Vonvendi Approved for von Willebrand Disease

On Dec. 8, 2015, the U.S. Food and Drug Administration (FDA) approved Baxalta’s Vonvendi, a recombinant von Willebrand factor to treat and control bleeding episodes in adults who have von Willebrand disease (VWD). The recommended initial dose is 40 to 80 international units (IU) per kg of body weight as an intravenous infusion. This dose should be adjusted based on the extent and location of the bleeding. If the patient’s factor VIII levels are not known or are below 40%, Vonvendi should be used in combination with an infused recombinant factor VIII product. Launch plans have not been established; however, the product is expected to become available in the U.S. by the end of 2016. Complete prescribing information may be accessed at: [http://www.baxalta.com/assets/documents/VONVENDI_PI.pdf](http://www.baxalta.com/assets/documents/VONVENDI_PI.pdf)

**At a Glance**

- **Brand (Generic) Name:** Vonvendi (von Willebrand factor [Recombinant])
- **Manufacturer:** Baxalta
- **Date Approved:** Dec. 8, 2015
- **Indication:** On-demand treatment and control of bleeding episodes in adults diagnosed with von Willebrand disease.
- **Dosage Forms Available:** Lyophilized powder in single-use glass vials containing 650 or 1300 international units (IU) per vial of von Willebrand factor for intravenous use after reconstitution
- **Launch Date:** The product should be available by the end of 2016.
- **Estimated Annual Cost:** Pricing information is not yet available.
- **Specialty Status:** Vonvendi will be added to Express Scripts’ specialty drug list.
- **VWD affects approximately 1% to 2% of the U.S. population. The bleeding disorder is characterized by the body’s inability to produce von Willebrand factor, which is a protein necessary to help the blood clot.
- **Vonvendi is the first recombinant treatment for adults with VWD. Factor concentrates for VWD contain both factor VIII and von Willebrand factor (e.g. Alphanate®, Humate-P® and Wilate®). Recombinant factor VIII products, which do not have von Willebrand factor, should be used in combination with Vonvendi, if required.