NATIONAL BLOOD AUTHORITY
AUSTRALIA

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.