

1. ADMINISTRATION OF IMMUNOGLOBULIN INFUSION (INTRAGAM P)

Purpose

To facilitate the safe delivery of Intravenous immunoglobulin to patients of Barwon Health.

Policy

- To correctly identify patient's who require Intravenous immunoglobulin product prior to administration
- To safely administer Intravenous immunoglobulin, including product description and indications.

Scope

This policy and procedure applies to Division 1 Nursing staff, and Medical officers.

Procedure

Issue

All **intravenous immunoglobulin infusions** are available through **PathCare Blood bank laboratory**, which holds a small stock. Intravenous immunoglobulin **requires authorization by the duty medical officer of the Australian Red Cross Blood Service (ARCBS)**. The treating clinician should arrange this.

Product Description

CSL produce INTRAGAM P, which contains normal immunoglobulin (human) that has been purified by electrophoresis. At least **98%** of the protein is **immunoglobulin G**. It has a concentration of **6-gm/100 ml** and is available in **50 ml (3g), 200 ml (12 g) and 500 ml (30g) bottles**.

Indications

To ensure demands can be met from the **limited supply**, Intragam P is issued in accordance with guidelines released in 2000 by a Working party of the Australian Health Ministers' Advisory Council (AHMAC) Blood and Blood Products Committee¹⁴. Intragam P is supplied for Category 1 indications as follows:

- **Primary immunodeficiencies**
- **Other immunological disorders:**
 - Allogeneic stem cell or bone marrow transplant
 - Kawasaki's disease
 - Paediatric HIV/AIDS with recurrent bacterial infections, hypogammaglobulinaemia and impaired antibody response
- **Neurological Disorders:**
 - Guillain Barre syndrome
 - Chronic inflammatory demyelinating polyneuropathy
 - Multi-focal motor neuropathy with persistent conduction block
 - Polymyositis or dermatomyositis with failed corticosteroids with/without immunosuppression
 - Myasthenia gravis – for myasthenic crisis or failed primary treatment
 - Other neurological disorders such as polymyositis, IgM paraproteinaemic neuropathy childhood epilepsy and Lambert-Eaten myasthenic syndrome with failed primary treatment.

Date Revised:	May 1998, August 2001, July 2004, Dec 2004, May 2005	A2.7.11 Administration of Blood Products
Insertion:	August 2005 Refusal Of Blood Products (Lisa Stevenson & Dr Philip Campbell, Haematologist)	11. Administration of Immunoglobulin Infusion (Intragam P)
Reviewed by:	Lisa Stevenson (Blood Nurse), Dr Geoff Davey (PathCare)	Page 25 of 3
Approved by:	Nursing Quality and Safe Practice Committee	

- **Haematological Disorders:**

- Idiopathic thrombocytopenic purpura (ITP) with potentially life-threatening haemorrhage; or unresponsive to corticosteroids or where steroids are contraindicated
- Post-transfusion purpura
- Neonatal alloimmune thrombocytopenia
- HIV-associated thrombocytopenia
- CLL with hypogammaglobulinaemia and documented recurrent infections
- Acute leukaemia in childhood
- Multiple myeloma with hypogammaglobulinaemia and recurrent bacterial infections.

Some of the above Category 1 indications have additional prerequisites and review requirements. Depending on the available supply of Intragam P, a number of Category 2 indications, as detailed in the AHMAC guidelines, may also be able to be supported. Category 3 indications lacking convincing clinical trials or other evidence to support the use of intravenous immunoglobulin are currently not supported.

Management of Immunoglobulin Infusions

Dosage

- Replacement therapy - 0.4g/kg as a single dose every 3 to 4 weeks.
- Autoimmune thrombocytopenia - 0.4g/kg/day for 3 days, discontinue when platelet count adequate, i.e. $>30-50 \times 10^9/L$.
- Autoimmune haemolytic anaemia - 0.8g/kg/day for 3 days.
- Kawasaki Disease - 2g/kg, given over at least 6-8 hours, repeated if fever persists after 48 hours.

Administration

- For complete instructions, refer to the package insert.
- Immunoglobulin is administered through an **IMED or similar infusion pump**. It is administered **undiluted**, directly from the bottle; a standard blood filter can be used in the infusion set.

Rate of Infusion

- Commence infusion at **1ml /minute (60ml/hr) for first 15 minutes**
- Gradually **increase to maximum 3-4ml/minute (240ml/hr)** over the **next 15 minutes**
- Continue at **240ml/hr until completed (or as tolerated by patient)**
- **Note: Infusion for neonates and paediatrics needs to be reduced refer to HW3**

Observations

- **Pulse, BP, respiratory rate, and temperature** are to be taken **prior to the commencement** of the infusion.
- Then at **5 and 15 minutes after commencement, hypotension and anaphylaxis can occur during this time**, then
- **Every 30 minutes** until the infusion is **completed**.

Date Revised:	May 1998, August 2001, July 2004, Dec 2004, May 2005	A2.7.11 Administration of Blood Products
Insertion:	August 2005 Refusal Of Blood Products (Lisa Stevenson & Dr Philip Campbell, Haematologist)	11. Administration of Immunoglobulin Infusion (Intragam P)
Reviewed by:	Lisa Stevenson (Blood Nurse), Dr Geoff Davey (PathCare)	Page 26 of 3
Approved by:	Nursing Quality and Safe Practice Committee	

Adverse Reactions

Reactions to intravenous immunoglobulin tend to be **related to the infusion rate** and are most likely to occur **during the first hour of the infusion**.

Anaphylaxis can occur, but is rare, if occurs this **denotes a Medical emergency** – notify **MET** or **Code Blue**, management as for **Anaphylaxis policy (A2.5.8)** and **CPR policy (A2.7.6)**.

Sometimes a premedication may be ordered prior to commencement of infusion.

Signs and Symptoms	Management	Delayed Reactions
<ul style="list-style-type: none"> • Abdominal pain • Headache • Chest-tightness • Facial flushing or pallor • Feeling hot • Dyspnoea • Non-urticarial skin rash • Itching • Hypotension • Nausea and vomiting 	<ul style="list-style-type: none"> • The infusion should be stopped temporarily • Once the patient improves clinically • Cautiously recommence at a slower rate. • Notify the RMO 	<ul style="list-style-type: none"> • Nausea • Vomiting • Chest pain • Rigor • Aching legs <p>These reactions may occur once infusion completed and normally within 24 hours –Notify RMO</p>

References:

1. Australian Red Cross Blood Service – Victoria, Circular of Information –an extension of blood component labels 2003.
2. Australian Red Cross Blood Service- Transfusion Medicine Manual 2003. Blood Transfusion and clinical use of Blood in Australia.
3. CSL Bioplasma product information Intragam P, July 2000

Date Revised: May 1998, August 2001, July 2004, Dec 2004, May 2005 Insertion: August 2005 Refusal Of Blood Products (Lisa Stevenson & Dr Philip Campbell, Haematologist) Reviewed by: Lisa Stevenson (Blood Nurse), Dr Geoff Davey (PathCare) Approved by: Nursing Quality and Safe Practice Committee	A2.7.11 Administration of Blood Products 11. Administration of Immunoglobulin Infusion (Intragam P) Page 26 of 3
---	--