Ixinity® (coagulation factor IX [recombinant]) — New Drug Approval

- On April 30, 2015, Emergent BioSolutions announced the FDA approval of Ixinity (coagulation factor IX [recombinant]) injection, for use in adults and children ≥ 12 years of age with hemophilia B for control and prevention of bleeding episodes and for perioperative management.
  - Ixinity is not indicated for induction of immune tolerance in patients with hemophilia B.
- Hemophilia B is a congenital bleeding disorder caused by a deficiency of coagulation factor IX.
  - It affects an estimated 1 in 25,000 male births, with approximately 4,000 persons affected in the U.S.
  - The clinical spectrum may include spontaneous or trauma-induced bleeding into joints, muscles, and soft tissues, resulting in joint damage, reduced mobility, and severe arthritis.
- Ixinity is a coagulation factor IX product that replaces the deficient clotting factor.
- The safety and efficacy of Ixinity were based on an open-labeled, uncontrolled trial involving 77 subjects with hemophilia B. Subjects received Ixinity either as routine or on-demand treatment of bleeding episodes.
  - A majority of the bleeds, 84%, were resolved by one or two infusions of Ixinity.
  - In addition, administration of Ixinity resulted in hemostasis in study participants who underwent major surgical procedures.
- Ixinity is contraindicated in patients who have known hypersensitivity to Ixinity or its excipients, including hamster protein.
- Warnings and precautions of Ixinity include: hypersensitivity reactions, inhibitors, nephrotic syndrome, thromboembolism, and monitoring laboratory tests.
- The most common adverse event (> 2%) with Ixinity use was headache.
- The initial recommended dose of Ixinity is based on the empirical finding that one international unit (IU) of Ixinity per kilogram (kg) of body weight increases the circulating level of factor IX by 0.98 IU/dL of plasma in adults and children ≥ 12 years of age. The dose is calculated as follows:

  Initial Dose = body weight (kg) x desired factor IX increase (% of normal or IU/dL) x reciprocal of observed recovery (IU/kg per IU/dL)
  - Ixinity is administered intravenously.
  - The maintenance dose depends on the type of bleed or surgery, clinical response, and severity of the underlying factor IX deficiency.
- Emergent BioSolutions launch plans for Ixinity are pending. Ixinity will be available in single-use vials containing 500 IU, 1000 IU, and 1500 IU per vial.

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