NATIONAL BLOOD AUTHORITY AUSTRALIA

# INTRAVENOUS IMMUNOGLOBULIN (IVIg)
## Authorisation Request Form (effective from 1 Sept 2015)
## RENAL INDICATIONS

Governance

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

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

**PATIENT DETAILS (or affix hospital label)**

Surname:
Given names:
DOB:
Gender: ☐ Female ☐ Male
UR:
Hospital:
Weight: kg Height: cm

**Previous Immunoglobulin treatment:**

Yes ☐ No ☐ Unknown ☐

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

**PRODUCT DELIVERY INSTRUCTIONS**

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

Dispenser name:
Street:
Suburb:
State/Territory:
Postcode:
Phone: Fax:
Email:

Additional delivery instructions:

**PLEASE INDICATE PATIENT DIAGNOSIS: CONSULTANT'S LETTER MAY BE ATTACHED TO DEMONSTRATE THAT ALL QUALIFYING CRITERIA HAVE BEEN MET.**

Diagnosis Transplant date:

**Pre-transplant** ☐ ABO Incompatible ☐ Highly Sensitised (HLA)

**Post-transplant** ☐ Antibody Mediated Rejection ☐ Steroid Resistant ☐ Cellular Rejection

☐ BK Virus ☐ CMV ☐ Other transplant risk (please specify)

☐ Conventional immunosuppression contraindicated Details:

**Biopsy Results** - attached ☐ Yes ☐ No Details:

**Concurrent Therapy**

☐ Plasma Exchange Number of Planned Exchanges Dates:

☐ Immunosuppression Details:

**Dose required:** g **OR** Number of doses planned (e.g. 2x24g): DOSE/kg:

Frequency: Please specify Date required:

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

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

| | | | |
|---|---|---|---|
| Available until 31 December 2015* | ☐ Kiovig 10% | ☐ Octagam 5% | ☐ Octagam 10% |
| * These products are available for existing patients until 30 June 2016. | | | |
| Available from 1 November 2015 | ☐ Privigen 10% | ☐ Flebogamma 5% | ☐ Flebogamma 10% |

OFFICE USE ONLY (Blood Service authorisation) Delegate: Designation (MO/TN/Other):

Qualifying Criteria ☐ met ☐ not met Request approved ☐ yes ☐ no Referred to JDO/IVIg Group for Review: ☐ yes ☐ no

Product: Dose: g Frequency:

Review required by: (continuing supply will be conditional on this review)

Australian Red Cross BLOOD SERVICE

NATIONAL BLOOD AUTHORITY AUSTRALIA

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## RENAL INDICATIONS

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Patient details:

Surname: | Given names:

DOB: | Hospital:

Requesting Medical Officer Name: | Position:

Pager/Mobile: | Phone: | Fax: | Date:

Renal physician/nephrologist:

Name: | Phone:

Email: | Mobile:

Postal Address:

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

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

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

I have provided and/or explained to my patient (or parent/carer/guardian) the Privacy Statement and Notice (Notice) and Patient Information Brochure and they have had the opportunity to ask questions. I believe that they are aware of and understand:

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

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

- the collection and recording of personal information (including sensitive health information) in secure databases, held by the Australian Red Cross Blood Service (Blood Service) and the National Blood Authority (NBA),
- the use of this information by clinicians to submit a request for, and for the assessment of, initial or ongoing authorisation for access to publicly funded immunoglobulin products, against the criteria determined by clinical experts and approved by Australian governments for this purpose,
- the use of limited identifying details (for example, name, date of birth, sex and hospital identifiers) within search functions of the above mentioned databases to ensure that patients are correctly identified,
- the disclosure to and use of this information by clinicians in Australian treatment facilities that they attend for health care, in order to deliver health services according to the purposes set out in the Notice and
- the disclosure and use of this information in a manner which will not readily identify them, (such as through the removal of directly identifying personal information, or use of summary level grouped data) for the secondary purposes of: identifying priorities for research, prescriber education and training; performance evaluation and improvement of the supply, authorisation and use of immunoglobulin products; further developing the criteria upon which government policy is based; supply planning so the NBA can make sure enough Ig products are available to meet patients' needs; and enabling reporting on the program for supply, authorisation and use of publicly funded immunoglobulin products.

My patient understands that any additional use of information held by the Blood Service and NBA will only be undertaken in accordance with the requirements of the Privacy Act 1988 (Cth) and any relevant state/territory laws, and that the information may be made available for medical or public health research only with approval of a properly constituted human research ethics committee (HREC).

Signature: | Date:

Name: | Position:

The Australian Red Cross Blood Service is contracted by the National Blood Authority to perform the roles of Authoriser and Distributor of immunoglobulin products supplied and funded under the national blood arrangements.

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

PRINT

BLOODSTAR

# Privacy Statement and Notice

1 September 2015

This statement explains how the National Blood Authority (NBA) manages personal and sensitive information that it collects about you. The NBA is the Commonwealth Government agency responsible for the supply of blood and blood products in Australia, including immunoglobulin (Ig) products derived from human blood plasma.

The NBA is currently developing BloodSTAR (System for Tracking Authorisations and Reviews) to support the *Immunoglobulin Governance National Policy: Access to Government Funded Immunoglobulin Products in Australia*[1]. BloodSTAR will replace the current paper based processes and the Blood Service's Information management system, and will be rolled out in early 2016. Information about patients approved to receive government funded immunoglobulin products that is expected to extend beyond 2015 will need to be recorded in BloodSTAR and cannot be stored without your explicit consent.

**How your information is collected**

The NBA collects your personal and sensitive information from organisations or persons who provide healthcare products or services such as doctors, nurses, hospitals and pathology laboratories.

**What information will be collected?**

The information collected about you will include identification details such as your name, date of birth, sex, and may include your individual health identifier (IHI), hospital identifiers and sensitive health information.

## Purpose of collection

**Why is my personal and sensitive information collected?**

Ig products are a precious and high cost resource. Government policy requires that government funded Ig products can only be approved for specific medical conditions. Accordingly, the primary purpose for collecting your information is to correctly identify you and to assess your eligibility to receive these products. It will also help your doctor or nurse to quickly access reliable information about your continuing eligibility.

As a secondary purpose, summary level grouped information which does not identify you, is also important for:

- identifying priorities for research
- prescriber education and training
- performance evaluation and improvement of the supply, authorisation and use of immunoglobulin products
- further developing the Criteria upon which government policy is based
- supply planning so the NBA can make sure enough Ig products are available to meet patients' needs
- enabling reporting on the program for supply, authorisation and use of government funded immunoglobulin products.

Any additional research will only be undertaken in line with the requirements of the *Privacy Act 1988* (Cth) and any relevant laws. The data may only be made available for research if it has a properly constituted human research ethics committee (HREC) approval.

**How long will my information be kept for?**

Patient records will be retained for a minimum period of 20 years in line with the requirements of the *Archives Act 1983* (Cth) and the National Pathology Accreditation Advisory Council (NPAAC) requirements (laboratory accreditation).

[1] National Blood Authority, Immunoglobulin Governance National Policy: Access to Government Funded Immunoglobulin Products in Australia, November 2014, (www.blood.gov.au/Ig-program)

# BLOODSTAR

**Can I choose not to provide consent or be included in BloodSTAR?**

Yes. However, your doctor will not be able to submit your personal information to enable assessment of your eligibility and you will therefore not be able to receive government funded Ig products. Alternative arrangements are available, including Jurisdictional Direct Order or Private Order and should be discussed with your doctor. For more information visit: http://www.blood.gov.au/Ig-publications

**Who will access my personal information?**

Only authorised users involved directly or indirectly in your treatment via a secure log in. These include: your doctor, nurse, laboratory staff, pharmacy staff, Authorisers (specified staff at the Blood Service) and NBA staff that provide technical and user support.

**How can I be confident that my personal information is protected?**

The NBA uses a security protected system with strict rules around access. We will also not pass on your personal information to anyone without your consent, unless the law requires us to do so. These procedures protect your information from unauthorised access, interference, alteration, disclosure, loss or misuse.

**Do I have to use my name in BloodSTAR?**

Yes. Your name and personal details are used to uniquely identify you to ensure that you receive the appropriate treatment. Pseudonym and anonymity will not be possible as these cannot be reliably cross checked with hospital processes and may potentially put you or other patients at risk of not receiving appropriate treatment.

**Can I access and correct my personal information?**

Yes, you can do this in line with privacy laws. Contact your doctor in the first instance. If you are unhappy with the response you receive, you can contact the NBA at privacy@blood.gov.au, the privacy commissioner or equivalent in your State or Territory, or the Australian Privacy Commissioner.

**How long is my consent to collection of my information valid for?**

Your initial consent to the collection, use and disclosure of your personal information will remain valid unless you withdraw it. This applies whether such information is used for the primary purpose or for the secondary purpose.

**If I have changed my mind, how do I opt out of BloodSTAR?**

You can withdraw your consent by contacting your doctor. From that point on, no further details about you will be collected. Information already recorded in your individual patient record will not be deleted but will be retained for historical reporting purposes. However ongoing access to government funded Ig products will cease. Alternative arrangements are available, including Jurisdictional Direct Order or Private Order and should be discussed with your doctor. For more information visit: http://www.blood.gov.au/Ig-publications

**If I have withdrawn my consent can I change my mind and opt back in to BloodSTAR?**

If you withdraw your consent to BloodSTAR, you may at a later date choose to reactivate your patient record by providing consent again.

**NBA Privacy Policy**

The privacy policy gives more details on how the NBA manages personal information generally and how you can make a privacy complaint to the NBA. A copy of the policy can be found at http://www.blood.gov.au/privacy

## Contact us

If you have any questions in relation to this information or require more information, please contact the Health Provider Engagement Team on 13 000 BLOOD (25663) or email: support@blood.gov.au

[2] Criteria for the clinical use of intravenous immunoglobulin, Second Edition (July 2012), COAG Health Council (www.blood.gov.au/ivig-criteria).

You will be asked to provide your express consent (explicit oral or written) to the collection, retention and use of personal information and clinical data to assess authorisation for initial and continuing access to government funded product.

If you don't qualify for government funded product, there are other options available. Please see the National Blood Authority website (www.blood.gov.au) for more information.

## Why have I been prescribed this treatment?

There are two major types of conditions where immunoglobulin infusions are used as treatment.

### Replacement therapy

Replacement therapy is given to people who do not make enough of their own immunoglobulins (antibodies) to fight infection and maintain a healthy immune system. This can be because of genetic problems from birth (primary) or because of certain diseases or treatments (secondary). Low immunoglobulin levels can occur with certain types of cancers, before or during treatment (such as non-Hodgkin lymphoma and multiple myeloma). People with these cancers need to have immunoglobulin treatment to protect them from infections.

### Immunomodulation therapy

Immunodulation therapy is given to people when their immune system attacks their own body's tissues by mistake. This is called an auto-immune disorder. Immunoglobulin infusions can modulate the immune system to improve some of these conditions. The infusions must be given intravenously.

Examples of auto-immune disorders include:

- chronic inflammatory demyelinating polyneuropathy (CIDP)
- Guillain-Barré syndrome
- inflammatory myopathies
- auto-immune disorders of the blood.

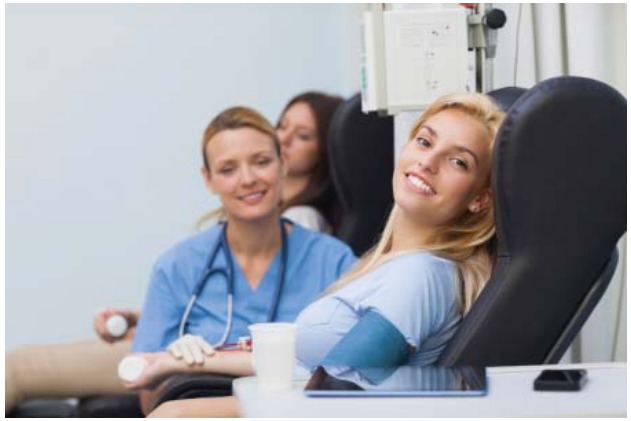
However, not everyone with these conditions will respond to this treatment and your doctor will need to assess your response to see whether immunoglobulin remains the right treatment for you.

## How is it given?

The most common way of giving this treatment is by an infusion through a needle into a vein (IV), but in some cases it can be given as a subcutaneous (SC) infusion, with a needle inserted in to the fat tissue under the skin.

## How is the dose determined?

The treatment dose varies with each diagnosis and is also based on body weight. The dose given, the timing between treatments and the number of treatments given depends on your response to treatment and test results. Your doctor will inform you of what is best for you and look at your progress at set times. It is important that your doctor sees you at regular intervals to make sure the treatment is working and to make changes if needed.



## What are the risks of infection from a blood product?

All immunoglobulin products have been screened and tested to protect patients from diseases such as hepatitis (B and C) and human immunodeficiency virus (HIV/AIDS). These products have also gone through at least two processes that destroy viruses. There is a risk of infection but it is very low. In Australia, there has never been a reported case of an infection from this treatment.

## What are the side effects?

All medical treatment products, including blood products, have risks.

The most common reactions or side effects to immunoglobulin products are:

- tiredness
- headache
- nausea (feeling sick)
- stomach and back pain

Rarely, more serious allergic reactions occur. Symptoms include:

- shortness of breath
- wheezing
- tongue/throat swelling
- chest tightness
- skin rash
- dizziness
- low blood pressure

Very rarely there can be an increased risk of blood clotting which in some people may contribute to heart attack, stroke or other vascular problems or worsening renal failure. These almost only occur in people who already have risk factors.

Any of these or any other symptoms should be reported to a doctor or nurse immediately, or before your next treatment.

## Are there alternative treatments?

There may be other treatments for your condition. Discuss these with your doctor. Stopping treatment without first talking with your doctor can be dangerous.

## When do I need to call the doctor or treatment centre?

### Before the infusion

Tell your doctor or nurse of any change in your health or medication, even if it is for a short time or if it is simple such as a minor infection, dehydration or conditions that could cause dehydration including loss of appetite, vomiting or diarrhoea and if you have taken a non-drowsy antihistamine and paracetamol (at home) to prevent some of the side effects.

### After the infusion

Sometimes after the infusion and for the next day or two, you might experience flu-like symptoms such as fever, chills, aching joints and muscles. These usually disappear within 24 to 48 hours and are easily treated. Your doctor or nurse can suggest some treatments for you. Sometimes people have reported a severe headache with their eyes being very sensitive to light after an infusion. If this happens please call your doctor or the nurse in your treatment centre.

### Regular treatment reviews

All patients on immunoglobulin products must be regularly reviewed by a doctor. Depending on your diagnosis the immunoglobulin treatment may only be required for a limited period. If you are prescribed continuing immunoglobulin treatment, regular consultations with your doctor help measure how the treatment is affecting your health, any dose adjustments to be made, and any side effects to be reported. Your doctor will assess your response to the treatment and may stop your infusions temporarily to reassess your immune system or your response to treatment. Immunoglobulin treatment may not be effective and may no longer be required. Your doctor will advise you of when the reviews should be carried out. Your doctor will also be required to periodically report on your response to treatment for you to continue to access immunoglobulin.

### Questions to ask your doctor

Below is a list of questions that you may like to ask your doctor to help you make an informed decision before agreeing to treatment:

- Why do I need this product?
- Are there any other treatment options?
- What are the expected outcomes of this treatment?

Your doctor should discuss any queries you have regarding the treatment and you should be offered written information. You have the right to ask questions and expect those questions to be answered.

Other questions I would like to discuss with my doctor:

_____
_____
_____
_____
_____

## Contact details

Hospital: _____
Phone: _____
Doctor: _____
Phone: _____
Treatment centre: _____
Phone: _____

## More information

Additional information can be obtained from the following sites:

- National Blood Authority www.blood.gov.au
- Australian Red Cross Blood Service www.mytransfusion.com.au
- National Health and Medical Research Council www.nhmrc.gov.au



Last updated: December 2014

# Patient Information: Immunoglobulin Treatment

Governance

Your doctor has recommended that, as a part of your treatment, you will be receiving medication called immunoglobulin.

## What are immunoglobulins?

These are antibodies made by the body's immune ("defense") system to fight infections and disease. They are normally produced by a type of white blood cell called a B-lymphocyte. All immunoglobulin products are produced from pooled healthy donated blood plasma. All immunoglobulin products used in Australia have been approved by the Therapeutic Goods Administration.

## How are immunoglobulin products made available in Australia?

To ensure sustainability of these precious and high cost products, governments have established the Criteria for the clinical use of intravenous immunoglobulin in Australia 2nd Edition (Criteria) as the basis for access to government funded products. The product type that you receive (including between Australian and imported products) may change from time to time due to:

- A clinical decision; and/or
- National supply contract arrangements.

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