CRESTOR® PATENT EXPIRATION

On May 2, 2016, the U.S. Food and Drug Administration (FDA) approved Activas’ generic version of AstraZeneca’s blockbuster cholesterol lowering drug Crestor® (rosuvastatin calcium), the agency’s first such approval for the drug.

Activas was allowed to introduce its generic 67 days before Crestor’s patent expires on July 8, 2016. Other generic manufacturers plan to launch their generic Crestor after the United States patent on Crestor expires. According to IMS Health estimates, Crestor is a commonly prescribed drug product in the U.S., with sales of $6.5 billion in 2015-2016.

Crestor, a HMG-CoA reductase inhibitor, commonly known as a “statin”, initially received FDA approval in 2003 for the treatment of high cholesterol. Crestor helps to reduce high LDL cholesterol, “bad cholesterol”, by stopping an enzyme called HMG-CoA reductase from making cholesterol. All statins should be used in addition to a diet restricted in saturated fat and cholesterol.

Based on the FDA’s approval, Activas will supply rosuvastatin in 5mg, 10mg, 20mg and 40mg tablets to treat high cholesterol and/or high triglycerides in adults. Since there is a 67 day exclusivity period, Citizens Rx anticipates the introduction of new generic versions to the market within the coming months, which will further reduce drug costs.

The formulary status of Crestor will change. Crestor will no longer be covered as a Preferred medication under the Citizens Rx Preferred Drug Formulary, effective immediately.

Crestor is the last major statin drug to go generic. Other generic statins currently available, include atorvastatin (Lipitor®), fluvastatin (Lescol XL®), lovastatin (Mevacor®), pravastatin (Pravachol®), and simvastatin (Zocor®). Based upon available drug study data, Crestor has the most potent cholesterol lowering effect, followed by atorvastatin. However, studies and clinical practice suggest that with appropriate dose adjustments other statin’s can be equally efficacious in decreasing cholesterol.

While AstraZeneca’s strategies will push patients towards brand name Crestor, Citizens Rx will continue to focus on generic optimization, as generic drug products offer numerous advantages, such as significant cost savings and increased accessibility. It is Citizens Rx goal to ensure optimal generic utilization so the benefits and lower out-of-pocket costs of generic medications are realized by both the member and client.

References: