Consultation Paper on the Pricing Framework for Australian Public Hospital Services 2023-24

What changes, if any, to the national pricing model should IHPA consider to account for innovative models of care and services related to virtual care?

This submission supports subcutaneous immunoglobulin (SCIg) homed-based therapy as an innovative model of care supporting hospital avoidance to be included in the national pricing model.

Background

The supply of immunoglobulin products for the treatment of conditions identified in the 'Criteria for the clinical use of immunoglobulin in Australia' (the Criteria), is funded by all governments through the national blood arrangements.

Management of standardised access, supply and tracking of immunoglobulin is recorded in the National Blood Authority (NBA) national BloodSTAR (Blood System for Tracking Authorisations and Reviews) system. Subcutaneous immunoglobulin (SCIg) has been available through in the national blood arrangements since 2013 and 2019 for five conditions specified in the Criteria.
https://www.blood.gov.au/SCIg

The NBA approval process ensures governance requirements are met prior to approving a hospital based SCIg program SCIg-hospital-acknowledgment-form-2021.pdf (blood.gov.au)

1.Service description

SCIg is derived from large pools of human plasma for immune replacement or immune modulating therapy.
Home-based SCIg therapy, for eligible patients, is an alternative and equivalent therapy to intravenous immunoglobulin (IVIg) which usually requires day case hospital admission every 3-4 weeks.
SCIg infusions are given by slowly injecting the purified immunoglobulin into the fatty tissue just underneath the skin and is often self-administered or administered by a trained carer in the patient's home.

In Victoria, 22 hospitals have received approval from the NBA to commence a hospital based SCIg program to offer eligible patients this home-based treatment. Currently 13 metro hospitals and 9 regional hospitals throughout Victoria have an approved hospital based SCIg program.

Process:

Treating specialist:

- oversees treatment of the condition, consent for treatment, patient review and approval of SCIg via BloodSTAR.

Nurse specifically trained in SCIg administration:

- ensures logistics and complete coordination of the program.
- identifies eligible patients, providing information along with the treating specialist
- provides or facilitates patient/carer education
- arranges supply of consumables and collection of SCIg (usually every 2 months)
- act as a central point of contact for patients and treating specialists.

For the administrative responsibilities, the SCIg nurse is required to update dispensing requests in BloodSTAR.

Pharmacy – ordering and dispensing of product

- As SCIg is a S4 drug it must be dispensed by a pharmacist (when dispensed for self/carer administration)
- Pharmacist must be approved to use BloodNet for ordering and dispensing of product
- Product can be dispensed by the hospital in-house pharmacy or by a local pharmacy nearer the patient's home.

While SCIg is funded through the national blood arrangements other aspects of a program such as specialist nursing support, infusion pumps, and consumables are not funded, except for the Victorian Department of Health who currently provide funding for public hospitals through the SCIg Access Program. However, for a long term sustainable national SCIg model, funding needs to be included in the national pricing model. NBA governance arrangements and state legislations related to S4 drugs create substantial work for hospital pharmacies and pathologies, to dispense SCIg, which are not recognised in the activity based funding model

These factors influence the uptake or participation in SCIg programs despite substantial evidence supporting the benefits of SCIg.

The lack of a national funding model has resulted in only 3 patients treated in private hospitals transitioning to SCIg in Victoria.

2. Patient profile

SCIg is an approved treatment for:

- Primary immunodeficiency diseases with antibody deficiency
- Specific antibody deficiency
- Acquired hypogammaglobulinaemia secondary to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)
- Secondary hypogammaglobulinaemia unrelated to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)
- Chronic inflammatory demyelinating polyneuropathy (CIDP) was added to the above SCIg approved patient conditions.

The conditions outlined above are chronic and as such treatment is generally lifelong and subject to regular review according to the Criteria.

Reported benefits of SCIg (home therapy) compared to intravenous immunoglobulin (IVIg) (admitted day patient therapy)

- Steady state of Ig levels (avoiding peaks and troughs), leading to reduced emergency department presentations and hospitalisation
- Reduced hospital bed resources per patient required, and reduced nursing time after initial training
- Potential to travel
- Patient-centred care allowing the patient to have more control
- Reduces lost time from school/employment
- Reduces patient expenses such as travel, parking, work absences
- Overall improvement of quality of life.

Patients eligible for SCIg by medical diagnosis in Victoria, (Q3 2021-2022), is 2269 (across all age groups) and currently 387 (51 paediatric) [17%] patients have transitioned from IVIg to SCIg.

Intravenous immunoglobulin:

- Requires day case hospital admission (i.e. day unit, day oncology or infusion centre)
- Approximately 4-5 hours treatment time (excluding administrative time) (range 2-8 hours) depending on IVIg dose and patient condition
- Infusions are required approximately every 3-4 weeks, with some patients requiring 2 weekly therapy
- Additional hospital admissions may be required for some patients for treatment of infections or other associated therapies.

Each IVIg admission requires multiple processes (each admission) and involves multiple staff

- Administration clerk – retrieval of medical records (if not electronic) prepare admission paperwork, complete paperwork with patient, make appointment for next treatment, discharge patient, collated notes and send for coding
- Pathology provider - pathology tests prior to treatment, complete documentation/product for specific patient
- Nurse – patient assessment including baseline observations, IV access, prime and connect IV-line, product and patient check with a second nurse, observations throughout infusion, reinforce infusion side effects, complete all documentation, remove IV access, clean patient area prior to next patient,
- Treating specialist – patient review, arrange IVIg administration order/prescription, order pathology tests, BloodSTAR ordering and documentation of review in BloodSTAR
- IVIg delivered/collected from pathology provider/blood bank/pharmacy (Orderly or other specified staff)

3. Current program expenditure

The Victorian Department of Health (DH) support public health service SCIg programs with a $600 per patient per quarter payment and public dispensing pharmacies receive $80 per patient per quarter through the SCIg Access Program. While this funding is paid to public health services and pharmacies, no formal cost analysis has been undertaken by the Victorian DH to determine the actual cost incurred from a hospital based SCIg program.

This funding assists public health services with the ongoing cost of their SCIg program, including:

- equipment and consumables required to administer SCIg,
- nursing time to educate patient/carer on administration and management of the ongoing logistics of the program.

Annual SCIg Access Program funding for 1 patient treated with SCIg = $2,720.

$2,400.00/patient/year (Victorian DH SCIg Access Program funding $600/patient/quarter) paid to the hospital & $320.00/patient/year ($80/patient/quarter) paid to the dispensing pharmacy.

Estimated annual cost for 1 patient treated with IVIg = $8,359.00 (based on an estimated WEIS payment of $643 x13 treatments)

Victorian data (Q1 2018-19 to Q3 2021-22) reflecting actual patient numbers having homed based treatment with SCIg, instead of attending hospital for a day case admission for IVIg is:

- 12,588 bed days saved (based on the assumption of 3 treatments per patient per quarter)
- 62,940 estimated day unit hours saved = cumulative bed days saved x estimated average time per treatment (5 hours)
- $8,094,084.00 in estimated WEIS payments saved = cumulative bed days saved x estimated WEIS payment of $643
- $2,839,000.00 has been paid by Victorian DH payments to health services to support SCIg Access Program.

The above costs and savings have been based on an estimated WEIS payment of $643 and the Victorian DH funding paid to hospitals through the SCIg Access Program. It is noted that MSAC Review of immunoglobulin use for primary immunodeficiency diseases with antibody deficiency (PID) *1592 Final PSD_Nov2020.pdf simplified cost-consequence analysis states that "costs for IVIg delivery was estimated to be $5,202 per patient per year, whereas SCIg delivery incurred much lower costs at $1,404.20".

In Victoria, there are currently 2,269 patients eligible to have SCIg (by medical diagnosis), this could result in a potential saving of 147,485 hours/year of treatment time. [2,269 service events (Q3 2021–2022 SCIg eligible patients by medical diagnosis) x 13 per year (4weekly treatment) = 29,497 service events x 5 hours treatment time = 147,485 hours/year]

4. Documentation/evidence to support the assessment against the General List eligibility criteria and interpretive guidelines

Australian Government Medical Services Advisory Committee (MSAC) Public Summary Document – Review of immunoglobulin use for primary immunodeficiency diseases with antibody deficiency (PID) 1592 Final PSD_Nov2020.pdf (msac.gov.au)

This review did not compare IVIg and SCIg, however it included several statements which highlight the benefits of SCIg including:
"Overall, stakeholders were highly supportive of the use of Ig to treat PID and considered that Ig significantly improves patients' quality of life and the ability to contribute to society. **Stakeholders were supportive of SCIg use and considered SCIg to be associated with fewer side effects and better patient tolerability".**

"Noted IVIg disadvantages included adverse events, regular attendance at hospital for Ig infusions, time spent travelling to hospital and waiting times for treatment due to delays in day units".

"Severe events (severe chest pain, severe wheezing/breathlessness, severe headache, severe dizziness, tightness of the throat, pressure in the chest sensation, collapse and moderate events that were persistent and could not be prevented by pre-infusion treatment with steroids and antihistamines) were rare, occurring in 0% to 5% of patients and 0% to 0.2% of infusions. These events required adrenaline, hospitalisation, withdrawal of treatment, or **changing to SCIg administration**".

"consultation feedback indicated that consumers were supportive of Ig therapy and considered Ig therapy to be superior to No Ig. For people living with PID, perceived benefits included prevention of infections, significant improvements in the quality of life and the ability to contribute to society. Noted disadvantages of Ig therapy included the burden of travelling to and attending appointments for infusions, and adverse events such as headache, nausea, fever, chills, flushing, malaise, rash, and itching. **SCIg was seen to reduce inconvenience for patients, compared with IVIg".**

In November 2018, the Australian Primary Immunodeficiency Patient Support (AusPIPs) group facilitated a consumer feedback forum.
The SCIg patient focus group involved 7 patients from 4 health services. Benefits of SCIg were broadly agreed by patients participating and reflections included:

- Gives patients control of their treatment and greater level of flexibility
- Improved quality of life
- Increase independence and it is convenient, allowing patients to continue with their activities of daily living
- Children not missing out on school or picking up infections when attending health services on a frequent basis
- Increase in patient opportunity to maintain work and other obligations
- Saves health services resources as patients do not need to be treated in facilities
- SCIg is well tolerated, and patients generally find the treatment effective.

Three Victorian health services have conducted a patient survey/questionnaire including:

Quality of life in patients with primary and secondary immune deficiency disease receiving subcutaneous immunoglobulin replacement therapy: A prospective cohort study
Results reflected:

- Adequate education experience – 100% (n=20)
- Ongoing support has met patient needs – 100% (n=20)
- SCIg is better option than IVIg – 98.75% (n=20)

Please give us a short summation of your SCIg experience?

- “So far it makes a big difference to my immune system, and it makes a huge difference to my life and a huge thank you for the help”
- ” Just so much easier you can administer when you want”
- “The initial thought of doing it at home was off putting but after training and doing it at home for the first couple of times it soon became second nature and to have more freedom during the administration time makes it more comfortable and less painful”

Further patient feedback:

- “Having to come to hospital for IVIg made me feel like I was “sick” again. I feel like I have my independence back”
- “I’m so grateful to be able to isolate during Covid”
- “I feel so well and haven’t had the run down / flu-like feeling I got from IVIg”

In summary, SCIg offers eligible patients the choice of a home-based treatment which is an alternative and equivalent therapy to IVIg supporting patient-centred care, whilst providing productivity and cost savings.
Inclusion of this therapy in the national pricing model would encourage health services to offer this treatment choice to more eligible patients.

Reference

Australian Government (MSAC) Public Summary Document Application No. 1592 – Review of immunoglobulin use for primary immunodeficiency diseases with antibody deficiency (PID)
http://www.msac.gov.au/internet/msac/publishing.nsf/Content/2167292B1B5142CDCA25845F0017A84B/$File/1592%20Final%20PSD_Nov2020.pdf

Application form for inclusion of new services on the General List

Contact Details	
Name	Anne Graham
Position	Project Nurse SCIg
Organisation	Blood Matters
Email address	angraham@redcrossblood.org.au
Phone number	0432632489
Contact person for further information	Anne Graham

Prior to completing this application form, please ensure you have reviewed the *General List of In-Scope Public Hospital Services Eligibility Policy*, available at www.ihpa.gov.au. This application form is intended as a guide only.

The General List is published in March every year as part of the national efficient price (NEP) Determination. For health services or innovative models of care and services to be considered for inclusion on, or exclusion from, the General List, the request for assessment must be received by IHPA by no later than 31 May each year.

Requests sent after that date will be considered for the following NEP Determination.

Application Details

Assessment against the General List eligibility criteria and interpretive guidelines:

This application form has been developed to assist jurisdictions in providing information that clearly demonstrates how the service or program meets one or more of the eligibility criteria outlined below:

- Closely related to an inpatient admission or an emergency department (ED) service attendance provided by a recognised ED service
- Intended to substitute for an inpatient admission or ED attendance provided by a recognised ED service
- Expected to improve the health or better manage the symptoms of persons with physical or mental health conditions who have a history of frequent hospital attendance or admission

Documentation and evidence in the application should also support the service or program's assessment against the interpretive guidelines outlined in Chapter 3. The interpretive guidelines provide detail about the key attributes of health services or innovative models of care and services that are considered to meet the eligibility criteria.

1. Service description, including (but not limited to):

- Name of service
- Local Hospital Network where the service is provided
- Geographic location (for example, is it based on hospital grounds or elsewhere)
- Composition of staff by profession (for example, number of nurses, number of doctors or allied health staff)
- Objective of care
- Commencement date of program/service
- Evidence of innovations in clinical pathways
- After hours services
- Evidence that the service is closely linked to a clinical service or governance structure
- Similarity to existing in-scope public hospital programs or services (for example, Tier 2 series)

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2. Patient profile, including (but not limited to):

- Diagnosis / presenting problems
- Age group, sex and other relevant patient characteristics
- Proportion of patients who were referred following an admission, readmission or ED presentation
- Median and average time per patient between hospital stay
- Information on the length of time patients are enrolled
- Average number of service events per enrolled patient and total number of service events
- Evidence of formal discharge protocols

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3. Current program expenditure, including (but not limited to):

- The cost of delivering the program across the jurisdiction (for example, annual expenditure, expenditure per patient)
- Proportion of expenditure which is potentially in-scope (for example, the treatment of patients for primary care in the program or by the service would be excluded as well as treatment of private patients)
- How the jurisdiction proposes to report the program or service (for example, block funded through the national efficient cost determination or through a Tier 2 class)

3. Current program expenditure

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4. Documentation/evidence to support the assessment against the General List eligibility criteria and interpretive guidelines including (but not limited to):

- Any evaluation demonstrating the program or similar programs has an impact on ED presentations or hospital admission rates (for example, the number of prevented ED service presentations/ hospital admissions, the type of patients in the target group, the number of patients in the target group seen in the community and their admission rates per year)
- Quantitative evaluations of the program or similar programs which demonstrate that it has an impact on admission rates (for example, number of prevented presentations or admissions)
- Qualitative studies around clinical governance (for example, relationship between non-government organisations and hospitals)
- Surveys demonstrating that the service supports hospital avoidance
- Longitudinal or linked data analyses of participating patients
- Additional statistical information

Please attach as Word, PDF or Excel

Declaration by applicant

I make this application on the basis that the details in this form are true and accurate.

Applicant name, position and signature	**Date**
Anne Graham Blood Matters Project Nurse SCIg	7/21/22