

8th September 2015

NEW PRODUCT NOTIFICATION

Introduction of a Commercial Intravenous Immunoglobulin Product

In November this year NZBS will be introducing a commercial intravenous immunoglobulin (Privigen) to supplement the Intragam®P produced from plasma collected in New Zealand. The introduction of Privigen® will improve security of supply during a period of sustained growth in clinical use of immunoglobulin. The price of Privigen® will be the same as that of Intragam®P (on a gram for gram basis) and so there will be no financial impact on DHBs.

Privigen® is produced by CSL Behring from plasma collected in the United States and Europe. It is registered by Medsafe for distribution in New Zealand. The product is also extensively used in the United States, Canada, and United Kingdom and will be introduced into Australia later this year. The product datasheet is available on the NZBS website (www.nzblood.co.nz).

Initially the use of Privigen® will be restricted to the 6 DHBs where NZBS manages the Blood Bank. These 6 DHBs account for almost 70% of total immunoglobulin use. This approach will avoid the need for a dual inventory at the DHB managed sites. It will also allow NZBS to control more effectively the way that the two products are allocated to individual patients and to provide support to clinical areas within the hospitals.

NZBS currently utilises a pre-approval process for accessing Intragam®P. With the introduction of Privigen we will identify which product will be provided for a patient as part of this process and inform the clinician of this. The approval form is being updated to support this change. Informed consent leaflets provided by NZBS for immunoglobulin products have also been updated to reflect the introduction of Privigen.

Intragam®P and Privigen® are not interchangeable medicines. The concentration of immunoglobulin is different (6% for Intragam®P and 10% for Privigen®), the dose sizes are different (3 and 12g for Intragam®P and 5, 10 and 20g for Privigen®) and the recommended rates of infusion are different. For these reasons clinicians will need to prescribe a specific IVIg product for their patient and the product prescribed will need to be identified on the order sent to the NZBS Blood Bank.

Some patients who receive immunoglobulin therapy experience side effects. This is a particular issue with IVIg. The reactions commonly occur during the infusion itself and are often related to the speed of administration. When these reactions occur, patients may continue to experience symptoms for periods from several hours to weeks following the infusion. Available data indicates that the adverse reaction rate for Privigen is comparable to that of Intragam P. Reactions may include headaches, flu like symptoms, general malaise and a rash. The Medsafe datasheets for both Intragam®P and Privigen® identify that the likelihood of adverse reactions is higher in patients receiving IVIG for the first time, or when there has been a long interval since the previous infusion, and when the normal human immunoglobulin product is switched.

NZBS therefore plans to use Privigen® in patients receiving IVIg for short term or intermittent use. Regular long term users of IVIg will be maintained on Intragam®P. This approach mirrors that used in Australia where commercial IVIg products have been in place for several years. It has been discussed with the New Zealand Clinical Immunology Advisory Group (NZCIAG) who are supportive of the approach.

The NZBS Transfusion Medicine Specialists and Transfusion Nurse Specialists will be available to support clinicians during the change period and will proactively manage any issues that arise to ensure there are no delays in providing the right product to the patient.

This initial communication aims to provide awareness of the planned changes and I will appreciate if it is distributed widely to clinicians who may prescribe IVIg within your DHB. A copy of the letter will be placed on the NZBS Blood Resource website that is accessible via the DHB intranet (<http://tiny.cc/igg>).

NZBS is developing additional tools to support the implementation of Privigen. These will be introduced onto the NZBS Blood Resource website as they become available. The plans will also be discussed at Hospital Transfusion Committee meetings.

Please let me know if you have any specific questions or concerns.

Yours sincerely

A handwritten signature in black ink that reads "Peter Flanagan". The signature is written in a cursive style with a large initial 'P'.

DR PETER FLANAGAN
NZBS National Medical Director