NATIONAL BLOOD AUTHORITY
AUSTRALIA

Forthcoming change to Australia's domestically produced IVIg

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

Dear Colleague,

I am writing to advise you of the forthcoming change to Australia's domestically produced intravenous immunoglobulin (IVIg) product.

Following a review of the remaining inventory of Intragam P, the introduction of Intragam 10 has been delayed from the previously communicated date of 1 February 2017. This delay has been required in order to optimise product management during the transition period.

From March 2017, the 10% concentration 'INTRAGAM 10' will be introduced and will eventually replace the current 6% concentration 'INTRAGAM P'.

INTRAGAM 10 will provide lower infusion volumes for patients compared with the same immunoglobulin (Ig) dose of INTRAGAM P, and is manufactured using the same core plasma fractionation process as INTRAGAM P.

The following information is supplied with this letter:

- Fact sheets, providing information regarding the domestic IVIg product transition.
  - Fact sheet for Healthcare Professionals **(Attachment A)**
  - Fact sheet for Patients **(Attachment B)**
- INTRAGAM 10 Product Information (PI) and Consumer Medicine Information (CMI) **(Attachment C)**
- A high-level comparison of IVIg products available under national supply arrangements, updated to include INTRAGAM 10 **(Attachment D)**

Transition arrangements

1. In all states and territories except NSW:
   a. New patients – From 1 March 2017, new patients with conditions for which domestic IVIg is allocated will be allocated to receive INTRAGAM 10 in BloodSTAR.
   b. Existing patients who are currently authorised to receive INTRAGAM P
      i. From 1 March 2017, existing patients for whom an authorisation request is submitted in BloodSTAR will be allocated to receive INTRAGAM 10 - this includes initial authorisation requests, continuing authorisation requests, requests to change the patient's dose or requests for an additional dose.
      ii. All remaining existing patients will be transitioned to INTRAGAM 10 as national inventories of INTRAGAM P are reduced. Once the transition date for existing authorised patients is known, the National Blood Authority (NBA) will use BloodSTAR to automatically change all existing authorisations for INTRAGAM P to INTRAGAM 10 and automatically update dosing calculations. Any change to products authorised for patients will automatically update BloodNet for dispensers.

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2. In NSW only:

   a. New patients – From 1 March 2017, new patients with conditions for which domestic IVIg is allocated will be allocated to receive INTRAGAM 10.

   b. Existing patients who are currently authorised to receive INTRAGAM P will be transitioned to INTRAGAM 10 when national inventories of INTRAGAM P are depleted. If BloodSTAR has not been implemented in NSW by the INTRAGAM 10 transition date, the Blood Service will manage the transition of the NSW patients to INTRAGAM 10 using the existing processes.

In preparation for this upcoming change, clinicians are requested to communicate the product change to patients and to other relevant parties including pathology provider/pharmacy and infusion clinic staff, and ensure that relevant protocols are updated or developed for INTRAGAM 10.

Further queries on national supply arrangements for Ig products 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.

Yours sincerely

Michael Stone

Deputy General Manager and General Counsel

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