Management Model for Fibrinogen Concentrate supplied under the national blood arrangements for congenital fibrinogen deficiency

Governance

- In general, management and use of Fibrinogen Concentrate for congenital deficiency will be subject to oversight by a recognised Haemophilia Treatment Centre (HTC).
- Any arrangements for supply, stocking or use of Fibrinogen Concentrate for congenital deficiency outside an HTC will be specifically approved on an exception basis by the relevant HTC director.
- Australian Haemophilia Centre Directors’ Organisation (AHCDO) will establish a committee to review Australian Bleeding Disorder Registry (ABDR) data for all Fibrinogen Concentrate for congenital deficiency cases each 6 months.

Supply chain

- In general, stock of Fibrinogen Concentrate for congenital deficiency will be held at HTCs, with HTC director authorisation required for access.
- Ordering will be based on requirements for known patients, with minimal additional stock to be held for precautionary purposes.
- Product distribution will be direct from the product supplier to HTCs. Where appropriate HTCs may authorise home delivery for a patient under their direct supervision. Orders and inventory of product for home delivery must be initiated by a HTC for a patient who is authorised to receive home deliveries.
- There will be a requirement for a specific statement on the product order to ensure fibrinogen concentrate is being ordered for a congenital deficiency patient and in accordance with this management model. The required statement is:

  This product order is for Fibrinogen Concentrate as supplied and funded under the National Blood Arrangements:

  a) For treatment of acute bleeding (including prophylaxis for high risk patients) in patients with congenital fibrinogen deficiency (including afibrinogenaemia, hypofibrinogenaemia and dysfibrinogenaemia); and

  b) In accordance with management arrangements and oversight by a recognised Haemophilia Treatment Centre
• The 5 year shelf life (from date of manufacture) will largely address risk of wastage. Nonetheless, AHCDO will coordinate a process to facilitate transfer of stock coming to 1 year remaining shelf life between HTCs to ensure that the product can be used
• NBA will not pay for orders where the relevant statement is not given and will conduct sample based supply chain audits of supplier order records with verification from HTC records.

**Recording and reporting**

• All use of Fibrinogen Concentrate for congenital deficiency will be recorded in ABDR, including arrangements for supply, stocking or use outside an HTC.
• The AHCDO committee will provide a regular summary report to the NBA.
• The NBA will reconcile supply data, ABDR data and the AHCDO report to provide assurance to JBC.