Coagadex® (coagulation Factor X [human]) – New and expanded indications

- On September 21, 2018, the FDA approved Bio Products Laboratory's Coagadex (coagulation factor X [human]), in adults and children with hereditary Factor X deficiency, for on-demand treatment and control of bleeding episodes, perioperative management of bleeding in patients with mild and moderate hereditary Factor X deficiency, and for routine prophylaxis to reduce the frequency of bleeding episodes.
    - The labeling was updated to remove age restrictions, expanded to include perioperative management of bleeding in patients with moderate hereditary Factor X deficiency, and updated to include a new use for routine prophylaxis.
    - Previously, Coagadex was approved for adults and children (aged 12 years and above) with hereditary Factor X deficiency for: (1) on-demand treatment and control of bleeding episodes and (2) perioperative management of bleeding in patients with mild hereditary Factor X deficiency.
- The new indication of Coagadex is supported by efficacy data from an open-label clinical trial with Coagadex use in routine prophylaxis of bleeding episodes in patients with hereditary Factor X deficiency. The study included 9 children aged < 12 years.
    - Investigators' assessment following 6 months of routine prophylaxis was rated excellent in all 9 patients (defined as 'no minor or major bleeds occurred during the study period' or 'lower frequency of bleeds than expected, given patient's medical/treatment history').
    - A total of 22 infusions were given to treat a bleed, equivalent to 2.1 bleeds per patient per year.
- The recommended initial dose of Coagadex for prophylaxis of bleeding episodes is 40 IU/kg twice weekly for children < 12 years and 25 IU/kg twice weekly for adults and adolescents ≥ 12 years of age.
- Refer to the Coagadex drug label for monitoring information and dosing for all other indications, including perioperative management of bleeding in patients with moderate hereditary Factor X deficiency.