Policy Directive

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Immunoglobulins, use of in NSW

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Functional Sub group Clinical/ Patient Services - Governance and Service Delivery
Population Health - Health Promotion

Summary The Policy Directive provides clinicians (medical practitioners, nurses and mid-wives) and transfusion medicine professionals with advice about the NSW Ministry of Health's policy in relation to the use of intravenous immuniglobulins and normal human immunoglobulin.

Replaces Doc. No. Intravenous Immunoglobulin (IVIg) - Use and Supply in NSW [PD2007_009]

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Applies to Local Health Districts, Speciality Network Governed Statutory Health Corporations, Board Governed Statutory Health Corporations, Chief Executive Governed Statutory Health Corporations, Affiliated Health Organisations, Public Health System Support Division, Community Health Centres, Dental Schools and Clinics, Government Medical Officers, NSW Ambulance Service, Private Hospitals and Day Procedure Centres, Public Health Units, Public Hospitals

Audience Clinicians (medical practitioners, nurses and mid-wives) and transfusion medicine professionals

Distributed to Public Health System, Divisions of General Practice, Government Medical Officers, Health Associations Unions, NSW Ambulance Service, Ministry of Health, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

Review date 25-Jul-2017

Policy Manual Patient Matters

File No. 08/7061-6

Status Active

Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

NSW GOVERNMENT Health

POLICY STATEMENT

USE OF IMMUNOGLOBULINS IN NSW

PURPOSE

This Policy Directive sets out the NSW Ministry for Health's policy in relation to the use of intravenous immunoglobulin (IVIg) and normal human immunoglobulin. The policy should be read in conjunction with the Australian Health Ministers' Conference (AHMC) "Criteria for the Clinical Use of Intravenous Immunoglobulins in Australia" and the AHMC Statement on National Stewardship Expectations for the Supply of Blood and Blood Products[1] (Attachment 1).

MANDATORY REQUIREMENTS

All staff involved with the provision of transfusion therapy must adhere to the provisions of this Policy Directive. Each health facility in NSW that provides transfusion therapy must have effective systems and procedures in place to enable compliance with this Policy Directive.

Intravenous Immunoglobulins

Intravenous immunoglobulins (IVIg) are used to treat a variety of neurological, haematological, immunological and a small number of miscellaneous conditions.

Access to IVIg funded under the National Blood Arrangements is tightly controlled through the application of the Australian Health Ministers' Conference Criteria for the Clinical Use of Intravenous Immunoglobulin (IVIg) in Australia (*"the Criteria")* 2012. This document lists the conditions and circumstances for which IVIg use is appropriate as determined by a systematic review of evidence-based literature and clinical consensus.

"The Criteria" is reviewed every three years to take into account any new evidence relating to the use of IVIg. A copy of "the Criteria" is available on the National Blood Authority's website at: www.nba.gov.au

Chapter 5 of the "Criteria" lists the conditions for which IVIg has an established role. Chapter 6 lists conditions for which IVIg has an emerging therapeutic role in selected patients. Chapter 7 lists conditions for which IVIg is used in exceptional circumstances only and Chapter 8 lists conditions for which IVIg use is not indicated.

The NSW Ministry for Health endorses the "Criteria". *It is also the Ministry's policy that if there are clinical reasons why a patient with a primary immunodeficiency disease cannot be treated with an intravenous preparation of immunoglobulins, they can be treated with normal human immunoglobulin provided that the same criteria used for the supply of IVIg are met.*

Clinicians wishing to treat a medical condition with IVIg that is not funded under "the Criteria" can order imported product from any commercial supplier of IVIg or access product under the Jurisdictional Direct Order Arrangement established by the National Blood Authority. In either case, the product must be placed directly with the relevant supplier and the cost of the product will have to be paid for by either the clinician's hospital or the patient.

[1] Statement endorsed by the Australian Health Ministers' Conference, 12 November 2010

Normal Human Immunoglobulin

In NSW, the use of Normal Human Immunoglobulin funded under the National Blood Arrangements is restricted to disease control activities undertaken at the behest of Public Health Units and, where appropriate, to treat patients diagnosed with primary immunodeficiency diseases. Normal Human Immunoglobulin will not be supplied for other purposes including travel prophylaxis for Hepatitis A. Advice in relation to prophylaxis for Hepatitis A can be found on the Immunise Australia website at:

www.health.gov.au/internet/immunise/publishing.nsf/content/Handbook-hepatitisa

IMPLEMENTATION

Chief Executives must ensure that:

- the principles and requirements of this policy are applied, achieved and sustained;
- all relevant staff are made aware of their obligations in relation to the Policy Directive; and
- documented procedures are in place to support the Policy Directive.

Clinicians and transfusion medicine professionals

- must comply with this Policy Directive.

REVISION HISTORY

Version	Approved by	Amendment notes
July 2012 (PD2012_041)	Deputy Director-General Population and Public Health and Chief Health Officer	Replaces PD2007_009. Reflects changes made to the AHMC "Criteria for the clinical use of intravenous immunoglobulins in Australia" and articulates the NSW Ministry of Health's policy relating to the use of normal human immunoglobulin.
February 2007 (PD2007_009)	Director-General	New Policy

ATTACHMENTS

1. AHMC Statement on National Stewardship Expectations for the Supply of Blood and Blood Products

ATTACHMENT A

AUSTRALIAN HEALTH MINISTERS' CONFERENCE STATEMENT ON NATIONAL STEWARDSHIP EXPECTATIONS FOR THE SUPPLY OF BLOOD AND BLOOD PRODUCTS

The Australian Health Ministers' Conference (AHMC) has determined that a clear statement is needed on governments' stewardship expectations for the providers of blood and blood products within the health sector. Stewardship, in this context, means responsible, sustainable and appropriate use of blood and blood products.

Blood and blood products are provided under the *National Blood Agreement* 2003 to which all Commonwealth, State and Territory Governments are signatories. Achieving a blood supply that can meet the growing needs of an ageing population at an affordable cost requires the commitment from blood donors to be matched by an equal commitment from other parties in the supply chain.

All governments are committed to:

- Providing an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services; and
- Promoting safe, high quality management and use of blood products, blood related products and blood related services in Australia.

A key component of the blood sector and one which plays an invaluable part is that of the health providers of blood and blood products. Hospitals, doctors, laboratories and other health providers serve a vital role in ensuring these key resources reach the patients in need.

In fulfilling this role, Ministers expect that these health providers will contribute to the sustainability of the blood supply by adopting these stewardship measures for their own organisation and requiring their adoption by any other party to whom they supply blood.

Blood Stewardship Principles

Blood should be managed in ways that ensure:

- All blood products are used in a clinically appropriate manner in accord with relevant professional guidelines and standards;
- Informed patient consent procedures are implemented for all patients;
- Processes, programs and facilities are in place to minimise the wastage of blood products;
- Facilities are accredited with the appropriate bodies to meet all quality and safety obligations; and
- Transfusion related adverse event information is collected and managed according to jurisdictional requirements.

National blood product planning, management and governance are supported by:

- Health providers having an ordering and receipt verification process in place which provides adequate financial accountability as required by governments; and
- Inventory data is provided on a regular and timely basis to assist in supply and demand planning, especially in times of national shortages.

Governments and the National Blood Authority will continue to manage the Australian blood supply to meet the needs of the community. Health providers play a vital role in making sure that products are available to meet clinical need, when and where required. The contribution of these health providers to safe and appropriate use, including minimisation of cost and wastage in the supply, is equally important. Ministers look to health providers to increase their efforts in these areas to ensure that Australia has a sustainable and affordable blood supply into the future.

Statement Approved by the Australian Health Ministers' Conference, 12 November 2010.