Adynovate Approved for Hemophilia A

On Nov. 13, 2015, Baxalta received approval from the U.S. Food and Drug Administration (FDA) for Adynovate [Antihemophilic Factor (Recombinant), PEGylated] for the treatment of hemophilia A. Adynovate is an infused long-acting recombinant Factor VIII product for patients 12 years of age and older with hemophilia A for on-demand treatment of bleeding episodes and routine prophylaxis to reduce the frequency of bleeding episodes. For routine prophylaxis, the recommended dose is 40-50 IU/kg twice weekly. Baxalta plans on launching Adynovate within a few weeks. It will be available through a large network of specialty pharmacies that includes Accredo. Full prescribing information is available at: www.adynovate.com

At a Glance

- **Brand (Generic Drug):** Adynovate [Antihemophilic Factor (Recombinant), PEGylated]
- **Manufacturer:** Baxalta Incorporated
- **Date Approved:** November 13, 2015
- **Indications:** Treatment of hemophilia A in patients 12 years of age and older for on-demand treatment of bleeding episodes and routine prophylaxis to reduce the frequency of bleeding episodes.
- **Launch Date:** By early December
- **Estimated Annual Cost:** Pricing information is not yet available; however, Adynovate is expected to cost between $300,000 and $400,000 per year.
- **Dosage Forms Available:** Lyophilized powder in single-use vials containing approximately 250, 500, 1000 or 2000 international units (IUs)
- **Specialty Status:** Adynovate 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.
- Biogen Idec’s Eloctate [Antihemophilic Factor (Recombinant), Fc Fusion Protein] was the first long-acting recombinant, clotting factor VIII therapy approved for hemophilia A. For routine prophylaxis, Eloctate is infused every three to five days. Hemophilia A factors other than Adynovate and Eloctate require prophylactic infusions three to four times per week.