Forthcoming change to Australia’s domestically produced IVIg

INTRAGAM® 10 to replace INTRAGAM® P, commencing February 2017

The National Blood Authority (NBA) advises a forthcoming change to Australia’s domestically produced intravenous immunoglobulin (IVIg) product. During the first half of 2017, the 10% concentration ‘INTRAGAM 10’ will be introduced and will eventually replace the current 6% ‘INTRAGAM P’.

INTRAGAM 10 will provide lower volume doses for patients compared with the same Ig dose of INTRAGAM P.

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|  | INTRAGAM P | INTRAGAM 10 |
| 1 | Ig concentration | 6%(6g/100mL) | 10%(10g/100mL) |
| 2 | Presentations supplied | 3g in 50mL12g in 200mL | 2.5g in 25mL10g in 100mL20g in 200mL |

Key Transition Dates:

INTRAGAM 10 will be introduced in a two-step process.

Phase 1 - Supplied to ‘new patients’ with conditions for which domestic IVIg is allocated

Mon 23 Jan 2017: Centres may commence ordering the incoming INTRAGAM 10 in small volumes to meet anticipated needs from 1 February for ‘new patients with conditions for which domestic IVIg is allocated’.

Wed 1 Feb 2017: Date from which INTRAGAM 10 will be supplied to new patients with conditions for which domestic IVIg is allocated via BloodSTAR.

Phase 2 - Supplied to ‘existing patients’ currently receiving INTRAGAM P

Upon commencing INTRAGAM 10 manufacture, CSL Behring will cease INTRAGAM P manufacture and the Blood Service will draw down national INTRAGAM P inventories. When these inventories are exhausted only INTRAGAM 10 will be supplied, and patients who are currently receiving INTRAGAM P will be required to transition to INTRAGAM 10.

It is currently anticipated that INTRAGAM P inventories will be exhausted at some time between mid-March and mid-April 2017. The Blood Service will work closely with approved health providers (AHPs) to facilitate the structured transition of inventory closer to the time. This may require AHPs to reduce their stock holdings of INTRAGAM P as national inventory levels fall, in order to ensure a smooth transition to INTRAGAM 10.

Figure 1: Timeline for Domestic IVIg Transition



Distribution, authorisation and allocation of Ig products

There will be no change to the distribution, authorisation and allocation processes for Ig products supplied under the National Blood Supply arrangements.

Further Transition Information

The NBA is finalising transition arrangements with the Australian Red Cross Blood Service (the Blood Service), clinical stakeholders, State and Territory health department representatives, and the manufacturer CSL Behring.

More detailed information regarding the transition processes for key stakeholders including clinicians, hospitals, blood banks, medical directors, infusion clinics, medical colleges and societies and patient groups will be distributed over the coming months. The information will include:

* Timeframes for availability of INTRAGAM 10 and cessation of the outgoing INTRAGAM P.
* Either hard copies or web links to the following information for INTRAGAM 10:
	+ Updated high-level comparison of available Ig products
	+ INTRAGAM 10 Product Information and Consumer Medicine Information sheets, Healthcare Professional brochure including administration guidance, FAQ leaflet, dosing calculator, Patient brochure
* Product information will also be available through the manufacturer’s website (CSL Behring)

Queries on the National Supply Arrangements for Ig can be directed to:

• National Blood Authority: support@blood.gov.au

• Australian Red Cross Blood Service: by contacting a member of your local Transfusion Medicine team.

National Blood Authority

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