Kovaltry Approved for Hemophilia A

On March 17, 2016, Bayer announced that the U.S. Food and Drug Administration (FDA) had approved Kovaltry® [antihemophilic factor (recombinant)]. Indicated for treating adults and children who have hemophilia A, it is a full length Factor VIII concentrate. It will be used, through intravenous (IV) infusions, to prevent bleeds as well as to manage bleeding episodes and to control bleeding associated with surgical or dental procedures. Dosing and dose frequency depend on the patient’s age and weight, and on whether the dose is for prevention or for treating an acute bleed. For routine prophylaxis, most patients will require infusions two to three times per week. Bayer plans on launching Kovaltry in the near future. It will be available through a limited network of specialty pharmacies that includes Accredo. Complete prescribing information is at: http://labeling.bayerhealthcare.com/html/products/pi/Kovaltry_PI.pdf

At a Glance

- **Brand (Generic) Name:** Kovaltry® [antihemophilic factor (recombinant)]
- **Manufacturer:** Bayer HealthCare
- **Date Approved:** March 17, 2016
- **Indication:** To treat and control bleeding episodes, to manage perioperative bleeding and to reduce the frequency of bleeding episodes in adults and children with hemophilia A.
- **Dosage Forms Available:** Single-use vials containing 250 international units (IUs), 500IUs, 1,000IUs, 2,000IUs or 3,000IUs of powdered Kovaltry.
- **Launch Date:** Bayer plans on launching Kovaltry within a few weeks.
- **Estimated Annual Cost:** Pricing information is not yet available.
- **Specialty Status:** Kovaltry will be added to Express Scripts’ specialty drug list.
- **Hemophilia A** is a rare, chronic, genetic bleeding disorder affecting approximately 16,000 adults and children in the United States. It is caused from insufficient clotting Factor VIII activity, which is a protein in the blood that controls bleeding. Patients with hemophilia A experience bleeding episodes that cause pain, irreversible joint damage and life-threatening hemorrhages.
- Several recombinant Factor VIII products already are on the U.S. market. They include Advate (Baxalta), Helixate® FS (CSL Behring), Kogenate FS (Bayer), Novoeight® (Novo Nordisk), Recombinate (Baxalta) and Xyntha® Solofuse® (Wyeth Biopharma). Two other long-acting products, Adynovate [antihemophilic Factor (Recombinant), PEGylated] and Eloctate [antihemophilic Factor (Recombinant), Fc Fusion Protein] are also available. Other Factor VIII products on the market are derived from human plasma and some also include von Willebrand factor.