NATIONAL BLOOD AUTHORITY
AUSTRALIA

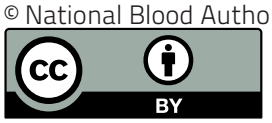
IMMUNOGLOBULIN GOVERNANCE

National Policy: Access to Government-Funded Immunoglobulin Products in Australia

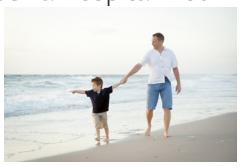
> THIRD EDITION
> JULY 2019

Governance

BLOODSTAR







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1. PURPOSE AND SCOPE

In Australia, blood products are provided under the National Blood Agreement[1] at no cost to patients, through arrangements managed by the National Blood Authority (NBA). The role of the NBA is to manage the national blood supply to ensure that healthcare providers have reliable and efficient access to blood and blood products needed for appropriate patient care. Immunoglobulin (Ig) products are included in these national blood arrangements when the prescription, use and management are in accordance with this document: *National Policy: access to government–funded Ig products in Australia* (National Policy).

This document sets out the process that must be followed and describes the rules and requirements that must be complied with to access government-funded Ig products in Australia. This document should be read in conjunction with the Criteria for the clinical use of immunoglobulin in Australia[2] (Criteria) available on the NBA website at https://www.criteria.blood.gov.au/. The Criteria identify the conditions and circumstances for which the use of Ig is clinically appropriate and accessible to patients under the National Policy.

The products covered by this document include intravenous Ig (IVIg), subcutaneous Ig (SCIg) and normal human Ig (NHIg). For a full list of products supplied and funded under the national blood arrangements please refer to the NBA website at www.blood.gov.au/national-product-list.

The remainder of this document includes the following sections:

Background	Captures information relevant to patient access to government-funded Ig products and may assist readers of this document to understand the various policies and processes associated with the National Policy and the Ig Governance Program more broadly.
National Policy: Principles	Provides the foundation for the provision of Ig products under the National Blood Agreement and the remaining sections in this document.
National Policy: Access Arrangements	Describes the processes, rules and requirements that must be followed to access Ig products under the National Blood Agreement.
National Policy: Roles and Responsibilities	Identifies those directly involved in the prescription, use and management of government-funded Ig products throughout the supply chain and within health services and describes the responsibilities, authority and accountability of each of those roles.
Tools and Resources	Provides guidance on where to find useful tools and resources.
Glossary	Identifies and defines terms and acronyms relevant to this policy and associated processes.

This document replaces all previous editions of the National Policy and applies to all Australian States and Territories from 15 July 2019.

The National Policy does not apply when Ig products are sourced outside of national blood arrangements. If Ig is required to treat a medical condition that is not funded by governments, access for imported product may be organised at a local level under the jurisdictional direct order (JDO) arrangements. For more information about JDO and other supply arrangements, please refer to the NBA website at http://www.blood.gov.au/Intravenous-Ig.

Seeking Authorisation for Access to Government Funded Ig

INITIAL DIAGNOSIS
The patient is diagnosed with a condition that may benefit from immunoglobulin therapy.

PATIENT CONSENT
The doctor provides information to the patient and explains the access arrangements. The doctor obtains the patient's consent for treatment and for the recording, retention and use of their personal information in BloodSTAR for the purpose of assessing the patient's eligibility to receive immunoglobulin via the National Ig Governance Program.

CREATING AND SUBMITTING IG REQUEST
The doctor answers the questions relating to their patient and their medical condition in BloodSTAR and submits request.

ASSESSMENT OF REQUEST
An authoriser from the Australian Red Cross Blood Service receives the request and assesses the request in accordance with the Criteria for the clinical use of Ig in Australia

REQUEST APPROVED

APPROVED
The doctor is notified via an email alert that the patient is approved to receive Ig via the National Ig Governance Program and is directed to log into BloodSTAR.

NOTIFICATION TO PATIENT AND PRESCRIPTION OF IG
The doctor informs the patient/carer that their request was approved and prescribes Ig in accordance with the BloodSTAR authorisation. Appointments are scheduled for infusions and review.

REQUEST NOT APPROVED

NOT APPROVED
The doctor is notified via an email alert and directed to log into BloodSTAR. The decline is recorded in BloodSTAR.

The doctor may wish to:

EXPLORE OTHER OPTIONS
The patient is not eligible to access Ig via the National Ig Governance Program. The doctor may wish to seek Ig via a Jurisdictional Direct Order, purchase Ig at the patient's expense or seek alternative treatment.

or

REVISE AND RESUBMIT
The doctor may wish to revise and resubmit the request.

Prior to patient attending appointment for IVIg infusion or collection of SCIg

SUBMITTING DISPENSE REQUEST
The nurse prepares and submits the Dispense Request in BloodSTAR.

RECEIVING DISPENSE REQUEST
The dispenser receives the Dispense Request and checks patient authorisation in BloodNET.

Is the patient authorised in BloodSTAR?

NO

The patient is not authorised in BloodSTAR

UNAUTHORISED REQUEST
The requesting clinic is informed. Requesting doctor resubmits authorisation request.

YES

The patient is authorised in BloodSTAR

CHECKING INVENTORY LEVELS
The dispenser checks the inventory levels against planned infusions

Is there enough stock available?

YES

ENOUGH STOCK AVAILABLE
The product is dispensed to the requesting location

RECONCILE DISPENSE
The dispenser reconciles the dispense against the patient's authorisation in BloodNET

PATIENT RECEIVES IG
The patient attends and receives their IVIg infusion or SCIg for self-administration

NO

NOT ENOUGH STOCK AVAILABLE
The dispenser submits a BloodNET order for Ig

The Australian Red Cross Blood Service receipts and fulfils order and sends to the dispenser.

Order Product to replenish Ig stock levels.

2. BACKGROUND

Immunoglobulin (Ig) 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.

Ig is a precious blood product, offering significant therapeutic benefit to a substantial number of people. However, due to the high cost of Ig and the demand for use in Australia, eligibility for access to government-funded Ig is managed through strong governance arrangements, like many other high cost treatments.

In 2003, the Australian and State and Territory Governments signed the National Blood Agreement[1] where all parties agreed to implement a coordinated national approach to policy setting, governance and management of the Australian blood sector, including administrative and financial arrangements.

Under the National Blood Agreement, blood and blood products are provided at no direct cost to patients. The blood sector is funded by the Australian Government (63%) and by the States and Territories (37%), with the funding from each State and Territory determined by the quantity of product provided to each particular State and Territory.

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.

The National Blood Authority (NBA) provides the framework for access to Ig products funded under the National Blood Agreement. The NBA manages contracts with suppliers to ensure the safe, secure, adequate and affordable supply of blood and blood products and blood related products including Ig from domestic and imported sources. Since 2007, access criteria (see the Criteria below) have been determined by governments to identify the specific circumstances in which Ig products may be accessed under the National Blood Agreement. The NBA contracts the Australian Red Cross Blood Service (Blood Service) to provide clinical advice to those involved in the management and use of Ig, and assess and authorise requests for access in accordance with the Criteria and to distribute Ig products throughout Australia as the Distributor.

2.1 National Immunoglobulin Governance Program

In 2012, on behalf of all Australian Governments, the NBA commissioned a review of the adequacy of the existing intravenous Ig (IVIg) authorisation and clinical governance arrangements, with a view to recommending options for improvements to deliver Governments' goals for the management of IVIg in particular. The *Review of the clinical governance and authorisation process for IVIg*[3] (Review) examined the framework in place at that time whereby access to government-funded Ig was subject to the Criteria and implemented through the Australian Red Cross Blood Service distribution and authorisation arrangements.

The Review highlighted significant variation in IVIg use, management and processes nationally, with a number of inefficiencies being described. Recommendations that arose from the Review included enhancing governance arrangements for IVIg, SCIg and NHIg, and the National Immunoglobulin (Ig) Governance Program was established as a result.

The National Ig Governance Program was introduced in 2014 to achieve Governments' objectives for Ig products funded and supplied under the national blood arrangements, namely to:

- ensure Ig 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;
- ensure that access to Ig products is consistent with the criteria for access determined by Governments; and
- improve the capture of information of the need for, use of, and outcomes of treatment with Ig products to inform future decisions.

Under the National Ig Governance Program, Australians can be assured that Ig products provided under the National Blood Agreement are directed consistently to those patients across Australia who are most likely to benefit based on reliable evidence, using the lowest effective dose, and where alternative therapies are limited. Health professionals are integral to the program, and drive its success. When prescribing and managing the use of government-funded Ig products, health professionals must comply with the National Policy.

The NBA is responsible for administering the National Ig Governance Program. This is done through the development and maintenance of a national governance framework comprising the National Policy, the Criteria, and the national online system BloodSTAR (Blood System for Tracking Authorisation and Review) with support from a national network of committees. Reporting, education, research, and performance improvement are additional components of the National Ig Governance Program intended to drive the program toward successful outcomes.

Jurisdictions have agreed to the framework developed by the NBA and, in accordance with the National Blood Agreement, have a role in implementation. State and Territory Governments are each responsible for managing the day to day activities related to Ig products in their jurisdiction, including ensuring Ig products are dispensed in accordance with legislated State or Territory requirements. Within each jurisdiction, all individuals and facilities involved in the process of requesting, authorising, supplying, dispensing, and administering Ig products have allocated roles and responsibilities introducing stakeholder accountability into the process of managing Ig products. These roles and responsibilities are described later in this document.

2.2 The Criteria

The *Criteria for the clinical use of Immunoglobulin in Australia*[2] (the Criteria) identifies the conditions and circumstances for which the use of Ig is considered to be clinically appropriate and for which Ig products are able to be accessed under this National Policy. The Criteria determines patient eligibility to access government-funded Ig and should not be relied upon to guide treatment as they are not clinical practice guidelines. Adherence to the Criteria and this document, the National Policy, ensures government-funded Ig is prescribed for the treatment of patients who are likely to benefit from Ig therapy, consistent with the evidence base, and for whom there are no safe and effective alternative treatments.

The Criteria are based on evidence identified through systematic reviews of the literature. Where insufficient evidence was found to exist, the Criteria are based on the opinions provided by clinical experts as individuals, clinical colleges and/or clinical societies.

The first version of the Criteria was published in 2007. The Criteria was updated and republished in 2012, and subsequently adapted for use within BloodSTAR. Version 3 Criteria were released nationally and into BloodSTAR in 2018. The Criteria will continue to be reviewed regularly to ensure the conditions supported and qualifying, exclusion, review criteria and indicative dosages remain, in the light of emerging evidence, appropriate and in keeping with an evidence-based approach. Further information on the development of the current version of the Criteria, and previous versions is available on the NBA website at https://www.blood.gov.au/ivig-criteria.

2.3 Funding Ig under the National Blood Agreement

Guided by National Blood Agreement policy objectives and aims, and following publication of the first edition of the Criteria, Health Ministers, through the then Australian Health Ministers' Conference, agreed in December 2007, to limit access to Ig funded under the National Blood Agreement for patients with medical conditions where the indication for use is identified in the Criteria[3] under one of three categories:

1. Conditions for which Ig has an established therapeutic role.
2. Conditions for which Ig has an emerging therapeutic role.
3. Conditions for which Ig use is in exceptional circumstances only.

Ig products are not available under the National Blood Agreement for conditions that have been assessed and identified in the Criteria as conditions for which Ig use is not supported.

2.4 BloodSTAR

Introduced in 2016, BloodSTAR (Blood System for Tracking Authorisations and Reviews) was developed by the NBA on behalf of all Australian Governments to serve the needs of health providers and support users to meet their obligations under the National Policy. Through BloodSTAR, Medical Officers seeking to prescribe Ig are able to determine whether patients are eligible to receive government-funded product and seek authorisation for access. Nurses/Midwives and those dispensing Ig products (Dispensers) also utilise BloodSTAR and associated systems (i.e. BloodNet) to manage infusions and dispensing practices to approved patients.

BloodSTAR streamlines the authorisation process, reduces variability and standardises prescribing practices, and increases efficiency and transparency while strengthening decision-making and improving data capture. The BloodSTAR system is subject to a planned program of enhancement and improvement to improve user experience, ensure it is fit for purpose, and continues to support the National Ig Governance Program.

Prescribers and Nurses/Midwives managing patients authorised to receive government-funded Ig product require unique user access to BloodSTAR. User access is only granted where the person requesting access can be verified by a Facility Administrator of the facility at which they are employed. BloodSTAR user access is requested through the NBA BloodPortal on the NBA website www.portal.blood.gov.au. Dispensers access BloodSTAR through a module in BloodNet and are not required to register for a separate BloodSTAR user access.

The NBA's Blood Operations Centre (BOC) monitors the operations of the NBA's blood systems, including BloodSTAR, and supports end users with all technical system issues. BOC operates 24 hours a day, 7 days a week to support users and the blood sector and can be contacted on 13 000 BLOOD (13 000 25663) or at support@blood.gov.au.

Clinically trained staff at the Australian Red Cross Blood Service (Blood Service) are able to provide clinical advice to those involved in the management and use of Ig and to use BloodSTAR to assess and authorise requests for access in accordance with the Criteria as Authorisers.

3. NATIONAL POLICY: PRINCIPLES

3.1 Immunoglobulin Products

Australian governments have agreed to provide Immunoglobulin (Ig) under the National Blood Agreement when the prescription, use and management of Ig accords with the following principles:

1. Ig product is prescribed according to clinical need, appropriate clinical practice and in accordance with the Criteria and an approved authorisation in BloodSTAR.
2. Ig product is dispensed for a patient assessed as eligible against the Criteria and with an approved authorisation in BloodSTAR.
3. The prescription, use and management of Ig products is consistent with processes described in this document.
4. Appropriate policies and procedures are in place to support compliance with this policy and accord with relevant legislation, guidelines and safety and quality standards for healthcare and privacy.

Ig product is prescribed according to clinical need, appropriate clinical practice and in accordance with the Criteria and an approved authorisation in BloodSTAR

Ig products should be directed to patients who are most likely to benefit and for whom there are no safe and effective alternative treatments, based on reliable evidence, and using the lowest effective dose. Guided by this, and the National Blood Agreement policy objectives, governments have determined criteria for clinically appropriate and equitable access to the supply of government-funded Ig products.

The Criteria identifies the conditions and circumstances for which the use of Ig is clinically appropriate and accessible to patients under the National Blood Agreement. Prescription of Ig must be in accordance with the Criteria including consideration of alternative therapies and relative cost effectiveness. Trial cessation of Ig therapy may be necessary to assess clinical benefit and treatment outcomes.

All authorisation requests for patient-specific access to Ig products are submitted through BloodSTAR. The authorisation request will be assessed against the Criteria as it appears at https://www.criteria.blood.gov.au/ to determine patient eligibility.

Evidence necessary to assess the patient against the Criteria must be provided in the authorisation request. All authorisation requests are received and assessed by authorisers, who interpret the evidence provided in the request against the Criteria to determine if access to government-funded treatment can be approved. Following approval, the patient can begin Ig therapy at their nominated facility for the approved authorisation period.

Ig product is dispensed for a patient assessed as eligible against the Criteria and with an approved authorisation in BloodSTAR

Ig products received from the Distributor should only be dispensed by the relevant dispenser (e.g. pathology laboratory or pharmacy) in accordance with an approved authorisation as it appears in BloodSTAR.

Where Ig product is dispensed in the absence of an approved patient-specific authorisation, the hospital or health facility may be invoiced directly for the full cost of the product in accordance with jurisdictional direct order processes. More information is available on the NBA website at https://www.blood.gov.au/Intravenous-Ig#2.%Direct%order%and%other%supply%arrangements.

The prescription, use and management of Ig products is consistent with processes described in this document

This document sets out the process that must be followed and describes the rules and requirements that must be complied with to access government-funded Ig products. The roles, responsibilities, authority and accountability of those directly involved in prescription, use and management of Ig products throughout the supply chain and within health services are also described.

Those involved in the prescription, use and management of Ig provided under the national blood arrangements must comply with the processes described in this document.

Appropriate policies and procedures are in place to support compliance with this policy and accord with relevant legislation, guidelines and safety and quality standards for healthcare and privacy

Appropriate policies and procedures should be in place within hospitals and health facilities to support those directly involved in the prescription, use and management of Ig products in meeting their obligations as described in this document, and should accord with relevant standards and guidelines including the:

- National Safety and Quality Health Service (NSQHS) Standards[4] , particularly the Clinical Governance, Partnering with Consumers and Blood Management Standards
- Australian and New Zealand Society of Blood Transfusion (ANZSBT) Guidelines for the Administration of Blood Products[5]
- Australian and New Zealand Society of Blood Transfusion (ANZSBT) Guidelines for Transfusion and Immunohaematology Laboratory Practice[6]
- National Blood Authority (NBA) Blood and Blood Products Charter – Pathology Laboratories[7];
- Australian Health Ministers' Statement on National Stewardship Expectations on the Supply of Blood and Blood Products[8] and
- Managing Blood and Blood Product Inventory: Guidelines for Australian Health Providers[9], particularly Module 2: Managing Intravenous and Subcutaneous Ig Inventory[10].

Additionally, Ig products should be prescribed and dispensed in accordance with any applicable national, state or territory legislative requirements including the *Commonwealth Privacy Act 1988*[11] (Privacy Act). In accordance with the Privacy Act, patients must provide explicit consent (written or verbal) to the collection, retention and use of their personal and sensitive information for the purposes of assessing eligibility before an authorisation request is submitted through BloodSTAR. The BloodSTAR Privacy Statement and Notice and the Privacy Impact Assessment Report which explains how the NBA manages patient privacy can both be found in BloodSTAR and on the NBA website at https://www.blood.gov.au/bloodstar-privacy-controls.

3.2 Subcutaneous Immunoglobulin (SCIg)

In addition to the above principles, access to subcutaneous immunoglobulin (SCIg) products under the National Blood Agreement is provided through an assurance framework for the appropriate use of the product. SCIg may be supplied under the National Blood Agreement only for patients:

- with a medical condition where there is support for use cited in the Criteria. A list of the medical conditions currently supported is provided at https://www.blood.gov.au/SCIg; and
- the patient must be under the care of a clinical specialist within a hospital participating in the National SCIg Program.

Hospitals participating in the National SCIg Program are required 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, and at no additional cost to patients. More information including the requirements for hospitals participating in the National SCIg Program, can be found on the NBA website at https://www.blood.gov.au/SCIg.

All requests for patient-specific authorisation are submitted through BloodSTAR. The authorisation request must be for SCIg product specifically. A dose change request facilitates changes from IVIg to SCIg without the need to submit a new authorisation.

3.3 Normal Human Immunoglobulin (NHIg)

Access to normal human immunoglobulin (NHIg) products under the National Blood Agreement is restricted to two purposes only.

NHIg may be supplied under the National Blood Agreement only for:

- public health disease control activities; or
- the treatment of a small number of medical conditions as indicated at https://www.blood.gov.au/NHIg when both IVIg and SCIg are contraindicated.

Where the indication for use is for public health disease control activities, NHIg may only be accessed 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 http://www.health.gov.au/internet/main/publishing.nsf/Content/cdnasongs.htm.

To access NHIg for public health disease post-exposure prophylaxis, an order form must be completed and submitted to the relevant State or Territory contact via email or fax. The form is available on the NBA website at https://www.blood.gov.au/NHIg . Details for State and Territory contacts are also available via this link.

Where the indication for use is not for public health disease control activities, NHIg may only be accessed to treat a small number of medical conditions as indicated on the NBA website at https://www.blood.gov.au/NHIg when both IVIg and SCIg are contraindicated. To access NHIg for these conditions, a patient-specific authorisation must first be submitted through BloodSTAR. The authorisation request must be for NHIg product specifically.

Access to NHIg products for the treatment of these medical conditions is subject to the same access framework applied to SCIg products. To be eligible to receive NHIg, a patient must be under the care of a clinical specialist located at a hospital participating in the National SCIg Program and the governing requirements for a hospital based SCIg program apply. NHIg may only be accessed for patients for whom treatment with IVIg and SCIg are both contraindicated.

NHIg cannot be provided for any purpose other than those listed above, including travel prophylaxis for hepatitis A. Advice in relation to prophylaxis for hepatitis A can be found in the Australian Immunisation Handbook[12] available at: https://immunisationhandbook.health.gov.au/.

4. NATIONAL POLICY: ACCESS ARRANGEMENTS

Australian governments have agreed to fund Immunoglobulin (Ig) products under the National Blood Agreement where Ig is prescribed for the treatment of patients who are likely to benefit from Ig therapy, consistent with the evidence base as described in the Criteria, and for whom there are no safe and effective alternative treatments.

This section describes the process by which patient-specific authorisation is requested and approved, and Ig product is ordered and dispensed. Eight separate roles have been identified throughout the process. Each of these roles align with specific responsibilities which are further defined in the next section of this document.

The information provided in this section is intended to support implementation of the National Policy Principles. Application of processes should always be in accordance with any State and Territory legislative requirements, local policies and procedures.

The access arrangements consist of four main elements:

1. Initial authorisation process;
2. Ordering, dispensing and reconciling Ig products;
3. Changes to approved authorisations; and
4. Review and continuing authorisation.

4.1 Initial authorisation process

Patient-specific authorisation is required for initial and continuing access to the supply of government-funded immunoglobulin products. An overview of the process for initial authorisation is shown in Figure 1.

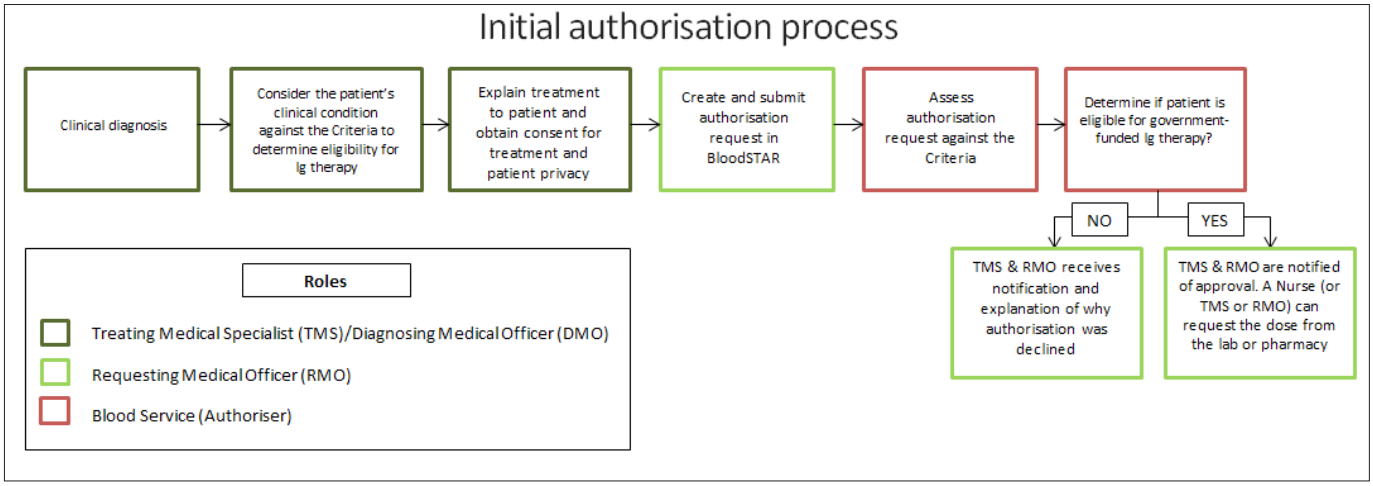

Figure 1 – Initial authorisation process

4.2 Clinical diagnosis

The authorisation process begins with the clinical diagnosis of a patient which must be made by a Medical Specialist. In accordance with the Criteria[2], some conditions require the clinical diagnosis be made by a particular type of specialist. Once a clinical diagnosis has been made, a patient's Treating Medical Specialist can determine if Ig therapy will be appropriate for the patient.

4.3 Eligibility

To establish if a patient is eligible for access to government-funded Ig, a patient's clinical diagnosis is considered in conjunction with eligibility requirements and indications for Ig use as set out in the Criteria. Considerations 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 and
- dose and frequency – specific to the indications and circumstances to aim for the minimum dose to achieve optimum clinical outcome for a patient.

The same authorisation process used for the supply of IVIg used for the relevant conditions to authorise the supply of SCIg and NHIg. Where a request is made for NHIg, a Requesting Medical Officer is required to provide the specific clinical reason why treatment with IVIg and SCIg are both contraindicated.

Clinical specialists and patient eligibility

The Criteria requires patients to be diagnosed or under the care of a specific type of Medical Specialist to be eligible under some conditions. The application of the Criteria in BloodSTAR facilitates whether these requirements have been met by utlising regular crosschecks with the Australian Health Practitioner Regulation Agency (AHPRA) database at https://www.ahpra.gov.au. Therefore, the NBA recommends Medical Officers ensure their registration with AHPRA is maintained and up to date. Where a particular field of specialty practice is not registered with AHPRA, it cannot be recognised for the purposes of meeting eligibility requirements as specified in the Criteria.

It is acceptable for telephone or video-consultation with the appropriate specialist to be used to enable patients who are not located in a metropolitan area to receive convenient access to timely treatment. This may be particularly relevant for suburban, rural or remote areas. The use of telephone or video consultation is at the discretion of the Medical Specialist that has taken responsibility for the diagnosis or prescription of Ig treatment for a patient.

4.4 BloodSTAR User Registration

A BloodPortal account must first be created by completing a Blood Portal User Registration. Once a BloodPortal account has been created, access to BloodSTAR can be requested. The process is described on the NBA website at https://www.blood.gov.au/bloodstar-support-materials

A request to access BloodSTAR must be approved by a Facility Administrator for full access and functionality to become available.

Emergency user access

Where emergency access to product is required and a RMO has not registered or been approved to use BloodSTAR, an authorisation request may be submitted using provisional BloodSTAR access. This requires a Prescriber to request access to the system following the same instructions as all other Prescribers detailed in the section *BloodSTAR Authorisation Request*, but allows for provisional access while waiting for full access to be approved.

Provisional access is automatically granted to Prescribers once they have provided their AHPRA registration details and submitted a request for access at their facility's BloodSTAR site. Under provisional access arrangements, a Prescriber:

- may complete and submit new initial authorisation requests only , including editing, recalling and resubmitting those requests. A Prescriber will be advised of the outcome of the authorisation assessment in BloodSTAR notifications; and
- may conduct patient searches in BloodSTAR with limited results. Prescribers will be presented with probable matches when searching for a patient but will not be able to view the entire patient record.

Provisional access will be revoked automatically if not approved by the facility within 14 days of submitting the request.

4.5 BloodSTAR authorisation request

The BloodSTAR authorisation request is not a prescription for treatment. Prescribers should follow local requirements for prescribing Ig products in accordance with relevant legislation.

Patients must consent to the collection, retention and use of their personal and sensitive information in BloodSTAR prior to the submission of an authorisation request. The Requesting Medical Officer is responsible for documenting in BloodSTAR that consent has been obtained by the Treating or Requesting Medical Specialist. Patient Privacy Consent Forms and more information regarding the privacy controls in BloodSTAR are available on the NBA website at https://www.blood.gov.au/bloodstar-privacy-controls.

In BloodSTAR, each medical officer involved in the patient's Ig therapy has a different role.

- The Specialist responsible for the overall care of the patient will be listed as the Treating Medical Specialist (TMS) .
- The medical officer submitting the authorisation request is referred to as the Requesting Medical Officer (RMO).
- The medical Specialist that made the clinical diagnosis is nominated as the Diagnosing Medical Officer (DMO) in BloodSTAR.
- The medical officer responsible for reviewing the effectiveness of Ig therapy in accordance with the Criteria is listed on continuing authorisation requests as the Reviewing Medical Officer (RvMO).

Note: The RMO may be the same Medical Officer as any of the TMS, DMO, or RvMO or may be a different medical officer submitting the request on their behalf.

The roles and responsibilities of each medical officer involved in the patient's Ig therapy are described in more detail in section 6 of this document.

Submission of an authorisation request will require the RMO to enter relevant patient and diagnosis details and supporting substantiation, as prompted by BloodSTAR, to enable an assessment of eligibility to be made against the Criteria. When submitting the authorisation request, the RMO will also need to specify the arrangements for Treating Facility (where the patient receives specialist treatment), the Administering Facility (where the patient receives infusions) and Dispensing Facility (the facility responsible for dispensing product to the Administering Facility). .

RMOs submitting a request categorised as an "emergency" should phone the Blood Service to alert them to the urgency of a submitted request.

When submitting an authorisation request, the RMO will be asked to allocate a priority to the request to indicate how urgently it will need to be assessed by an Authoriser. The priority categories are defined as "emergency", "serious" or "standard". BloodSTAR contains information regarding the timeframes that these requests will be authorised, however submission of an emergency request should be reserved for life threatening circumstances and must be followed with a telephone call to the Blood Service in the corresponding state or territory, advising of the circumstances.

Adjusting Ig dose for ideal body weight

The amount of Ig prescribed for a patient may vary depending on the indication as well as a patient's weight and is set out in the Criteria. When prescribing Ig, Prescribers should aim to use the lowest dose possible that achieves the appropriate clinical outcome for each patient. The dose may be adjusted for Ideal Body Weight (IBW) for some patients and a calculator is available in BloodSTAR to facilitate this where appropriate.

Use of the calculator may be at the discretion of the Prescriber, or to comply with State, Territory or local policy. In addition, the NBA does not recommend the calculator be used for some patients. More information on the calculator, including the circumstances in which the NBA recommends it not be used, is available on the NBA website at https://www.blood.gov.au/bloodstar-calculator-adjusting-ig-dose-ideal-body-weight .

4.6 Allocation

Both domestic and imported Ig products are available under the national blood arrangements.

Each year governments agree a National Supply Plan and Budget that sets a specific volume of domestic Ig products to be supplied each year, based on the expected levels of Australian plasma collection and Ig product manufacture. The National Supply Plan and Budget also includes a forecast of the additional volume of imported Ig products expected to be required to meet demand under the Criteria.

To ensure that the planned volume of domestic Ig products is utilised each year, new approved authorisation requests are allocated within BloodSTAR to domestic or imported Ig products based on the patient's specific condition, according to a pre-determined allocation matrix within BloodSTAR. The allocation matrix is updated as forecasts of demand and supply change over time, and there can be differences in allocation between States and Territories according to patient demographics. Product allocation rules may also be applied in BloodSTAR for specific supply management purposes, including management of supply risk events.

A Prescriber making an authorisation request may request a change from the allocated Ig product to an alternative Ig product that is available under the arrangements for clinically appropriate reasons, for example, patient experience of adverse reaction to a particular Ig product initially allocated by BloodSTAR. More information regarding allocation of Ig products is available on the NBA website at https://www.blood.gov.au/Intravenous-Ig .

A list of products available under the National Blood Agreement is available on the NBA website at https://www.blood.gov.au/national-product-list.

4.7 'Downtime' authorisation requests

If access to BloodSTAR is unavailable, for example because of internet or system 'downtime', paper authorisation forms can be obtained from the Blood Service. This process should only be used in an emergency situation, for patients with an immediate life-threatening clinical condition. In all other circumstances, medical officers should wait for access to BloodSTAR to become available.

In an emergency, the authorisation request forms must be completed and faxed to the appropriate Blood Service centre for assessment. The downtime process to follow during an outage can be found at https://www.blood.gov.au/system/files/BloodSTAR-BloodNet-Downtime-Process.pdf . Where the authorisation request is approved, a retrospective authorisation request should be entered into BloodSTAR as soon as practicable, but must be entered within seven working days of the request being approved. If the details are not entered into BloodSTAR within this time, funding of product under the national blood arrangements cannot be guaranteed, and hospitals and health facilities may be invoiced for the full cost of the product.

4.8 Authorisation assessment

Authorisation requests are assessed against the Criteria by clinically trained personnel at the Blood Service, using the information provided by a RMO in the request. Where necessary and appropriate, Authorisers can decline the request, or vary the dose, product and frequency of an authorisation request where they have identified the original request is inappropriate or outside the Criteria.

Where an authorisation request is missing information or needs to be clarified for assessment against the Criteria to occur, an Authoriser will contact the Requesting Medical Officer to obtain clarification. The Requesting Medical Officer may be required to recall the authorisation request from the Authoriser to enter the missing information and then resubmit. An Authoriser will assess the resubmission against the Criteria to determine if authorisation can be approved. Where the authorisation is missing important information and an Authoriser cannot contact the Requesting Medical Officer, the request may be declined.

When an authorisation request has been declined, the Treating Medical Specialist and Requesting Medical Officer will receive notification of the outcome, which will include decision notes from the Authoriser explaining the rationale for the authorisation assessment outcome.

Patients may be authorised to receive a single one-off dose of government-funded immunoglobulin or a course of treatment over a number of months. A Treating Medical Specialist and Requesting Medical Officer are notified electronically of the assessment outcome recorded by an Authoriser. Where an authorisation request is approved, the dispenser nominated in the authorisation request will receive notification through the authorisation module in BloodNet.

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.

4.9 Ordering, dispensing and reconciling Ig products

The ordering and dispensing of Ig can only be performed by the business unit designated by a hospital/health facility as having the ordering and inventory management responsibility for Ig. In BloodSTAR, this business unit is referred to as the Dispenser. Dispensers must have the management competencies, facilities and appropriate endorsement commensurate with managing a high-cost blood-derived product and are required to meet the Australian Health Ministers' Statement on National Stewardship Expectations on the Supply of Blood and Blood Products[8]. Generally, this will be the health provider blood bank or pathology laboratory, or pharmacy, either in-house or under third party provider arrangements.

Dispensers are responsible for product ordering, inventory management and dispensing product for use in accordance with the access arrangements. Product ordering by a Dispenser is managed through BloodNet as stock orders or as transfer of stock between dispensing facilities based on clinical demand for authorised patients, and with consideration of stock on hand as described in Module 2: *Managing Intravenous and Subcutaneous Immunoglobulin Inventory*[10].

Dispensers must:

- ensure the inventory does not exceed one months' supply of IVIg or two months' supply of SCIg
- only issue government-funded Ig products in accordance with an approved authorisation in BloodSTAR; and
- regularly reconcile dispense records with authorisations to identify, investigate and correct anomalies.

Where possible, all dispenses of Ig should be recorded in BloodNet by a Dispenser within 14 days of the dispense activity. Where dispenses are not recorded appropriately, the hospital/health facility may be invoiced directly for the full cost of the Ig product in accordance with the jurisdictional direct order process. Where product has been transferred from one Dispenser to another, the dispense should be recorded by the Dispenser who issued the product to the clinical area or patient.

The product ordering and dispensing process is shown at **Figure 2** – Product ordering and dispensing process diagram.

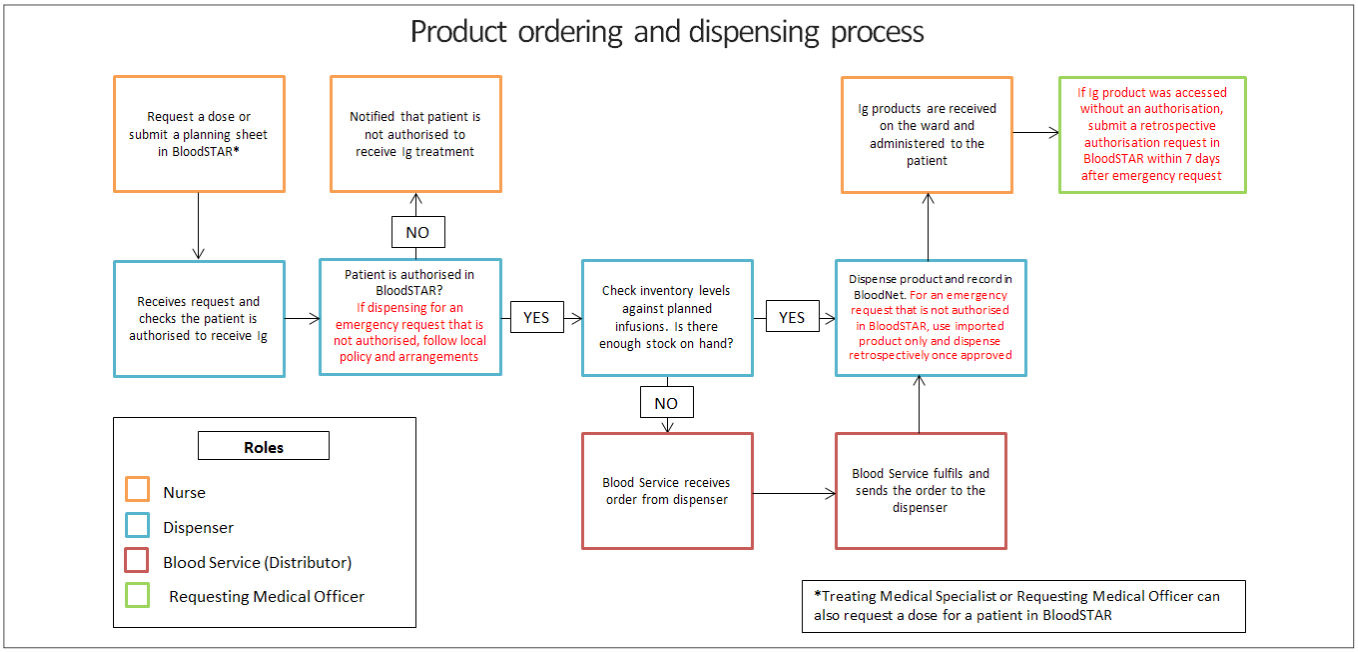

Figure 2 – Product ordering and dispensing process.

4.10 Dispensing product where patient authorisation has not been obtained

In non-emergency situations, a patient authorisation should be approved before dispensing product. It is possible that in an emergency situation, Ig products may need to be dispensed to a patient without an approved authorisation. Facilities are advised to have a policy that describes arrangements at a local level for dispensing in an emergency.

Where product is dispensed in the absence of an approved authorisation:

- only imported product should be dispensed (provided a Dispenser holds imported product) in accordance with allocation arrangements, and
- an authorisation request must be submitted within seven business days through BloodSTAR and approved for access under the National Blood Agreement, along with retrospective recording of the dispense in BloodNet. If this does not occur, the hospital/health facility may be invoiced directly for the full cost of the Ig product in accordance with the jurisdictional direct order process. More information available on the NBA website at http://www.blood.gov.au/Intravenous-Ig

4.11 Patients travelling overseas

Provision for the supply of product for Australian patients temporarily travelling or studying overseas may be granted in accordance with the National Blood Agreement. For more information and the application form, please refer to the NBA website at https://www.blood.gov.au/supply-australians-overseas .

4.12 Changes to approved authorisations

All changes to approved patient authorisations must be advised through BloodSTAR. This includes changes to product type and dose, dose frequency, additional doses, changes to Treating, Administering or Dispensing Facilities, and Treating Medical Specialists.

4.13 Changes to product or dose

Dose changes, including product type (including changing from IVIg to SCIg and vice versa), dose size or dose frequency should be submitted in BloodSTAR by a medical officer against the existing authorisation, rather than by completing a new initial authorisation request.

Before requesting any changes to current treatment the Requesting Medical Officer must ensure that there is at least one dose remaining on the treatment plan. The change request must include dose details and the justification for the change in treatment. Once the request is submitted it will be assessed against the Criteria by an Authoriser, and notifications will occur as for authorisation requests.

The dose change process is shown at Figure 3 – Dose change and additional dose process.

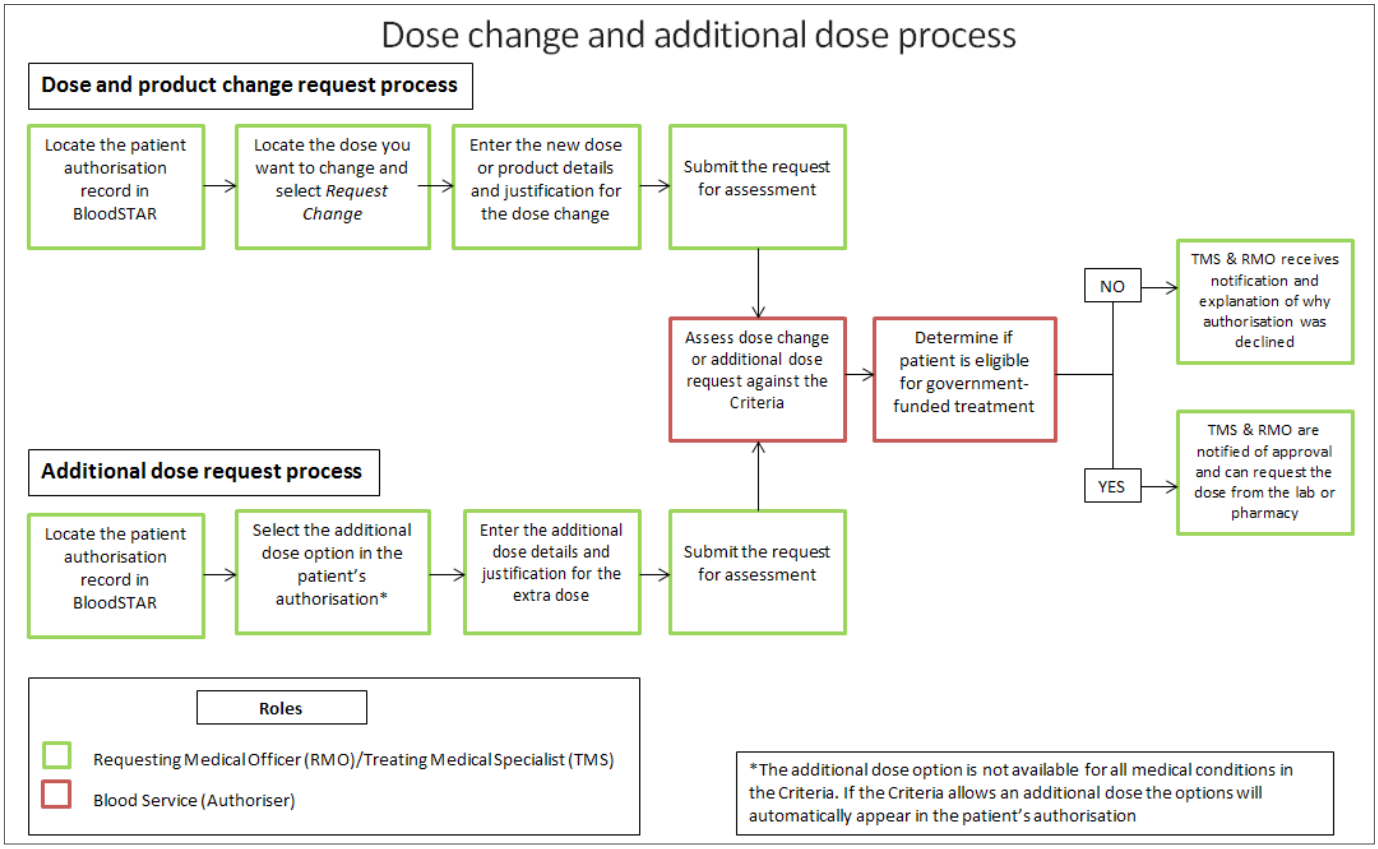

Figure 3 – Dose change and additional dose process

4.14 Additional dose requests

Where it is permitted in the Criteria, additional dose requests allow Prescribers to seek authorisation for a further dose for an authorised patient where required. To determine if this functionality is available for a specific medical condition, refer to the Criteria. This may be used to request additional 'one-off' type doses, or to add a type of dose that may not have been requested in the original request.

Additional dose requests should be submitted through BloodSTAR against the patient's existing authorisation, rather than by completing a new initial authorisation request, and must include dose details and justification for the additional dose. Once the request is submitted it will be assessed against the Criteria by an Authoriser.

An overview of requesting an additional dose is shown in Figure 3– Dose change and additional dose process.

4.15 Changes to Facility or Treating Medical Specialist

Facility changes and changes to the Treating Medical Specialist listed on a patient's authorisation do not need to be assessed against the Criteria and can be updated by any user role in BloodSTAR (except Authorisers).

Where a change is made to a patient's Treating, Administering or Dispensing Facility, which can occur as a result of a change in Treating Medical Specialist, the Dispenser will receive a notification generated in BloodNet to alert the Dispenser that a new patient has been transferred to their facility.

Where a change is made to the Treating Medical Specialist, the new and previous Treating Medical Specialists will both receive a notification of the change in care.

4.16 Review and continuing authorisation

Regular clinical review to assess clinical benefit of treatment for ongoing therapy should be conducted at periods specified within the Criteria. The Criteria describe the major clinical factors that should be taken into account when reviewing the progress of a patient who is receiving government-funded Ig products along with the required frequency of review. Evidence of clinical benefit of Ig should be provided within the review request, to warrant ongoing treatment where required.

The review and continuing treatment process is shown at Figure 4 – Review for continuing treatment process.

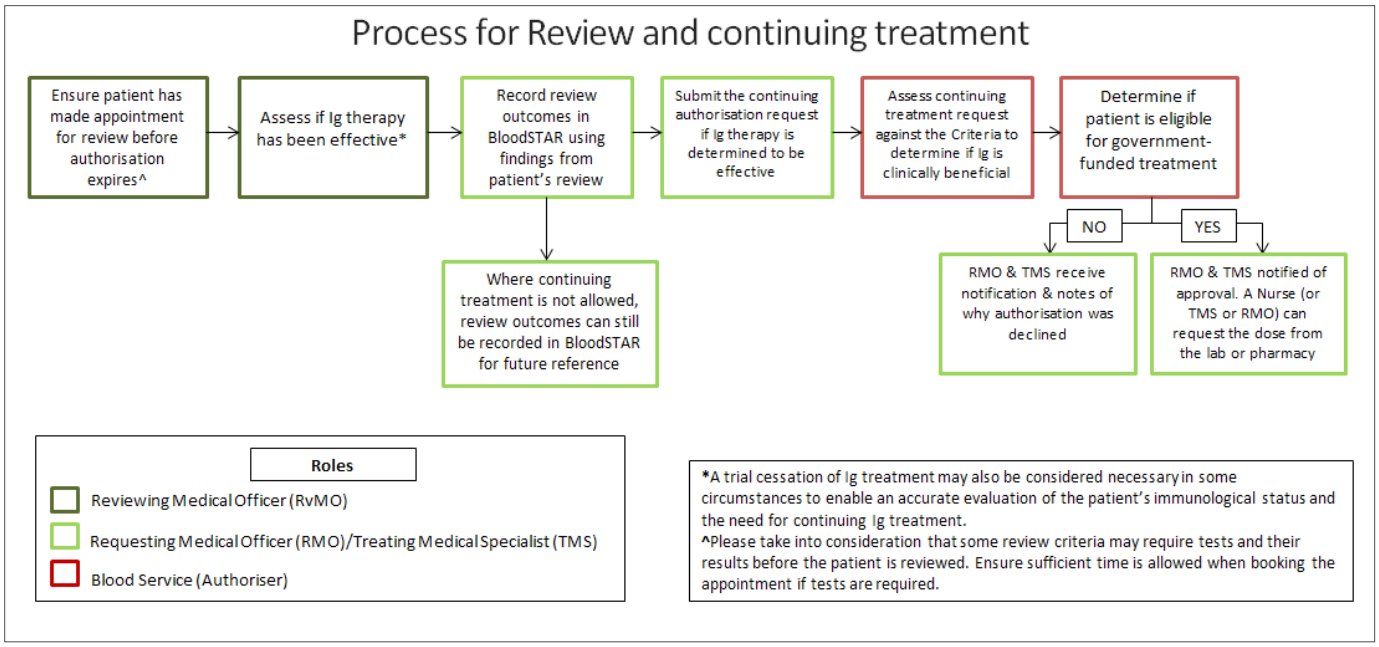

Figure 4 – Review for continuing treatment process

4.17 Assessment of clinical benefit

Review and assessment of clinical benefit of Ig therapy is required for all conditions allowing continuing authorisation for access to government-funded Ig. In principle, Ig treatment should only be continued where there is a demonstrated clinical benefit. At review, clinical factors and patient's response to therapy are required to be assessed to inform whether to:

- continue therapy – clinical benefit is evident and demonstrable
- cease therapy – clinical benefit is not evident or demonstrable, or treatment is no longer required
- alter dose – increase or decrease dosage for improved efficacy and/or
- change dosage frequency.

The review timeframes allow time for an assessment of the patient's response to treatment to be made. A trial cessation of Ig therapy may also be considered necessary in some circumstances to enable an accurate evaluation of the patient's immunological status and the need for continuing Ig therapy.

4.18 Recording a review and requesting continuation of authorisation

For some medical conditions, review by a particular type of specialist is required. Appropriate evidence of the patient treatment review outcomes is required to be recorded in BloodSTAR, along with the name of the medical officer who performed the review (Reviewing Medical Officer), prior to the existing authorisation end date for assessment of eligibility for access to continuing supply of Ig products.

If there is a lapse in time between the authorisation end date and the patient treatment review outcomes being recorded in BloodSTAR, product will not be supplied during that time. A continuing request may be submitted up to 8 weeks after the end of the authorisation end date. Beyond this period, a new initial authorisation request is required to be submitted for assessment.

For patients requiring 'one-off' treatment, or for patients with no requirement for continuing authorisation, clinical outcomes should be recorded in BloodSTAR to assess efficacy and inform future development of the Criteria.

4.19 Cessation of authorisation

Authorisation for continuing access and supply of government-funded Ig product will be ceased, in any of the following cases:

- the authorisation end date has been reached and a review has not been recorded within 8 weeks of that date
- clinical benefit defined in the patient treatment review criteria is not achieved (not evident or demonstrable)
- a Treating Medical Specialist advises that immunoglobulin is no longer required.

5. NATIONAL POLICY: ROLES AND RESPONSIBILITIES

This section describes the roles, responsibilities, authority and accountability of those directly involved in prescription, use and management of government-funded Immunoglobulin (Ig) products throughout the supply chain and within health services. The information provided in this section is intended to support the individuals in these roles to meet their obligations under the National Policy. Application of processes should be in accordance with any State and Territory legislative requirements, local policies and procedures.

Eight specific roles have been identified, each of which include specific responsibilities which must be undertaken when Ig products are provided under the national blood arrangements. The eight roles are:

1. Hospital/Health Facility Management
2. BloodSTAR Facility Administrator
3. Prescriber (further defined as a Treating Medical Specialist, Diagnosing Medical Officer, Requesting Medical Officer and Reviewing Medical Officer)
4. Authoriser
5. Dispenser
6. Registered Nurse and/or Registered Midwife
7. Distributor
8. Courier

National Policy: Access to Government–Funded Immunoglobulin Products in Australia

National Policy: Access to Government–Funded Immunoglobulin Products in Australia (National Policy) sets out the process that must be followed and describes the rules and requirements that must be complied with to access government-funded Ig products in Australia. The National Policy supports all healthcare professionals involved in the prescription, use and management of Ig to understand their roles and responsibilities under the governance arrangements. Below is a summary of the responsibilities for each role under the National Policy.

Hospital/Health Facility Management

Hospital/Health Facility Management (e.g. Chief Executive Officers, Medical Directors) have a responsibility to ensure the appropriate clinical governance of Ig, promote performance improvement activities and ensure appropriate use of BloodSTAR.

BloodSTAR Facility Administrator

BloodSTAR Facility Administrators are responsible for approving BloodSTAR user role access requests and deactivating user role access when no longer required.

Authoriser

Authorisers are responsible for assessing authorisation requests submitted in BloodSTAR against the Criteria and ensuring they are in line with the National Policy. Authorisers also provide advice on the clinical aspects of authorisation requests when contacted by Prescribers.

Distributor

Distributors are responsible for holding and managing appropriate inventory, issuing product against dispensers' orders, distributing product to dispensers and ensuring product integrity during transportation.

Dispenser

The Dispenser's responsibilities include ordering product from the distributor appropriate to clinical demand and applying appropriate inventory management practices, storing and handling Ig products appropriately to ensure cold chain integrity, dispensing product for authorised patients only, and reporting adverse events and other incidents as necessary.

Prescriber

The term Prescriber collectively refers to all types of medical officers that have a role in the process of seeking patient-specific authorisation to access Ig products.

Diagnosing Medical Officer (DMO)

Diagnosing Medical Officers are responsible for ensuring diagnostic criteria as specified in the Criteria have been met.

Treating Medical Specialist (TMS)

Treating Medical Specialists are responsible for prescribing Ig therapy in accordance with the Criteria and obtaining patient consent to treatment and the collection of personal and sensitive information for the purposes of assessing eligibility.

Requesting Medical Officer (RMO)

Requesting Medical Officers are responsible for requesting patient-specific authorisation through BloodSTAR.

Reviewing Medical Officer (RvMO)

Reviewing Medical Officers are responsible for reviewing the effectiveness of Ig therapy in accordance with the Criteria, to determine whether continuing treatment, a trial off period or cessation of treatment is appropriate.

Couriers

Couriers and staff within hospitals who retrieve blood products from a Dispenser or a blood and medication fridge are responsible for product integrity during transportation.

Registered Nurse and Registered Midwife

Registered Nurses and Midwives are responsible for the coordination of treatment for authorised patients and communication with the Dispenser for product order requirements where relevant.

NATIONAL BLOOD AUTHORITY AUSTRALIA

Ig Governance

For more information visit: www.blood.gov.au | email: support@blood.gov.au | call: 13000 BLOOD (25663).

5.1 Hospital/Health Facility Management

Hospital/Health Facility Management (e.g. Chief Executive Officers, Medical Directors), including hospital-level governance committees such as blood product committees, quality committees or drug and therapeutics committees in both the public and private sectors, have a responsibility to ensure appropriate governance arrangements are in place to facilitate and promote compliance with this document, promote performance improvement activities, ensure appropriate use of BloodSTAR, and where the facility has a SCIg program in place, to ensure appropriate governance requirements for that program are met.

Ensuring appropriate clinical governance

Hospital/Health Facility Management is responsible for:

- ensuring that appropriate policies and procedures are in place, and complied with to accord with the following:
    - National Policy (this document)
    - National Safety and Quality Health Service (NSQHS) Standards, particularly the Clinical Governance and Blood Management Standards
    - Australian and New Zealand Society of Blood Transfusion (ANZSBT) Guidelines for the Administration of Blood Products
    - Guidelines for Transfusion and Immunohaematology Laboratory Practice
    - Blood and Blood Products Charter – Pathology Laboratories
    - Australian Health Ministers' Statement on National Stewardship Expectations on the Supply of Blood and Blood Products
    - Managing Blood and Blood Product Inventory: Guidelines for Australian Health Providers, particularly Module 2: Managing Intravenous and Subcutaneous Ig Inventory and
    - any other applicable state or territory legislative requirements.
- communicating aspects of these policies and procedures to relevant staff within the organisation as appropriate, including where changes are made.

Promoting performance improvement

Hospital/Health Facility Management is responsible for:

- regularly reviewing prescribing practices within the facility to identify opportunities to improve clinical practice
- identifying opportunities to drive improvement in governance, management systems and processes and
- providing feedback to government to drive improvement in governance including on improved data capture, reporting and analysis.

Ensuring appropriate use of BloodSTAR

Prescribers and nurses managing patients authorised to receive government-funded Ig product require access to BloodSTAR. User access is only granted where the person requesting access can be verified by a Facility Administrator at the facility at which they are employed.

Hospital/Health Facility Management is responsible for:

- nominating at least two BloodSTAR Facility Administrators to review and approve requests for access to BloodSTAR at the hospital/health facility
- ensuring BloodSTAR Facility Administrators have access to the support and resources required to undertake the role and

- promoting BloodSTAR user compliance with BloodSTAR User Terms and Conditions including the requirement to keep logon details secure and not to disclose to any other person.

Ensuring appropriate governance in National SCIg Program Facilities

Participation in the National SCIg Program requires hospitals to establish their capability and capacity to manage a hospital based SCIg program within specific governing requirements. More information on requirements for facilities participating in the National SCIg Program including the Hospital Acknowledgement Form, is available on the NBA website at https://www.blood.gov.au/SCIg.

Hospital/Health Facility Management at facilities participating in the National SCIg Program are responsible for:

- establishing a SCIg program and providing an acknowledgement of the governing requirements to participate in the National SCIg Program (refer to the website link above) before the facility orders or provides SCIg products to patients
- ensuring the governing requirements of the National SCIg Program are met and maintained and
- ensuring no additional cost (for example for equipment and consumables necessary to administer the product) is incurred by patients.

5.2 BloodSTAR Facility Administrator

BloodSTAR Facility Administrators are responsible for approving BloodSTAR user role access requests and deactivating user role access when no longer required. This role is important to ensure the integrity of patient privacy.

Facility Administrators are also responsible for maintaining facility relationships in BloodSTAR (system links between the treating facility and the dispensing facilities from which product is dispensed) in consultation with appropriate internal and external stakeholders.

Approving BloodSTAR user access requests

BloodSTAR Facility Administrators are responsible for:

- reviewing user access requests and acting upon these within two business days
- verifying the employment of Prescribers and Nurses/Midwives who request access to BloodSTAR at the facility before approving, or
- declining the user access request where appropriate.

Provisional BloodSTAR access is automatically granted to medical officers once they have provided their AHPRA registration details and submitted a request for access at their facility in BloodSTAR. Under provisional access arrangements, a Prescriber may perform only limited tasks in BloodSTAR. Provisional access will be revoked automatically if a Facility Administrator has not approved BloodSTAR user access within 14 days of submitting the request. See section on Emergency user access for further information.

Removing BloodSTAR user access

BloodSTAR Facility Administrators are responsible for:

- deactivating user access promptly, and within 14 days of notification that a user is no longer practicing or employed at the facility and
- periodically reviewing the user access report (FM01 – Facility User Report) against staff employment directories to confirm that each of the users legitimately require access and either:
  - verifying any identified system access anomalies, and confirming if access is required or
  - taking the necessary action to deactivate a user's access where access is no longer required.

Maintaining facility relationships

BloodSTAR Facility Administrators are responsible for updating the facility details in BloodSTAR to list all related facilities that dispense Ig product for the treatment of patients at that facility.

5.3 Prescriber

The term Prescriber collectively refers to all types of medical officers that have a role in the process of seeking patient-specific authorisation to access Ig products under this policy. This includes the BloodSTAR roles of Treating Medical Specialist (TMS), Diagnosing Medical Officer (DMO), Requesting Medical Officer (RMO) and Reviewing Medical Officer (RvMO). A nurse practitioner may also be a Requesting Medical Officer.

Specific responsibilities that apply to all Prescriber roles are discussed below. Specific responsibilities relating to each of the Prescriber subtypes is described further below.

Registering for access to BloodSTAR

All Prescribers are responsible for registering for access to BloodSTAR at each hospital/health facility where they practice and/or are employed. Medical specialists must have their particular speciality field of practice registered with the Australian Health Practitioner Regulation Agency (AHPRA) for the specialty field to be recognised for the purposes of meeting eligibility requirements as specified in the Criteria.

Notification of changes to approved authorisations

All Prescriber roles are responsible for notifying changes to approved authorisations through BloodSTAR. This includes updating the Treating, Administering or Dispensing Facility or a Treating Medical Specialist where this has changed. Changes to doses including dividing a dose or changing a dose dispense date are also the responsibility of a Prescriber.

Where multiple Prescribers are involved in the care of a patient (for example, a Treating Medical Specialist is different to a Requesting Medical Officer), only one Prescriber needs to perform the task, however all Prescribers are responsible for ensuring it has occurred.

Reporting adverse events and other incidents

All Prescriber roles are responsible for reporting adverse events or other incidents related to a patient's treatment within the hospital and to the Therapeutic Goods Administration (TGA), the Blood Service and the product supplier, as appropriate, and in accordance with local policies and procedures. Where multiple Prescribers are involved in the care of a patient (for example, a Treating Medical Specialist is different to a Requesting Medical Officer), only one Prescriber needs to perform the task, however all Prescribers are responsible for ensuring it has occurred.

Notification of changes to Ig treatment

Changes to treatment arrangements for authorised patients must be notified through BloodSTAR.

5.4 Diagnosing Medical Officer (DMO)

Most conditions included in the Criteria require patients to be diagnosed by a particular type of specialist to access government-funded Ig. This requirement is to ensure correct diagnosis in a patient. Diagnosing Medical Officers are responsible for ensuring diagnostic criteria as specified in the Criteria have been met.

Ensuring diagnostic criteria have been met

The Criteria describe the methods that should be used to diagnose a condition in a patient. Diagnosing Medical Officers are responsible for ensuring the methods described in the Criteria have been applied when diagnosing a medical condition in a patient.

5.5 Treating Medical Specialist (TMS)

Treating Medical Specialists are responsible for prescribing Ig therapy in accordance with the Criteria and obtaining patient consent to treatment and the collection of personal and sensitive information for the purposes of assessing eligibility.

Prescribing Ig therapy in accordance with the Criteria

Treating Medical Specialists are responsible for:

- prescribing Ig therapy in accordance with the Criteria and product-specific information, including consideration of alternative therapies (where relevant), trial-off from Ig therapy and documenting the clinical outcome
- prescribing Ig therapy with the aim of using the lowest dose possible that achieves the appropriate clinical outcome for each patient
- advising patients of the requirement for regular treatment monitoring and review
- ensuring appointments are scheduled in line with the treatment plan described in the authorisation and notifying patients of upcoming medical appointments associated with their Ig therapy including treatment monitoring and review, and
- supporting patients to access alternative specialist care where necessary, such as when the Criteria specifies that a diagnosis or review must be made by a different specialist.

Obtaining patient consent to treatment and the collection of personal and sensitive information for the purposes of assessing eligibility

Treating Medical Specialists are responsible for:

- obtaining patient consent (written or verbal) to treatment in accordance with national, local or State/Territory standards and policies
- obtaining explicit patient consent (written or verbal) to the collection and use of personal and sensitive information and the retention of that information in BloodSTAR as per the BloodSTAR Privacy Statement and Notice and in doing so:
    - explaining the governance and administration arrangements for access to government-funded Ig products
    - explaining that the purposes of collecting and retaining personal clinical information is for the primary purpose of assessing eligibility to access Ig under the National Blood Agreement
    - informing patients that their personal clinical information may be used for secondary purposes and if so, de-identified
    - providing a copy of the BloodSTAR Privacy Statement and Notice available at https://www.blood.gov.au/bloodstar-privacy-controls
    - ensuring patients understand the information provided to them and accept that they are responsible for providing expressed consent (written or verbal) to the collection, retention and use of their personal and sensitive information
    - recording the consent in the patient medical record.

5.6 Requesting Medical Officer (RMO)

Requesting Medical Officers are responsible for requesting patient-specific authorisation through BloodSTAR.

Requesting patient-specific authorisation

Requesting Medical Officers are responsible for:

- requesting patient-specific authorisation through BloodSTAR for access to government-funded Ig products
- requesting patient-specific authorisation through BloodSTAR for changes in product type, dose amount, dose frequency or additional dose as necessary
- providing sufficient detail and, where required, supporting evidence to allow authorisers to make an informed decision about whether a patient meets eligibility requirements as set out in the Criteria
- nominating a patient's treatment arrangements at the time of request, including the Treating, Administering and Dispensing Facility
- indicating the urgency of a request to inform timeframe for assessment and
- ensuring a Treating Medical Specialist understands that they will be nominated in BloodSTAR and will consequently receive notification emails in relation to a patient's authorisation

5.7 Reviewing Medical Officer (RvMO)

Reviewing Medical Officers are responsible for reviewing the effectiveness of Ig therapy in accordance with the Criteria, to determine whether:

- clinical benefit has been achieved (evident and demonstrable) and continuation of treatment is appropriate
- a trial period off treatment is appropriate (where relevant), or
- clinical benefit has not been achieved (not evident and demonstrable) and product is no longer required.

Reviewing the effectiveness of Ig therapy in accordance with the Criteria

Reviewing Medical Officers are responsible for:

- regular monitoring and assessment of the effectiveness of patient-specific treatment within the required review timeframe and against the review criteria specified in the Criteria
- recording a patient's treatment review outcomes in BloodSTAR. Where continuing treatment is required, the review should be entered prior to the authorisation end date
- modify treatment dosage and/or frequency where appropriate
- scheduling review appointments in line with the treatment plan described in the authorisation and notifying patients of upcoming medical appointments associated with their Ig therapy treatment monitoring and review and
- informing patients of the purpose of review and that the review outcomes will recorded in BloodSTAR.

5.8 Authoriser

The Australian Red Cross Blood Service (Blood Service) is contracted by the NBA to provide clinical advice to assist with access and assess all patient requests for authorisation to access government-funded Ig and. This role is referred to as an Authoriser. When a Prescriber submits an authorisation request in BloodSTAR, the request is electronically referred to an Authoriser for consideration.

Authorisation for access to product

Authorisers are responsible for authorising access to Ig products. This includes:

- having specialist medical officers available to provide advice on the clinical aspects of authorisation requests when contacted by prescribers
- assessing authorisation requests against the Criteria and either approving if the request is in line with the National Policy and the qualifying criteria are met, or declining
- assessing changes to approved authorisations against the Criteria and either approving if the request is in line with the National Policy and the qualifying criteria are met, or declining
- reviewing supporting information against all applicable qualifying, review and dose criteria as set out in the Criteria
- reviewing the product type requested including the reason provided if different to the allocated product (Australian or imported product) and either approving or modifying in accordance with agreed local and national arrangements
- following up with a Requesting Medical Officer to seek additional information to determine patient eligibility for access and supply of product, where necessary, and
- seeking further information as required to be able to assess a request for authorisation.

5.9 Distributor

Distributors are responsible for holding and managing appropriate inventory, issuing product against Dispensers' orders, distributing product to Dispensers and ensuring product integrity during transportation.

Holding and managing appropriate inventory

Distributors are responsible for planning and managing an appropriate inventory for supply distribution in accordance with government-agreed standards for timely distribution. This includes ordering and receiving product from suppliers.

Issuing product against orders

Distributors are responsible for accepting product orders from Dispensers through BloodNet and issuing product accordingly.

Distributing product to dispensers

Distributors are responsible for distributing the ordered product in accordance with agreed service requirements and standards. This includes supporting Dispensers in the timely supply of replacement product in emergency situations.

Ensuring product integrity during transportation

Distributors are responsible for ensuring product integrity by:

- ensuring all blood products are transported in dedicated and designated insulated containers
- advising 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, and
- providing advice regarding management of the product that breaches cold chain integrity.

5.10 Dispenser

A Dispenser's responsibilities include ordering product from a Distributor appropriate to clinical demand and applying appropriate inventory management practices, storing and handling Ig products appropriately to ensure cold chain integrity, dispensing product for authorised patients only, and reporting adverse events and other incidents as necessary, following relevant guidelines and standards.

Ordering product and applying appropriate inventory management practices

Dispensers are responsible for:

- monitoring product orders, current inventory and dispense records and applying appropriate inventory management practices
- ordering Ig products from a Distributor based on clinical demand for authorised patients as specified in BloodSTAR with consideration of inventory holdings
- placing product orders and receipting orders in BloodNet
- ensuring inventory does not exceed one months' supply of IVIg or two months' supply of SCIg
- recording product transfers in BloodNet and other relevant information systems if product is transferred to, or received from, another dispensing facility
- recording product fate (breakages/discards) in BloodNet and other relevant information systems, and
- reconciling product ordering records with dispense records to identify, investigate and correct anomalies.

Storing and handling Ig products to ensure cold chain integrity

Dispensers are responsible for:

- maintaining and handling Ig products in accordance with the required product-specific temperature conditions
- taking all reasonable measures to ensure that Ig products are stored in accordance with Medical Refrigeration Equipment Australian Standard (AS) 3864.2-2012[13] or manufacturers requirements
- ensuring Ig products are transported in dedicated and designated insulated containers
- advising couriers, ward and nursing staff on the appropriate transportation and storage of Ig products, and
- advising patients and carers on the appropriate transportation and storage of SCIg product, or advising the registered nurse and/or registered midwife to communicate this information to patients or their carers and in accordance with State/Territory requirements.

Dispensing product for authorised patients only

Dispensers are responsible for:

- reviewing the hospital/facility product orders from the clinical area (this may be in the form of the dispense request submitted through BloodSTAR or another process recognised within the hospital/health service governance arrangements)
- dispensing approved product and dose in accordance with current patient authorisations as confirmed in BloodNet/BloodSTAR
- ensuring a reason has been provided demonstrating extenuating circumstance where product is requested outside of the approved treatment schedule (product should not be dispensed unless extenuating circumstances exist)
- dispensing no more product than is required for two months' treatment when dispensing SCIg product
- recording the dispense in BloodNet within 14 days to ensure treatment plan is updated and to support dispense reconciliation and ensure traceability of product dispensed to patients in case of product recall, and
- reconciling dispense records with authorisations to identify, investigate and correct anomalies.

Reporting adverse events and other incidents

Dispensers are responsible for reporting adverse events or other incidents related to a patient's treatment within the hospital and to the Therapeutic Goods Administration (TGA), the Blood Service and product suppliers, as appropriate, and in accordance with local policies and procedures. Where multiple hospital staff are involved in the care of a patient, only one person needs to report the incident. However all staff are responsible for ensuring reporting has occurred.

5.11 Registered Nurse and Midwife

Registered Nurses and Midwives are responsible for the coordination of treatment for authorised patients and communication with the Dispenser for product order requirements where relevant. This could include scheduling treatments, requesting product from a Dispenser, ensuring patient consent to treatment, safe administration of treatment, training and support for patients to self-administer SCIg, and reporting adverse events and other incidents as necessary. In BloodSTAR the role is referred to as Nurse/Midwife.

Scheduling appointments

Registered Nurses and Midwives are responsible for assisting with the scheduling of appointments in line with the treatment plan and notifying patients of upcoming medical appointments associated with Ig therapy where relevant.

Requesting product

Registered Nurses and Midwives are responsible for:

- requesting product from the Dispenser in accordance with the approved treatment schedule through BloodSTAR (planning sheet or dispense request) or another process recognised within the hospital/ health service governance arrangements
- changing the required infusion date where the patient's treatment is rescheduled
- providing a reason where product is requested outside of the approved treatment schedule (product should not be dispensed unless extenuating circumstances exist), and
- returning unused product to the Dispenser.

Ensuring patient consent to treatment

Registered Nurses and Midwives responsible for:

- ensuring that each patient has consented to treatment and that consent has been documented in the patients' medical records prior to commencing an infusion in accordance with national, local or State/ Territory standards and policies, and
- explaining the infusion process and reminding patients regarding the potential for adverse events and their responsibility to advise/report symptoms during and after the infusion.

Safe administration of treatment

Registered Nurses and Midwives are responsible for:

- identifying patients correctly and undertaking procedures in accordance with the National Safety and Quality Health Service Standards and ANZSBT Guidelines
- ensuring they are familiar with specific product information before commencing an infusion
- monitoring patients during the infusion and carrying out the appropriate actions should an adverse reaction occur, and
- ensuring there is adequate documentation in the medical notes to ensure product traceability to the patient.

Training and support for patients to self-administer SCIg

Registered Nurses and Midwives are responsible for:

- ensuring patients who self-administer SCIg understand and accept that they are responsible for:
  - completing competency-based supported training sessions for self-administration of SCIg therapy
  - performing self-administration infusions in a safe and clean environment with a support person present, and maintaining equipment as instructed
  - disposing of consumables and sharps in the rigid sharps disposal container (provided)
  - completing required documentation (for example patient receipt or diary to document infusions) and providing information as required by a Treating Medical Specialist, and
  - collecting, transporting and storing SCIg product according to instructions
- educating patients on safe and effective self-administration of SCIg treatment and providing support to enable them to achieve an agreed level of competency
- conducting follow-up with patients to assess ongoing competency for self-administered treatment
- ensuring patients have access to consumables and supplies
- reviewing and completing patients' agreements for self-administered treatment (where this exists) with the patient or carer
- ensuring all necessary prescriptions have been provided to patients, and
- managing follow-up arrangements for patients' treatment review of clinical benefit for continuing treatment.

Reporting adverse events and other incidents

Registered Nurses and Midwives are responsible for reporting adverse events or other incidents related to a patient's treatment within the hospital and to the TGA, the Blood Service and product suppliers, as appropriate, and in accordance with local policies and procedures. Where multiple hospital staff are involved in the care of a patient, only one person needs to report the incident. However all staff are responsible for ensuring reporting has occurred. Registered Nurses and Midwives also have a responsibility to report any product incidents (for example, breakages) to a Dispenser.

5.12 Couriers

Couriers and staff within hospitals who retrieve blood products from a Dispenser or a blood and medication fridge are responsible for product integrity during transportation.

Ensuring product integrity during transportation

Couriers are responsible for:

- ensuring that all Ig products are transported in dedicated and validated insulated containers, where required
- maintaining the appropriate cold chain integrity for storage and handling of product, in accordance with the product-specific temperature conditions, and
- ensuring that receipt of the product is acknowledged by an appropriate receiver.

6. TOOLS AND RESOURCES:

Resources developed by the National Blood Authority

- Criteria for the clinical use of Immunoglobulin in Australia (the Criteria)
  https://www.criteria.blood.gov.au/
  The Criteria identifies the condition and specific circumstances for which Ig is clinically appropriate and accessible to patients under the national blood arrangements.

- National Product Price List - www.blood.gov.au/national-product-list
  This resource identifies the specific Ig products available (including vial sizes) under the national blood arrangements.

- Jurisdictional direct order (JDO) arrangements and allocation -
  http://www.blood.gov.au/Intravenous-Ig
  This page provides information about how to access Ig products outside of the national blood arrangements.

- Australian Health Ministers' Statement on National Stewardship Expectations on the Supply of Blood and Blood Products - https://www.blood.gov.au/stewardship
  This page provides information about the National Stewardship Program including the measures that Health Ministers expect all health providers to adopt within their organisation in relation to the supply and management of blood products.

- Subcutaneous immunoglobulin - https://www.blood.gov.au/SCIg
  This page provides more information about subcutaneous immunoglobulin SCIg including the requirements for hospitals participating in the National SCIg Program and the medical conditions that are approved for SCIg as cited in the Criteria

- Normal human immunoglobulin - https://www.blood.gov.au/NHIg
  This page provides more information about the national policy position on access, supply and use of normal human immunoglobulin (NHIg) under the national blood arrangements

- Patients travelling overseas - https://www.blood.gov.au/supply-australians-overseas
  This page provides more information about the supply of blood products for Australian patients temporarily travelling or studying overseas.

BloodSTAR Tools and Resources

- BloodPortal access - https://portal.blood.gov.au/Portal/
  The Blood Portal is the central management system that allows users create an account to access NBA Blood Systems, including BloodSTAR. Users can also manage their account details and subscriptions to NBA newsletters.

- BloodSTAR Support Materials - https://www.blood.gov.au/bloodstar-support-materials
  This page provides links to a collection of instructional guides and tip sheets to assist BloodSTAR users to use the system.

- BloodSTAR Privacy Controls - https://www.blood.gov.au/bloodstar-privacy-controls
  This page provides information about the privacy measures in place for BloodSTAR, including the BloodSTAR Privacy Impact Assessment Report and the Privacy Statement and Notice. The Privacy Consent form can also be downloaded from this page.

- BloodSTAR calculator for adjusting Ig dose for ideal body weight -
  https://www.blood.gov.au/bloodstar-calculator-adjusting-ig-dose-ideal-body-weight
  This page provides information to assist Prescribers to understand the calculator for adjusting the Ig dose for ideal body weight built into BloodSTAR.

Resources specifically for Dispensers

- Blood and Blood Products Charter – Pathology Laboratories https://www.blood.gov.au/system/files/documents/health-provider-blood-and-blood-products-charter-labs_0.pdf
  The Charter outlines the national service requirements and standards (service level) facilities can expect from suppliers of blood and blood products, and the actions facilities need to undertake to receive that service level.

- Managing Blood and Blood Product Inventory: Guidelines for Australian Health Providers https://www.blood.gov.au/inv-mgt-guideline
  These guidelines outline better practice processes that should be applied by health providers to support safe and efficient receipt, storage, and transport of blood and blood products, reduce wastage and minimise associated risks

- Module 2: Ig Inventory Management Guidelines – https://www.blood.gov.au/module-2-ig-inventory-management-guidelines
  This Module is an extension of Managing Blood and Blood Product Inventory: Guidelines for Australian Health Providers to assist health providers in meeting the requirements of this document, the National Policy.

Other

- Australian Health Practitioner Regulation Agency (AHPRA) -https://www.ahpra.gov.au
  The Australian Health Practitioner Regulation Agency (AHPRA) is the national organisation responsible for implementing the National Registration and Accreditation Scheme (the National Scheme) across Australia, including the regulation of healthcare professionals.

- Therapeutic Goods Administration (TGA) - https://www.tga.gov.au/
  The TGA is Australia's regulatory authority for therapeutic goods and are responsible for the regulation of blood, blood components and plasma derivatives.

- Series of National Guidelines (SoNGs) http://www.health.gov.au/internet/main/publishing.nsf/Content/cdnasongs.htm
  The SoNGs have been developed to provide nationally consistent advice and guidance to public health units in responding to a notifiable disease event.

7. GLOSSARY

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

Term	Acronym	Definition
Additional dose		An extra dose that can be requested during the course of an authorisation if certain criteria are met. Applies to one off doses only, for example indication dose, not maintenance therapy.
Administering Facility		The facility recorded in BloodSTAR where the product will be given or infused. The administering facility is selected by the Requesting Medical Officer when an authorisation request is submitted for a patient in BloodSTAR and can be updated at any time to accommodate changes in a patient's care.
Adverse event		A harmful or serious reaction to immunoglobulin product administration requiring further treatment that should be reported within the hospital and to the Therapeutic Goods Administration (TGA), the Authoriser and suppliers, as appropriate.
Allocation		Allocation of product type 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.
Alternative therapy		Other clinical treatments that can be substituted for immunoglobulin therapy to treat a condition (e.g. plasma exchange).
Australian Red Cross Blood Service	Blood Service	The organisation that collects, processes and distributes blood and blood components sourced from voluntary non-remunerated Australian blood donors.
Authorisation		Where eligibility for patient access to government-funded immunoglobulin products has been assessed and approved. May also be used to refer to the process for assessing eligibility in accordance with the National Policy and the Criteria.
Authorisation date		The point at which the patient is approved for initial qualifying or continuing immunoglobulin therapy. Patients will be authorised for a single dose or period of continuing treatment according to the Criteria.
Authorisation request		A form containing details of a patient and their medical condition for which a prescriber wishes to prescribe immunoglobulin therapy, used to obtain initial access to the supply of government-funded immunoglobulin product. An electronic form is used in BloodSTAR.
Authoriser		A person or group responsible for overseeing authorisation requests for immunoglobulin products and delegating the approval or rejection of an authorisation request.
Blood Operations Centre	BOC	The Blood Operations Centre monitors the operations of the NBA's blood systems, including BloodSTAR, and supports end users with all technical system issues. BOC operates 24 hours a day, 7 days a week to support users and the blood sector.

Term	Acronym	Definition
BloodNet		A web-based system that allows staff in health providers (hospitals) across Australia to order, receipt and record the fate of blood and blood products.
BloodPortal		The Blood Portal is the central management system that allows users to create an account to access NBA Blood Systems, including BloodSTAR. Users can also manage their account details and subscriptions to NBA newsletters.
BloodSTAR		A web-based system that facilitates authorisation for access and management of immunoglobulin products for the treatment of medical conditions identified in the Criteria.
Cessation		When authorisation for continuing access and supply of government-funded Ig product is no longer required or the authorisation has expired.
Condition		Clinical conditions are categorised according to the quality of the available evidence and whether immunoglobulin therapy is considered beneficial.
Contraindicated		A situation where therapy should not be used because it may be harmful to a patient.
Criteria for the clinical use of intravenous immunoglobulin in Australia	Criteria	Identifies the conditions and circumstances for which the use of immunoglobulin is clinically appropriate and accessible to patients under the National Blood Agreement.
Date of assessment		The date a patient was reviewed by the Treating Medical Specialist.
Date of infusion		The date a patient requires or receives the infusion.
Diagnostic conditions		Condition determined from medical examination of signs and symptoms and other investigations.
Diagnosing Medical Officer	DMO	In BloodSTAR, the Diagnosing Medical Officer is responsible for diagnosing the patient's condition in accordance with the Criteria and determining whether initial Ig treatment is required. If treatment is required, the Diagnosing Medical Officer will be nominated on the request for initial treatment in BloodSTAR.
Dispenser		A person or group responsible for the release of a specific amount of immunoglobulin to the clinical ward or patient (SCIg), stock inventory management and product orders.
Dispensing		The release of immunoglobulin product from inventory to the clinical ward or patient (SCIg) in accordance with the prescription and patient authorisation.
Distributor		A Distributor is responsible for completing product orders and supplying Dispensers with immunoglobulin products.
Divided dose		Dividing a large dose of Ig into two or more smaller doses to assist patient tolerance of the infusion .
Facility Administrator		BloodSTAR Facility Administrators are responsible for approving BloodSTAR user role access requests and deactivating user role access when no longer required.

Term	Acronym	Definition
Ideal Body Weight	IBW	Ideal body weight refers to a weight that is considered within normal range for a patient's age and height.
Immune modulation therapy		Treatment with immunoglobulin product to induce, enhance or suppress an immune response.
Immune replacement therapy		Treatment with immunoglobulin product in people with insufficient antibodies (immune deficiency).
Immunoglobulin	Ig	An antibody protein used by the immune system to identify and neutralise bacteria and viruses.
Indication		A reason to prescribe a medication or perform treatment.
Induction Dose		A type of one off dose usually administered at the beginning of a treatment plan. It is often a larger or additional dose.
Infusion Method		The method used to administer the Ig product, such as intravenous or subcutaneous infusions.
Initial therapy		A type of dose usually given as a one off treatment but occasionally requires a second dose.
Intramuscular	IM	Intramuscular injection is the injection of a substance directly into a muscle.
Intravenous immunoglobulin	IVIg	Immunoglobulin administered into a vein (as opposed to intramuscular or subcutaneous injection), to reduce susceptibility to infections and manage many immune system disorders.
Jurisdiction		A signatory to the National Blood Authority. This includes the Australian Government and all the State and Territory Governments.
Jurisdictional Blood Committee	JBC	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.
Jurisdictional Direct Orders	JDO	Arrangements implemented by the National Blood Authority (NBA) with suppliers to facilitate the purchase of immunoglobulin at the same prices negotiated by the NBA, for the treatment of conditions not satisfying the Criteria for the clinical use of immunoglobulin in Australia.
Maintenance dose		A dose type that occurs on a regular basis over a period of time. Prescribers can request the dose timing, number of courses and division if required as long as it is within the dosing criteria.
Medical Specialist		A medical officer who specialises in a particular field of medicine.
Midwife		Registered Midwives are responsible for the coordination of treatment for authorised patients and communication with the Dispenser for product order requirements where relevant. In BloodSTAR the role is referred to as Nurse/Midwife.

Term	Acronym	Definition
National Blood Agreement		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.
National blood arrangements		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.
National Blood Authority	NBA	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.
National Immunoglobulin Governance Advisory Committee	NIGAC	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.
National Immunoglobulin Governance Program		Administered by the NBA, the National Ig Governance Program was introduced to achieve Governments' objectives for Ig products funded and supplied under the national blood arrangements.
National Safety and Quality Health Service Standards	NSQHS Standards	A nationally consistent and uniform set of measures of safety and quality for application by health service providers.
National Subcutaneous Immunoglobulin Program		The program outlines the governing requirements for hospitals for ordering and providing subcutaneous immunoglobulin (SCIg) products under the national blood arrangements within a hospital based SCIg program.
National Supply Plan and Budget		The National Supply Plan and Budget sets a specific volume of domestic Ig products to be supplied each year, based on the expected levels of Australian plasma collection and Ig product manufacture. The National Supply Plan and Budget also includes a forecast of the additional volume of imported Ig products expected to be required to meet demand under the Criteria.
Normal human immunoglobulin (NHIg)	NHIg	Immunoglobulin administered by intramuscular injection (as opposed to intravenous or subcutaneous 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.
Nurse		Registered Nurses or midwives are responsible for the coordination of treatment for authorised patients and communication with the Dispenser for product order requirements where relevant. In BloodSTAR the role is referred to as Nurse/Midwife.
One-off dose		Generally refers to any dose that is not ongoing and includes terms such as initial dose, induction dose, loading dose or dose.
Patient		A person requiring immunoglobulin therapy under the national blood arrangements.

Term	Acronym	Definition
Plasma		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.
Plasma exchange		Plasma exchange is an alternative treatment to Ig therapy. A percentage of a patient's plasma (the liquid part of the blood) is replaced by plasma from a donor or a plasma substitute.
Prescriber		Collectively refers to all types of medical officers that have a role in the process of requesting immunoglobulin products. This includes the Treating Medical Specialist (TMS), the Diagnosing Medical Officer (DMO) and the Requesting Medical Officer (RMO). RMO also refers to nurse practitioners.
Prescription		A prescription is when a medical officer provides a direction for a patient to be issued with a medicine or treatment. The BloodSTAR authorisation request is not a prescription for treatment. Prescribers should follow local requirements for prescribing Ig products in accordance with relevant legislation.
Prophylaxis		A treatment designed and used to prevent an episode or worsening of disease.
Provisional access		Provisional access allows Prescribers to perform limited functions in BloodSTAR while they are waiting to be granted full access by a Facility Administrator, such as submitting an initial authorisation request. Provisional access is automatically granted to Prescribers once they have provided their AHPRA registration details and submitted a request for access at their facility's BloodSTAR site.
Public health disease control activities		Measures taken by a public health unit in responding to a notifiable disease event.
Public health unit	PHU	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.
Qualifying criteria		Describes the clinical criteria that must be fulfilled to be eligible to receive Ig products under the National Policy.
Recurrent/Repeated Dose		A type of dose used where a number of small additional doses may be required over a short period of time depending on response.
Requesting Medical Officer	RMO	Refers to the medical officer that submits an authorisation request in BloodSTAR. The RMO may also be the Treating Medial Specialist (TMS) or the Diagnosing Medical Officer, or the medical officer submitting the request on their behalf.

Term	Acronym	Definition
Review		Assessment of the patient's response to immunoglobulin therapy 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. A review can also be submitted in BloodSTAR for conditions that do not allow continuing treatment.
Review criteria		The review criteria are made up of clinical measurements that indicate a patient's response to Ig therapy. Evidence of clinical benefit of Ig should be demonstrated to warrant ongoing treatment where required. Review outcomes may be required in order to determine whether Ig therapy is to be continued or ceased, or to alter the dose or frequency of administration.
Review outcome notification due date		The date a patient treatment review outcomes are required to ensure continuing access and supply of immunoglobulin products where clinical benefit is evident.
Reviewing Medical Officer	(RvMO)	In BloodSTAR, a Reviewing Medical Officer is responsible for reviewing a patient's response to Ig therapy in accordance with the Criteria and determining whether continuing treatment is required. If continuing treatment is required, a Reviewing Medical Officer will be nominated on the request for continuing treatment in BloodSTAR.
Subcutaneous Immunoglobulin (SCIg)	SCIg	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 or carers.
Therapeutic Goods Administration	TGA	An agency of the Department of Health responsible for regulating therapeutic goods, including medicines, devices, blood and blood products.
Treating Facility		The treating facility is where a patient is diagnosed and clinically reviewed. BloodSTAR will automatically record the facility associated with a Treating Medical Specialist as the treating facility when submitting an authorisation request. If a Treating Medical Specialist practices at multiple facilities, a Requesting Medical Officer will need to specify the correct treating facility manually.
Treating Medical Specialist	TMS	In BloodSTAR, a Treating Medical Specialist is responsible for managing the patient's medical care. A Treating Medical Specialist must be registered as an applicable specialist with the Australian Health Practitioner Regulation Agency (AHPRA).
Trial cessation		A period of time that the patient is taken off therapy to allow a clinical assessment of the clinical benefit of immunoglobulin treatment.

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NATIONAL BLOOD AUTHORITY
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