March 8, 2016

**Idelvion Approved for Hemophilia B**

The U.S. Food and Drug Administration announced on March 4, 2016, that it had approved CSL Behring’s Idelvion®, [Coagulation Factor IX (Recombinant), Albumin Fusion Protein]. Idelvion is bonded with albumin, so its activity lasts over periods as long as two weeks when it is used to prevent bleeding episodes in patients with hemophilia B. Given by intravenous (IV) infusion, the recommended doses, time between doses and length of treatment for Idelvion depend on the indication, the type and extent of the bleeding and the patient’s body weight. To prevent bleeds, Idelvion is recommended for use once every seven days, at first. Based on how well the patient responds, the time between infusions may eventually be as long as 14 days. CSL Behring plans on launching Idelvion later this month. It will be available through a limited network of specialty pharmacies that includes Accredo. Complete prescribing information is at:


### At a Glance

- **Brand (Generic) Name:** Idelvion® [Coagulation Factor IX (Recombinant), Albumin Fusion Protein]
- **Manufacturer:** CSL Behring
- **Date Approved:** March 4, 2016
- **Indication:** Idelvion is approved for use as-needed to control and prevent bleeding episodes; before, during and after surgery to manage procedure-associated bleeding; and regularly to prevent or reduce the frequency of bleeding episodes for hemophilia B patients.
- **Dosage Forms Available:** Single-dose vials containing 250 international units (IUs), 500 IUs, 1,000 IUs or 2,000 IUs of powdered Idelvion. Each vial is packaged with the appropriate size vial of sterile water to reconstitute (mix with) the powder and the equipment necessary for reconstitution.
- **Launch Date:** March 2016
- **Estimated Annual Cost:** Pricing information is not yet available.
- **Specialty Status:** Idelvion will be added to Express Scripts’ specialty drug list.
- **Hemophilia B** is a bleeding disorder affecting approximately 4,000 patients in the United States. It is caused from insufficient amounts of clotting Factor IX, which is a protein in the blood that controls bleeding. Patients with hemophilia B experience bleeding episodes that cause pain, irreversible joint damage and life-threatening hemorrhages.
- Other recombinant Factor IX products for Hemophilia B include Alprolix® (Biogen), BeneFIX® (Pfizer), Ixinity® (Emergent Biosolutions) and Rixubis® (Baxter). Idelvion and Alprolix have a prolonged duration of action compared to BeneFIX, Ixinity and Rixubis.