Legacy Health

Balfaxar® as the Preferred 4-Factor Prothrombin Complex Concentrate at Legacy (except LMP) Go-Live February 11, 2025

Background:

- In 2023, the FDA approved Balfaxar® brand 4-factor prothrombin complex concentrate (factors II, VII, IX, X and proteins C and S). Prior to this, the only brand of 4-factor prothrombin complex concentrate (4F-PCC) available in the US was Kcentra®.
- Efficacy and safety of Balfaxar® are proven in clinical trials. Balfaxar® has been approved and in use in Europe since 2003, under a different name.

Key Practice Points:

- Dosing of Balfaxar® is the same as Kcentra®. LH will continue to use fixed dosing for bleeding related to an anticoagulant, as outlined in 900.5010 Guideline for Reversal.
- Similar to Kcentra®, Balfaxar® is supplied in vials of approximately 500 units or 1,000 units, based on units of factor IX.
- Current practice for provision of 4F-PCC will continue, with emergent doses prepared by pharmacists at bedside and by anesthesiologists for cardiac cases. Non-emergent doses will be prepared in the pharmacy IV room.
- Providers must continue to order 4F-PCC via order set in EPIC.
- Upon go-live, the default 4F-PCC product will be Balfaxar® for all sites, except LMP.
- Legacy may update the preferred 4F-PCC (either Balfaxar® or Kcentra®) if needed, based on contracting, cost, or shortages. Note: LMP cannot contractually change to Balfaxar® at this time.

Admixing Key Points:

- Balfaxar® is stored at room temperature and supplied as a kit with diluent and transfer device.
- See Balfaxar® steps for reconstitution and admixing video.
- **1.)** First The **BLUE** part of transfer device attaches to the diluent vial, straight down **2.)** Second, the **WHITE** part of the transfer device attaches to the lyophilized powder vial, upside down, straight down.
- Swirl (don't shake) to reconstitute. Contents of multiple vials may be pooled, but a separate transfer device should be used for each vial.
- Reconstituted Balfaxar® is a clear solution that may be colorless to slightly blue in color.
- For IVPB admixing, the product-specific diluent vial does not have a valid barcode to scanned during Dispense Prep. See Dispense Prep instructions for the dummy NDC that will need to be manually entered during Dispense Prep for the product-specific sterile water diluent.

See the SBAR for more details