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11th May 2023

All Hospital Transfusion Committee Chairs
IgO Prescribers

Dear Colleagues

Re: INTRAGAM® P production has ceased. PRIVIGEN® NZ to be introduced into Blood Bank inventory.

CSL Behring received Medsafe consent to distribute PRIVIGEN® NZ on the 1st March 2023. The approval has now been published in the NZ Gazette (https://gazette.govt.nz/notice/id/2023-go899). CSL Behring, on behalf of New Zealand Blood Service (NZBS), commenced the manufacture of PRIVIGEN® NZ, from New Zealand plasma, in April 2023. The first batch of product will arrive into New Zealand / Aotearoa in July 2023.

What to Expect and Key Milestones

From the **15th August 2023**, PRIVIGEN® NZ will be the product of choice for all **new requests** for **long-term intravenous immunoglobulin** (IVIg) treatment.

Whilst maintaining strategic self-sufficiency from NZ-sourced plasma, NZBS will continue to supplement Blood Bank inventory with PRIVIGEN®, a commercial IVIg, produced from paid donor plasma. PRIVIGEN® will be utilised for patients receiving short term (3 months or less) or intermittent IVIg treatment. Primarily, PRIVIGEN® will be held at the six NZBS Blood Banks, to streamline other Blood Banks inventory to one preparation of Privigen only.

From **25th July 2023**, a **phased transition** of PRIVIGEN® NZ, for patients currently on INTRAGAM® P, will commence.

In addition, from **25th July 2023**, GAMUNEX® 10%, a commercial IVIg product from Grifols, will be added to inventory, as an alternative product for patients unable to tolerate Privigen preparations.

Resources including patient information (change notification, product information) and a clinical tool-kit (administration guidance, prescription charts, teaching slides) will be located in the Immunoglobulin page (Ig-HUB) on the NZBLOOD website from the1st June https://www.nzblood.co.nz/healthcare-professionals/.

The following information outlines the overall process, as NZBS change the IVIg product inventory. Further information and hard copies of resources will be available from your local Transfusion Nurse Specialist (TNS) or Transfusion CNS.

Who will be changing products?

Patients who are currently approved to receive INTRAGAM® P will transition to PRIVIGEN® NZ.

Patients currently approved PRIVIGEN®, which is issued by a non-NZBS Blood Bank, may also need to transition to PRIVIGEN® NZ, to simplify local inventory.

Approximately three months prior to the local transition date, NZBS will

- contact all prescribing clinicians
- provide a patient list of who will change to PRIVIGEN® NZ
- confirm the new dose equivalent they will receive (bottle size variance)
- provide individual patient letters to the prescriber, outlining the transition process, new product and dose-equivalent
- advise patient advocacy groups

Patients with known intolerance or reactions to Privigen preparations

A group of patients have been identified who will not transition to PRIVIGEN® NZ due to a documented intolerance to, or adverse event with PRIVIGEN®. The prescribing clinician will be contacted directly to discuss transitioning to the alternative IVIg product, GAMUNEX® 10%. NZBS will provide information to the prescriber, outlining the process for the patient, including dose-equivalents.

Timeline Summary

PRIVIGEN® NZ: Transition of Current Patients
All patients who have been identified for transition across Otago and Southland will commence on the 25th July 2023. For all other patients, a phased regional transition will occur. Refer to Table. 1.

PRIVIGEN® NZ: Requests for Long-Term IVIg
Product will be available at all sites from the 15th August 2023, for new patients requiring long-term treatment.

Table 1. Transition Schedule for INTRAGAM® P (6% solution) to PRIVIGEN® NZ (10% solution)

Region	Blood Bank	Transition Date*
Southern	NZBS Dunedin; Southland; Dunstan; Oamaru	25/07/2023*
South Island	NZBS Christchurch; Timaru; West Coast; Nelson; Wairau	15/08/2023*
Waikato	NZBS Waikato; Tauranga; Whakatane; Taranaki; Rotorua; Taupo; Taumaranui; Te Kuiti; Thames; Tokoroa	29/08/2023*
Central	NZBS Wellington; Hutt; Masterton; Hawkes Bay; NZBS Palmerston North; Whanganui	12/09/2023*
Northern	NZBS Auckland; Middlemore; North Shore; Waitakere; Gisborne; Whangarei; Kaitaia; Dargaville; Bay of Islands /Kawakawa	26/09/2023*

* Dates are subject to minor changes.

Preparing for the Transition

As a new registered medicine, all patients transitioning to PRIVIGEN® NZ or GAMUNEX® 10% will require a revised IVIg approval documented, and a new consent form and prescription; prior to their first infusion of the product.

The first infusion will need to be given in the hospital setting; the time taken to administer will likely increase. Rate calculators are available from the TNS / CNS.

IVIg Approvals

NZBS will manage all electronic updates in the IgO approval system for the patients identified to transition to PRIVIGEN® NZ or GAMUNEX® 10%.

The electronic updates will be completed prior to the patient's first infusion of the new product, and after their last infusion of INTRAGAM® P. The current approval review date will not change. This work should occur in the background and not result in an electronic notification to the prescriber. For other sites refer to Table 2.

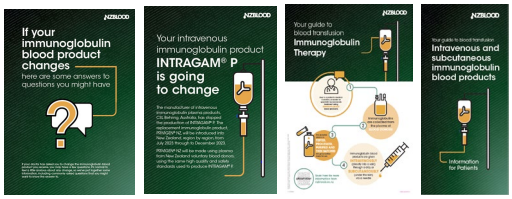
Table 2. Approach for Sites with Partially Implemented IgO or no IgO

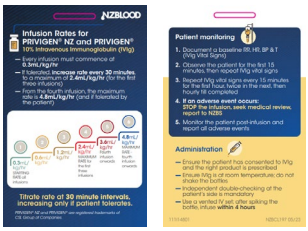
Partially Implemented IgO	No IgO Implemented
The Transfusion Medicine Specialist (TMS) will contact the prescriber regarding patients without an IgO approval. The prescriber will be requested to apply for IVIg via the IgO approval system. Thereafter, NZBS will manage the electronic update as the site transitions.	The update of the approvals cannot be completed by NZBS. Updates should be conducted in line with hospital approval protocols. Documentation must be supplied to the local Blood Bank prior to transition confirming the review has been undertaken.

Resources to Support Informed Consent, Prescribing and Administration

Patient and Healthcare Professional pages will be available on the Immunoglobulin information page (Ig-HUB) on the NZBLOOD website.

Product change flyers, a Frequently Asked Questions leaflet and information to support informed consent, in various formats, will be available in the Patient Ig-HUB https://www.nzblood.co.nz/patients/ from the 1st June 2023.





The TNS / CNS team will deliver in-service education sessions to healthcare professionals (HCP). A HCP tool-kit includes prescription chart templates, titration guidance, monitoring, rate calculators as well as lanyard cards and pens.
Electronic posters, screensavers and a teaching resource will be available during the transition. The NZBS administration guide can be adapted to inform local policy updates and will be available on the Healthcare Professional Ig-HUB https://www.nzblood.co.nz/healthcare-professionals/ from the 1st June 2023.

Adverse Events

Continue to report all adverse events to IVIg products. A reporting form can be obtained from your Blood Bank or on the NZBLOOD website. Send to adverse.reaction@nzblood.co.nz

Further Information

For clinical or patient specific questions contact your local Transfusion Medicine Specialist or Transfusion Nurse Specialist.

For project specific queries email plasmaproductschange@nzblood.co.nz

The CSL Behring Resource Hub for Healthcare Professionals can be accessed at https://hcp.cslbehring.co.nz/

Thank you for your support in ensuring a safe and effective transition. Please circulate to your team as required.

Yours faithfully

DR SARAH MORLEY
Chief Medical Officer

cc: All Blood Bank Team Leaders
All NZBS Transfusion Team
Senior Team