

Tender Outcomes - Imported Plasma and Recombinant Products – Patients with Bleeding Disorders

Information for Health Professionals

The National Blood Authority (NBA), on behalf of Australian governments, has successfully concluded the tender process for the supply of recombinant Factor VIII (rFVIII) and IX (rFIX) products, to replace the contracts for these products which expire on 30 June 2014.

Patients will continue to have access to these products free of charge under the national blood arrangements.

As a result of this process the NBA has obtained significantly improved prices, while continuing to ensure supply of high quality rFVIII and rFIX products from multiple suppliers together with a range of supplier service obligations.

The products available under the new arrangements are in the table below:

<i>Product</i>	<i>Supplier</i>	<i>Vial sizes available (international units)</i>	<i>Price per IU (\$A, GST inclusive*)</i>
Recombinant factor VIII			
<i>National preferred rFVIII product</i> ADVATE	Baxter Healthcare	250IU, 500IU, 1000IU, 1500IU, 2000IU, 3000IU	\$0.33
Xyntha	Pfizer Australia	250IU, 500IU, 1000IU, 2000IU, 3000IU	\$0.45
Kogenate FS** <i>Not available after a transition period</i>	Bayer Healthcare	250IU, 500IU, 1000IU, 2000IU, 3000IU	\$0.65
Recombinant factor IX			
BeneFIX	Pfizer Australia	250IU, 500IU, 1000IU, 2000IU, 3000IU	\$1.06
RIXUBIS***	Baxter Healthcare	250IU, 500IU, 1000IU, 2000IU, 3000IU	\$0.86

* Prices rounded to two decimal places

** For patients on active immune tolerance therapy using Kogenate FS as at the time of the tender announcement, exceptional arrangements will be available for continuation of this product for a longer period where this is clinically necessary.

***At the time of implementation of the new arrangements from 1 July 2014, the registered indications for RIXUBIS will include routine prophylaxis, treatment and prevention of bleeding episodes, and perioperative management in adults (18 years and older) in haemophilia B, but will not include registered indications for paediatric patients.

From 1 July 2014 the rFVIII products provided under the national supply arrangements to treat Haemophilia A will be the Baxter product ADVATE and the Pfizer product Xyntha. The new supply arrangements will apply for up to five years.

ADVATE was previously available under the national blood arrangements in the Australian market and Xyntha is already used by many Australian patients.

For the first time in the Australian market there will be two imported recombinant products for Haemophilia B patients, the Pfizer product BeneFIX and the Baxter product RIXUBIS. BeneFIX is already used by Australian patients whereas RIXUBIS is a new entrant to the Australian market.

These products were chosen as a result of an extensive tender process which took into account clinical and patient requirements and appropriate high-level supply security and other support arrangements that suppliers will be required to provide.

The new supply arrangements will commence from 1 July 2014. The transition arrangements from the current contracts are described in more detail below.

Please note for patients on active immune tolerance therapy using Kogenate FS, exceptional arrangements will be available for continuation of this product for a longer period where this is clinically necessary.

National Preferred Product Arrangement

To maximise value for money outcomes from the Tender, the rFVIII product ADVATE has been designated as the national preferred rFVIII product. This means that the NBA recommends that rFVIII patients should, where possible, be treated with ADVATE in order to obtain the best value for money from the more favourable price obtained for this product. Patients may be treated with the second product Xyntha in cases where direction of the patient to the national preferred product is likely to compromise appropriate treatment and care.

These arrangements will include the following:

- A managed transition of patients from Kogenate to ADVATE as the national preferred product
- A managed allocation of new patients on an ongoing basis to ADVATE as the national preferred product
- Consideration being given to the transition of patients currently being treated with Xyntha to ADVATE as the national preferred product at the next suitable patient review opportunity
- Best endeavors being made across all Haemophilia Treatment Centres to maintain an appropriate minimum level of supply of Xyntha to provide clinical choice and to enhance supply security.

It is important to note that designation of ADVATE as the national preferred rFVIII product does not relate to any difference in safety and quality between the rFVIII products or the product support services available from either rFVIII supplier under the national arrangements.

Because both ADVATE and Xyntha are imported products, there are supply security benefits in ensuring that there is a level of active supply of both products around Australia. While ADVATE is designated as the national preferred rFVIII product for value for money purposes, the NBA will also work with all Haemophilia Treatment Centres and other stakeholders to ensure that an appropriate minimum level of Xyntha is maintained in supply.

Transition Process

The new supply arrangements will commence from 1 July 2014. The expectation is that transitioning patients will be switched to ADVATE as the national preferred product over a period of 6 months (1 July to 31 December 2014) in order to obtain the best value for money from the more favourable price obtained for this product.

Patients are encouraged to discuss the preferred national product arrangement and product transition with their specialist and Haemophilia Treatment Centre to ensure patient care and treatment.

Patients currently treated with Kogenate FS

In most cases, patients currently using Kogenate FS will change to the national preferred rFVIII product ADVATE. This change should be made before 31 December 2014.

For patients on active immune tolerance therapy using Kogenate FS exceptional arrangements will be available for continuation of this product for a longer period where this is clinically necessary. The NBA will work closely with the Tolerisation Advisory Committee of the Australian Haemophilia Centre Directors Organisation (AHCDO) and with individual Haemophilia Treatment Centres to coordinate the supply of product for this purpose.

Patients currently treated with Xyntha

For patients currently being treated with Xyntha, consideration should be given to transitioning these patients to ADVATE as the national preferred product at the next suitable patient review opportunity.

Patients may continue to be treated with Xyntha in cases where direction of the patient to ADVATE is likely to compromise appropriate treatment and care.

New patients commencing treatment after 1 July 2014

In most cases these patients should be commenced on treatment with the national preferred product ADVATE.

Xyntha will be available:

- where direction to the national preferred rFVIII product ADVATE would be likely to compromise appropriate treatment and care of a patient
- so that an appropriate minimum level of Xyntha is maintained in supply at all treatment centres.

Clinical advice

All products selected through the tender are registered on the Australian Register of Therapeutic Goods and are assessed as fulfilling tender requirements to a high standard. In addition, the tender process included consideration of clinically relevant product characteristics by a specialist Clinical Advisory Group.

With regard to the question of inhibitor development, a recent review article (Hemophilia (2014), 20 (Suppl. 4), 87-93) has confirmed advice previously obtained by the NBA from AHCDO to the following effect:

- The evaluation of data currently available in the literature does not prove unequivocally that a difference in the immunogenicity exists between FVIII products.
- National product switches have occurred and switching was not associated with an enhanced inhibitor risk.

Further information

Further information on the tender process can be obtained by contacting the National Blood Authority by email at supply.management.plasma@blood.gov.au