

DRAFT IMMUNOGLOBULIN GOVERNANCE AND BLOODSTAR DEFINITIONS

Term	Acronym	Synonym	Definition
Administering Facility (authorisation request, authorisation)		Hospital, Clinic, Private Rooms, Infusion Clinic, Outpatient Clinic, Institution	The facility at which immunoglobulin infusions are administered. This may differ from the facility at which the treatment (and the authorisation) is normally managed. See Treating Facility and Treatment Facility
Adverse event			A harmful or serious reaction to immunoglobulin product administration requiring further treatment that should be reported within the hospital and to the TGA, the Authoriser and Suppliers, as appropriate.
Allocated Product			The product determined appropriate for a given medical condition based on allocation rules. See Allocation
Allocation			Allocation of product to patients based on available domestic and imported immunoglobulin product, taking into account supply security reserve levels endorsed by governments to ensure sufficiency of supply.
Alternative therapy		Substitute therapy	Other clinical treatments that can be substituted for immunoglobulin therapy to treat a condition (i.e. plasma exchange).
Australian Health Ministers' Advisory Council	AHMAC		The Australian Health Ministers' Advisory Council (AHMAC) provides support to the COAG Health Council (CHC), by advising health ministers on strategic matters relating to the coordination of health services. AHMAC considers blood sector matters referred to it by the JBC through the Hospitals Principle Committee, and reports as necessary to the CHC.
Australian Health Practitioner Regulation Agency		AHPRA	The Australian Health Practitioner Regulation Agency is the organisation responsible for the implementation of the National Registration and Accreditation Scheme across Australia.
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			Approval for a patient to receive one or more authorised doses of immunoglobulin until the end of the authorised period. An authorisation also sets out the requirements for a review of the patient prior to the end of the authorisation period.
Authorisation Date			The point at which the patient is approved for initial qualifying or continuing immunoglobulin treatment. Patients will be authorised for a single dose or period of continuing treatment according to the Criteria.
Authorisation End Date			The date at which access to funded immunoglobulin treatment will cease.
Authorisation Period			The authorisation period is determined at the time of authorisation approval based on the constraints set out in the criteria for each medical condition. The end of the authorisation period is often referred to as the Review Date .
Authorisation Process			The process for assessing eligibility for access to immunoglobulin products funded under the national blood arrangements based on the Criteria.

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Authorisation Request			Either an Initial or Continuing request for access to immunoglobulin products. See Initial Authorisation Request , Continuing Authorisation Request
Authorised Dose			An authorised dose consists of three components: the authorised product, the total quantity per dose and the interval at which the dose should be given.
Authoriser			A person or group responsible for overseeing authorisation requests for immunoglobulin products and has the delegation to approve or reject an Authorisation Request. The Australian Red Cross Blood Service is the service provider contracted to Australian Governments to undertake Authorisations.
BloodNet			A web-based system that allows staff in health providers (hospitals) across Australia to order and receipt blood and blood products.
Concurrent Authorisation			A rare circumstance where a patient is authorised for immunoglobulin for two or more medical conditions or indications at the same time.
Condition		Diagnosis, Medical Condition	Clinical conditions categorised according to the quality of the available evidence and whether immunoglobulin treatment is considered beneficial.
Continuing Authorisation Request			An authorisation request made at the end of a course of treatment for a given indication to request continued access to funded immunoglobulin treatment for the same indication. A continuing authorisation request addresses the Review Criteria set out in the Criteria and specifies the proposed dosing for the continuing treatment period. See Initial Authorisation Request
Continuing Treatment		Continuing Therapy	Immunoglobulin treatment that follows an initial course of treatment for the same indication
Contraindicated			A situation where therapy should not be used because it may be harmful to the patient.
Council of Australian Governments Health Council	CHC		The CHC is responsible for overseeing and managing the blood sector. It sets the governance, policy and financial frameworks under which the NBA operates.
Criteria for the clinical use of intravenous immunoglobulin in Australia, Second Edition 2012.	Criteria		Definition Identifies the indications for which immunoglobulin is funded under national blood arrangements by all Australian governments; the book is not a medical or clinical guideline on treatment of the indications listed. Regular review of the Criteria is needed to align funded access to immunoglobulin products with the latest evidence, or in the case of limited evidence, a consensus of expert opinion.
Diagnostic conditions			Condition determined from medical examination of signs and symptoms and other investigations.

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Dispenser		Blood Bank, Pathology laboratory, Pharmacy, Dispensing Facility	A Dispenser is responsible for the release of a specific amount of immunoglobulin to the clinical ward or patient (SCIg), stock inventory management and Product Orders.
Dispensing			The release of immunoglobulin product from inventory to the clinical ward or patient (SCIg) in accordance with the prescription and patient authorisation.
Dispensing Facility (authorisation request, authorisation)		Blood Bank, Pathology laboratory, Pharmacy, Dispenser	The facility from which it is anticipated product for a given authorisation will be normally dispensed.
Distributor			A Distributor is responsible for distributing immunoglobulin products to Dispensers.
Divided Dose			A fraction of the total quantity of a dose to be given at short intervals.
Dose			The quantity of immunoglobulin to be administered at one time, as a specified amount. A dose may be given multiple times at a set interval.
Dose Determining Weight	DDW		The second of two calculations used in the adjustment of a patients weight for the purpose of dosing. $IBW + 0.4 \times (\text{patient weight} - IBW)$ <p>See Ideal Body Weight and Ideal Body Weight Adjusted Dosing</p>
Effective Weight			The weight used to calculate an authorised dose adjusted based on each state and territory's rules applying either Ideal Body Weight Adjusted Dosing, Weight Capping, both or none at all. <p>See Ideal Body Weight, Dose Determining Weight, Weight Capping and Ideal Body Weight Adjusted Dosing</p>
Evidence Item			Additional information required in an authorisation request to support an assertion that the patient meets a particular qualifying or review criterion.
Exclusion Criteria			The circumstances in which immunoglobulin should not be used in patients who have the specified indication.
Facility		Hospital, Private Rooms, Medical Centres	A place at which immunoglobulin a related function may take place. This activity may be Treatment, Dispensing or Authorising.
Hospitals Principal Committee	HPC		The Hospitals Principal Committee provides advice to the Australian Health Ministers' Advisory Council (AHMAC) on matters relating to hospital care.

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Iatrogenic illness			Illness caused by medical treatment.
Ideal Body Weight	IBW		The first of two calculations used in the adjustment of a patients weight for the purpose of dosing. Male: $50 + (2.3 \times ((\text{height} / 2.54) - 60))$ Female: $45.5 + (2.3 \times ((\text{height} / 2.54) - 60))$ See Dose Determining Weight, Ideal Body Weight Adjusted Dosing
Ideal Body Weight Adjusted Dosing	IBWAD		Calculation of a patients weight adjusted to an ideal weight. Using the Ideal Body Weight and the Dose Determining Weight calculations. See Ideal Body Weight, Dose Determining Weight
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			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			TO BE DEFINED
Infusion Method			The route of administration of immunoglobulin to be used in the authorisation period. See Intravenous immunoglobulin, Subcutaneous immunoglobulin
Initial Authorisation Request			An Authorisation Request is a form containing details of a patient and their medical condition for which a prescriber wishes to prescribe immunoglobulin treatment, used to obtain initial access to the supply of government funded immunoglobulin product. See Continuing Authorisation Request
Intravenous immunoglobulin	IVIg		Immunoglobulin administered into a vein (as opposed to intramuscular or subcutaneous injection), provided under the national blood arrangements to reduce susceptibility to infections and manage many immune system disorders.
Jurisdiction		States and Territories	A signatory to the National Blood Agreement. This includes the Australian Government and all the state and territory governments.
Jurisdictional Blood Committee	JBC		The Jurisdictional Blood Committee (JBC) is a committee of senior government officials with member representation from the Australian Government, the six State Governments and two Territory Governments. JBC is responsible for all jurisdictional issues relating to the national blood supply, including <u>planning, production, supply and budgeting.</u>

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Jurisdictional Direct Orders	JDO		Arrangements implemented by the NBA with suppliers to facilitate the purchase of immunoglobulin products at the same prices negotiated by the NBA, for the treatment of conditions not satisfying the Criteria for the clinical use of IVIg in Australia.
Loading Dose			A dose of medication, often larger than subsequent doses, administered for the purpose of establishing a therapeutic level of the medication .
Maintenance Dose			A dose of a medication administered after achieving stable levels in the body, to maintain a therapeutic status quo .
Medical Specialist		Consultant, Treating Medical Specialist, Medical Officer, Clinician, Prescriber	In the context of this policy, a treating medical specialist refers to an immunologist, neurologist, haematologist, transplantation medicine specialist, dermatologist, rheumatologist, foeto- maternal specialist and neonatologist.
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 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.
Normal Human Immunoglobulin	NHlg		Immunoglobulin administered by intramuscular injection (as opposed to intravenous or sub-cutaneous injection). The product is approved in Australia for use in the management of hypogammaglobulinaemia and for the public health purposes to treat susceptible contacts of hepatitis A, measles, poliomyelitis and rubella.
Patient			A person receiving immunoglobulin therapy under the national blood arrangements.
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.

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Preferred Product			The immunoglobulin product chosen by a prescriber that is contrary to the allocated product determined by allocation rules. See Allocation. Allocated Product
Prescriber		Consultant, Treating Medical Specialist, Medical Officer, Clinician	A prescriber is a person who is a registered medical practitioner as determined by the Australian Health Practitioner Regulation Agency (AHPRA)
Prophylaxis			A treatment designed and used to prevent an episode or worsening of disease.
Proposed Dose			A dose set out in an authorisation request by a prescriber as the dose that is being requested and to be assessed against the Criteria. See Authorised Dose
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			The criteria that should be fulfilled if immunoglobulin is to be used. The qualifying criteria generally refer to matters such as patient selection, particular disease characteristics, disease severity, and any requirement for other treatments to have been demonstrably unsuccessful before immunoglobulin is considered.
Review			Assessment of the patient's response to Immunoglobulin treatment at the current dose and frequency to determine clinical benefit for access to continuing therapy. The Review is usually performed at 3, 6 or 12 monthly intervals.
Review Criteria			The major clinical factors that should be taken into account when reviewing the progress of a patient who is receiving immunoglobulin. They comprise parameters that indicate the patient's response to immunoglobulin and may be used to decide whether to: - continue or cease therapy; - or alter the dose or frequency of administration.
Review Outcome Notification Due Date			The date the Patient Treatment Review Outcomes are required to ensure continuing access and supply of immunoglobulin products where clinical benefit is evident.
Subcutaneous Immunoglobulin	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/carers.

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Supplier			A Supplier is responsible for completing product orders and supplying Dispensers with immunoglobulin Products.
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 (authorisation request, authorisation)			The facility at which a patient's treatment will be managed. This may differ from the facility at which infusions are administered.
Treating Medical Specialist	TMS	Consultant, Medical Officer, Clinician, Prescriber	The Medical Specialist nominated on an authorisation request as the specialist responsible for the care of the patient. The nominated Treating Medical Specialist will be the point of contact for the authorisation and will be notified of upcoming reviews.
Treatment Facility		Hospital, Clinic, Private Rooms, Day Surgery	A facility at which medical treatment is administered or managed.
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.
Weight Capping			A process of applying a cap to the weight on which a total dose is calculated. Each state and territory may have a different weight cap, or no cap at all.