National Policy: Access to Government Funded Immunoglobulin Products in Australia

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CONTENTS

1 Purpose ........................................................................................................................................... 1
2 Background ....................................................................................................................................... 1
3 Principles ........................................................................................................................................ 4
   3.1 Access to government funded immunoglobulin products ......................................................... 4
4 Jurisdictional Direct Order and other supply arrangements ......................................................... 9
5 Administrative arrangements ........................................................................................................ 10
   5.1 Authorisation .......................................................................................................................... 10
   5.2 Review of patient treatment benefit for continuing access and supply ............................... 11
   5.3 Cessation of authorisation for continuing access and supply .............................................. 12
   5.4 Ordering and dispensing funded product .............................................................................. 13
   5.5 Patients travelling overseas ................................................................................................. 14
6 Roles and Responsibilities ............................................................................................................ 15
   6.1 Governance .......................................................................................................................... 15
   6.1.1 Governments ................................................................................................................ 15
   6.1.2 National Immunoglobulin Governance Committees ...................................................... 15
   6.1.3 Jurisdictional Immunoglobulin Advisory Committees .................................................. 16
   6.1.4 Hospital Management ..................................................................................................... 16
   6.2 Prescriber .............................................................................................................................. 17
   6.3 Patient (parent/carer/guardian) ............................................................................................ 19
   6.4 Authoriser ............................................................................................................................ 20
   6.5 Distributor ............................................................................................................................ 21
   6.6 Dispenser .............................................................................................................................. 22
   6.7 Registered Nurse and/or Registered Midwife ........................................................................ 23
   6.8 Couriers ............................................................................................................................... 24
7 References ...................................................................................................................................... 25
8 Definitions and acronyms ............................................................................................................... 26
9 Attachments .................................................................................................................................... 32
   9.1 Areas of accountability .......................................................................................................... 32
   9.2 Authorisation Request Forms ............................................................................................... 39
   9.3 Review Outcome Notification Form ...................................................................................... 51
   9.4 National Immunoglobulin Governance Advisory Committee (NIGAC) Terms of Reference .................................................................................................................. 53
1. PURPOSE

This document sets out the national policy position and access arrangements in relation to the supply of pooled normal human immunoglobulin products (administered intravenously, subcutaneously and intramuscularly) funded by all Australian governments under the national blood arrangements, managed by the National Blood Authority (NBA) and Jurisdictional Blood Committee (JBC). Immunoglobulin products supplied and funded under the national blood arrangements, to which this policy apply, are listed in the National Product Price List available on the NBA website at www.blood.gov.au/national-product-list1.

This document describes the roles, responsibilities, authority and accountability of those involved in requesting authorisation, authorising, supplying, managing and using government funded immunoglobulin products throughout the supply chain and within health services. This document should be read in conjunction with the Criteria for the clinical use of intravenous immunoglobulin in Australia Second Edition (Criteria)2.

This document will be maintained and updated to reflect changes in line with the development of the Immunoglobulin Governance Program and the development and implementation of the immunoglobulin authorisation and outcomes database.

2. BACKGROUND

Immunoglobulin products are human plasma derived products registered for use in Australia for the treatment of various conditions where immune replacement or immune modulation therapy is indicated. The NBA manages the contracts with suppliers of blood and blood products to ensure that Australians have an adequate, safe, secure and affordable supply.

Australia has a long standing commitment to a policy of self-sufficiency in the production and supply of blood and plasma products. Domestically produced intravenous immunoglobulin (IVIg) and subcutaneous immunoglobulin (SClglg) is made exclusively by CSL Behring, manufactured from plasma collected in Australia by the Australian Red Cross Blood Service (Blood Service) from voluntary non-remunerated donors. The supply of immunoglobulin is also imported from overseas suppliers to supplement the Australian made product to meet demand.
As immunoglobulin products are a precious and high cost resource, governments have determined the Criteria as the basis for access to government funded products. The Criteria were first published in 2007 and updated in 2012, through a process of systematic review of published evidence where available, or otherwise on a consensus of specialist opinion. The aim of the Criteria is to ensure that government funded immunoglobulin products are directed to patients whom are most likely to benefit based on reliable evidence, and where alternative therapies are limited.

National Immunoglobulin Governance Program

Governments have endorsed a program of measures, under the National Immunoglobulin Governance Program managed and coordinated by the NBA, to improve the governance and management of government funded immunoglobulin to ensure that product use and management reflects appropriate clinical practice and represents efficient, effective and ethical expenditure of government funds, in accordance with relevant national safety and quality standards for health care. The specific measures include:

- **Development and maintenance of policies and procedures for access to immunoglobulin products** - A defined set of policies and associated procedures developed and maintained, describing the roles and responsibilities of key participants in the governance and management framework for immunoglobulin products. This document forms part of this set of policies and procedures.

- **Establishment and support of a national network of committees** - It is envisaged that an integrated network of committees will be established, including the National Immunoglobulin Governance Advisory Committee (NIGAC) and specialist working groups. These committees will be integrated with a network of existing or new local governance committees and immunoglobulin user groups. The advice and recommendations of this committee network will fundamentally inform the development, implementation and ongoing operation of the other governance program measures.

- **Evolving the criteria for access** - The Criteria were issued in 2007 and updated in 2012, and have been successful in defining the eligibility for access to product funded by governments under the national blood arrangements. The Criteria will be further evolved through the improved governance framework, in particular through the role of the national committee network, improved data collection and analysis, and clinical practice development and targeted research. Considerations for the evolution of the Criteria will include appropriate evidence based clinical practice, requirements to capture clinical outcomes to build the available evidence base for future evaluation, alternative therapies and health economic evaluation of treatment options.

- **Development and implementation of a national ordering and outcomes database** - A national immunoglobulin ordering and outcomes database will support and contribute to the effectiveness of the program. The database will support the implementation of the Criteria, policies and processes for access to and management of immunoglobulin products, and will generate clinical and management information to support efficient and effective product management and appropriate usage. Improved national data will enhance the ability to further develop the Criteria, and provide a continuously improved evidence base for practice improvement and research.
Facilitate knowledge development - A knowledge development program will identify priorities for the development of better knowledge to support more informed decision making both at the clinician and system-wide management levels. In particular it will identify areas of need and evaluate the value of investment in research and in education and training to improve clinical practice, governance and management.

Development and implementation of a performance improvement program - It is envisaged that under the guidance of the national committee network, and utilising the Criteria and governance policies, and the outcomes and ordering database, and other sources which may provide relevant information, a program will be developed to monitor, assess and improve the performance of the governance system and identify improvements to systems and processes. This will include the development of key performance indicators (KPIs), reports and benchmarking processes, and an appropriate framework for auditing.

Potential efficiency improvements - In light of the other elements of the improved governance and management framework, consideration will be given to:

- automated authorisation of access to products through the national system, within appropriate safeguards, for conditions where use is sufficiently established and indications robust enough to ensure that automated approval is feasible and appropriate, and
- improved efficiency through streamlined product distribution.

Implementation of the Program will be managed and coordinated through the NBA, under the policy oversight of governments through the JBC, and working in conjunction with the range of participants involved in the governance and management of immunoglobulin products including health consumers, prescribers, nurses, health services, state and territory health departments, and product suppliers, distributors and authorisers.
3. PRINCIPLES

Blood products are provided under the National Blood Agreement at no direct cost to patients. The blood sector is funded by the Australian Government (63%) and state and territory governments (37%) based on the quantity of product provided.

The National Blood Agreement’s primary policy objectives are:

1. to provide an adequate, safe, secure and affordable supply of blood products, blood related products and blood-related services in Australia; and

2. to promote safe, high quality management and use of blood products, blood-related products and blood-related services in Australia.

3.1 Access to government funded immunoglobulin products

Guided by the National Blood Agreement policy objectives, government funded immunoglobulin products are provided to patients according to clinical need and appropriate clinical practice. Governments have determined the Criteria for appropriate and equitable access to the supply of government funded immunoglobulin products.

Immunoglobulin products should be prescribed and dispensed in accordance with any applicable state or territory legislative requirements. In hospital management of immunoglobulin products must also be in accordance with the National Safety and Quality Health Service (NSQHS) Standards, in particular Standards 1 and 7, and the Australian and New Zealand Society of Blood Transfusion (ANZSBT) Guidelines.

Authorisation

Patient specific authorisation is required for initial and continuing access to the supply of government funded immunoglobulin products. Authorisation is established by the Criteria and access rules for SCIg and access rules for NHIg. Patients may be authorised for a single dose or course of treatment with review requirements for continuing treatment, according to the Criteria. The Blood Service is contracted by the NBA to perform the role of Authoriser.

Where authorisation for initial or continuing access to the supply of product has been declined by the Authoriser, the application may be reconsidered if there are subsequent changes to the patient’s clinical circumstances such that they become eligible for access (e.g. further clarification of the diagnosis and/or changes in their clinical condition).

Review

Assessing clinical benefit of immunoglobulin treatment is required for a number of conditions, as specified in the review criteria defined within the Criteria, to determine if treatment should be continued, altered or ceased. In principle, immunoglobulin products should only be continued where there is a demonstrated clinical benefit. Written notification and appropriate evidence of the patient treatment review outcomes is required for access to continuing supply of products, where clinical benefit is evident and demonstrable.
Patients travelling overseas

Provision for the supply of product for patients temporarily travelling or studying overseas may be granted in accordance with the Policy for Issuing Blood Products and Blood Related Products in Australia For Use Overseas. For more information, please refer to the NBA website at www.blood.gov.au/supply-australians-overseas.

Intravenous immunoglobulin (IVIg)

The Criteria identifies conditions for which IVIg:

- has an established therapeutic role
- has an emerging therapeutic role
- is used in exceptional circumstances, and
- is not supported or funded.

Application of the Criteria is based on three key principles:

1. alternative therapies are considered – where safe, effective and cost effective alternative therapies exist, these are considered preferable to IVIg therapy
2. minimum effective dosing is achieved – when IVIg is used, the lowest dose for the shortest duration should be prescribed to achieve the desired outcome, and
3. clinical effectiveness is assessed – measurable clinical outcomes are required to demonstrate clinical benefit for ongoing therapy and therapy should not be continued if there is no evident clinical benefit.

To establish if a patient is eligible for access to funded product, the diagnostic conditions are considered in conjunction with the clinical criteria contained within the identified conditions described in the Criteria. The clinical criteria include:

- indication for use – the purpose for which therapy would be considered, to prevent or manage a particular manifestation of the disease
- qualifying criteria – patient selection, particular disease characteristics, disease severity, requirements for other treatments to have been demonstrably unsuccessful before IVIg is considered
- exclusion criteria – specific indications and circumstances where IVIg should not be used
- dose and frequency – specific to the indications and circumstances to aim for the minimum dose to achieve optimum clinical outcome for the patient
- review criteria – clinical factors and patient’s response to therapy assessed to inform whether to:
  - continue therapy – clinical benefit is evident and demonstrable
  - cease therapy – clinical benefit is not evident or demonstrable
  - alter dose – increase or decrease dosage for improved efficacy, and/or
  - change dosage frequency.
Subcutaneous immunoglobulin (SCIg)

The JBC approved the introduction of SCIg under the national blood arrangements in March 2013, through an assurance framework for the appropriate use of the product. Participation in the National SCIg program requires hospitals to establish their capability and capacity to manage a hospital based SCIg program, where the hospital provides access to all resources and takes full accountability for the management and use of the product within defined governing requirements (described below).

In addition to the access rules for IVIg, SCIg may be supplied under the national blood arrangements only for patients:

- with a medical condition where there is support for use cited in the Criteria, namely:
  1. primary immunodeficiency diseases with antibody deficiency
  2. specific antibody deficiency
  3. acquired hypogammaglobulinaemia secondary to haematological malignancies (chronic lymphocytic leukaemia, multiple myeloma, non-Hodgkin lymphoma and other relevant malignancies, and post-haemopoietic stem cell transplantation)
  4. secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency), AND
- being treated by a clinical specialist within a hospital-based SCIg program, where the hospital provides access to all resources and takes full accountability for the management and use of the SCIg product, at no additional cost to patients, AND
- following a patient-specific SCIg request submitted to, and authorised by, the Authoriser.

Governing requirements for a hospital based SCIg program

Quality Assurance

The hospital must have in place policies and procedures that provide quality assurance and monitor compliance for the management and use of SCIg in line with the National Safety and Quality Health Service (NSQHS) Standards, particularly Standards 1 and 7.

Clinical oversight

The hospital must have a recognised treatment program for the management and use of immunoglobulin for the relevant indications, including an appropriate supervising specialist.

The hospital based SCIg program must provide ongoing clinical oversight and support for participating patients. This may include community nursing, hospital in the home or contact persons for both routine and emergency support as required.

The responsible clinician must consider patient suitability for the self-management and administration of SCIg to ensure appropriate management and use of SCIg product.

Equipment and facilities

The hospital based SCIg program must ensure that patients have access to all necessary equipment and consumables to administer the product, at no additional cost to patients.
Education and training

The hospital based SCIg program must provide education and training for staff and patients to ensure the appropriate management and use of SCIg, including for transport, storage, use of equipment and infusion techniques.

Regular review

Regular review to assess clinical benefit of treatment for ongoing therapy should be conducted at periods specified by the responsible clinician in line with the Criteria. Patients should be encouraged to maintain a diary to record SCIg product use and any adverse reactions, as well as collection and management of product as an aid for the clinician at the assessment.

Supply of product

During this initial phase of implementation, orders for SCIg for authorised patients must be patient-specific orders through BloodNet (or alternative arrangement if necessary). The amount of SCIg supplied to a patient should not exceed more than is required for treatment for one month with a number of repeats up to 6 months, as determined by the prescriber. Dispensing of SCIg product to patients must be in accordance with relevant state/territory legal requirements.

Reporting unused, discarded, spoilt/broken product

Patients supplied with SCIg will be expected to report details of unused, discarded or spoilt/broken product to the hospital. This information should be reported by the hospital through BloodNet (or alternative arrangement if necessary). This, and other information relevant for authorisation of requests collected by the Authoriser, will be reported to the NBA to assist with supply reconciliation and planning.

Hospital based SCIg program participation

Hospitals, participating in the national SCIg program, are required to provide an acknowledgement of the governing requirements by the Chief Executive or Director of Clinical Services (or equivalent) prior to ordering and providing SCIg products to their patients, using the Hospital acknowledgement Form: National SCIg Program available at www.blood.gov.au/subcutaneous-immunoglobulin.

In New South Wales (NSW) these requirements are managed by the NSW Ministry of Health through communication with Local Health Districts (LHD) and Specialty Health Network Chief Executives and the acknowledgement form is not required.

In South Australia (SA) and Western Australia (WA) hospitals require endorsement from the relevant state health department.
Normal human immunoglobulin (NHlg)

NHlg, a scarce resource produced from the same plasma pool as domestically produced IVIg and SCIg, may be supplied under the national blood arrangements for two purposes, as follows:

1. NHlg may be supplied for public health disease control activities, to treat susceptible contacts of an indicated infectious disease (hepatitis A, measles, poliomyelitis or rubella), where directed by the public health physicians, infectious disease consultants or clinical microbiologists in each state and territory. Advice and guidance to public health units in responding to a notifiable disease event can be found in the Series of National Guidelines (SoNGs) at: www.health.gov.au/internet/main/publishing.nsf/Content/cdhasongs.htm.

2. NHlg may be supplied for the treatment of immunodeficiency conditions for which the product is indicated, for patients for whom treatment with IVIg and SCIg (where available) are both contraindicated, provided that:
   - the diagnosis and written prescription is provided by a relevant medical specialist
   - the same diagnostic, qualifying, exclusion and review criteria and authorisation process for the relevant conditions are used to authorise the supply of NHlg, as would apply for the supply of IVIg or SCIg for those conditions
   - at the time of seeking authorisation, the prescribing specialist clinician confirms in writing the specific clinical reason why treatment with IVIg and SCIg are both contraindicated
   - the governing requirements for SCIg are applied where NHlg is proposed to be used outside of the hospital setting, and
   - ongoing access to supply of NHlg may cease if the required review and supporting documentation demonstrating clinical effectiveness against the review criteria have not been met.

NHlg will NOT be routinely provided for any other purpose, including travel prophylaxis for hepatitis A. Advice in relation to prophylaxis for hepatitis A can be found in The Australian Immunisation Handbook available at www.health.gov.au/intranet/immunise/publishing.nsf/Content/handbook10-3-2. Requests directed by public health physicians, infectious disease consultants or microbiologists to access NHlg for public health disease purposes are made using the NHlg Order form available at www.blood.gov.au/normal-human-immunoglobulin.
4. JURISDICTIONAL DIRECT ORDER AND OTHER SUPPLY ARRANGEMENTS

If IVIg is required to treat a medical condition which is not funded under the Criteria, then access may be authorised through local arrangements for imported product under the Jurisdictional Direct Order (JDO) arrangements. Imported product may also be ordered directly from a commercial supplier. In these circumstances the costs will need to be met by the jurisdiction, health service or individual.

For more information about JDO, other supply arrangements and current pricing please see www.blood.gov.au/immunoglobulin-products. Please also refer to local state/territory policies, where these exist.
5. ADMINISTRATIVE ARRANGEMENTS

The administrative arrangements described below support implementation of the national policy position, described in section 3, for access to the supply of immunoglobulin products for the purpose of treating immunodeficiency diseases.

5.1 Authorisation

A patient specific request for authorisation for initial access to the supply of funded immunoglobulin products is submitted by the treating medical specialist for assessment by the Authoriser, using the Authorisation Request Form (see attachment 9.2) available at www.blood.gov.au/immunoglobulin-ig-governance-program. A patient specific request for authorisation will not be considered until all required information on the form is provided (mandatory fields are indicated on the form).

In those states and territories that choose to be involved in decisions for authorisation of initial access to treatment, continuing treatment, or cessation of treatment, a mechanism may be established to refer decisions for consideration by the state/territory health department or jurisdictional committee, as appropriate.

Figure 1 - Initial access and supply of government funded immunoglobulin products.
5.2 Review of patient treatment benefit for continuing access and supply

The review criteria for assessing the effectiveness of treatment are defined in the Criteria for each condition requiring patient treatment review. The review criteria timeframe, usually 3, 6 or 12 monthly, allows an assessment of the patient’s response to treatment at the current dose and frequency. A trial cessation of immunoglobulin treatment may also be considered necessary in some circumstances to enable an accurate evaluation of the patient’s immunological status and the need for continuing immunoglobulin treatment.

Written notification, from the treating medical specialist, regarding the patient treatment review outcomes is required to be provided to the Authoriser within one month of the Review Date to enable authorisation for continuing access and supply of product, where clinical benefit is evident and demonstrable.

A Review Notification letter and Patient Treatment Review Outcome Notification Form (see attachment 9.3) will be sent by the Authoriser to the treating medical specialist at least eight (8) weeks prior to the Review Date.

Following a patient treatment review, the treating medical specialist may:

- commence the patient on a trial cessation of treatment for the purpose of evaluation OR
- request continuing treatment, either at the current dose and frequency where clinical benefit is achieved (evident and demonstrable), or modify treatment dose and/or frequency (where appropriate) OR
- cease treatment where benefit has not been achieved (not evident or demonstrable) OR
- re-apply for authorisation for an indication other than the indication that the patient is currently authorised for treatment. In this instance, the treating medical specialist will need to complete a new Authorisation Request Form available at www.blood.gov.au/immunoglobulin-ig-governance-program.

Where a treating medical specialist does not provide the Patient Treatment Review Outcome Notification Form or similar correspondence* to the Authoriser within one month of the Review Date, access to supply of product will cease as at the Review Outcome Notification Due Date.

*Note: A letter from the treating medical specialist advising the patient treatment review outcomes will be accepted providing it fully addresses the review criteria.
Figure 2 - Timeframe for access and review of patient treatment benefit for continuing access and supply of government funded immunoglobulin products.

**Initial Authorisation** – the point at which the patient is authorised to access government funded immunoglobulin products.

**Review Date** – is the point at which the patient’s treatment should be reviewed and outcomes captured, after a period of product use, based on the review criteria for the patient’s condition, as specified in the Criteria.

**Review Outcome Notification Due Date** – is the date the treatment review outcomes are required to be provided to the Authoriser for continuing access and supply of government funded immunoglobulin products.

**Letters** – a Review Notification letter will be sent to the treating medical specialist at least eight (8) weeks before the Review Date. A second reminder letter may be sent 2 weeks before the Patient Treatment Review Outcomes Notification Due Date if the patient treatment review outcomes have not yet been provided to the Authoriser.

### 5.3 Cessation of authorisation for continuing access and supply

Authorisation for continuing access and supply of funded immunoglobulin product will be ceased, where:

- clinical benefit defined in the patient treatment review criteria is not achieved (not evident or demonstrable)
  
  OR

- written notification of the patient treatment review outcomes, from the treating medical specialist through the Patient Treatment Review Outcome Notification Form or similar correspondence is not provided to the Authoriser within one month of the review date*
  
  OR

- the treating medical specialist advises the Authoriser that immunoglobulin is no longer required.

*Where authorisation and supply of product has been ceased as a result of the Patient Treatment Review Outcome Notification Form or similar correspondence which addresses the review criteria not being provided to the Authoriser within one month of the Review Date, the review form will still need to be provided within 2 months of the Review Outcome Notification Due Date for authorisation of continuing access and supply of product, or a new Authorisation Request form will need to be completed.
5.4 Ordering and dispensing funded product

Product ordering and management within hospitals will be coordinated by centrally established arrangements for the management of blood and blood products (blood bank, pathology laboratory, pharmacy, private pathology or other delegate; the Dispenser). This will ensure product transparency, accountability for dispensing product and to maintain traceability.

The Dispenser will have primary responsibility for product ordering, inventory management and dispensing product for use by authorised patients only. The role of the Dispenser may be assisted by a coordinating nurse or ward role, with specific protocols in place to ensure that the requirements for dispensing which support the authorisation process are complied with.

The Authoriser will confirm patient specific authorisation, including the product type, dosage, frequency and treatment review date (where relevant).

Product ordering by the Dispenser will be through BloodNet (or alternative arrangement if necessary) as either patient-specific orders or stock orders, based on clinical demand for authorised patients only and with consideration of agreed inventory levels (where relevant) within jurisdictions.
5.5 Patients travelling overseas

In order to apply for approval for the supply of product for use overseas, the Australian resident must submit an application to the National Blood Authority (NBA). The application form and more information are available at www.blood.gov.au/supply-australians-overseas.
6. ROLES AND RESPONSIBILITIES

This section describes the roles, responsibilities, authority and accountability of those involved in requesting authorisation for immunoglobulin products for the purposes of treating immunodeficiency diseases, authorising, supplying, managing and using government funded immunoglobulin products throughout the supply chain and within health services.

This information is provided to support implementation of the policy and access arrangements. Application of processes should always be in accordance with any state and territory legislative requirements, local policies and procedures.

6.1 Governance

6.1.1 Governments

The Australian Government and state and territory governments are signatories to the National Blood Agreement which sets out the national approach to policy setting, governance and management of the Australian Blood Sector, including administrative and financial arrangements, administered by the National Blood Authority (NBA) and Jurisdictional Blood Committee (JBC). The JBC represents governments’ positions on blood policy, demand, supply planning and product distribution, funding and evidence based approaches to emerging products, services and technologies. The JBC is the conduit between governments and the NBA and oversees the NBA’s role in blood supply contracting, planning, funding and implementation. Under the agreement, the JBC provides advice to Health Ministers on blood and blood product related issues regarding product safety and quality, through the Australian Health Ministers’ Advisory Council (AHMAC) which provides support to the Council of Australian Governments (COAG) Health Council, by advising health ministers on strategic matters relating to the coordination of health services.

The COAG Health Council is ultimately responsible for the oversight and management of the Australian Blood Sector.

6.1.2 National Immunoglobulin Governance Committees

The National Immunoglobulin Governance Advisory Committee (NIGAC) is established as the national advisory body to provide advice and make recommendations to the JBC and NBA on clinical best practice, governance and cost effectiveness, of immunoglobulin products supplied and funded under the national blood arrangements. NIGAC is the peak committee in an integrated national network of committees, that receives and provides advice and makes recommendation to JBC and NBA to inform the national governance framework including:

- Oversight of the program of work to evolve the Criteria and determine eligibility for access to funded immunoglobulin product including strengthening of definitions and data capture of demonstrable clinical benefit and evaluation of benefit with health economic analysis of treatment options including alternative therapies
- Receive advice regarding opportunities to build the evidence base and systems supporting cost effective prescribing to achieve clinical best practice
- Review of datasets and other materials reporting national prescribing practice and make recommendations for performance improvement
- Consider advice regarding opportunities, prioritisation and conduct of targeted research supporting cost effective clinical practice and in the development of educational and guidance materials
- Consider advice regarding the Criteria, performance improvement, communication, training needs, adverse events and reporting requirements to support ongoing clinical governance.

NIGAC may establish subcommittees and specialist working groups for specific purposes including specialist expert groups to review and make recommendation on evolving the Criteria and other elements of the program. Specialist working groups will be established for haematology, immunology, neurology and transplantation medicine.

The role and functions of the NIGAC are outlined in the Terms of Reference (see attachment 9.4).

### 6.1.3 Jurisdictional Immunoglobulin Advisory Committees

States and Territories have committees appropriate to their requirement to fulfil responsibilities of review and governance regarding immunoglobulin prescribing and usage including the monitoring of jurisdictional use by institution, condition and speciality to identify and act on trends, issues and benchmarking data.

The jurisdictional immunoglobulin advisory committees will provide advice and recommendations to NIGAC regarding the local immunoglobulin governance framework including performance improvement, feedback on the Criteria, opportunities for feedback on communication, education and training needs, adverse events and reporting requirements to support clinical governance.

### 6.1.4 Hospital Management

Hospital administration and management (CEOs, Medical Directors), including hospital level governance committees such as blood product committees, or drug and therapeutics committees, are key stakeholders in the implementation of the clinical governance and authorisation of immunoglobulin both in the public and private sectors. Hospital management need to ensure that they have appropriate policies and procedures in place to comply with this policy and in accordance with National Safety and Quality Health Service (NSQHS) Standards, particularly Standards 1 and 7 in the clinical governance and safe administration of blood and blood products. As such, they play an important role in communication of this policy to relevant staff within the organisation.

In addition, Health Ministers expect that health providers will contribute to the sustainability of blood and blood products and play a vital advocacy role in ensuring that these resources are appropriately prescribed and managed.
Figure 4 - Network of committees supporting immunoglobulin governance and management

6.2 Prescriber

Consultant/treating medical specialists are responsible for:

Obtaining patient consent to treatment and providing information to patients

- Explain the potential risks, benefits and alternative treatments (where these exist) to support patients in making an informed decision about their treatment options
- Advise patients of the potential for adverse reactions and events, and the requirement for reporting these
- Advise patients on the requirement for regular treatment monitoring and review
- Advise patients on the collection, retention and use of their personal clinical data in a secure national database for the purposes of initial and continuing authorisation
- Advise patients that product brand (between Australian and imported products) may change from time to time
- Explain the expected clinical outcome of treatment, the high cost of treatment and that therapy may be a trial where treatment may be ceased if the expected outcome is not achieved, and that periods off treatment may also be required to prove treatment efficacy
- Ensure patient is aware of the response and review criteria and their responsibilities to actively participate in their care
• Obtain patient explicit written or oral consent to treatment with immunoglobulin products and record it in the patients’ medical records, at least annually.
• Obtain patient explicit written or oral consent to the collection, retention and use of their personal data for the purposes of initial and continuing authorisation and record it in the patient’s medical records, at least annually.

**Requesting patient-specific authorisation**

• Request patient-specific authorisation for initial access to funded product using the Authorisation Request Form available at [www.blood.gov.au/immunoglobulin-ig-governance-program](http://www.blood.gov.au/immunoglobulin-ig-governance-program)
• Provide sufficient information and, where required, supporting evidence, for an authorisation decision (e.g. evidence that the qualifying criteria have been met)
• Nominate the Dispenser at the time of the authorisation request
• Nominate the appropriate contact address for future correspondence (e.g. Patient Treatment Review Outcome Notification Form and correspondence) and advise the Authoriser if this changes.

**Prescribing in accordance with the Criteria and product specific information**

• Prescribe treatment in accordance with the Criteria and product specific information, including consideration of alternative therapies (where relevant), trials off therapy and documenting the clinical outcome.
• Aim to use the lowest dose possible that achieves the appropriate clinical outcome for each patient

**Reviewing the effectiveness and ongoing need of continuing treatment in accordance with the Criteria**

• Regularly monitor and assess the effectiveness of patient specific treatment within the required review timeframe and against the review criteria specified in the Criteria
• Provide the Authoriser with written notification of the patient treatment review outcome, using the Patient Treatment Review Outcome Notification Form supplied (or similar correspondence which addresses the qualifying and review criteria), within one month of the review date. The purpose of the review outcome notification is to:
  • inform trial period off treatment to prove efficacy (where relevant)
  OR
  • ensure continuation of treatment where clinical benefit has been achieved and document the demonstrable benefit, and modify treatment dosage and/or frequency (where appropriate)
  OR
  • advise cessation of treatment where clinical benefit has not been achieved (not evident and demonstrable) or product is no longer required.

**Reporting**

• Report adverse events or other incidents related to the treatment within the hospital and to the Therapeutic Goods Administration (TGA), the Authoriser and Suppliers, as appropriate and in accordance with local policies and procedures.
6.3 Patient (parent/carer/guardian)

Patients are responsible for:

**Understanding the proposed treatment and product access rules**

- Understand that there are governance and administrative arrangements for access to government funded immunoglobulin products
- Understand the proposed treatment risks, benefits and alternatives (where these exist) by asking questions and seeking further clarification if required
- Understand that therapy may be a trial to assess clinical benefit and that therapy will cease if the expected clinical benefit is not achieved
- Understand that the product brand may be changed from time to time
- Provide express consent to treatment with blood products
- Provide express consent to the collection, retention and use of personal clinical data in a national secure database, in accordance with the Australian Privacy Principles and all relevant state and territory laws.

**Attending scheduled appointments**

- Attend medical appointments associated with therapy and undergo periodic clinical review and assessment as advised by the treating medical specialist.

**Where self-administering therapy with subcutaneous immunoglobulin (SClG)**

- Complete competency based supported training sessions for self-administration of therapy
- Perform self-administered infusion in a safe and clean environment with a support person present, and maintain equipment as instructed
- Dispose of consumables and sharps in the provided rigid sharp disposal container
- Complete patient receipt and use diary for each infusion and provide information as required by the treating medical specialist
- Record and report any adverse reactions
- Order, collect, transport and store SClG product according to instructions.

**Reporting**

- Report adverse reactions or other incidents related to the treatment to the treating medical specialist or nurse.
6.4 Authoriser

The Authoriser responsibilities include:

**Authorisation for initial access to product**

- Assess the patient specific Authorisation Request Form and supporting information against all the qualifying criteria, seeking further information when required
- Follow up with the requesting medical specialist seeking additional information to determine patient authorisation for access and supply of product, where necessary
- Decline authorisation for access to product where the qualifying criteria are not met and notify the requesting medical officer
- Notify the requesting medical specialist (or delegate) the outcome of the assessment and required review date (where applicable)
- Determine and allocate product type (Australian or imported product), in accordance with agreed local and national arrangements
- Confirm patient specific authorisation with the Dispenser, including product type, dosage, frequency, time period and required patient treatment review due date (where relevant)
- Record patient demographics, eligibility, clinical and treatment data in relevant information systems.

**Notification of patient treatment review due date**

- Send correspondence and Patient Treatment Review Outcome Notification Form to the treating medical specialist at least eight (8) weeks prior to patient treatment review due date
- Send a reminder notification to the treating medical specialist, if the patient treatment review outcomes have not been provided, at least two (2) weeks prior to the patient treatment Review Outcomes Notification Due Date.

**Authorisation for continuing access to funded product**

- Assess Patient Treatment Review Outcome Notification Form or similar correspondence against the review criteria described in the Criteria for the specific condition, seeking further information if required
- Decline authorisation for access to product where the review criteria are not met and notify the requesting medical specialist
- Notify the requesting medical specialist of the outcome of the assessment and new review due date (where relevant)
- Confirm patient specific authorisation for continuing access and supply of product with the Dispenser, including product type, dosage, frequency and review due date (where relevant)
- Record review outcomes and relevant patient data in relevant information systems.
Cessation of authorisation for access and supply of funded product

- Cease authorisation for access and supply of funded product, where
  - the patient treatment review criteria have not been achieved (not evident or demonstrable)
  - the Patient Treatment Review Outcome Notification Form or similar correspondence has not been received by the Review Outcome Notification Due Date
  - the treating medical specialist has advised that product is no longer required.

6.5 Distributor

The Distributor responsibilities include:

Holding and managing appropriate inventory

- Plan and manage appropriate inventory in accordance with government agreed standards for timely distribution
- Assist Dispensers with stock inventory levels (where approved by the NBA)
- Coordinate the management of unused product at dispensaries.

Receiving product orders

- Accept product orders for the purpose of treating authorised patients with immunodeficiency diseases from Dispensers only, via BloodNet (or alternative arrangements if necessary)
- Support dispensers in the timely supply of replacement product in emergency situations and the operation of stock replenishment ordering systems, where approved.

Distributing product to Dispensers

- Ensure that Australian and imported IVIg products are distributed within the defined ratios for states and territories as required by the NBA.

Ensuring product integrity during transportation

- Ensure all blood products are transported in dedicated and designated insulated containers
- Advise Blood Couriers and Dispensers on the appropriate transportation, storage and handling of product to maintain cold chain integrity in accordance with the required product specific temperature conditions
- Provide advice regarding management of product which breaches cold chain integrity.
6.6 Dispenser

The Dispenser responsibilities include:

Ordering product appropriate to clinical demand

- Coordinate product ordering from the Distributor based on clinical demand for authorised patients as specified in the prescription by the Prescriber and subsequent blood product order, with consideration of inventory holdings (where relevant)
- Place product orders and receipt orders in BloodNet (or alternative arrangement if necessary)
- Record product transfers in BloodNet and/or other relevant information systems if product is transferred to, or received from, another dispensary
- Record product fate (breakages/discards) in BloodNet and/or other relevant information systems.

Ensuring product cold chain integrity

- Maintain and handle the product in accordance with the required product specific temperature conditions
- Take all reasonable measures to ensure that product is stored in accordance with medical refrigeration equipment Australian Standard (AS) 3864.2 2012
- Ensure all blood products are transported in dedicated and designated insulated containers
- Advise blood couriers, ward and nursing staff on the appropriate transportation and storage of product
- Advise patients/carers on the appropriate transportation and storage of SCIg product.

Dispensing product for authorised patients only

- Only dispense product on receipt of a prescription/order from a prescriber
- Review order and dispense product for the treatment of authorised patients only
- Dispense no more product than is required for one month’s treatment with SCIg directly to authorised patients/carers
- Record dispensing information in relevant information systems to ensure traceability of product dispensed to patients in case of product recall
- Where necessary and approved, manage and reconcile product or stock for emergency use.
Applying appropriate inventory management practices

- Monitor product orders, current inventory and dispensary records to apply appropriate inventory management practices.

Reporting

- Report adverse events or other incidents related to the treatment within the hospital and to the TGA, the Authoriser and Suppliers, as appropriate
- Provide reports to the Authoriser, on product ordering, receipting and dispensing, as required.

The NBA has developed guidance for good inventory management and better practice processes, the document Managing Blood and Blood Product Inventory: Guidelines for Australian Health Providers is available at www.blood.gov.au/inventory-management.

6.7 Registered Nurse and/or Registered Midwife

Nursing staff and midwives are responsible for:

Ensuring patient consent to treatment

- Ensure patient consent to treatment has been obtained and documented in the patients’ medical records prior to commencing an infusion
- Explain infusion process and remind patient regarding the potential for adverse events and the need to advise/report symptoms during and after the infusion.

Safe administration of treatment

- Identify patients and procedure in accordance with the National Safety and Quality Health Service Standard
- Be familiar with specific product information
- Monitor patients during IVIg infusion and carry out the appropriate actions should an adverse reaction occur
- Ensure adequate documentation in the medical notes to ensure product traceability to patient.

Training and support for patients to self-administer SCIg

- Educate patients on safe and effective self-administration of SCIg treatment and provide support to enable them to achieve an agreed level of competency
- Conduct follow up of competency for self-administered treatment with patients independent self-administration of SCIg treatment
- Ensure patients have access to consumables and supplies
- Review and complete patient agreement for self-administered treatment (where this exists) with the patient/carer
- Ensure all necessary prescriptions have been provided to patients

Reporting

- Report adverse events or other incidents related to the treatment within the hospital and to the TGA, the Authoriser and Suppliers, as appropriate and in accordance with local policies and procedures.
6.8 Couriers

Couriers and staff within hospitals who retrieve blood products from blood and medication fridges are responsible for:

**Ensuring product integrity during transportation**

- Ensure all immunoglobulin products are transported in dedicated and validated insulated containers
- Maintain the appropriate cold chain integrity for storage and handling of product in accordance with the product specific temperature conditions
- Ensure receipt of the product is acknowledged by an appropriate receiver.
7. REFERENCES


8. DEFINITIONS AND ACRONYMS

This table of definitions and acronyms is specifically intended for interpretation of terms in relation to this policy and associated processes.

<table>
<thead>
<tr>
<th>Term</th>
<th>Acronym</th>
<th>Related Terms</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse event</td>
<td></td>
<td></td>
<td>A harmful or serious reaction to immunoglobulin product administration requiring further treatment that should be reported within the hospital and to the TGA, the Authoriser and Suppliers, as appropriate.</td>
</tr>
<tr>
<td>Allocation</td>
<td></td>
<td></td>
<td>Allocation of product to patients based on available domestic and imported immunoglobulin product, taking into account supply security reserve levels endorsed by governments to ensure sufficiency of supply.</td>
</tr>
<tr>
<td>Alternative therapy</td>
<td>Substitute</td>
<td></td>
<td>Other clinical treatments that can be substituted for immunoglobulin therapy to treat a condition (ie plasma exchange).</td>
</tr>
<tr>
<td>Australian Health Ministers’ Advisory Council</td>
<td>AHAMAC</td>
<td></td>
<td>The Australian Health Ministers’ Advisory Council (AHMAC) provides support to the COAG Health Council (CHC), by advising health ministers on strategic matters relating to the coordination of health services. AHAMAC considers blood sector matters referred to it by the JBC through the Hospitals Principle Committee, and reports as necessary to the CHC.</td>
</tr>
<tr>
<td>Australian Red Cross Blood Service</td>
<td>Blood Service</td>
<td></td>
<td>The organisation that collects, processes and distributes blood and blood components sourced from voluntary non-remunerated Australian blood donors.</td>
</tr>
<tr>
<td>Authorisation</td>
<td></td>
<td></td>
<td>The process for assessing eligibility for access to immunoglobulin products funded under the national blood arrangements based on the Criteria.</td>
</tr>
<tr>
<td>Term</td>
<td>Acronym</td>
<td>Related Terms</td>
<td>Definition</td>
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</tr>
<tr>
<td>Authorisation Date</td>
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<td></td>
<td>The point at which the patient is approved for initial qualifying or continuing immunoglobulin treatment. Patients will be authorised for a single dose or period of continuing treatment according to the Criteria.</td>
</tr>
<tr>
<td>Authorisation Request</td>
<td></td>
<td></td>
<td>An Authorisation Request is a form containing details of a patient and their medical condition for which a prescriber wishes to prescribe immunoglobulin treatment, used to obtain initial access to the supply of government funded immunoglobulin product.</td>
</tr>
<tr>
<td>Authoriser</td>
<td></td>
<td></td>
<td>A person or group responsible for overseeing authorisation requests for immunoglobulin products and has the delegation to approve or reject an Authorisation Request.</td>
</tr>
<tr>
<td>BloodNet</td>
<td></td>
<td></td>
<td>A web-based system that allows staff in health providers (hospitals) across Australia to order and receipt blood and blood products.</td>
</tr>
<tr>
<td>Condition</td>
<td>Diagnosis</td>
<td></td>
<td>Clinical conditions categorised according to the quality of the available evidence and whether immunoglobulin treatment is considered beneficial.</td>
</tr>
<tr>
<td>Contraindicated</td>
<td></td>
<td></td>
<td>A situation where therapy should not be used because it may be harmful to the patient.</td>
</tr>
<tr>
<td>Council of Australian Governments Health Council</td>
<td>CHC</td>
<td></td>
<td>The CHC is responsible for overseeing and managing the blood sector. It sets the governance, policy and financial frameworks under which the NBA operates.</td>
</tr>
<tr>
<td>Term</td>
<td>Acronym</td>
<td>Related Terms</td>
<td>Definition</td>
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<tr>
<td>Criteria for the clinical use of intravenous immunoglobulin in Australia, Second Edition 2012.</td>
<td>Criteria</td>
<td></td>
<td>Identifies the indications for which IVIg is funded under national blood arrangements by all Australian governments; the book is not a medical or clinical guideline on treatment of the indications listed. Regular review of the Criteria is needed to align funded access to IVIg with the latest evidence, or in the case of limited evidence, a consensus of expert opinion.</td>
</tr>
<tr>
<td>Diagnostic conditions</td>
<td></td>
<td></td>
<td>Condition determined from medical examination of signs and symptoms and other investigations.</td>
</tr>
<tr>
<td>Dispenser</td>
<td></td>
<td>Blood Bank, Pathology laboratory, Pharmacy</td>
<td>A Dispenser is responsible for the release of a specific amount of immunoglobulin to the clinical ward or patient (SCIg), stock inventory management and Product Orders.</td>
</tr>
<tr>
<td>Dispensing</td>
<td></td>
<td></td>
<td>The release of immunoglobulin product from inventory to the clinical ward or patient (SCIg) in accordance with the prescription and patient authorisation.</td>
</tr>
<tr>
<td>Distributor</td>
<td></td>
<td></td>
<td>A Distributor is responsible for distributing immunoglobulin products to Dispensers.</td>
</tr>
<tr>
<td>Hospitals Principal Committee</td>
<td>HPC</td>
<td></td>
<td>The Hospitals Principal Committee provides advice to the Australian Health Ministers’ Advisory Council (AHMAC) on matters relating to hospital care.</td>
</tr>
<tr>
<td>Iatrogenic illness</td>
<td></td>
<td></td>
<td>Illness caused by medical treatment.</td>
</tr>
<tr>
<td>Immune modulation therapy</td>
<td></td>
<td></td>
<td>Treatment with immunoglobulin product to induce, enhance or suppress an immune response.</td>
</tr>
<tr>
<td>Immune replacement therapy</td>
<td></td>
<td></td>
<td>Treatment with immunoglobulin product in people with insufficient antibodies (immune deficiency).</td>
</tr>
<tr>
<td>Immunoglobulin</td>
<td></td>
<td></td>
<td>An antibody protein used by the immune system to identify and neutralise bacteria and viruses.</td>
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<tr>
<td>Term</td>
<td>Acronym</td>
<td>Related Terms</td>
<td>Definition</td>
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</tr>
<tr>
<td>Indication</td>
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<td>A reason to prescribe a medication or perform treatment.</td>
</tr>
<tr>
<td>Intravenous immunoglobulin</td>
<td>IVIg</td>
<td></td>
<td>Immunoglobulin administered into a vein (as opposed to intramuscular or subcutaneous injection), provided under the national blood arrangements to reduce susceptibility to infections and manage many immune system disorders.</td>
</tr>
<tr>
<td>Jurisdiction</td>
<td></td>
<td>States and Territories</td>
<td>A signatory to the National Blood Agreement. This includes the Australian Government and all the state and territory governments.</td>
</tr>
<tr>
<td>Jurisdictional Blood Committee</td>
<td>JBC</td>
<td></td>
<td>The Jurisdictional Blood Committee (JBC) is a committee of senior government officials with member representation from the Australian Government, the six State Governments and two Territory Governments. JBC is responsible for all jurisdictional issues relating to the national blood supply, including planning, production, supply and budgeting.</td>
</tr>
<tr>
<td>Jurisdictional Direct Orders</td>
<td>JDO</td>
<td></td>
<td>Arrangements implemented by the NBA with suppliers to facilitate the purchase of IVIg at the same prices negotiated by the NBA, for the treatment of conditions not satisfying the Criteria for the clinical use of IVIg in Australia.</td>
</tr>
<tr>
<td>Medical Specialist</td>
<td></td>
<td>Treating medical specialist, consultant</td>
<td>In the context of this policy, a treating medical specialist refers to an immunologist, neurologist, haematologist, transplantation medicine specialist, dermatologist, rheumatologist, foeto-maternal specialist and neonatologist.</td>
</tr>
<tr>
<td>National Blood Agreement</td>
<td></td>
<td></td>
<td>The administrative and policy agreement signed by all state and territory Health Ministers for a national approach to policy setting, governance and management for the supply of blood products and services in the Australian blood sector.</td>
</tr>
<tr>
<td>Term</td>
<td>Acronym</td>
<td>Related Terms</td>
<td>Definition</td>
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</tr>
<tr>
<td>National Blood Arrangements</td>
<td></td>
<td></td>
<td>The management and coordination (arrangements) for the supply of blood and blood products and services by the NBA on behalf of the Australian Government and state and territory governments, referred to in the National Blood Agreement.</td>
</tr>
<tr>
<td>National Blood Authority</td>
<td>NBA</td>
<td></td>
<td>A statutory agency within the Australian Government Health Portfolio that manages and coordinates arrangements for the supply of blood and blood products and services on behalf of all Australian governments.</td>
</tr>
<tr>
<td>National Immunoglobulin Governance Advisory Committee</td>
<td>NIGAC</td>
<td></td>
<td>The national committee established as a subcommittee of JBC to provide advice and make recommendations to funding governments to support cost effective and appropriate clinical governance, management and use of immunoglobulin products.</td>
</tr>
<tr>
<td>National Safety and Quality Health Service Standards</td>
<td>NSQHS Standards</td>
<td></td>
<td>A nationally consistent and uniform set of measures of safety and quality for application by health service providers.</td>
</tr>
<tr>
<td>Normal Human Immunoglobulin (NHig)</td>
<td>NHig</td>
<td></td>
<td>Immunoglobulin administered by intramuscular injection (as opposed to intravenous or sub-cutaneous injection). The product is approved in Australia for use in the management of hypogammaglobulinaemia and for the public health purposes to treat susceptible contacts of hepatitis A, measles, poliomyelitis and rubella.</td>
</tr>
<tr>
<td>Patient</td>
<td></td>
<td></td>
<td>A person receiving immunoglobulin therapy under the national blood arrangements.</td>
</tr>
<tr>
<td>Plasma</td>
<td></td>
<td></td>
<td>The liquid part of the blood and lymphatic fluid, which makes up approximately half of its volume. Blood plasma contains antibodies and other proteins. It is taken from donors and made into products to treat a variety of medical conditions.</td>
</tr>
<tr>
<td>Term</td>
<td>Acronym</td>
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<td>Definition</td>
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</tr>
<tr>
<td>Prescriber</td>
<td></td>
<td>Consultant, Treating Medical Specialist or Medical Officer</td>
<td>A prescriber is a person who is authorised to prescribe IVIg treatment to patients.</td>
</tr>
<tr>
<td>Prophylaxis</td>
<td></td>
<td></td>
<td>A treatment designed and used to prevent an episode or worsening of disease.</td>
</tr>
<tr>
<td>Public Health Unit</td>
<td>PHU</td>
<td></td>
<td>A PHU provides public health services; to identify, prevent and minimise public health risks to the community. Areas of responsibility may include Infectious Diseases, Immunisation, Environmental Health, Epidemiology, Research, and Administration.</td>
</tr>
<tr>
<td>Review</td>
<td></td>
<td></td>
<td>Assessment of the patient’s response to Immunoglobulin treatment at the current dose and frequency to determine clinical benefit for access to continuing therapy. The Review is usually performed at 3, 6 or 12 monthly intervals.</td>
</tr>
<tr>
<td>Review Outcome Notification Due Date</td>
<td></td>
<td></td>
<td>The date the Patient Treatment Review Outcomes are required to ensure continuing access and supply of immunoglobulin products where clinical benefit is evident.</td>
</tr>
<tr>
<td>Subcutaneous Immunoglobulin (SCIg)</td>
<td>SCIg</td>
<td></td>
<td>Immunoglobulin administered by injection into the layer of the skin directly below the dermis and epidermis (as opposed to intravenous or intramuscular injection). Currently approved for a limited range of conditions through specific hospital based programs that may support home therapy being administered by patients/carers.</td>
</tr>
<tr>
<td>Supplier</td>
<td></td>
<td></td>
<td>A Supplier is responsible for completing product orders and supplying Dispensers with immunoglobulin Products.</td>
</tr>
<tr>
<td>Therapeutic Goods Administration</td>
<td>TGA</td>
<td></td>
<td>An agency of the Department of Health responsible for regulating therapeutic goods including medicines, devices, blood and blood products.</td>
</tr>
<tr>
<td>Trial Cessation</td>
<td></td>
<td></td>
<td>A period of time that the patient is taken off therapy to allow a clinical assessment of the clinical benefit of immunoglobulin treatment.</td>
</tr>
</tbody>
</table>
9. ATTACHMENTS

9.1 Areas of accountability

The following table represents the areas of accountability for key stakeholders involved with the supply, prescribing, dispensing, administration and use of intravenous immunoglobulin (IVIg) and subcutaneous immunoglobulin (SCIg) and normal human immunoglobulin (NHIg).

<table>
<thead>
<tr>
<th>KEY STAKEHOLDERS</th>
<th>COST EFFECTIVE &amp; EQUITABLE ACCESS TO PRODUCT</th>
<th>APPROPRIATE PRACTICE &amp; QUALITY HEALTHCARE OUTCOMES</th>
<th>DATA &amp; INFORMATION MANAGEMENT</th>
<th>PERFORMANCE IMPROVEMENT</th>
<th>KNOWLEDGE DEVELOPMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>NATIONAL BLOOD AUTHORITY (NBA)</td>
<td>• Manage contracts with suppliers to ensure the safe, secure, adequate, and affordable supply of blood and blood products in Australia.</td>
<td>• Promote safe, high quality management and use of blood products, blood related products and blood related services in Australia.</td>
<td>• Maintain integrity of data collected and held in relevant information systems.</td>
<td>• Monitor and review demand and supply data to assess performance of the governance system.</td>
<td>• Prioritise research programs for the development of better clinical practice knowledge to support more informed decision making both at the prescriber (clinician) and system-wide (management) levels.</td>
</tr>
<tr>
<td></td>
<td>• Establish governance and authorisation arrangements to ensure application of product access rules.</td>
<td>• Review and revise the Criteria to align product use with evidence for its efficacy and effectiveness in the treatment of identified conditions.</td>
<td>• Monitor and review demand and supply data to support product supply planning and management.</td>
<td>• Ensure that usage data by condition and institution is made available quarterly for performance review and benchmarking purposes</td>
<td>• Establish processes to develop guidelines and consensus statements to support better clinical practice and reduce variability in prescribing.</td>
</tr>
</tbody>
</table>
## IMMUNOGLOBULIN GOVERNANCE FRAMEWORK

<table>
<thead>
<tr>
<th>KEY STAKEHOLDERS</th>
<th>COST EFFECTIVE &amp; EQUITABLE ACCESS TO PRODUCT</th>
<th>APPROPRIATE PRACTICE &amp; QUALITY HEALTHCARE OUTCOMES</th>
<th>DATA &amp; INFORMATION MANAGEMENT</th>
<th>PERFORMANCE IMPROVEMENT</th>
<th>KNOWLEDGE DEVELOPMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FUNDING GOVERNMENTS</strong></td>
<td>• Provide funding for supply of immunoglobulin products under the national blood arrangements.</td>
<td>• Promote safe, high quality management and use of blood products, blood related products and blood related services in Australia.</td>
<td>• Monitor and review demand and supply data to support product supply planning and management.</td>
<td>• Endorse and support the development and implementation of the national Ig System.</td>
<td>• Endorse identified research priorities for the development of better clinical practice knowledge to support more informed decision making both at the prescriber (clinician) and system-wide (management) levels.</td>
</tr>
<tr>
<td><strong>NATIONAL AND LOCAL COMMITTEES</strong></td>
<td>• Provide advice to government on options to strengthen prescribing practice to ensure evidence based and cost-effective clinical outcomes are achieved for patients.</td>
<td>• Provide advice to government on new and existing immunoglobulin products and their current and emerging clinical use including epidemiological and cost effectiveness evaluation.</td>
<td>• Review local and national demand and supply data to identify areas for further investigation and analysis</td>
<td>• Regularly review prescribing practice and use by condition and jurisdiction/ institution to identify opportunities to improve clinical practice</td>
<td>• Provide advice to government on the opportunities, prioritisation and conduct of research supporting cost-effective clinical practice and in the development of educational and guidance materials.</td>
</tr>
<tr>
<td></td>
<td>• Endorse policies and procedures that ensure fair and equitable immunoglobulin authorisation and governance.</td>
<td>• Ensure appropriate resources and processes are implemented in the public health and broader sector in their jurisdiction to facilitate all aspects of the policy.</td>
<td>• Endorse and support the development and implementation of the national Ig System.</td>
<td>• Endorse and support the development and implementation of the national Ig System.</td>
<td>• Provide advice to government on options including improved data capture, reporting and analysis.</td>
</tr>
<tr>
<td></td>
<td>• Review adverse event data for all products</td>
<td>• Review product management practices including product expiry and wastage data</td>
<td>• Provide advice to government on options including improved data capture, reporting and analysis.</td>
<td>• Endorse identified research priorities for the development of better clinical practice knowledge to support more informed decision making both at the prescriber (clinician) and system-wide (management) levels.</td>
<td>• Provide advice to government on options including improved data capture, reporting and analysis.</td>
</tr>
</tbody>
</table>
## IMMUNOGLOBULIN GOVERNANCE FRAMEWORK

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<th>DATA &amp; INFORMATION MANAGEMENT</th>
<th>PERFORMANCE IMPROVEMENT</th>
<th>KNOWLEDGE DEVELOPMENT</th>
</tr>
</thead>
</table>
| PRESCRIBER       | • Prescribe immunoglobulin treatment in accordance with the Criteria including consideration of alternative therapies and relative cost effectiveness.  
                  • Conduct regular patient treatment review to assess and report on the clinical benefit achieved to justify continuing therapy.  
                  • Provide patient treatment review outcome notification to the Authoriser within the review requirements.  
                  • Explain to patients the expected treatment benefit, the period of treatment planned and the cost.  
                  • Conduct trial cessation of treatment (where appropriate) to assess clinical benefit and treatment outcomes.  
                  • Prescribe the lowest dose for the shortest duration to achieve the desired clinical benefit.  
                  • Nominate the Dispenser at the time of the Authorisation Request to facilitate product supply accountability.  
                  • Report patient adverse events as required.  
                  • Provide sufficient clinical data to support authorisation for initial and ongoing access to treatment.  
                  • Review, monitor and record clinical notes in the patient medical records to support the provision of information required for initial and continuing access to funded treatment and support product recalls.  
                  • Provide patient clinical information on request to support initial and continuing therapy.  
                  • Understand the authorisation and governance arrangements.  
                  • Understand the provision of data required to support initial and ongoing access to immunoglobulin treatment.  
                  • Regularly review policies and procedures to identify opportunities for improvement.  
                  • Provide feedback and clinical advice to contribute to improvement in systems, processes, educational and guidance materials.  
                  • Advise patients of the access rules for funded immunoglobulin treatment. |
## Immunoglobulin Governance Framework

<table>
<thead>
<tr>
<th>Key Stakeholders</th>
<th>Cost Effective &amp; Equitable Access to Product</th>
<th>Appropriate Practice &amp; Quality Healthcare Outcomes</th>
<th>Data &amp; Information Management</th>
<th>Performance Improvement</th>
<th>Knowledge Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients/Carers</td>
<td>• Understand immunoglobulin authorisation and governance arrangements for initial access and continuing therapy.</td>
<td>• Participate in and complete competency based training for self-administering SCIg (where relevant).</td>
<td>• Provide consent to the collection and retention of personal and clinical information held in secure information systems.</td>
<td>• Provide feedback to clinician on health, changes in symptoms and response to treatment to support improved prescribing decisions and assist in identifying opportunities for system improvement.</td>
<td>• Provide feedback on educational and guidance materials to assist in identifying opportunities for improvement to processes, systems and supporting documentation.</td>
</tr>
<tr>
<td></td>
<td>• Understand treatment risks, benefits, cost and alternatives (where relevant).</td>
<td>• Record and report adverse events and reactions to treating clinician.</td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>• Provide consent to treatment with a biological product and in the collection and retention of personal and clinical data to support initial and continuing access to treatment.</td>
<td>• Cooperate in treatment assessments and attend all scheduled appointments with medical specialist.</td>
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</tr>
<tr>
<td></td>
<td>• Understand that therapy may be a trial to assess clinical benefit and that therapy may cease if the expected clinical benefit is not achieved.</td>
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</tr>
<tr>
<td>KEY STAKEHOLDERS</td>
<td>COST EFFECTIVE &amp; EQUITABLE ACCESS TO PRODUCT</td>
<td>APPROPRIATE PRACTICE &amp; QUALITY HEALTHCARE OUTCOMES</td>
<td>DATA &amp; INFORMATION MANAGEMENT</td>
<td>PERFORMANCE IMPROVEMENT</td>
<td>KNOWLEDGE DEVELOPMENT</td>
</tr>
<tr>
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</tr>
<tr>
<td>AUTHORISER</td>
<td>Authorise initial and continuing access to government funded product for eligible patients based on the Criteria and treatment access rules.</td>
<td>Allocate product type (domestic or imported) to approved patients in accordance with supply planning and management.</td>
<td>Collect and maintain integrity of data in relevant information systems.</td>
<td>Support clinical governance activities in hospitals and user groups as required.</td>
<td>Identify needs and contribute to the development of educational and guidance materials.</td>
</tr>
<tr>
<td></td>
<td>Cease supply of product where patient treatment review outcome (where relevant) is not notified or clinical benefit as per the review criteria for the patient condition is not achieved (evident or demonstrable).</td>
<td>Allocate product type in accordance with agreed local arrangements and approved patient clinical needs (where relevant).</td>
<td>Provide monthly reports to government to assist with supply planning and management.</td>
<td>Regularly assess systems and processes including the Patient Treatment Outcome Review and guidance in the Criteria to identify and advise the NBA of opportunities for improvement.</td>
<td>Provide advice regarding identified opportunities to conduct research supporting improved clinical practice.</td>
</tr>
<tr>
<td></td>
<td>• Participate in and complete competency based training for self-administering SCIg (where relevant).</td>
<td>• Provide training and support to prescribers to ensure they are aware of treatment risks, benefits, costs and alternatives.</td>
<td>• Provide quarterly usage reports to jurisdictions and institutions to support analysis and clinical governance activities.</td>
<td>• Educate prescribers in understanding access rules for initial and continuing treatment with immunoglobin.</td>
<td>• Provide feedback to prescribers on educational and guidance materials to assist in identifying opportunities for improvement to processes, systems and supporting documentation.</td>
</tr>
<tr>
<td>KEY STAKEHOLDERS</td>
<td>COST EFFECTIVE &amp; EQUITABLE ACCESS TO PRODUCT</td>
<td>APPROPRIATE PRACTICE &amp; QUALITY HEALTHCARE OUTCOMES</td>
<td>DATA &amp; INFORMATION MANAGEMENT</td>
<td>PERFORMANCE IMPROVEMENT</td>
<td>KNOWLEDGE DEVELOPMENT</td>
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</tbody>
</table>
| DISPENSER | • Plan and manage product ordering appropriate to clinical demand for approved patients only, taking into consideration current stock levels (where relevant).  
• Dispense product for the treatment of approved patients only, in accordance with the authorisation and governance arrangements.  
• Ensure policies and procedures are in place to ensure the appropriate ordering, storage and handling of product.  
• Ensure that policies and procedures are in place to maintain cold chain integrity in accordance with product specific temperature conditions.  
• Advise courier, ward and nursing staff on the appropriate storage and handling of product.  
• Ensure product to patient traceability in case of product recall. | • Record dispensing information in relevant information systems and provide reconciliation reports as required.  
• Reconcile records held in relevant information systems to identify anomalies and improvements to systems and processes. | • Review management practices and apply continuous improvement principles to ensure that product expiry and wastage are minimised  
• Participate in and support local clinical governance activities including the provision of usage and cost data  
• Regularly assess systems and processes to identify opportunities for improvement. | • Provide feedback and advice to contribute to improvement in systems, processes, educational and guidance materials.  
• Educate local prescribers and nursing staff to understand the authorisation and governance arrangements for access to product, including ordering and the costs of treatment. |
<table>
<thead>
<tr>
<th>KEY STAKEHOLDERS</th>
<th>COST EFFECTIVE &amp; EQUITABLE ACCESS TO PRODUCT</th>
<th>APPROPRIATE PRACTICE &amp; QUALITY HEALTHCARE OUTCOMES</th>
<th>DATA &amp; INFORMATION MANAGEMENT</th>
<th>PERFORMANCE IMPROVEMENT</th>
<th>KNOWLEDGE DEVELOPMENT</th>
</tr>
</thead>
</table>
| DISTRIBUTOR     | • Plan and manage inventory levels in accordance with government set standards and clinical demand.  
• Ensure that policies and procedures are in place to distribute product to approved Dispensers for the treatment of approved patients only.  
• Support dispensers in advice regarding inventory management processes including Imprest and emergency access as required  
• Ensure policies and procedures are in place to ensure product cold chain integrity.  
• Educate blood couriers in understanding and maintaining product cold chain integrity.  
• Record distribution data in relevant information systems.  
• Reconcile records held in relevant information systems to identify anomalies and identify opportunities for improvement.  
• Regularly review policies and procedures to identify opportunities for improvement.  
• Provide feedback and advice to contribute to improvement in systems, processes, educational and guidance materials.  |  |  |  |
| NURSE           | • Ensure that patient is authorised and has provided consent to treatment with immunoglobulin therapy.  
• Support prescribers to undertake patient treatment review outcomes (where relevant) through patient education and the scheduling of review appointments where required  
• Understand product specific information and ensure safe administration techniques.  
• Report patient adverse events as required  
• Educate and support patients in self-administered treatment with subcutaneous immunoglobulin (SCig).  
• Ensure follow-up with patients trained in self-administered treatment with SCig.  
• Events and product information for traceability in the patient medical record.  
• Processes to identify opportunities for improvement.  
• Improvement in systems, processes, educational and guidance materials.  |  |  |  |
9.2 Authorisation Request Forms

**INTRAVENOUS IMMUNOGLOBULIN (IVIg)**

**Authorisation Request Form**

**HAEMATOLOGICAL INDICATIONS**

**Previous Immunoglobulin treatment:**
- IVIg
- Subcutaneous Immunoglobulin (SCIg)
- Unknown

**Surname:**

**Given names:**

**DOB:**

**Gender:**
- Female
- Male

**UR:**

**Hospital:**

**Weight:** kg

**Height:** cm

**Product Delivery Instructions**

 dispenser (hospital blood bank/pathology laboratory/pharmacy/private pathology)

**Dispenser name:**

**Street:**

**Suburb:**

**State/Territory:**

**Postcode:**

**Phone:**

**Fax:**

**Email:**

**CONSULTANT’S LETTER MAY BE ATTACHED TO DEMONSTRATE THAT ALL QUALIFYING CRITERIA HAVE BEEN MET.**

**Dose required:**

**Number of doses planned (e.g. 2x24g):**

**DOSE/kg:**

**Frequency:**

**Date required:**

**IMPORTANT:** Your patient will be allocated either Intragam P 6% or an imported IVIg product provided your order meets policy requirements for the supply of IVIg for clinical indications funded under the Criteria. Some hospitals have local policies for imported IVIg product. Please check with your blood and blood products Dispenser (blood bank, pathology laboratory, pharmacy or private pathology).

**Please indicate your preferred imported IVIg product:**
- Kiovig 10%
- Octagam 5%
- Octagam 10%

**OFFICE USE ONLY (Blood Service authorisation)**

**Delegated (MO/TN/Other):**

**Designation (MO/TN/Other):**

**Review required by:**

**(continuing supply will be conditional on this review)**

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**FORM ID - NBA301001**

Template was last updated September 2014

Uncontrolled version when printed
# INTRAVENOUS IMMUNOGLOBULIN (IVIg)

**Authorisation Request Form**

**HAEMATOLOGICAL INDICATIONS**

FOR NEUROLOGICAL & IMMUNOLOGICAL INDICATIONS PLEASE USE DEDICATED FORM

<table>
<thead>
<tr>
<th>Patient details:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surname:</td>
</tr>
<tr>
<td>Given names:</td>
</tr>
<tr>
<td>DOB:</td>
</tr>
<tr>
<td>Hospital:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Requesting Medical Officer Name:</th>
<th>Position:</th>
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<tr>
<th>Pager/Mobile:</th>
<th>Phone:</th>
<th>Fax:</th>
<th>Date:</th>
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<table>
<thead>
<tr>
<th>Consultant Confirming Diagnosis:</th>
<th>Specialty:</th>
</tr>
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<tbody>
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<table>
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<tr>
<th>Name:</th>
<th>Phone:</th>
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<table>
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<th>Email:</th>
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<table>
<thead>
<tr>
<th>Postal Address:</th>
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</table>

**IMPORTANT:** The addresses above will be used for any relevant future correspondence, including the patient treatment review outcome notification form for patients requiring continuing access to government funded immunoglobulin product. For some conditions, the Criteria require review by a specialist in a specific discipline - please refer to the Criteria.

**Prescriber acknowledgement and confirmation** (to be completed by the treating medical specialist or appropriate delegate following discussion with the patient)

I acknowledge the governance and management arrangements for the appropriate supply and use of immunoglobulin products, funded under the national blood arrangements, and the provision of information required to support authorisation. To the best of my knowledge, the information provided in this form is true and correct.

I have explained to the patient (or parent/carer/guardian) and I believe that they are aware of and understand:

- the risks and benefits of treatment with immunoglobulin products and alternative treatments (where these exist),
- the national access conditions and governing requirements for the appropriate supply and use of immunoglobulin products under the national blood arrangements, including that immunoglobulin products may need to change from time to time
- (for patients requiring ongoing treatment only) the nature of ongoing monitoring and review and that access to product will cease if response to treatment does not demonstrate clinical benefit.

I confirm that the patient (or parent/carer/guardian) has provided express consent (explicit oral or written consent) to:

- their personal information and clinical data being collected, reported and stored in a secure database held by the Australian Red Cross Blood Service for the purposes of authorisation;
- de-sensitised data being collated, reported and disclosed by the Australian Red Cross Blood Service to the National Blood Authority to assist with product supply monitoring and planning and for quality and research purposes to improve treatment programs;
- de-sensitised data being reported and disclosed by the National Blood Authority to state and territory health departments and an aggregated report of the de-sensitised data being published on an annual basis on the NBA Website, and treatment.

<table>
<thead>
<tr>
<th>Signature:</th>
<th>Date:</th>
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<tbody>
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<table>
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<tr>
<th>Name:</th>
<th>Position:</th>
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</tbody>
</table>

**YOU MUST SELECT YOUR STATE OR TERRITORY BEFORE PRINTING**

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## INTRAVENOUS IMMUNOGLOBULIN (IVIg)

### Authorisation Request Form

**IMMUNOLOGICAL OR GENERAL INDICATIONS**

**Subcutaneous Immunoglobulin (SCIg)**

**Previous Immunoglobulin treatment:**
- IVIg

**Surname:**

**Given names:**

**DOB:**

**Gender:**
- Female
- Male

**UR:**

**Hospital:**

**Requesting Medical Officer Name:**

**State/Territory:**

**Position:**

**Phone:**

**Fax:**

**Date:**

**Pager/Mobile:**

### PATIENT DETAILS (or affix hospital label)

- **Height:**
- **Weight:**

**PRODUCT DELIVERY INSTRUCTIONS**

- **Dispenser (hospital blood bank/pathology laboratory/pharmacy/private pathology):**
- **Dispenser name:**
- **Street:**
- **Suburb:**
- **State/Territory:**
- **Postcode:**
- **Phone:**
- **Email:**

**CONSULTANT’S LETTER MAY BE ATTACHED TO DEMONSTRATE THAT ALL QUALIFYING CRITERIA HAVE BEEN MET.**

**Dose required:**

**OR**

**Number of doses planned (e.g. 2x24g):**

**DOSE/kg:**

**PLEASE INDICATE PATIENT DIAGNOSIS:**

- **Common variable immunodeficiency**
- **X-linked agammaglobulinemia**
- **Severe combined immunodeficiency**
- **Wiskott-Aldrich syndrome**
- **X-linked lymphoproliferative syndrome**
- **Hyper IgM syndrome**
- **Severe T-cell immunodeficiency**
- **Specific antibody deficiency**
- **Impaired antibody response**
- **Severe T-cell immunodeficiency**
- **Other conditions**

**For all indications above, please complete the following:**

- **Total:** IgG g/L, IgA g/L, IgM g/L
- **Chronic Suppurative Lung Disease:**
  - Yes
  - No

**OTHER CONDITIONS**

- **Impaired IgG**
- **Impaired IgA**
- **Not Performed**

**Primary Immunodeficiency Diseases**

- **Impaired IgG**
- **Impaired IgA**
- **Not Performed**
- **Secondary hypogammaglobulinaemia**

**Invasive or life threatening bacterial infections in the previous year**

**DATE PERFORMED:**

**Review required by:**

**OFFICE USE ONLY (Blood Service authorisation):**

- **Delegate:**
- **Designation (MO/TN/Other):**

**Your patient will be allocated either Intragam P 6% or an imported IVIg product provided your order meets policy requirements for the supply of IVIg for clinical indications funded under the Criteria. Some hospitals have local policies for imported IVIg product. Please check with your blood and blood products Dispenser (blood bank, pathology laboratory, pharmacy or private pathology).**

**Please indicate your preferred imported IVIg product:**

- **Kiovig 10%**
- **Octagam 5%**
- **Octagam 10%**

**Please provide details (including date, product and response, if known):**

**Additional delivery instructions:**

**FOR HAEMATOLOGICAL INDICATIONS PLEASE USE DEDICATED FORM**

** You must select your state or territory before**

**This form is used to request patient specific authorisation from the Australian Red Cross Blood Service (Blood Service) for initial access to immunoglobulin products, assessed against the Criteria for the clinical use of intravenous immunoglobulin in Australia Second Edition July 2012 (Criteria). All fields must be completed, please note that incomplete forms will delay processing.**

**Once complete, signed and dated, please FAX. For enquiries and urgent requests please PHONE:**

**AFTER HOURS PHONE:**

**State/Territory: [ ]**

**Requesting Medical Officer Name:**

**Position:**

**Date:**

**Pager/Mobile:**

**Phone:**

**Fax:**

**Email:**

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**INTRAVENOUS IMMUNOGLOBULIN (IVIg)**
**Authorisation Request Form**

**IMMUNOLOGICAL OR GENERAL INDICATIONS**
FOR HAEMATOLOGICAL & IMMUNOLOGICAL INDICATIONS PLEASE USE DEDICATED FORM

<table>
<thead>
<tr>
<th>Patient details:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Surname:</td>
<td>Given names:</td>
</tr>
<tr>
<td>DOB:</td>
<td>Hospital:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Requesting Medical Officer Name:</th>
<th>Position:</th>
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<tr>
<td>Pager/Mobile:</td>
<td>Phone:</td>
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<td>Fax:</td>
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<td></td>
<td>Date:</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Immunologist Confirming Diagnosis:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
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<tr>
<td>Email:</td>
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<tr>
<td>Postal Address:</td>
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<table>
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<tr>
<th>Treating Medical Specialist:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
</tr>
<tr>
<td>Email:</td>
</tr>
<tr>
<td>Mobile:</td>
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</table>

**IMPORTANT:** The addresses above will be used for any relevant future correspondence, including the patient treatment review outcome notification form for patients requiring continuing access to government funded immunoglobulin product. For some conditions, the Criteria require review by a specialist in a specific discipline – please refer to the Criteria.

<table>
<thead>
<tr>
<th>IMPORTANT: The addresses above will be used for any relevant future correspondence, including the patient treatment review outcome notification form for patients requiring continuing access to government funded immunoglobulin product. For some conditions, the Criteria require review by a specialist in a specific discipline – please refer to the Criteria.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prescriber acknowledgement and confirmation</strong> (to be completed by the treating medical specialist or appropriate delegate following discussion with the patient)</td>
</tr>
</tbody>
</table>

I acknowledge the governance and management arrangements for the appropriate supply and use of immunoglobulin products, funded under the national blood arrangements, and the provision of information required to support authorisation. To the best of my knowledge, the information provided in this form is true and correct.

I have explained to the patient (or parent/carer/guardian) and I believe that they are aware of and understand:

- the risks and benefits of treatment with immunoglobulin products and alternative treatments (where these exist),
- the national access conditions and governing requirements for the appropriate supply and use of immunoglobulin products under the national blood arrangements, including that immunoglobulin products may need to change from time to time,
- (for patients requiring ongoing treatment only) the nature of ongoing monitoring and review and that access to product will cease if response to treatment does not demonstrate clinical benefit.

I confirm that the patient (or parent/carer/guardian) has provided express consent (explicit oral or written consent) to:

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- de-sensitised data being reported and disclosed by the National Blood Authority to state and territory health departments and an aggregated report of the de-sensitised data being published on an annual basis on the NBA Website, and
- treatment.

**YOU MUST SELECT YOUR STATE OR TERRITORY BEFORE PRINTING**

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Form ID - NBA301004
Template was last updated September 2014
Uncontrolled version when printed
**NEUROLOGICAL INDICATIONS**

- Guillain Barré syndrome
- Chronic inflammatory demyelinating polyneuropathy
- Inflammatory myopathy (please select one of the below)
  - Dermatomyositis
  - Polymyositis
  - Inclusion body myositis - with dysphagia
- Multifocal motor neuropathy
- Myasthenia gravis
- Lambert-Eaton myasthenic syndrome
- IgM paraproteinaemic neuropathy
- Other neurological conditions (please specify)

**Induction dose required:**
- Number of doses planned (e.g. 2x24g):
  - Dose/kg:
  - Date required:

**Maintenance dose required:**
- Number of doses planned (e.g. 2x24g):
  - Dose/kg:
  - Date required:

**Please indicate your preferred imported IVIg product:**
- Kiovig 10%
- Octagam 5%
- Octagam 10%

**OFFICE USE ONLY (Blood Service authorisation) Delegate:**

**Designation (MD/TN/Other):**

**Qualifying Criteria:**
- met
- not met
- Request approved
- Referred to [IgG/IgA] Group for Review
- Frequency

**Review required by:**

(continuing supply will be conditional on this review)

---

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**NEUROLOGICAL INDICATIONS**

FOR HAEMATOLOGICAL & IMMUNOLOGICAL INDICATIONS PLEASE USE DEDICATED FORM

<table>
<thead>
<tr>
<th><strong>Patient details:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surname:</strong></td>
<td><strong>Given names:</strong></td>
</tr>
<tr>
<td><strong>DOB:</strong></td>
<td><strong>Hospital:</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Requesting Medical Officer Name:</strong></th>
<th><strong>Position:</strong></th>
</tr>
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<tbody>
<tr>
<td><strong>Payer/Mobile:</strong></td>
<td><strong>Phone:</strong></td>
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<td><strong>Fax:</strong></td>
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<td></td>
<td><strong>Date:</strong></td>
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<table>
<thead>
<tr>
<th><strong>Neurologist Confirming Diagnosis:</strong></th>
<th></th>
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<tbody>
<tr>
<td><strong>Name:</strong></td>
<td><strong>Phone:</strong></td>
</tr>
<tr>
<td><strong>Email:</strong></td>
<td><strong>Mobile:</strong></td>
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<tr>
<td><strong>Postal Address:</strong></td>
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<td></td>
<td><strong>Mobile:</strong></td>
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</table>

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**Prescriber acknowledgement and confirmation** (to be completed by the treating medical specialist or appropriate delegate following discussion with the patient)

I acknowledge the governance and management arrangements for the appropriate supply and use of immunoglobulin products, funded under the national blood arrangements, and the provision of information required to support authorisation. To the best of my knowledge, the information provided in this form is true and correct.

I have explained to the patient (or parent/carer/guardian) and I believe that they are aware and understand:

- the risks and benefits of treatment with immunoglobulin products and alternative treatments (where these exist),
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- an aggregated report of the de-sensitised data being published on an annual basis on the NBA Website, and
- treatment.

**YOU MUST SELECT YOUR STATE OR TERRITORY BEFORE PRINTING**

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# INTRAVENOUS IMMUNOGLOBULIN (IVig) Authorisation Request Form

**RENAITAL INDICATIONS**

**About this form:** This form is used to request patient specific authorisation from the Australian Red Cross Blood Service (Blood Service) for initial access to immunoglobulin products, assessed against the Criteria for the clinical use of intravenous immunoglobulin in Australia Second Edition July 2012 (Criteria). All fields must be completed, please note that incomplete forms will delay processing. Once complete, signed and dated, please FAX. For enquiries and urgent requests please PHONE.

**Patient Details (or affix hospital label)**

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surname</td>
<td></td>
</tr>
<tr>
<td>Given names</td>
<td></td>
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<tr>
<td>DOB</td>
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<tr>
<td>Gender</td>
<td>Female</td>
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<tr>
<td>Weight</td>
<td></td>
</tr>
<tr>
<td>Height</td>
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</tbody>
</table>

**Previous Immunoglobulin treatment:**

- Yes
- No
- Unknown

Please provide details including date, product and response, if known:

**Product Delivery Instructions**

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispenser (hospital blood bank/pathology laboratory/pharmacy/private pathology)</td>
<td></td>
</tr>
<tr>
<td>Dispenser name</td>
<td></td>
</tr>
<tr>
<td>Street</td>
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<tr>
<td>Suburb</td>
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<td>State/Territory</td>
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<td>Fax</td>
<td></td>
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<tr>
<td>Email</td>
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</tbody>
</table>

**Dose Required:**

- **g**
- Number of doses planned (e.g. 2 x 2,4 g)
- DOSE/kg

**Important:** If your patient will be allocated either Intragam P 6% or an imported IVig product provided your order meets policy requirements for the supply of IVig for clinical indications funded under the Criteria. Some hospitals have local policies for imported IVig product. Please check with your blood and blood products Dispenser (blood bank, pathology laboratory, pharmacy or private pathology).

**Consultant’s Letter may be attached to demonstrate that all qualifying criteria have been met.**

**Office Use Only (Blood Service authorisation):**

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delegate (MO/TN/Other)</td>
<td></td>
</tr>
</tbody>
</table>

**Reviewer required by:**

(continuing supply will be conditional on this review)

---

**PLEASE INDICATE PATIENT DIAGNOSIS:**

Consultant’s Letter may be attached to demonstrate that all qualifying criteria have been met.

**Diagnosis**

- Pre-transplant
  - ABO incompatible
  - Highly Sensitised (HLA)

- Post-transplant
  - Antibody Mediated Rejection
  - Steroid Resistant
  - Antibody mediated rejection
  - Cellular Rejection
  - BK Virus
  - CMV
  - Other transplant risk (please specify)
  - Conventional immunosuppression contraindicated
  - Details

- Biopsy Results - attached
  - Yes
  - No

- Concurrent Therapy
  - Plasma Exchange
  - Number of Planned Exchanges
  - Number of Exchanges
  - Dates

- Immunosuppression
  - Details

**Conventional immunosuppression contraindicated**

**Dose required:**

- **g**
- Number of doses planned (e.g. 2 x 2,4 g)
- DOSE/kg

**Frequency:**

Please specify

**Date required:**

---

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## INTRAVENOUS IMMUNOGLOBULIN (IVIg) Authorisation Request Form

### RENAL INDICATIONS

**Patient details:**

<table>
<thead>
<tr>
<th>Surname:</th>
<th>Given names:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DOB:</th>
<th>Hospital:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Requesting Medical Officer Name:**

<table>
<thead>
<tr>
<th>Pager/Mobile:</th>
<th>Phone:</th>
<th>Fax:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Renal physician/nephrologist:**

<table>
<thead>
<tr>
<th>Name:</th>
<th>Phone:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Email:</th>
<th>Mobile:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Postal Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Important:** The addresses above will be used for any relevant future correspondence, including the patient treatment review outcome notification form for patients requiring continuing access to government funded immunoglobulin product. For some conditions, the Criteria require review by a specialist in a specific discipline – please refer to the Criteria.

**Prescriber acknowledgement and confirmation** (to be completed by the treating medical specialist or appropriate delegate following discussion with the patient)

I acknowledge the governance and management arrangements for the appropriate supply and use of immunoglobulin products, funded under the national blood arrangements, and the provision of information required to support authorisation. To the best of my knowledge, the information provided in this form is true and correct.

I have explained to the patient (or parent/carer/guardian) and I believe that they are aware of and understand:

- the risks and benefits of treatment with immunoglobulin products and alternative treatments (where these exist),
- the national access conditions and governing requirements for the appropriate supply and use of immunoglobulin products under the national blood arrangements, including that immunoglobulin products may need to change from time to time
- (for patients requiring ongoing treatment only) the nature of ongoing monitoring and review and that access to product will cease if response to treatment does not demonstrate clinical benefit.

I confirm that the patient (or parent/carer/guardian) has provided express consent (explicit oral or written consent) to:

- their personal information and clinical data being collected and recorded in a secure database held by the Australian Red Cross Blood Service for the purposes of authorisation,
- de-sensitised data being collated, reported and disclosed to the Australian Red Cross Blood Service to the National Blood Authority to assist with product supply monitoring and planning and for equality and research purposes to improve treatment programs,
- de-sensitised data being reported and disclosed by the National Blood Authority to state and territory health departments and an aggregated report of the de-sensitised data being published on an annual basis on the NBA Website, and
- treatment.

**Signature:**

<table>
<thead>
<tr>
<th>Name:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Position:**

<table>
<thead>
<tr>
<th>PRINT</th>
</tr>
</thead>
</table>

---

**YOU MUST SELECT YOUR STATE OR TERRITORY BEFORE PRINTING**

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Form ID - NBA301003  Template was last updated September 2014  Uncontrolled version when printed
**SUBCUTANEOUS IMMUNOGLOBULIN (SCig)**

**Authorisation Request Form**

**HAEMATOLOGICAL INDICATIONS**

**About this form:** This form is used to request patient specific authorisation from the Australian Red Cross Blood Service (Blood Service) for initial access to immunoglobulin products, assessed against the Criteria for the clinical use of intravenous immunoglobulin in Australia Second Edition July 2012 (Criteria).

All fields must be completed, please note that incomplete forms will delay processing.

Once complete, signed and dated, please FAX:

**FOR IMMUNOLOGICAL INDICATIONS PLEASE USE DEDICATED FORM**

**YOU MUST SELECT YOUR STATE OR TERRITORY BEFORE PRINTING**

---

**CSL SCIg Trial**

**Unknown**

**Surname:**

**Given names:**

**DOB:**

**Gender:**

Female  Male

**UR:**

**Hospital:**

**SCIg Program Hospital:**

**Requesting Medical Officer Name:**

**State/Territory:**

**Position:**

**Phone:**

**Fax:**

**Date:**

**Pager/Mobile:**

**PATIENT DETAILS**

(affix hospital label)

**PRODUCT DELIVERY INSTRUCTIONS**

**Dispenser** (hospital blood bank/pathology laboratory/pharmacy/private pathology)

**Dispenser name:**

**Street:**

**Suburb:**

**State/Territory:**

**Postcode:**

**Phone:**

**Fax:**

**Email:**

---

**CONSULTANT’S LETTER MAY BE ATTACHED TO DEMONSTRATE THAT QUALIFYING CRITERIA HAVE BEEN MET.**

---

**Dose per infusion:**

**Total dose per month:**

**Date required:**

**Preferred SCIg product:**

Evogam  Gammanorm  Kiovig

---

**OFFICE USE ONLY (Blood Service authorisation)**

**Delegate:**

**Designation (MO/TN/Other):**

---

**Qualifying Criteria**

met  not met  Request approved  yes  no  Referred to ID/O/lg Group for Review: yes  no

**Product:**

Dose per infusion:  g  Total dose per month:  g

---

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Form ID: NBA301006  Template was last updated September 2014  Uncontrolled version when printed  Page 1 of 2

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**IMMUNOGLOBULIN GOVERNANCE**

**NOVEMBER 2014**

---

**IMMUNOGLOBULIN GOVERNANCE**

**NOVEMBER 2014**

---

**SAMPLE**

---

**SAMPLE**
**SUBCUTANEOUS IMMUNOGLOBULIN (SCig)**

**Authorisation Request Form**

**HAEMATOLOGICAL INDICATIONS**

*FOR IMMUNOLOGICAL INDICATIONS PLEASE USE DEDICATED FORM*

<table>
<thead>
<tr>
<th>Patient details:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surname:</strong></td>
</tr>
<tr>
<td><strong>DOB:</strong></td>
</tr>
<tr>
<td><strong>Hospital:</strong></td>
</tr>
<tr>
<td><strong>Given names:</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Requesting Medical Officer:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name:</strong></td>
</tr>
<tr>
<td><strong>Position:</strong></td>
</tr>
<tr>
<td><strong>PAGER/ MOBILE:</strong></td>
</tr>
<tr>
<td><strong>Phone:</strong></td>
</tr>
<tr>
<td><strong>Fax:</strong></td>
</tr>
<tr>
<td><strong>DATE:</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consultant Confirming Diagnosis:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name:</strong></td>
</tr>
<tr>
<td><strong>Specialty:</strong></td>
</tr>
<tr>
<td><strong>Phone:</strong></td>
</tr>
<tr>
<td><strong>Mobile:</strong></td>
</tr>
</tbody>
</table>

**IMPORTANT:** The addresses above will be used for any relevant future correspondence, including the patient treatment review outcome notification form for patients requiring continuing access to government funded immunoglobulin product. For some conditions, the Criteria require review by a specialist in a specific discipline - please refer to the Criteria.

**Prescriber acknowledgement and confirmation** (to be completed by the treating medical specialist or appropriate delegate following discussion with the patient)

- I acknowledge the governance and management arrangements for the appropriate supply and use of immunoglobulin products, funded under the national blood arrangements, and the provision of information required to support authorisation. To the best of my knowledge, the information provided in this form is true and correct.

- I have explained to the patient (or parent/carer/guardian) and I believe that they are aware of and understand:
  - the risks and benefits of treatment with immunoglobulin products and alternative treatments (where these exist),
  - the national access conditions and governing requirements for the appropriate supply and use of immunoglobulin products under the national blood arrangements, including that immunoglobulin products may need to change from time to time,
  - (for patients requiring ongoing treatment only) the nature of ongoing monitoring and review and that access to product will cease if response to treatment does not demonstrate clinical benefit.

- I confirm that the patient (or parent/carer/guardian) has provided express consent (explicit oral or written consent) to:
  - their personal information and clinical data being collected and stored in a secure database held by the Australian Red Cross Blood Service for the purposes of authorisation,
  - de-sensitised data being collated, reported and disclosed by the Australian Red Cross Blood Service to the National Blood Authority to assist with product supply monitoring and planning, and for quality and research purposes to improve treatment programs,
  - de-sensitised data being reported and disclosed by the National Blood Authority to state and territory health departments and an aggregated report of the de-sensitized data being published on an annual basis on the NBA Website, and
  - treatment.

- I also confirm:
  - the patient is suitable for self-administered treatment within a participating hospital based SCig program (as specified on page 1 of this form), and
  - the approved access conditions and governing requirements will be complied with through the hospital based SCig program.

<table>
<thead>
<tr>
<th>Signature:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name:</strong></td>
<td><strong>Position:</strong></td>
</tr>
</tbody>
</table>

**YOU MUST SELECT YOUR STATE OR TERRITORY BEFORE PRINTING**

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### Patient Details

| Surname: |  |
| Given names: |  |
| DOB: |  |
| Gender: |  |  |
| UR: |  |
| Hospital: |  |
| SCIG Program Hospital |  |

### Previous Immunoglobulin Treatment

- Intravenous Immunoglobulin (IVIg)
- CSL SCIG Trial
- Other SCIG
- Normal Human Immunoglobulin (NHIG)
- Unknown

Please provide details (including date, product and response, if known).

### Product Delivery Instructions

| Dispenser (hospital blood bank/pathology laboratory/pharmacy/private pathology) |  |
| Dispenser name: |  |
| Street: |  |
| Suburb: |  |
| State/Territory: |  |
| Postcode: |  |
| Phone: |  |
| Fax: |  |

### Additional Delivery Instructions:

Please provide details (including date, product and response, if known).

### Immunological Indications

#### Primary Immunodeficiency Diseases

- Common variable immunodeficiency
- X-linked agammaglobulinemia
- Severe combined immunodeficiency
- Wiskott-Aldrich syndrome
- X-linked lymphoproliferative syndrome
- Hyper-IgM syndrome
- Severe T-cell immunodeficiency
- Other conditions (please specify)

For all indications above please complete the following:

- Specific antibody deficiency (please complete the following)
- Frequent bacterial infections despite continuous oral antibiotic therapy for three months
- Yes          No
- Please provide details
- Antibody response to
- Tetanus Vaccine
  - Normal
  - Impaired
  - Not Performed
- Total IgG
  - Normal
  - Impaired
  - Not Performed
- Invasive or life threatening bacterial infections in the previous year
  - Yes          No
  - Please provide details

### Dosage Per Infusion

Dose per infusion:  
Total dose per month:  
Date required:  

### Preferred SCIG Product

- Evogam
- Gammanorm
- Kiovig

### Office Use Only (Blood Service authorisation)

Delegated:  
Designation (MD/TN/Other):  

Qualifying Criteria:  
- met not met
- Request approved:  
  - yes
  - no
- Referred to [DO/IVIG Group for Review]:  
  - yes
  - no

Product:  
Dose per infusion:  
Total dose per month:  

Review required by:  
(Continuing supply will be conditional on this review)
SUBCUTANEOUS IMMUNOGLOBULIN (SCIg)  
Authorisation Request Form  
IMMUNOLOGICAL INDICATIONS  
FOR HAEMATOLOGICAL INDICATIONS PLEASE USE DEDICATED FORM

Patient details:  
Surname:  
DOB:  
Hospital:  

Requesting Medical Officer Name:  
Position:  
Pager/Mobile:  
Phone:  
Fax:  
Date:  

Immunologist Confirming Diagnosis:  
Name:  
Email:  
Postal Address:  
Phone:  
Mobile:  

Treating Medical Specialist:  
Specialty:  
Name:  
Email:  
Postal Address:  
Phone:  
Mobile:  

IMPORTANT: The addresses above will be used for any relevant future correspondence, including the patient treatment review outcome notification form for patients requiring continuing access to government funded immunoglobulin product. For some conditions, the Criteria require review by a specialist in a specific discipline - please refer to the Criteria.

Prescriber acknowledgement and confirmation (to be completed by the treating medical specialist or appropriate delegate following discussion with the patient)

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▪ (for patients requiring ongoing treatment only) the nature of ongoing monitoring and review and that access to product will cease if response to treatment does not demonstrate clinical benefit.

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▪ their personal information and clinical data being collected and recorded in a secure database held by the Australian Red Cross Blood Service for the purposes of authorisation,
▪ de-sensitised data being collated, reported and disclosed by the Australian Red Cross Blood Service to the National Blood Authority to assist with product supply monitoring and planning, and for quality and research purposes to improve treatment programs,
▪ de-sensitised data being reported and disclosed by the National Blood Authority to state and territory health departments and an aggregated report of the de-sensitised data being published on an annual basis on the NBA Website, and
▪ treatment.

I also confirm:

▪ the patient is suitable for self-administered treatment within a participating hospital based SCIg program (as specified on page 1 of this form), and
▪ the approved access conditions and governing requirements will be complied with through the hospital based SCIg program.

Signature:  
Date:  
Name:  
Position:  

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Form ID - NBA301005  
Template was last updated September 2014  
Uncontrolled version when printed
9.3 Review Outcome Notification Form

REVIEW OUTCOME NOTIFICATION FORM
Please complete one of the following review outcomes, sign and fax back to the above contacts.

RE: «Patient» DOB: «ONE»/«TWO»/«THREE»
Consultant: «Title» «FirstName» «LastName»
Diagnosis: Chronic inflammatory demyelinating polyneuropathy
Product, dose and frequency: «Product» «Dose»g «Frequency»
Review Date: «<<Date>>»
Review Outcome Notification Due Date: {{<<Date>>}}

<table>
<thead>
<tr>
<th>Outcome 1 – Cessation of IVlg</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ This patient will be ceasing IVlg therapy. Final infusion date ____________ (please specify)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome 2 – Request for continuation of IVlg</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Patient has been reviewed by a neurologist within the last 12 months</td>
</tr>
<tr>
<td>Effectiveness can be demonstrated by objective findings of either of the outcomes below. (Please tick the relevant box):</td>
</tr>
<tr>
<td>□ Improvement in functional scores (activities of daily living – ADL) or quantitative muscle scores or Medical Research Council (MRC) muscle assessment or neuropathy score;</td>
</tr>
<tr>
<td>OR</td>
</tr>
<tr>
<td>□ Stabilisation of disease as defined by stable functional scores (ADLs) or quantitative muscle scores or MRC muscle assessment or neuropathy score after previous evidence of deterioration in one of these scores.</td>
</tr>
</tbody>
</table>

Review of Dose, Frequency and Duration – Please aim for the minimum effective dose.

| □ I would like to continue IVlg at the current dose and frequency for ____________ months. |
| OR |
| □ I would like to reduce / increase (please circle) the dose and/or frequency as follows: |
| Patient Weight: ________ (kg) Dose ________ (g) Frequency __________________ for ____________ months |
| Please specify reason: |

Signed: ______________________ Name: __________________________ Date: ___ / ___ / 20__
Name of treating neurologist: _______________________________________________________
Contact phone number: ___________________ Fax number: ___________________
(Please provide contact details to facilitate confirmation of authorisation)

BLOOD SERVICE AUTHORISATION (BLOOD SERVICE ONLY)
Approved at current dose and frequency □ Yes □ No Review Required By / / 20
Other: Dose ____________ g Frequency __________________
Name of Blood Service Delegate (please print): ___________________ Designation (MO/TN/Other): ___________________
Signature: __________________________ Date: ___ / ___ / 20__
I acknowledge the governance and management arrangements for the appropriate supply and use of immunoglobulin products, funded under the national blood arrangements, and the provision of information required to support authorisation. To the best of my knowledge, the information provided in this form is true and correct.

I have explained to the patient (or parent/carer/guardian) and I believe that they are aware of and understand:
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- de-sensitised data being reported and disclosed by the National Blood Authority to state and territory health departments and an aggregated report of the de-sensitised data being published on an annual basis on the NBA Website, and
- treatment.

I also confirm (if applicable):
- the patient is suitable for self-administered treatment within a participating hospital (based SC Ig program as specified on page 1 of this form), and
- the approved access conditions and governing requirements will be complied with through the hospital based SC Ig program.

Signature: 
Name: 
Date: 
Position: 
9.4 National Immunoglobulin Governance Advisory Committee (NIGAC) Terms of Reference

Overview
The NIGAC is established as the national advisory body to support the Jurisdictional Blood Committee (JBC) and National Blood Authority (NBA) with effective and efficient governance of immunoglobulin (Ig) products supplied and funded under the national blood arrangements.

Role
The NIGAC will:

- Provide advice and make recommendations to support the development and implementation of the National Immunoglobulin Governance Program (described below) by the NBA
- As the peak committee within the national network of committees, provide advice and make recommendations to support cost effective and clinically appropriate governance, management and use of Ig products through the ongoing National Ig Governance Program, once established, including advice and recommendations in relation to each of the measures within the Program
- Provide advice as requested by governments on other matters concerning the availability, governance, management or use of immunoglobulin products.

Establishment and support
The NIGAC will be established as a subcommittee of JBC and committee support will be provided by the NBA.

Membership
The membership of the NIGAC will comprise:

<table>
<thead>
<tr>
<th>Member</th>
<th>Nominating organisation or process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair</td>
<td>JBC</td>
</tr>
<tr>
<td>Medical Specialty Representatives*:</td>
<td>Nominees of:</td>
</tr>
<tr>
<td>- Neurology</td>
<td>- Australian and New Zealand Association of Neurologists (ANZAN)</td>
</tr>
<tr>
<td>- Haematology</td>
<td>- Haematology Society of Australia and New Zealand (HSANZ)</td>
</tr>
<tr>
<td>- Immunology</td>
<td>- Australasian Society of Immunology and Allergy (ASCIA)</td>
</tr>
<tr>
<td>- Transplantation Medicine</td>
<td>- Transplantation Society of Australia and New Zealand (TSANZ)</td>
</tr>
<tr>
<td>One consumer (patient/carer) representative</td>
<td>Patient support organisation nominations</td>
</tr>
<tr>
<td>Nurse with expertise in immunoglobulin product administration</td>
<td>Jurisdictional nominations</td>
</tr>
<tr>
<td>Health economist</td>
<td>Expert selection</td>
</tr>
<tr>
<td>Epidemiologist</td>
<td>Expert selection</td>
</tr>
<tr>
<td>Commonwealth representative</td>
<td>Department of Health nomination</td>
</tr>
<tr>
<td>State/territory representatives</td>
<td>Nominees from states and territories</td>
</tr>
<tr>
<td>- large jurisdiction</td>
<td></td>
</tr>
<tr>
<td>- small jurisdiction</td>
<td></td>
</tr>
<tr>
<td>NBA Representative - NBA General Manager</td>
<td>Ex officio</td>
</tr>
</tbody>
</table>

Observers

<table>
<thead>
<tr>
<th>Nominating organisation or process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Representative of national authoriser</td>
</tr>
</tbody>
</table>
Proxies, subcommittees and expert advice

Proxies for the medical specialty representatives, health economist, epidemiologist, consumer representative, nurse and jurisdictional representatives will be identified through the initial nomination and selection process. For other members a proxy may be nominated as required.

The NIGAC may request the establishment of subcommittees for specific purposes. The NIGAC may also request the assistance of other clinical specialists for advice on matters relating to specific conditions, or other expert advisers.

Frequency of meetings and teleconferences

Up to four full day face-to-face meetings (quarterly) per year may be required. Additional teleconferences may also be organised for more urgent single-issue advice, specifically any Criteria clarifications that may be required.

Duration of membership

Appointments to NIGAC will be for a period of two years, with the possibility of reappointment. The process of reappointment may be staggered over a period of time to provide for continuity of membership, and incumbent appointments may be extended for this purpose.

Conflicts of Interest

All members (representatives and experts) are required to declare any conflicts of interest that may bias their input. The Chair examines conflicts of interest and makes decisions as to the member’s ongoing participation or limitation to participation.

Remuneration and allowances

The NBA will make best endeavours to ensure that members are not out of pocket when providing services to the committee. Sitting fees will be paid in accordance with the NBA Management Instruction for remuneration for Non-NBA staff. For this committee the Remuneration Tribunal Determination for holders of part-time public office (category 3) applies. Expenses associated with travel will be managed in accordance with the NBA’s travel policy for third parties.