Earlier this week[1], we discussed two novel drugs that could potentially revolutionize the treatment and prevention of cardiovascular disease. Both drugs are antibodies, and work by an entirely new mechanism by binding to, and inactivating a protein called PCSK9. PCSK9 plays a part in the regulation of circulating cholesterol (homeostasis).

It does so by binding to, and subsequently degrading LDL receptors that are on the surface of liver cell. This results in fewer LDL receptors. Since their job is to remove LDL cholesterol from the blood, fewer receptors will lead to more circulating LDL (bad) cholesterol.

The new drugs (Praluent, Regeneron/Sanofi, and Repatha, Amgen) are not your everyday pill. The (like all other antibodies) do not survive the digestive processes in the stomach, and must be injected. Injectable biologics (drugs that are derived from living organisms) are almost always more expensive than pills.

These drugs are no exception. It has been announced that the price will be about $15,000 per year. By comparison, atorvastatin, the generic name of Lipitor, costs as little as $17 per month. Since Lipitor and other statin drugs are usually very effective in lowering both cholesterol and LDL cholesterol, it was not hard to predict that a drug that does the same thing (although better), but costs 75-times more, would cause controversy. It has.

Express Scripts, the largest pharmacy benefit manager in the U.S., is not happy with the prospect of having to shell out what could be a very substantial amount of money. This is not without reason. According to the company, about 70 million people take statins in the U.S.

Glen Stettin, a spokesman for the company, estimates that 10 percent of this group would be candidates for the antibody drugs under the FDA approval guidelines [2]: Praluent is approved for use in addition to diet and maximally tolerated statin therapy in adult patients with heterozygous familial hypercholesterolemia (HeFH) or patients with clinical atherosclerotic cardiovascular disease such as heart attacks or strokes, who require additional lowering of LDL cholesterol.

Dr. Josh Bloom, the director of chemical and pharmaceutical sciences at the American Council on Science and Health, says: Seven million patients the Express Scripts estimate for the number of people who fall under the approval guidelines getting a $15,000 drugs adds up to $105 billion. This number isn’t even close to reality, since it is certain that the real price (after negotiation with the pharmacy benefit companies) will be less than $15,000 per year, and not all eligible patients will
get the drug. Nonetheless, the projected annual cost to our healthcare system has been estimated to be $23 billion [3] still a huge amount of money. To put this in perspective, Lipitor, the best selling drug in history, earned $141 billion [4] during the 15 years when Pfizer had exclusive sales rights, and never exceeded $13 billion in any year.

Another concern of the pharmacy benefit companies is label creep off label use for people who don't quite meet the guidelines. This is not a theoretical concept. Indeed, it has been reported that many cardiologists are excited enough about the new drugs to want to use them off label.

Dr. Bloom says, It should be very interesting how this plays out, because we are in new territory. There are new drugs that are better than older ones, which are already effective. But they carry a hefty price tag, and, unlike the new, costly hepatitis C drugs, will presumably be used for life. Of course, those patients qualified to get one of these drugs are at high risk for life-threatening or disabling heart events. Avoiding those will save a lot of healthcare dollars. Interesting times.