High Cholesterol PCSK9 Drugs Could be Next To Bust Budgets, Stretch Pocketbooks

Prime Therapeutics analysis warns insurers to brace for substantial new costs, as much as $23.3 billion nationally

ST. PAUL, MINN. – June 9, 2015 – A new class of cholesterol-lowering medicines aimed at helping some people improve their low density lipoprotein (LDL), or “bad” cholesterol, could quickly cost the U.S. health system up to $23.3 billion a year, according to new research by pharmacy benefit manager Prime Therapeutics LLC (Prime). Prime’s internal analysis finds PCSK9 inhibitors (Proprotein Convertase Subtilisin/Kexin type 9) could add between $0.93 and $6.71 per member per month (PMPM) to commercially insured coverage costs and up to $15.66 PMPM to Medicare coverage costs depending on which conditions the drugs are approved to treat.

Two PCSK9 inhibitors –Praluent™ from Regeneron & Sanofi, and Repatha™ from Amgen – are expected to be approved by the U.S. Food and Drug Administration this summer. Unlike traditional statins, which are oral medicines and have inexpensive generic alternatives, PCSK9 inhibitors are self-injected monoclonal antibodies. These drugs act by preventing the protein PCSK9 from interfering with the liver LDL removal process, allowing more LDL cholesterol removal from the blood.

It’s expected that the drugs will be approved to treat more than 200,000 Americans with familial hypercholesterolemia, a rare genetic condition which leads to abnormally high cholesterol levels that cannot be effectively managed with traditional statins. Additionally, these medicines could be approved to help reach lower cholesterol goals in people who are statin intolerant or have failed to achieve expected reduction in cholesterol from statin therapy. This population could be as many as 2.3 million Americans.

While prices of the drugs have not yet been disclosed, initial estimates indicate the drugs could be priced between $7,000 and $12,000 per year. Using an estimated price of $10,000 per year, Prime researchers reviewed both pharmacy and medical claims of commercially insured and Medicare Part D members in 2014 and 2015 to develop a trend forecast model. This model estimates the number of members likely to use these medicines and associated costs for various management scenarios.

The researchers outlined various scenarios for approval of PCSK9s and forecasted potential use and associated costs among Prime’s commercial population at one year after launch:

- If the drugs are approved to treat people with familial hypercholesterolemia who are intolerant or resistant to traditional statins, an estimated 112 per 100,000 commercially insured members (0.11 percent) could receive the drugs, costing $0.93 PMPM.
- If the drugs are approved to treat people with familial hypercholesterolemia who are intolerant or resistant to traditional statins, and also approved for secondary prevention in those with cardiovascular disease who are at high risk and are statin intolerant or resistant, an estimated 395 per 100,000 commercially insured members (0.40 percent) could receive the drugs, costing $3.29 PMPM.
- If the drugs are available to all statin intolerant or resistant people regardless of risk, an estimated 806 per 100,000 commercially insured members (0.81 percent) could receive the drugs, costing $6.71 PMPM.
The estimated costs could be much higher in the Medicare Part D market as those people are at higher risk for heart disease and thus higher users of medicines to control cholesterol. Estimates range from 1,500 per 100,000 people being treated at a cost of $12.56 PMPM to 1,880 per 100,000 being treated at $15.66 PMPM.

Researchers noted the scenarios would be impacted by the drug’s labeling guidelines, as well as prescribing behavior and adherence to treatment.

“While these new drugs offer hope to those who aren’t able to effectively manage their cholesterol with existing therapy (i.e., statins), they need to be affordable. Just to treat those with familial hypercholesterolemia alone, these drugs could cost the U.S. health system billions of dollars per year, and as much as $23.3 billion to treat all potential people who could receive the drug,” said Patrick Gleason, PharmD, director of health outcomes at Prime. “It’s also reasonable to assume that some prescribers will be interested in using these drugs for additional people with high cholesterol. Contributing to the high cost is the fact that these drugs are considered maintenance medicines, so people would expect to take them for many years.”

At a time when biosimilar drugs are just beginning to enter the U.S. market and offer hope of savings on high-cost specialty medicines, PCSK9 drugs alone have the potential to offset a substantial portion of the savings biosimilars could achieve. Prime recommends deploying utilization management strategies such as prior authorization and quantity limits, and care management through Prime Therapeutics Specialty Pharmacy LLC, to help improve care and manage costs for health plans and those who use the drug.

“If PCSK9 inhibitors are approved by the FDA, it is critical that we have the right level of utilization management in place to help ensure that these medicines are used in those high-risk members where therapy is most warranted,” said Pete Clagett, senior vice president of integrated care and specialty at Prime. “If not managed appropriately, the costs of PCSK9s could have a dramatic impact on overall drug spend starting later this summer. In a couple years PCSK9s could cost America the equivalent of $73 per person per year.”

About Prime Therapeutics
Prime Therapeutics LLC (Prime) helps people get the medicine they need to feel better and live well. Prime manages pharmacy benefits for health plans, employers, and government programs including Medicare and Medicaid. The company processes claims and delivers medicine to members, offering clinical services for people with complex medical conditions. Headquartered in St. Paul, Minn., Prime serves more than 26 million people. It is collectively owned by 13 Blue Cross and Blue Shield Plans, subsidiaries or affiliates of those plans. Prime has been recognized as one of the fastest-growing private companies in the nation.

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