Coagadex® (coagulation Factor X [human]) – New Orphan Drug Approval

- On October 20, 2015, the FDA announced the approval of Bio Products Laboratory’s Coagadex (coagulation Factor X [human]) injection, for adults and children (≥ 12 years of age) with hereditary Factor X deficiency for on-demand treatment and control of bleeding episodes, and for perioperative management of bleeding in patients with mild hereditary Factor X deficiency.
  - Coagadex has not been studied in the perioperative management of bleeding in major surgery in patients with moderate and severe hereditary Factor X deficiency.

- Factor X deficiency is a rare, inherited bleeding disorder where the blood does not clot as it should. In healthy individuals, the Factor X protein activates enzymes to help with normal blood clotting in the body.

- Coagadex is the first specific coagulation factor approved by the FDA for replacement therapy in patients with hereditary Factor X deficiency. It was granted orphan drug designation, fast track designation, and priority review.

- Coagadex’s approval was based on an open-label study involving 16 patients with moderate to severe hereditary Factor X deficiency. Patients were treated for spontaneous, traumatic, and menorrhagic bleeding episodes.
  - Coagadex was considered to be good or excellent in treating 98% of bleeding episodes.
  - Most (83%) bleeding episodes were treated with one infusion of Coagadex. Only 4 bleeding episodes in 2 subjects were considered treatment failures.

- Coagadex was also evaluated in 5 patients with mild to severe Factor X deficiency who were undergoing surgery. These patients received Coagadex for perioperative management of 7 surgical procedures.
  - Coagadex demonstrated to be effective in controlling blood loss during and after surgery in patients with mild Factor X deficiency.
  - No individuals with moderate or severe Factor X deficiency received Coagadex for perioperative management of major surgery.

- Coagadex is contraindicated in patients who have had life-threatening hypersensitivity reactions to Coagadex or any of its components.

- Warnings and precautions for Coagadex include neutralizing antibodies, transmissible infectious agents, and monitoring and laboratory tests.

- The most common adverse reactions (≥ 5%) with Coagadex use were infusion site erythema, infusion site pain, fatigue, and back pain.

- The dose and duration of Coagadex treatment depend on the severity of the Factor X deficiency, location and extent of the bleeding, and the patient’s clinical condition.

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The maximum dose is 60 international units (IU)/kg daily.

- For on-demand treatment and control of bleeding episodes, the recommended intravenous dose of Coagadex is 25 IU/kg body weight, repeated at intervals of 24 hours until the bleed stops.

- For perioperative management, the intravenous dosing recommendations for Coagadex are as follows:
  
  - For pre-surgery, raise plasma Factor X levels to 70 – 90 IU/dL using the following formula:

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    \text{Required dose (IU)} = \text{body weight (kg)} \times \text{desired Factor X rise (IU/dL)} \times 0.5
    \]

  - For post-surgery, maintain plasma Factor X levels at a minimum of 50 IU/dL until the patient is no longer at risk of bleeding due to surgery.

- Bio Products Laboratory plans to launch Coagadex by mid December 2015. Coagadex will be available as a lyophilized powder for reconstitution in single-use vials containing nominally (approximately) 250 IU or 500 IU of Factor X activity.