Governance

BLOODSTAR

INTRAVENOUS IMMUNOGLOBULIN (IVIG) AUTHORISATION REQUEST FORM FOR EMERGENCY AUTHORISATIONS DURING BLOODSTAR SYSTEM DOWNTIME

IMMUNOLOGICAL OR GENERAL INDICATIONS

IMPORTANT! This is only to be used for emergency initial authorisation requests during BloodSTAR system downtime. This form is for single doses of IVIg only and must not be used to request maintenance therapy or for routine requests. The details of this authorisation request should be entered into BloodSTAR within 7 working days of the request. If the details are not entered into BloodSTAR within this timeframe, funding of product under the National Blood Arrangements cannot be guaranteed.

About this form: This form is used to request patient specific authorisation from the Australian Red Cross Lifeblood (Lifeblood) for access to IVIg products, assessed against Version 3 of the *Criteria for the Clinical Use of Immunoglobulin in Australia* (the Criteria). All fields must be completed, incomplete forms will delay processing. Completed forms are to be faxed to the relevant contact at the bottom of this form.

Tip: To move to the next field, click TAB on your keyboard.

State/Territory: **Requesting Medical Officer Name:** **Position:**

Pager/Mobile: **Phone:** **Fax:** **Date:**

PATIENT DETAILS (or affix hospital label)

Surname:

Given names:

DOB (DD/MM/YYYY):

Gender: ☐ Female ☐ Male

UR:

Hospital:

Weight: kg Height: cm

PREVIOUS IMMUNOGLOBULIN TREATMENT:

☐ IVIg ☐ Subcutaneous Immunoglobulin (SCIg)

☐ Unknown ☐ Normal Human Immunoglobulin (NHIg)

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

Treating facility (where clinically reviewed):

Administering facility (where Ig infused):

Dispensing facility (where Ig dispensed from):

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

INBORN ERRORS OF IMMUNITY (please select one of the below):

☐ Severe combined immunodeficiency (SCID)

☐ Combined immunodeficiency generally less profound than SCID (e.g. thymoma)

☐ Combined immunodeficiency with associated or syndromal features (e.g. Wiskott Aldrich syndrome; ataxia telangiectasia)

☐ Severe reduction in all Ig isotypes with decreased or absent B-cells (e.g. XLA def)

☐ Severe reduction in at least two Ig isotypes with low/normal B-cells (e.g. CVID)

☐ Severe reduction in serum IgG and IgA with normal/elevated IgM (e.g. CD40L def)

☐ Transient hypogammaglobulinaemia of infancy

☐ Lymphoproliferative syndromes (e.g. XLP1, XLP2, CD27 def)

☐ Possible common variable immune deficiency (CVID) - below normal serum IgG but normal serum IgA level

For all indications above please complete the following:

Total: IgG: g/L IgA: g/L IgM: g/L

Date performed:

Invasive or life threatening bacterial infections in the previous year:

☐ Yes ☐ No Please provide details below (or attach letter):

Chronic suppurative lung disease: ☐ Yes ☐ No

OTHER CONDITIONS (please describe requirements for Ig and specify medical condition e.g. Kawasaki disease, toxic shock syndrome):

☐ **SPECIFIC ANTIBODY DEFICIENCY** (please complete the following):

Frequent bacterial infections despite continuous oral antibiotic therapy for three (3) months: ☐ Yes ☐ No

Please provide details (or attach letter):

Antibody response to:

Tetanus vaccine: ☐ Normal ☐ Impaired ☐ Not performed

Pneumovax: ☐ Normal ☐ Impaired ☐ Not performed

☐ **SECONDARY HYPOGAMMAGLOBULINAEMIA**

Please specify underlying disease/medical therapy:

Invasive or life threatening bacterial infections in the previous year:

☐ Yes ☐ No Please provide details below (or attach letter):

ONLY A SINGLE DOSE CAN BE AUTHORISED USING THIS EMERGENCY OFFLINE FORM

DOSE REQUIRED: g DOSE/kg:

IMPORTANT: Your patient will be allocated **Privigen AU** or an imported IVIg product provided your order meets policy requirements for the supply of IVIg for clinical indications funded under the Criteria.

Please indicate your preferred imported IVIg product:

☐ Privigen ☐ Flebogamma 5% ☐ Flebogamma 10% ☐ Octagam 10% ☐ Gamunex 10% ☐ Kiovig 10%

Indicate clinical reason for preferred product:

INTRAVENOUS IMMUNOGLOBULIN (IVIG) AUTHORISATION REQUEST FORM FOR EMERGENCY AUTHORISATIONS DURING BLOODSTAR SYSTEM DOWNTIME

IMMUNOLOGICAL OR GENERAL INDICATIONS

PATIENT DETAILS

Surname: Given names:

DOB (DD/MM/YYYY): Hospital:

REQUESTING MEDICAL OFFICER

Name: Position:

Pager/Mobile: Phone: Fax: Date:

TREATING MEDICAL SPECIALIST Specialty:

Name: Phone: Mobile:

IMPORTANT: The contact details above will be used for any relevant urgent correspondence.

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 Lifeblood (Lifeblood) 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 Lifeblood and the 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 National Blood Authority contracts Australian Red Cross Lifeblood to perform the roles of Authoriser and Distributor of immunoglobulin products supplied and funded under the national blood arrangements.

OFFICE USE ONLY (TO BE COMPLETED BY LIFEBLOOD AUTHORISER)

Delegate: Designation: (MO/TN/Other)

Qualifying Criteria: ☐ Met ☐ Not met Request approved: ☐ Yes ☐ No

Product: Dose: g

AUTHORISATION REQUESTS MUST BE PRECEDED BY, OR IMMEDIATELY FOLLOWED UP WITH, A TELEPHONE CALL TO LIFEBLOOD.

PLEASE COMPLETE, PRINT, SIGN AND FAX TO THE RELEVANT FAX NUMBER PROVIDED BELOW.

STATE	FAX TO:	FOR URGENT ENQUIRIES
ACT	02 9234 2050	1300 478 348 (After Hours: 1300 478 348)
NSW	02 9234 2050	1300 478 348 (After Hours: 1300 478 348)
NT	08 8927 5461	08 8928 5116 (After Hours: 1300 478 348)
QLD	07 3838 9421 (8:30am-4:30pm) or 07 3838 9400	07 3838 9223 (After Hours: 07 3838 9010)
SA	08 8223 5833 (After Hours: 08 8225 8199)	08 8112 1341 (After Hours: 1300 136 013)
TAS	03 9694 0245	03 9694 0200 (After Hours: 03 9694 0200)
VIC	03 9694 0245	03 9694 0200 (After Hours: 03 9694 0200)
WA	08 9221 1215	08 9421 2377 (After Hours: 08 9325 3030)