

Changes in supply arrangements for imported Intravenous Immunoglobulin (IVIg)

Current Arrangements

Under supply arrangements which commenced in 2007, Octapharma is currently contracted until 31 December 2011 as the primary supplier of imported IVIg under the National Blood Supply (NBS) arrangements for the supply of Octagam, a 5% concentration product. These arrangements provide funding for the supply of imported IVIg for clinical indications funded under the *Criteria for the Clinical Use of IVIg in Australia* (the [Criteria](#)).

A secondary contract for Jurisdictional Direct Order (JDO) supply is in place with Grifols Australia for the supply of Flebogamma 5% DIF. Under the JDO arrangements, states and territories may approve the funding of imported IVIg for indications which are not funded under the Criteria.

In response to a precautionary voluntary recall of Octagam in September 2010, the NBA worked closely with Grifols Australia and the Australian Red Cross Blood Service (Blood Service) to provide Flebogamma as the imported IVIg product supplied under the NBS arrangements. This was very effective in maintaining sufficient supply of IVIg.

All IVIg products supplied under the NBS arrangements are ordered from, and distributed by, the Blood Service operating under a contract established by the NBA on behalf of all Australian governments.

Reintroduction of Octagam 5% and continued availability of Flebogamma 5% DIF

On 4 August 2011 the Therapeutic Goods Administration approved a variation in the registration of Octagam 5%, and Octapharma have advised that following this approval, Octagam 5% will again be available for supply in Australia. More information on the voluntary recall and subsequent actions taken by Octapharma can be obtained at www.octapharma.com or at <http://tga.gov.au/safety/alerts-medicine-octagam-110826.htm>.

The NBA has arranged with the Blood Service for Octagam 5% to be available for ordering under the NBS arrangements from 24 October 2011.

Flebogamma 5% DIF will remain available to be ordered for continuing or new patients under the NBS arrangements until 31 December 2011. After that date, Flebogamma 5% DIF will be able to be ordered under NBS arrangements on a limited basis only, to allow for transition of continuing patients to another imported IVIg product within January and February 2012.

Outcomes of IVIg tender

The NBA recently conducted a tender process to establish new supply arrangements for imported IVIg to commence from 1 January 2012. This tender provided for an increase in the number of imported IVIg products available under the NBS arrangements.

Two imported IVIg products will be supplied and funded under the NBS arrangements from 1 January 2012 – Kiovig, a 10% concentration product supplied by Baxter Healthcare Pty Ltd, and Octagam 5% from Octapharma Australia Pty Ltd. These products will also be available under JDO

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

Flebogamma 5% DIF will continue to be available under the JDO arrangements from 1 January 2012. The current JDO contract with Grifols Australia expires on 31 December 2012 and the NBA has an option to extend up to a further year.

The new supply arrangements established by the imported IVIg tender will apply from 1 January 2012 to 31 December 2014, and may be extended for a further year.

Distribution and allocation of products

The Blood Service will continue to authorise and distribute domestic and imported IVIg under the NBS arrangements. The process for allocating orders for IVIg to either the domestically produced product (Intragam P) or to an imported IVIg product will also remain unchanged.

From the date of reintroduction of Octagam 5% on 24 October 2011, where an order is allocated to imported IVIg under the NBS arrangements, the ordering clinician will now have the choice of which available IVIg product will be supplied (operating within any relevant jurisdictional or hospital policy that may apply). 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.

Further information on IVIg supply arrangements

An NBA Fact Sheet on IVIg supply arrangements is attached and is available on the NBA website. This Fact Sheet describes the IVIg products available under the NBA arrangements and explains how orders for IVIg are allocated between the different products. An NBA Media Release on recent imported IVIg tender outcomes is also available on the NBA website.

The product barcode for Octagam 5% is unchanged. The Blood Service will distribute product barcode information for the other products for loading into Approved Health Provider (AHP) systems. The NBA will also update user profiles in BloodNet to include the appropriate products at the relevant dates for AHPs using BloodNet to order and receipt products.

Information supplied by the manufacturers on the IVIg products distributed by the Blood Service is available on the Blood Service website at:

http://www.transfusion.com.au/blood_products/fractionated_plasma/IVIg. This information includes:

- Product Information Sheets
- Consumer Medicine Information Leaflets
- Administration Guidelines
- A high-level comparison of the available IVIg products

Product information is also available through suppliers' websites:

- Domestic Product
 - CSL (Product: Intragam P) - http://www.csl.com.au/s1/cs/auhq/1196562765747/Web_Product_C/1196562710265/ProductDetail.htm

- Imported Products
 - Baxter (Product: Kiovig) – <http://www.baxterhealthcare.com.au/>
 - Grifols Australia (Product: Flebogamma) - <http://www.lateralgrifols.com/index.php/haemoderivatives>
 - Octapharma (Product: Octagam) - <http://www.octapharma.com/en/about-octapharma/products-therapies/immunotherapy/octagam.html>

Further queries on the national supply arrangements for IVIg can be directed to:

- National Blood Authority: supply.management.plasma@nba.gov.au
- Australian Red Cross Blood Service: by contacting a member of your local Transfusion Medicine team.

National Blood Authority
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