Transition Principles – rFVIII

The National Blood Authority (NBA), on behalf of all Australian governments has successfully concluded the tender process for the supply of recombinant Factor VIII (rVIII) 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 the tendering for rFVIII products, a number of patients will need to change from one product to another because the patient’s current product will no longer be supplied and funded under the national blood arrangements.

The details of the new supply arrangements for these products compared to the previous arrangement are outlined in the table below.

<table>
<thead>
<tr>
<th>Imported Product</th>
<th>New Arrangements</th>
<th>Previous Arrangements</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Trade Name (Supplier)</td>
<td>Trade Name (Supplier)</td>
</tr>
<tr>
<td>rFVIII</td>
<td>National preferred rFVIII product</td>
<td></td>
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<tr>
<td></td>
<td>ADVATE (Baxter)</td>
<td></td>
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<tr>
<td></td>
<td>Xyntha (Pfizer)</td>
<td>Xyntha (Pfizer)</td>
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<td></td>
<td>Kogenate FS* (Bayer)</td>
<td>Kogenate FS (Bayer)</td>
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<tr>
<td></td>
<td>Not available after a transition period</td>
<td></td>
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<tr>
<td>rFIX</td>
<td>BeneFIX (Pfizer)</td>
<td>BeneFIX (Pfizer)</td>
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</tbody>
</table>

* 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.

The Bayer product Kogenate FS will continue to be available during a transition period. 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 following principles have been developed by the NBA in conjunction with the Australian Haemophilia Centre Directors’ Organisation (AHCDO), Haemophilia Foundation Australia (HFA) and the Australian Haemophilia Nurses Group (AHNG) to guide the planning and communication for the transition process for patients.

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The NBA will work cooperatively with national clinical and patient stakeholder groups, as well as all Haemophilia Treatment Centres (HTCs) and state and territory health departments, on the detailed implementation of these arrangements.

**Implementation and Transition Arrangements**

The rFVIII products currently supplied under NBA contracts are Kogenate FS (Bayer) and Xyntha (Pfizer). Approximately 45% of current rFVIII patients receive Kogenate FS.

Supply of funded Kogenate FS under the national arrangements will not be available after the transition period. 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.

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 be treated where possible 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.

**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 AHCDO and with individual Haemophilia Treatment Centres to coordinate the supply of the 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.

**Management**

AHCDO will provide clinical leadership to inform the transition requirements in conjunction with the NBA. NBA will seek advice from HFA, AHNG, other allied health professionals through Australia/New Zealand Haemophilia Social Workers’ and Counsellors’ Group (ANZHSWCG) and Australian and New Zealand Physiotherapy Haemophilia Group (ANZPHG), and relevant suppliers and distributors.
HTC directors and staff are responsible for the management of the transition at each centre. The specific transition support arrangements for each HTC will be determined by that HTC.

For the transition of Kogenate FS patients, Baxter will be primarily responsible for providing product information materials and in-service training on ADVATE for HTC clinicians and other staff, as determined by the HTCs and in a timeframe determined by the HTCs. These activities will be overseen and coordinated with the NBA. All supplier activities and marketing materials must comply with Medicines Australia Code of Conduct.

In most jurisdictions, Baxter and Pfizer will be responsible for arrangements required to support delivery of products requested by HTCs.

In NSW and SA, where the Blood Service distributes these products, HTCs, suppliers and the Blood Service will coordinate transition arrangements consistent with these principles.

The NBA will provide regular reports to HTCs, AHCDO and jurisdictional health departments.

**Monitoring**

During the transition period, the capture and timely reporting of data by HTCs, suppliers and patients is essential to facilitate the monitoring and management of product supply.