**Intravenous Immunoglobulin (IVIg)**

**Plasma Derived Blood Components & Synthetic / Recombinant Products**

**Introduction**
This document guides how to prescribe, order, administer and manage patients receiving intravenous immunoglobulins (IVIg) at PMH. The full product information should be read prior to prescribing or administering IVIg and this can be obtained from the insert accompanying the product.

IVIg products available in Australia included local (Intragam P) and imported (Octagam and Kiovig) products. The NBA determines which patient conditions qualify for funded local or imported product.
Indications
IVIg is used in the treatment of a growing number of immunologic, haematologic and neurologic illnesses. The use of IVIg in Australia is governed by the National Blood Authority (NBA). Conditions where evidence of clinical efficacy exists are outlined in the Criteria for the clinical use of intravenous immunoglobulin in Australia.

Contraindications and precautions
- Caution must be used if administering the product for the first time or if the patient has had a reaction previously.
- IVIg is contraindicated in patients with a history of allergic reaction to any human immunoglobulin preparation or to any constituent of the IVIg preparation.

Patients with severe selective IgA deficiency (IgA < 0.05g/L) may develop anti-IgA antibodies that can result in a severe anaphylactic reaction. Patients with IgA deficiency should have the IVIg product with the lowest IgA content, such as Intragam P. See Comparison of INTRAGAM® P, KIOVIG 10%, OCTAGAM® 5%and OCTAGAM® 10% (2 July 2012) table.

- In patients with underlying renal disease or at risk of acute renal failure, or at risk of developing thrombotic events IVIg should be administered at the minimum rate of infusion and dose practicable.
- Patients should be optimally hydrated prior to commencing IVIg infusion.
- Live vaccine should not normally be given until three months after a dose of gammaglobulin injection. If a live virus vaccine has been given, gammaglobulin should not be given for at least two weeks except in exceptional circumstances. Contact the Clinical Immunologist for advice.
- Patients receiving regular gammaglobulins should have six monthly monitoring of liver function.

**WARNING** Diabetic Patients:

- Precaution regarding blood glucose determination:
  Some types of blood glucose testing systems may falsely interpret the maltose contained in Intragam and Octagam as glucose. This may result in falsely elevated glucose readings and, consequently in the inappropriate administration of insulin. If measurement of blood glucose is required, test prior to the infusion or measure with a glucose specific method.

The Optium Xceed meter and test strips currently in use at CAHS uses the glucose dehydrogenase – NAD method for measurement of glucose. The current CAHS Radiometer POCT blood gas analyser uses glucose oxidase methodology to measure blood glucose. **Patients SHOULD NOT utilise meters with GDH-PQQ methodology when receiving Intragam or Octagam. This type of meter could suffer from maltose interference.**
Consent

Document consent for IVIg treatment on the Consent for Blood Products form MR 843.80.

**Acute patients** who are receiving IVIg must be consented prior to the infusion. This consent will remain valid for the remainder of the admission.

**Chronic patients** requiring regular/frequent infusions must be consented at the commencement of their treatment or as their condition evolves. This consent will remain valid for 12 months.

Click here to open → CAHS Consent to Blood Product Form. If printing this form please print front and back (i.e. both sides of paper).

*Order PM315 05/14 - MR843.80*

Consumer Medicine Information

The following Consumer information brochure may assist in providing information to patients/families.

- [Intragam P Consumer Medicine Information](#)
- [Kiovig 10% Consumer Medicine Information](#)
- [Octagam 5% Consumer Medicine Information](#)
- [Octagam 10% Consumer Medicine Information](#)

General information about immunoglobulin can be found on the [transfusion.com](http://transfusion.com) website.
### IVIg Products

<table>
<thead>
<tr>
<th>Product Information</th>
<th>Intragam P 6%</th>
<th>Kiovig 10%</th>
<th>Octagam 5%</th>
<th>Octagam 10%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Leaflet</strong></td>
<td>Intragam P 6% Product Information</td>
<td>Kiovig 10% Product Information</td>
<td>Octagam 5% Product Information</td>
<td>Octagam 10% Product Information</td>
</tr>
<tr>
<td><strong>Consumer Information</strong></td>
<td>Intragam P Consumer Information</td>
<td>Kiovig 10% Consumer Information</td>
<td>Octagam 5% Consumer Information</td>
<td>Octagam 10% Consumer Information</td>
</tr>
<tr>
<td><strong>Presentation</strong></td>
<td>Solution in vial sizes: 3 g in 50 mL 12 g in 200 mL</td>
<td>Solution in vial sizes: 1 g in 10 mL 2.5 g in 25 mL 5g in 50 mL 10g in 100 mL 20 g in 200 mL</td>
<td>Solution in vial sizes: 1 g in 20 mL 2.5 g in 50 mL 5 g in 100 mL</td>
<td>Solution in vial sizes: 2 g in 20 mL 5 g in 50 mL 10 g in 100 mL 20 g in 200 mL</td>
</tr>
<tr>
<td><strong>Concentration</strong></td>
<td>6% (60 mg/mL)</td>
<td>10% (100 mg/mL)</td>
<td>5% (50 mg/mL)</td>
<td>10% (100 mg/mL)</td>
</tr>
</tbody>
</table>

### Infusion Rates

<table>
<thead>
<tr>
<th><strong>Commencement rate</strong></th>
<th>1 mL/Kg/hr</th>
<th>0.5 mL/Kg/hr</th>
<th>1 mL/Kg/hr</th>
<th>0.6 mL/Kg/hr</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incremental rate rises</strong></td>
<td><a href="#">Click here for incremental rate rises for Intragam P 6%</a></td>
<td>Increase by 0.5 -1 mL/kg/hr every 30 minutes as tolerated</td>
<td>Increase by 1 mL/kg/hr every 30 minutes as tolerated</td>
<td>Increase by 0.5 -1 mL/kg/hr every 30 minutes as tolerated</td>
</tr>
<tr>
<td><strong>Maximum rate</strong></td>
<td>4 mL/Kg/hr</td>
<td>5 mL/Kg/hr</td>
<td>5 ml/kg/hr</td>
<td>7.2 mL/kg/hr</td>
</tr>
</tbody>
</table>

Infusion rate must not exceed 240 mL/hr regardless of patient weight. Infusion rate must not exceed 300 mL/hr regardless of patient weight. Infusion rate must not exceed 480 mL/hr regardless of patient weight. Infusion rate must not exceed 300 mL/hr regardless of patient weight.

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Product comparison table – [Comparison of INTRAGAM® P, KIOVIG 10%, OCTAGAM® 5%and OCTAGAM® 10% (2 July 2012) table](#)
Ordering IVIg

For new patients, one off approvals OR where each dose requires ARCBS Haematologist approval, an ‘ARCBS IVIG Patient Information Form’ will be supplied to the requesting Clinician. The Transfusion Medicine (TM) Scientist will ask the requestor to specifically class the IVIg indication category as either:

a) Haematological
b) Neurological or
c) Immunological/General.

The relevant form (a, b or c) will then be supplied for completion by the Clinician. Clinicians must complete one form per treatment plan or a one-off order. A new form is required if the dose or frequency of infusion changes. The completed form must be returned to the Transfusion Medicine Unit before the product can be ordered.

For regular patients a "Weekly Infusion Schedule for Regular Intravenous Immunoglobulin Patients" form may be used. The TM Scientist will fax this form to ARCBS to order approved doses for multiple patients for infusion the following week.

For regular PMH Ambulatory Care Day Facility (ACDF) patients, ACDF must complete an IVIg ward order form and send it to Transfusion Medicine Unit every Monday or Tuesday. The TM Scientist will fax this form to ARCBS to order approved doses for multiple patients for infusion the following week.

Prescribing IVIg

The DOSE (grams) of IVIg prescribed will vary according to the indication and the age of the patient. Refer to the Clinical Immunologist or Consultant Haematologist for advice.

Document the medical order for IVIg on the fluid order form. This should include:

- The brand of IVIg and the % concentration
- Dose in grams
- Volume in mLs
- Rate of infusion prescription should include:
  - Initial rate
  - The incremental rises in rate and
  - The time period the infusion runs at each rate

*Important notes:*

The DOSE (grams) of IVIg prescribed will vary according to the indication, please refer to the Criteria for the clinical use of intravenous immunoglobulin in Australia.

**WARNING** The RATE of administration will vary according to the brand and concentration of IVIg prescribed.
Subsequent doses
Children over 5 years old must follow the above protocol for the first three infusions. Subsequently, if no adverse events are noted, infusions may commence directly at the rate previously tolerated. Any queries should be referred to the Clinical Immunology or Haematology team.

The product information available for these products indicates that all doses of IVIg should be commenced at the initial starting rate. In recognition of this, it is recommended that all patients’ receiving subsequent doses of the same brand of IVIg are closely monitored, if the decision to proceed at the previously tolerated rate is made. Patients receiving IVIg for the first time, a particular brand of IVIg for the first time, or if the child is under 5 years of age then the IVIg must be commenced at the initial starting rate and titrated up as per IVIg Rate of Administration.

Administration of IVIg
Refer to Clinical Practice Manual, Medication Checking and Administration. All blood products must be double checked and confirmed at the point of administration by the two nurses who prepared the infusion.

Prior to administration
Key points:

- Trough immunoglobulin levels, if ordered, should be taken prior to the commencement of the IVIg infusion.
- Patients should be optimally hydrated prior to commencing IVIg infusion.
- **WARNING** Ensure prescription is complete, including the BRAND and CONCENTRATION of IVIg
- Informed consent must be gained from the parent/carer and documented prior to commencement.
- Explain procedure to patient, including potential adverse reactions and symptoms.
- Record baseline observations: TPR and BP and general patient status including pre-existing rashes
- Ensure solution is clear or slightly opalescent. Do not use solutions which are cloudy or have deposits.
- Allow the product to reach room temperature, before infusing to the patient.
- IVIg should **NOT** be mixed or diluted with any solution, it is given in pure concentration form.
- Administer pre-medication, if prescribed, at a suitable time before the infusion commences to allow it to be effective.
Administration

- **WARNING** Verify CORRECT patient, product (including brand and concentration) and prescription.
- Using aseptic non touch technique, prime the line with IV Ig. A new standard IV line or blood administration set (170-200 micron filter) may be used. Refer to ANTT protocol for administering intravenous infusions.
- Administer intravenously through an infusion pump to ensure accurate delivery rates.
- Administration from a glass bottle requires a vented system.
- Administer via a separate IV line. DO NOT mix/piggy back this product with other medications or IV fluids.
- Use immediately after opening the bottle as it does not contain an antimicrobial preservative.
- To administer, refer to the Rate of Administration section in this document.
- The line may be flushed with Normal Saline or 5% Glucose following infusion.
- During an infusion, subsequent vials may commence at same rate that the preceding vial finished.
- Infusion time for a single vial must not exceed 24 hours. Giving sets must be changed every 24 hours.

**The product should only be used for the patient for whom it was issued. Any unwanted vials MUST be returned to the Transfusion Medicine Unit as soon as possible. Unused vials must not be kept on the ward for allocated patients OR reallocated to other patients.**

Patient monitoring

Close observation is required and the patient’s general status should be monitored regularly throughout the infusion. Patient observations of temp, pulse, respiratory rate and blood pressure should be recorded on the CEWT chart:

- prior to infusion commencing
- 15 minutes after commencement
- prior to adjusting the rate of infusion
- hourly once maximum rate is achieved
- on completion of the infusion
- if patient experiences any new or increased symptoms.

After the infusion is complete, flush the line with 0.9% Sodium Chloride.
Continue to observe the patient for adverse reaction for 2 hours before discharging them. However, patients on regular gammaglobulin infusions may be discharged 20 minutes after completion if their observations are stable.

**Adverse reactions**

Side effects include headache, nausea, vomiting, flushing and chills. Observe the IV site for signs of swelling or pain. These types of reaction may be rate dependent and may respond to a reduction in the rate of infusion. Reduce the rate by half and contact the Medical Officer.

Human normal immunoglobulins may cause chest tightness, coughing, sudden fall in blood pressure and in isolated cases anaphylactic shock, even when the patient has shown no hypersensitivity to previous administration.

If you suspect an adverse reaction:

- **STOP** transfusion
- Provide emergency patient care
- Arrange immediate medical review. **MET Call/CODE BLUE** if necessary
- Keep IV line open with normal saline (do not flush existing line – use a new IV line if required)
- Monitor vital signs at least every 15 minutes until stable (document in medical record).
- All suspected reactions should be reported to TMU for investigation, Ext 8497
- Refer to section 12 *The Management of and Reporting of Adverse Events* as a guide to further treatment and management of the patient.

Refer severe reactions to the Consultant Haematologist unless, the patient is under the care of the PMH Department of Immunology, in which case contact the immunology RMO, registrar or fellow (if unavailable contact the on call Immunologist). Also refer to *Allergy and Adverse Reaction Reporting*.

**Documentation**

A record should be kept in the patient’s history of the following

- Diagnosis and indication for treatment
- Discussion of treatment, benefits, risks and consent
- Prescription/medical order including doctors signature, date, time and product of ordered
• The batch number and expiry date of each bottle used (place a sticker with the batch number on the Transfusion Medicine Record sheet MR616). This information is important should the patient have a reaction to the infusion or if there is a need to trace recipients of certain batch numbers at a later date.

• Amount given

• Patient observation and general condition during the infusion.
Rate of Administration

**Intragam P**

*Kiovig 10%*

*Octagam 5%*

*Octagam 10%*

**Intragam P**

Infusion rates should be calculated and prescribed in mL/kg/hr by the treating Medical Officer. Intragam P should be infused intravenously at an initial rate of 1.0 mLs/kg/hr for 15-30 minutes. If the infusion at this rate and concentration does not cause the patient to have distress (see [adverse reactions](#)), the administration rate may be gradually increased every 15-30 minutes to a maximum rate of 4.0 mL/Kg/hr according to the table below.

*Consideration should be given to a lower rate of infusion in those patients with risk of acute renal failure or thromboembolic adverse reactions.***

<table>
<thead>
<tr>
<th>Rate</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commence infusion at a rate of 1.0 mL/kg/hr</td>
<td>After 15-30 minutes if tolerated increase rate to 2.0 mL/kg/hr</td>
</tr>
<tr>
<td>2 mL/kg/hr</td>
<td>After 15-30 minutes if tolerated increase rate to 4 mL/kg/hr</td>
</tr>
<tr>
<td>4 mL/kg/hr</td>
<td><strong>MAXIMUM RATE</strong> of 4.0 mL/kg</td>
</tr>
</tbody>
</table>

*A maximum of 4 ml/kg/hr should not be exceeded for any patient*, with a maximum infusion rate of **240 ml/hr regardless of patient weight.**
Kiovig 10%

Infusion rates should be calculated and prescribed in mL/kg/hr by the treating Medical Officer. Kiovig 10% should be infused at an initial rate of 0.5ml/kg/hr (0.8mg/kg/min). If the infusion at this rate and concentration does not cause the patient to have distress (see adverse reactions), the administration rate may be gradually increased every 30 minutes to a maximum rate of 5.0ml/kg/hr (8.9 mg/kg/min) according to the table below.

*Consideration should be given to a lower rate of infusion in those patients with risk of acute renal failure or thromboembolic adverse reactions.*

<table>
<thead>
<tr>
<th>Rate</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commence infusion at a rate of 0.5 mL/kg/hr</td>
<td>After 30 minutes if tolerated increase rate to 1 mL/kg/hr</td>
</tr>
<tr>
<td>1 mL/kg/hr</td>
<td>After 30 minutes if tolerated increase rate to 2 mL/kg/hr</td>
</tr>
<tr>
<td>2 mL/kg/hr</td>
<td>After 30 minutes if tolerated increase rate to 3 mL/kg/hr</td>
</tr>
<tr>
<td>3 mL/kg/hr</td>
<td>After 30 minutes if tolerated increase rate to 4 mL/kg/hr</td>
</tr>
<tr>
<td>4 mL/kg/hr</td>
<td>After 30 minutes if tolerated increase rate to 5 mL/kg/hr</td>
</tr>
<tr>
<td>5 mL/kg/hr</td>
<td><strong>MAXIMUM RATE 5 mL/kg/hr</strong></td>
</tr>
</tbody>
</table>

A maximum of **5 mL/kg/hr** should not be exceeded for any patient, with a maximum infusion rate of 300 ml/hr regardless of patient weight.
Octagam 5%

Infusion rates should be calculated and prescribed in mL/kg/hr by the treating Medical Officer. Octagam 5% must be infused intravenously at an initial rate of 1mL/kg/hr for 30 minutes. If the infusion at this rate and concentration does not cause the patient to have distress (see adverse reactions), the administration rate may be gradually increased every 30 minutes to a maximum rate of 5mL/kg/hr according to the table below.

Consideration should be given to a lower rate of infusion in those patients with risk of acute renal failure or thromboembolic adverse reactions.

<table>
<thead>
<tr>
<th>Rate</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 mL/kg/hour</td>
<td>After 30 minutes if tolerated increase rate</td>
</tr>
<tr>
<td>2 mL/kg/hour</td>
<td>After 30 minutes if tolerated increase rate</td>
</tr>
<tr>
<td>3 mL/kg/hour</td>
<td>After 30 minutes if tolerated increase rate</td>
</tr>
<tr>
<td>4 mL/kg/hour</td>
<td>After 30 minutes if tolerated increase rate</td>
</tr>
<tr>
<td>5 mL/kg/hour</td>
<td>5 ml/kg/hr with a maximum rate of 300 ml/hr</td>
</tr>
</tbody>
</table>

A maximum of 5 mL/kg/hour should not be exceeded for any patient, with a maximum infusion rate of 300ml/hr regardless of patient weight.
**Octagam 10%**

Infusion rates should be calculated and prescribed by the treating Medical Officer. Octagam 10% should be infused intravenously at an initial rate of 0.6 mLs/kg/hr for 30 minutes. If the infusion at this rate and concentration does not cause the patient to have distress (see adverse reactions), the administration rate may be gradually increased every 30 minutes to a maximum rate of 7.2 mL/Kg/Hr according to the table below.

*Consideration should be given to a lower rate of infusion in those patients with risk of acute renal failure or thromboembolic adverse reactions.*

<table>
<thead>
<tr>
<th>Rate</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commence infusion at a rate of 0.6 mL/kg/hr</td>
<td>After 30 minutes if tolerated increase rate to 1.2 mL/kg/hr</td>
</tr>
<tr>
<td>1.2 mL/kg/hr</td>
<td>After 30 minutes if tolerated increase rate to 2 mL/kg/hr</td>
</tr>
<tr>
<td>2 mL/kg/hr</td>
<td>After 30 minutes if tolerated increase rate to 3 mL/kg/hr</td>
</tr>
<tr>
<td>3 mL/kg/hr</td>
<td>After 30 minutes if tolerated increase rate to 4 mL/kg/hr</td>
</tr>
<tr>
<td>4 mL/kg/hr</td>
<td>After 30 minutes if tolerated increase rate to 5 mL/kg/hr</td>
</tr>
<tr>
<td>5 mL/kg/hr</td>
<td>After 30 minutes if tolerated increase rate to 6 mL/kg/hr</td>
</tr>
<tr>
<td>6 mL/kg/hr</td>
<td>After 30 minutes if tolerated increase rate to 7.2 mL/kg/hr</td>
</tr>
<tr>
<td>7.2 mL/kg/hr</td>
<td>MAXIMUM RATE of 7.2 mL/kg</td>
</tr>
</tbody>
</table>

A maximum of 7.2 ml/kg/hr should not be exceeded for any patient, with a maximum infusion rate of 300ml/hr regardless of patient weight.
References

Product Information Sheet Intragam P Product Information
Product Information Sheet Kiovig 10% Product Information
Product Information Sheet Octagam 5% Product Information
Product Information Sheet Octagam 10% Product Information

Related policies, procedures and guidelines
Clinical Practice Manual, Medication Checking and Administration
Clinical Practice Manual, Children’s Early Warning Tool
Peripheral and central Intravenous therapy protocol, ANTT
Clinical Practice Manual, Clinical Deterioration Response: MET Call and CODE BLUE
Clinical Practice Manual, Allergy and Adverse Reaction Reporting
Transfusion Medicine Protocols, Blood Product Prescription and Informed Consent
Transfusion Medicine Protocol, Adverse Effects of Transfusion

Useful resources
Criteria for the clinical use of intravenous immunoglobulin in Australia.
Comparison of INTRAGAM® P, KIOVIG 10%, OCTAGAM® 5%and OCTAGAM® 10% (2 July 2012) table
Intravenous Immunoglobulin (IVIg) W:\Executive\PMH\CAHS SQP\Transfusion Coordinator\Protocols\2014\14 Plasma Derived Blood Components & SyntheticRecombinant Products\Intravenous Immunoglobuline IVlg 2014 FINALV4v1.doc

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