

## Intravenous Immunoglobulin (IVIg) - Use and Supply in NSW

**Document Number** PD2007\_009

**Publication date** 19-Feb-2007

**Functional Sub group** Clinical/ Patient Services - Medical Treatment  
Clinical/ Patient Services - Pathology

**Summary** Describes the NSW Health policy on supply and use of intravenous immunoglobulin (IVIg).

**Author Branch** Clinical Policy

**Branch contact** Su Reid 9391 9271

**Applies to** Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations - Non Declared, Affiliated Health Organisations - Declared, Public Health System Support Division, Community Health Centres, Dental Schools and Clinics, NSW Ambulance Service, Private Hospitals and Day Procedure Centres, Public Hospitals

**Audience** Clinical, laboratory & nursing staff esp in haematology, neurology, immunology, pathology

**Distributed to** Public Health System, Community Health Centres, Dental Schools and Clinics, Divisions of General Practice, Government Medical Officers, Health Associations Unions, Health Professional Associations and Related Organisations, NSW Ambulance Service, NSW Department of Health, Public Hospitals, Private Hospitals and Day Procedure Centres

**Review date** 19-Feb-2012

**File No.** 05/7080

**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This Policy Directive may be varied, withdrawn or replaced at any time.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.

## INTRAVENOUS IMMUNOGLOBULINS (IVIG) - USE AND SUPPLY IN NSW

This Policy Directive advises Health Services of the policy for use and supply of intravenous immunoglobulins (IVIg) in NSW. It rescinds all previous letters of advice to the NSW health system concerning the use and supply of IVIg in NSW.

This Policy Directive has been developed in consultation with the NSW Immunoglobulin User Group (IUG), an advisory committee to the NSW Department of Health, with representation from the major relevant Colleges and specialist societies.

This Policy Directive should be read in conjunction with the guidelines developed by the Australian Health Ministers' Advisory Council (AHMAC) in June 2000<sup>1</sup>. The National Blood Authority (NBA) is developing new national guidelines for use of IVIg in Australia. This Policy Directive will be reviewed when the new national guidelines are released.

### Long-standing arrangements

In June 2000, AHMAC released guidelines for the clinical use of intravenous immunoglobulins (IVIg) in Australia. Under these guidelines:

- Category 1 - denoted indications for which there was strong evidence that IVIg had benefit;
- Category 2 - denoted indications for which evidence of benefit was inconclusive; and
- Category 3 - denoted indications for which there was convincing evidence that IVIg had no benefit.

Only IVIg used to treat Category 1 indications, at doses and dose frequencies recommended in the AHMAC 2000 Guidelines, is eligible for cost-sharing between the Australian Government (63% of cost) and the State/Territory Governments (37% of cost).

**IVIg to treat indications outside of Category 1 is not eligible for cost-sharing with the Australian Government. NSW Hospitals/Area Health Services must purchase IVIg at full cost (through their Drug Committee or similar mechanism) if they wish to treat indications outside of Category 1.**

In recent years, national shortages of Australian-produced IVIg (Intragam P®) led NSW Health to institute additional measures to manage supply and ensure the most appropriate use of Intragam P® within NSW. In April 2002 and again in July 2004, Area Health Services were advised of these measures, which included limits on doses for primary hypogammaglobulinaemia, subclass deficiency, idiopathic thrombocytopenic purpura (ITP) and Guillain Barré syndrome.

---

<sup>1</sup> Australian Health Ministers' Advisory Committee (June 2000) *Review of the use and supply of intravenous immunoglobulins in Australia* <http://www.nba.gov.au/PDF/ivig.pdf>

## Arrangements to apply from 1 July 2006

Since the establishment of arrangements by the National Blood Authority (NBA) to supplement the domestic IVIg supply with imported IVIg, there is no longer a need for NSW to continue with these additional measures.

From 1 July 2006, the additional measures will no longer apply. IVIg will be issued to treat Category 1 indications, generally in accordance with the AHMAC 2000 Guidelines. **Table 1 gives details of the new policy under which IVIg will be supplied by the ARCBS in NSW.** This policy will apply until the NBA national guidelines are released.

The Australian Red Cross Blood Service (ARCBS) distributes IVIg purchased under the cost-sharing arrangements. This includes the domestically-produced Intragam P® as well as the imported products: Octagam® and Sandoglobulin®, purchased by the National Blood Authority (NBA) to supplement the domestic supply.

The Chairs of the State/Territory IVIg User Groups (the National IVIg Forum) have determined national patient categories for eligibility for Octagam® and Sandoglobulin® issued by ARCBS, based upon the availability of Intragam P® and timeframes for rotation of products from the National Reserve. They are outlined in the ARCBS publication *Intravenous immunoglobulin: a clinician's guide. A comparison of products registered for use in Australia (September 2005)*, available on the ARCBS website at:

<http://www.transfusion.com.au/FILES/WhatDoYouWantToTransfuse/ivigguide.pdf>

**Octagam® or Sandoglobulin® for indications outside of Category 1 will not be distributed by the ARCBS and must be purchased directly from the relevant manufacturer: Octapharma Australia Pty Ltd (Octagam®) or CSL Ltd (Sandoglobulin®).**

Members of the IUG may be consulted to offer technical advice about the efficacy of IVIg for indications outside of Category 1. Please contact the Clinical Policy Unit on (02) 9391 9271 to obtain contact details for relevant IUG member(s).

Robyn Kruk  
**Director-General**

*Title: Intravenous Immunoglobulins (IVIg) – Use and Supply in NSW*

**Table 1. Policy for supply of IVIg by ARCBS for Category 1 indications - to apply from 1 July 2006<sup>2</sup>**

AHMAC Category 1 indication	Previous issue policy	Issue policy to apply from 1/7/06
<b>Primary Immunodeficiencies</b>		
<ul style="list-style-type: none"> <li>• X-linked hypogammaglobulinaemia</li> <li>• Common variable immunodeficiency</li> <li>• IgG subclass deficiencies</li> <li>• Wiskott Aldrich syndrome</li> </ul>	0.4g/kg/month. Increased doses or frequency based on trough levels and ongoing bacterial infections. Review after first 6 months treatment to confirm clinical response and dose is adequate.	0.4g/kg/month or more frequently if indicated. Increased doses and frequency based on trough levels and ongoing bacterial infections. Review after first 6 months treatment to confirm clinical response and dose is adequate. This issue policy will also apply to severe combined immunodeficiency (SCID) and other defined primary immunodeficiencies where there is hypogammaglobulinaemia for which IVIg replacement is indicated.
<b>Other immunological disorders</b>		
<ul style="list-style-type: none"> <li>• Paediatric HIV/AIDS</li> </ul>	0.4g/kg/month. Increased doses or frequency based on trough levels and ongoing bacterial infections. Review after first 6 months treatment to confirm clinical response and dose is adequate.	0.4g/kg/month or more frequently if indicated. Increased doses and frequency based on trough levels and ongoing bacterial infections. Review after first 6 months treatment to confirm clinical response and dose is adequate.
<ul style="list-style-type: none"> <li>• Kawasaki's disease</li> </ul>	One dose 2g/kg. May repeat dose in 24 hours.	Unchanged.

<sup>2</sup> This policy will apply until the National Blood Authority (NBA) national guidelines for use and supply of IVIg in Australia are released. The categorisation of some indications may change under the new national guidelines.

*Title: Intravenous Immunoglobulin (IVIg) – Use and Supply in NSW*

AHMAC Category 1 indication	Previous issue policy	Issue policy to apply from 1/7/06
<b>Neurological disorders</b>		
<ul style="list-style-type: none"> <li>Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)</li> <li>Multifocal motor neuropathy with persistent conduction block</li> </ul>	Initial course 0.4g/kg/day for 5 days then monthly with 6 monthly review for efficacy. More frequent doses to be purchased by AHS.	Initial course 0.4g/kg/day for 5 days then 0.4g/kg every four weeks, with a review at three months for efficacy. If effective, continue on maintenance dose of 0.4g/kg, which can be as frequent as every three weeks. Treatment plan may be individualised, to best assist the patient to maintain strength.
<ul style="list-style-type: none"> <li>Polymyositis</li> <li>Dermatomyositis</li> <li>Polymyositis and systemic connective tissue disease</li> </ul>	Patient must have failed corticosteroids with/without additional immunosuppressive therapy. Initial course 0.4g/kg/day for 5 days then monthly with 6 monthly review for efficacy. More frequent doses to be purchased by AHS.	Failed corticosteroids. Initial course 0.4g/kg/day for 5 days then 0.4g/kg every three weeks with review of efficacy at three months.
<ul style="list-style-type: none"> <li>Myasthenia gravis</li> </ul>	Initial course 0.4g/kg/month for 5 days then monthly. Repeat course if in acute crisis and not improved. More frequent doses – referred for commercial IVIg for extra doses.	Initial course 0.4g/kg/day for 5 days then 0.4g/kg every three weeks with review of efficacy at two months. Only one course for acute crisis.
<ul style="list-style-type: none"> <li>Lambert-Eaton myasthenic syndrome</li> </ul>	Initial course 0.4g/kg/month for 5 days then monthly. Repeat course if in acute crisis and not improved. More frequent doses – referred for commercial IVIg for extra doses.	Failed treatment for underlying tumour and failed plasma exchange. 0.4g/kg/day for 5 days then 0.4g/kg every three weeks with review of efficacy at two months.

**Title: Intravenous Immunoglobulin (IVIg) – Use and Supply in NSW**

AHMAC Category 1 indication	Previous issue policy	Issue policy to apply from 1/7/06
<ul style="list-style-type: none"> <li>IgM paraproteinaemic neuropathy resistant to treatment, with severe disability</li> </ul>	Failed plasma exchange combined with immunosuppression. Initial course 0.4g/kg/day for 5 days then monthly with 6 monthly review for efficacy. More frequent doses to be purchased by AHS.	Failed plasma exchange combined with immunosuppression. 0.4g/kg/day for 5 days then 0.4g/kg every three weeks with review of efficacy at two months.
<ul style="list-style-type: none"> <li>Guillain Barré syndrome</li> </ul>	One course only. A further course justified only if relapse occurs after initial improvement.	Unchanged.
<b>Haematological disorders</b>		
<ul style="list-style-type: none"> <li>Allogeneic stem cell or bone marrow transplant</li> </ul>	Previous NSW BMT network protocol recommended that all matched unrelated donor transplant (MUD) recipients receive intravenous immunoglobulin at a dose of 0.4g/kg/week up to day 84 post-transplantation.	Intravenous immunoglobulin replacement therapy is appropriate after haemopoietic stem cell transplantation when it is documented that the serum IgG level is below the lower limit of the reference range. 0.4g/kg/month, with dose or dose frequency adjusted according to trough serum IgG levels.
<ul style="list-style-type: none"> <li>Idiopathic thrombocytopenic purpura (ITP)</li> </ul>	Initial course 0.4g/kg/day for 5 days. One course per 12 months. Subgroup of patients on weekly or fortnightly dose of 0.4g/kg if resistant to all other therapies & cannot get commercial IVIg.	Persistent or potentially life-threatening haemorrhage. Unresponsive to steroids. Initial course 0.4g/kg/day for 5 days. May be given as frequently as 0.4g/kg weekly for patients resistant to a range of other therapies. Patients undergoing surgical procedures may be given an additional 5 day course.

**Title: Intravenous Immunoglobulin (IVIg) – Use and Supply in NSW**

AHMAC Category 1 indication	Previous issue policy	Issue policy to apply from 1/7/06
<ul style="list-style-type: none"> <li>Haematological malignancies associated with hypogammaglobulinaemia &amp; infection e.g. CLL, other lymphoproliferative disorders, multiple myeloma</li> </ul>	0.4g/kg/month. Increased doses based on trough levels and ongoing bacterial infections. Review after first 6 months treatment to confirm clinical response and dose is adequate.	Unchanged.
<ul style="list-style-type: none"> <li>Post transfusion purpura</li> </ul>	Initial course 0.4g/kg/day for 5 days. Steroids may be an alternative.	Unchanged.
<ul style="list-style-type: none"> <li>Alloimmune thrombocytopenia antenatal</li> </ul>	1g/Kg/week from week 14-16 until delivery. Monitor via fetal platelet counts if possible.	Unchanged.
<ul style="list-style-type: none"> <li>HIV associated thrombocytopenia</li> </ul>	No current policy.	Unchanged.
<ul style="list-style-type: none"> <li>Acute leukaemia in childhood</li> </ul>	0.4g/kg/month. Increased doses or frequency based on trough levels and ongoing bacterial infections. Review after first 6 months treatment to confirm clinical response and dose is adequate.	0.4g/kg/month or more frequently if indicated. Increased doses and frequency based on trough levels and ongoing bacterial infections. Review after first 6 months treatment to confirm clinical response and dose is adequate.