

FACT SHEET

Supply Arrangements for Intravenous Immunoglobulin (IVIg) in Australia

[Effective from 24 October 2011]

Availability of IVIg in Australia

IVIg is a critical plasma-derived blood product used to treat a range of neurological, immunological, haematological and other conditions.

This Fact Sheet outlines what IVIg products are available under the National Blood Supply (NBS) and Jurisdictional Direct Order (JDO) arrangements established by the National Blood Authority (NBA). It also explains how orders for IVIg are allocated between the different IVIg products available under the NBA arrangements.

There are two main ways IVIg is available in Australia:

1. Supply under National Blood Supply (NBS) arrangements

If the IVIg is ordered to treat a medical condition which is funded under the *Criteria for the Clinical Use of IVIg in Australia* ([Criteria](#)), then the product is supplied and funded under the NBS arrangements.

Under the NBS arrangements the cost of the product is shared between the Commonwealth and the relevant state or territory. Orders for IVIg under the NBS arrangements are made to the Australian Red Cross Blood Service (Blood Service), which is contracted by the NBA as the distributor of all IVIg funded under these arrangements.

At present this product is only funded and supplied under NBS arrangements for intravenous use.

2. Jurisdictional Direct Order (JDO) and other supply arrangements

If the IVIg is to treat a medical condition which is not funded under the [Criteria](#), then the individual state or territory may approve the accessing of product under the JDO arrangements established by the NBA, or the product may be ordered directly from a commercial supplier of IVIg.

In this case the supply of the product is not funded under the NBS arrangements, and the cost must be met in some other way. Information on ordering and the delivery of imported IVIg under the JDO arrangements is provided at the end of this Factsheet.

Ensuring IVIg supply

NBA contracts for supply of IVIg, whether imported or made in Australia, include various measures to ensure security of supply under the NBS arrangements. These include holding significant reserves in Australia, and having multiple sources of supply in the case of imported IVIg.

What IVIg products are available under NBA contracts?

The domestically produced product (Intragam P) is manufactured by CSL Limited from plasma donations collected in Australia by the Blood Service. To meet the gap between the available supply of the domestic product and total demand for IVIg, the NBA also has contracts in place for the supply of a number of imported IVIg products.

All products available under NBA contracts are registered with the Therapeutic Goods Administration and all meet the safety standards necessary for registration in Australia.

The IVIg products which are available under NBA contracts are summarised in the table below. At the present time, these products are funded and supplied under the NBS arrangements only as IVIg products even where the Product Information approved by the Therapeutic Goods Administration for a particular product includes subcutaneous administration for certain conditions.

| Funding arrangement | What indications are funded? | What products are available? | | Who pays for the product? | How are products accessed? |
|---|--|--|---|--|---|
| | | 24 Oct to 31 Dec 2011 | From 1 Jan 2012 | | |
| National Blood Supply (NBS) Arrangement | Indications funded under the Criteria for the Clinical Use of IVIg in Australia (Criteria) | Intragam P 6% (D) Octagam 5% (I) Flebogamma 5% DIF (I) | Intragam P 6% (D) Octagam 5% # (I) Kiovig 10% (I) | Cost is shared between the Commonwealth and the relevant State or Territory | Ordered from and distributed by the Blood Service. |
| Jurisdiction Direct Order (JDO) Arrangement | For indications that are not funded under the Criteria | Octagam 5% (I) Flebogamma 5% DIF (I) | Octagam 5% # (I) Flebogamma 5% DIF (I) Kiovig 10% (I) | Individual jurisdiction, hospital, patient's medical insurer by special agreement/arrangements, or patient bears full cost | Ordered from and supplied directly by the commercial supplier. Intragam P cannot be ordered under this arrangement |

KEY:

% = Product Concentration

D = Domestic Product

I = Imported Product

It is anticipated that a 10% formulation of Octagam will become available under the NBA contract during 2012.

Allocation between domestic and imported IVIg under National Blood Supply arrangements

When the Blood Service receives an order for IVIg under the NBS arrangements it first confirms that the order is for a condition funded under the [Criteria](#) and that the dosage ordered is consistent with the [Criteria](#). If the order is not for a condition funded under the [Criteria](#), the ordering clinician is informed of the options for availability of IVIg outside the NBS arrangements.

Orders under the NBS arrangements are then allocated by the Blood Service to be fulfilled by either the domestic IVIg product or by an imported product. This allocation is based on a plan agreed between the Blood Service and the NBA, which is developed in consultation with IVIg user groups and states and territories. The allocation plan specifies the categories of patients who will receive domestic IVIg and the categories who will receive imported IVIg. In general, the allocation plan seeks as far as possible to:

- allocate domestic IVIg for longer term conditions and imported IVIg for shorter term conditions, and
- keep the allocation categories consistent between jurisdictions,

noting that this may not be entirely possible taking into account the burden of disease in different jurisdictions, particular clinical requirements, and other relevant factors.

If the request is allocated to domestic IVIg, then the order is fulfilled with Intragam P.

If the request is allocated to imported IVIg, then it will be for the requesting clinician (operating within any relevant jurisdictional or hospital policy that may apply) to choose which imported IVIg product available under NBA contracts will be supplied to fulfil the request. The Blood Service will provide the clinician with information about the available products including relevant precautions, but will not provide any advice or recommendation on the choice of a particular imported IVIg product.

Information on ordering IVIg products from the Blood Service can be found at http://www.transfusion.com.au/blood_products/fractionated_plasma/IVIg.

Prices for imported IVIg products

The prices for imported IVIg products under NBA contracts are as follows:

| Product | Price per vial | Price per Gram | Price per vial | Price per Gram |
|-----------------------------|------------------------|---------------------|---------------------|---------------------|
| | (GST exclusive) | (GST exclusive) | (GST exclusive) | (GST exclusive) |
| | to 31 December 2011 | to 31 December 2011 | from 1 January 2012 | from 1 January 2012 |
| Flebogamma DIF 0.5g/10ml | \$38.11 | \$76.22 | \$39.25* | \$78.51 |
| Flebogamma DIF 2.5g/50ml | \$190.55 | | \$196.27* | |
| Flebogamma DIF 5g/100ml | \$381.10 | | \$392.53* | |
| Flebogamma DIF 10/200ml | \$762.20 | | \$785.07* | |
| Flebogamma DIF 20g/400ml | \$1,524.40 | | \$1,570.13* | |
| Octagam 5% 1g/20ml | - | \$72.50 | \$60.00 | \$60.00 |
| Octagam 5% 2.5g/50ml | \$181.25 | | \$150.00 | |
| Octagam 5% 5g/100ml | \$362.50 | | \$300.00 | |
| Octagam 5% 10g/200ml | \$725.00 | | \$600.00 | |
| Kiovig 10% 1g/10ml | - | - | \$54.75 | \$54.75 |
| Kiovig 10% 2.5g/25ml | - | - | \$136.88 | |
| Kiovig 10% 5g/50ml | - | - | \$273.75 | |
| Kiovig 10% 10g/100ml | - | - | \$547.50 | |
| Kiovig 10% 20g/200ml | - | - | \$1,095.00 | |

Ordering and Delivery of Imported IVIg under JDO arrangements

Unlike orders under the NBS arrangements which are placed with the Blood Service, orders under the JDO arrangements are placed directly with the relevant supplier. Contact details for the relevant suppliers are provided in the table below.

| Supplier | Distributor | Telephone | Facsimile | E-mail |
|---------------------------------|------------------------------|----------------|----------------|--|
| Octapharma Australia | DHL Exel | 1800 077421 | 1800 358199 | pharmacysupplycs@dhl.com |
| Grifols Australia Pty Ltd | Grifols Australia Pty Ltd | (03) 9535 9333 | (03) 9535 9300 | orders@lateralgrifols.com |
| Baxter Healthcare Pty Ltd | Baxter Healthcare | 1300 789 646 | 1300 659 877 | Australia_shs_customer_support@baxter.com |

Orders can be placed with suppliers either via phone, fax or email 24 hours a day, 7 days a week (including public holidays).

To process the order, suppliers will need the following information:

1. Name of the Product
2. Vial sizes required
3. Quantity of the Product
4. Name of the Approved Recipient
5. Shipping address (including street name and number, suburb and postcode)
6. Timeframe for delivery

Orders can be either Routine or Urgent as follows:

| Order category | Applies in the following situations | Required time for delivery |
|----------------|--|--|
| Routine | <p>An order is Routine when:</p> <ul style="list-style-type: none"> • the time for delivery specified in the order is 48 hours or more after the time of ordering • the order does not specify a time for delivery (unless it is specified as an Urgent order), or • it is a standing order | <p>The supplier must deliver by the time for delivery specified in the order.</p> <p>If no time for delivery is specified, the supplier must deliver within 48 hours after the order is placed.</p> <p>However, if the day on which delivery is required is a weekend or a public holiday (in the delivery location), the supplier must deliver by the same time on the next business day.</p> |
| Urgent | <p>An order is Urgent when:</p> <ul style="list-style-type: none"> • it is specified as an Urgent order; or • the time for delivery specified in the order is less than 48 hours after the time of ordering | <p>The supplier must deliver by no later than 24 hours after the order is placed (or a later time if that is specified in the order).</p> <p>If the order specifies a time for delivery within 24 hours of the time of ordering, the supplier must use best endeavours to try to deliver by the time specified in the order.</p> |

The supplier must ensure that, at the date of delivery, the remaining shelf-life of the imported IVIg Product is no less than:

- Octagam (Octapharma) - 12 months (but will use reasonable endeavours to ensure the remaining shelf life is no less than 15 months)
- Flebogamma (Grifols Australia) – 16 months
- Kiovig (Baxter) – 18 months (available from 1 January 2012)

An Order is filled when the product, as ordered, is:

- delivered to the Approved Recipient at the address specified in the order; and
- the delivery docket/receipt has been signed or delivery has been acknowledged.

If the delivered product is faulty or damaged, the supplier must be notified within 2 Business Days after delivery. If notified within 2 Business Days, the supplier will:

- facilitate the return of the product(s); and
- replace the product(s) within 2 Business Days of the notification.

Do you need more information?

Should you have any queries in relation to the supply arrangements for IVIg in Australia, please email the NBA at supply.management.plasma@nba.gov.au.