

August 9, 2016

Baxalta US Inc., now part of Shire, (“Shire”) is pleased to announce the market availability of VONVENDI [von Willebrand factor (recombinant)], the first recombinant von Willebrand factor approved by the US Food and Drug Administration on December 8, 2015 for on-demand treatment and to control bleeding episodes in adults (18 and over) diagnosed with von Willebrand disease (VWD). VONVENDI was first commercially available on August 9, 2016.

As manufacturing for VONVENDI is not yet at full capacity, we have instituted a limited distribution system and a patient activation program (the “Activation Program for VONVENDI”) to ensure that once a clinical decision is made to treat a VWD patient with VONVENDI, patients receive the product needed to start and stay on treatment. The goal of the Activation Program for VONVENDI is to ensure that once a patient is enrolled and begins treatment with VONVENDI, they will continue to have uninterrupted access to VONVENDI in accordance with their health care provider’s prescribed treatment. The program will employ a “first-in first-out” methodology so that all patients have equal opportunity to receive VONVENDI, regardless of health care provider, site of care or insurance status.

To help manage distribution of VONVENDI, Shire has implemented a limited distribution system with a qualified specialty network. However, all hemophilia treatment centers (both 340B and non-340B) and hospitals can purchase VONVENDI directly from Shire after the patient has been enrolled in the Activation Program for VONVENDI. All Eligible Covered Entities have access to VONVENDI at the 340B ceiling price for patients enrolled in the Activation Program for VONVENDI.

Shire will continue to evaluate production capacity in order to evaluate potential expansion of the limited distribution for VONVENDI while ensuring the unique needs of the von Willebrand patients are met. Shire will notify HRSA of any modification to our distribution plans as they occur.

For information on ordering VONVENDI or enrolling patients in the Activation Program for VONVENDI, contact your Shire Hematology representative or call the Hematology Support Center (HSC) at 1-855-229-7377.

VONVENDI is available under labeler Baxalta US Inc in the following vial sizes:

Color Code	VWF:RCo Potency Range	Carton NDC	sWFI fill size
Green	450-850 IU per vial	0944-7551-02	5 mL
Dark Red	900-1700 IU per vial	0944-7553-02	10 mL