This option would result in some costs being shifted** from health services, local governments and patients (who are currently responsible for sharps disposal) to the NBA (assuming the NBA would agree to fund costs associated with the disposal of SCIg-related medical waste on behalf of community pharmacies).
Total score	**11**	• **This option is recommended, as the disposal of sharps containers is a significant issue for SCIg patients and has been highlighted as a substantial area of concern by patient groups.** It is commonly raised on patient forums as a negative experience, as often community pharmacies will refuse to dispose of full sharps containers due to the cost of disposal. • The current process of disposal of sharps containers was reported to be “humiliating,” “discriminating” and “shameful” for multiple patients. This can lead to SCIg patients feeling judged about their condition and has led to some patients being reluctant to continue on SCIg • Although this option may not have a substantial impact on SCIg uptake, it would elevate this issue for SCIg patients and address a key inconvenience associated with using SCIg.

Appendix D: Project Working Group survey data

Data analysis was completed for the 19 options, based on the scoring of PWG survey responses against each of the six criteria. The options have been sorted into three categories: recommended options, options to consider and options that aren't recommended (Figure 7). A green-red colour scale has also been applied to each of the criteria, where green cells highlight criteria on which an option has scored well on, and red cells highlight criteria that an option has not scored well on. The options have been sorted in Figure 7 based on their overall score across all criteria (out of 5). The options are numbered as they were listed at the time of the survey.

Figure 7: Survey data analysis of all options

Option	Do you think implementation of this option will have an impact on SCIg usage?	If this option is progressed, would it be implementable by a health service?	Do you think this change is likely to be supported by the proposed lead organisation?	This option could be implemented with a reasonable amount of work by the proposed lead organisation	Could any barriers to implementation of this option be easily overcome?	This option is necessary	Overall
• Option 7: Review, update and enhance the National Policy	4.29	3.77	4.08	3.77	3.62	4.38	3.98
• Option 5: Consider SCIg for initiation of Ig treatment where clinically suitable	4.21	4.08	3.85	4.00	3.31	4.23	3.95
• Option 9: Distribute SCIg via community pharmacies	4.21	3.77	3.92	3.92	3.54	3.92	3.88
• Option 3: Establish national funding under the National Blood Arrangements	4.27	4.07	3.80	3.53	3.53	4.00	3.87
• Option 1: Establish national ABF funding for SCIg under non-admitted Tier 2 clinics for public patients	4.17	3.94	4.00	3.73	3.33	3.94	3.85
• Option 12: Bundle consumables & equipment into SCIg unit price	3.94	3.87	4.07	3.80	3.47	3.73	3.81
• Option 4: Improve education and awareness of SCIg among clinicians and consumers	4.13	3.67	4.00	3.60	3.40	4.07	3.81
• Option 17: Nationally consistent guiding documents to support National Policy	4.00	3.85	3.77	3.46	3.69	3.92	3.78
• Option 2: Establish bundled or capitalisation funding models through IHACPA for public patients	4.35	3.81	3.67	3.40	3.27	4.00	3.75
• Option 19: Extend SCIg services to clinic or private nursing services	4.00	3.85	3.85	3.69	3.15	3.92	3.74
• Option 15: Disposal of sharps containers	3.00	3.62	3.92	4.00	3.85	3.85	3.71
• Option 6: Establish SCIg as a hospital substitution treatment with private health insurers for private hospital fu	4.06	3.76	3.56	3.50	3.31	3.88	3.68
• Option 18: Improve reporting on SCIg use to jurisdictions	3.79	3.38	3.54	3.62	3.38	3.69	3.57
• Option 8: Change to state/territory regulatory arrangements to allow non-pharmacy supply of SCIg	3.64	3.77	3.54	3.54	3.08	3.38	3.49
• Option 16: Establish dedicated jurisdictional-level SCIg funding (similar to Victoria)	3.79	3.71	3.15	3.15	3.00	3.43	3.37
• Option 13: Establish jurisdictional state-wide SCIg coordinators	3.71	3.15	3.38	3.23	3.08	3.54	3.35
• Option 14: Enhance jurisdictional SCIg service planning and coordination	3.57	3.31	3.38	3.15	2.92	3.62	3.33
• Option 10: Home delivery of SCIg by suppliers	3.64	3.38	3.31	3.23	2.92	3.23	3.29
• Option 11: Home delivery of SCIg by hospitals	3.29	2.85	2.85	2.77	2.77	2.85	2.89

Appendix E: Stakeholder consultations

Table 18: Initial consultations

Group/Organisation	Date of consultation	Group/Organisation	Date of consultation
Professor Robert Moulds (chair of NIGAC)	06/05/2022	**ACT Jurisdiction**	09/05/2022
NIGAC	27/05/2022	**WA Jurisdiction**	19/05/2022
Immunology Specialist Working Group	30/05/2022	**QLD Jurisdiction**	13/05/2022
Haematology Specialist Working Group	25/05/2022	**Tas Jurisdiction**	18/05/2022
Neurology Specialist Working Group	25/05/2022	**SA Jurisdiction**	25/05/2022
Victoria Blood Matters	05/05/2022	**NSW Jurisdiction**	11/05/2022
ASCIA	30/05/2022	**Commonwealth Department of Health and Aged Care**	25/05/2022
Australian Red Cross Lifeblood	23/05/2022	**CSL Behring**	17/06/2022, 07/07/2022
NBA	31/05/2022	**Takeda**	24/05/2022
AusPIPs	15/06/2022	**IDFA**	3/6/2022

Table 19: Health Services consulted

Health service	Jurisdiction	Date of consultation	Health service	Jurisdiction	Date of consultation
The Canberra Hospital	Australian Capital Territory	7/7/2022	**Royal Darwin Hospital**	Northern Territory	22/6/2022
Western NSW LHD and Forbes Hospital	New South Wales	1/7/2022	**Townsville Hospital**	Queensland	21/6/2022
Sydney Children's Network	New South Wales	13/7/2022	**Royal North Shore Hospital**	New South Wales	25/8/2022
Cobar Hospital	New South Wales	10/6/2022	**Sunshine Coast Hospital**	Queensland	15/7/2022
Calvary Mater Newcastle Hospital	New South Wales	15/6/2022	**Northwest Regional Hospital**	Tasmania	1/7/2022
Flinders Medical Centre	South Australia	22/7/2022	**Launceston General Hospital**	Tasmania	3/8/2022
Women's and Children's Centre	South Australia	28/7/2022	**Peter MacCallum Cancer Centre**	Victoria	12/7/2022
Royal Perth Hospital	Western Australia	20/6/2022	**Monash Medical Centre**	Victoria	21/6/2022
Onslow Hospital	Western Australia	17/6/2022	**Latrobe Regional Hospital**	Victoria	20/6/2022

Table 20: Pathologies and Community Pharmacies consulted

Group/Organisation	Date of consultation	Group/Organisation	Date of consultation
SA Pathology	11/8/2022	Flinders Medical Centre	22/7/2022
Royal Darwin Hospital	22/6/2022	Monash Medical Centre	18/7/2022
Pathology Queensland	14/7/2022	West Gosford Amcal Pharmacy	12/7/2022
The Canberra Hospital	21/7/2022	Kanwal Medical Centre Amcal Pharmacy	18/7/2022