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Amgen wins approval for second biotech cholesterol drug

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This undated image provided by Amgen Inc. shows Repatha. Amgen Inc. has won federal approval for the second medicine in a new class of pricey biotech drugs that reduce artery-clogging cholesterol more than older statin drugs that have been used for decades. The Food and Drug Administration approved the drug Thursday, Aug. 27, 2015, for two groups of patients who are unable to control their cholesterol with existing drugs and treatments. (Amgen Inc. via AP)

Amgen Inc. has won federal approval for the second medicine in a new

class of pricey biotech drugs that reduce artery-clogging cholesterol more than older statin drugs that have been used for decades.

The drug Repatha could eventually help millions of Americans who face increased risks of heart disease because they cannot control their cholesterol with existing drugs and methods. But concerns about the medication's price tag—$14,100 per year—and long-term benefits will likely limit its use in the near-term.

The Food and Drug Administration approved the drug Thursday for two groups of patients who are unable to control their cholesterol with existing drugs and treatments, specifically:

— patients with extremely high levels of LDL, or bad cholesterol, due to inherited conditions

— patients with persistently high LDL levels and a history of heart attack, stroke and other cardiovascular problems

The drug is designed to be self-injected on a monthly or bi-monthly dosing schedule.

Thousand Oaks, California-based Amgen priced the drug slightly below a similar drug Praluent, which costs $14,600 per year. Sanofi and partner Regeneron Pharmaceuticals Inc. won FDA approval for that drug last month.

Analysts estimate between 8 million to 10 million patients are covered under the FDA-approved labeling for the drugs. But some experts worry the drugs could eventually be expanded for a much wider group of patients, driving up costs as the health care system absorbs a growing wave of retiring baby boomers.

With two competing products now on the market, employers and the companies that manage their medication costs will try to negotiate discounts.

Express Scripts, the largest pharmacy benefit manager, said in a statement it plans to "leverage this competition to achieve the best possible price for the patients and payers we represent." Neither Repatha nor Praluent are currently covered under Express Scripts' formulary, though the company plans to review them at a meeting next month.

The biologically-engineered drugs are considered the first major advance in managing cholesterol since the introduction of statin drugs more than 20 years ago, and analysts expect them to generate billions in sales.

But the prospect of introducing highly-expensive, injectable drugs for such a common medical problems is drawing concerns.

More than 73 million U.S. adults, or nearly one-third, have high LDL cholesterol, according to the Centers for Disease Control and Prevention. Those patients have twice the risk of heart disease, the leading cause of death worldwide.

The new drugs lower low-density lipoprotein, or LDL, cholesterol more powerfully and in a different way than statins. They block a substance called PCSK9, which interferes with the liver's ability to remove cholesterol from the blood. Adding the new drugs to older statins reduces LDL cholesterol by about 40 percent to 60 percent. Statins alone generally lower levels of the wax-like substance by about 25 to 35 percent.

Pfizer is working on its own PCSK9-blocking drug that is still in clinical testing.

Statistical analyses published earlier this year suggest patients taking PCSK9 drugs have half the risk of dying or suffering a heart problem as patients receiving statins or older drugs. But definitive studies about their life-saving benefits are still ongoing.

Pharmacy benefit managers have signaled they may limit coverage for the drugs until those studies are completed.

CVS Health said it will not cover the new cholesterol drugs under its formulary until they have been reviewed by an expert committee. A spokeswoman for the pharmacy benefit manager said in a statement that managing the medications' cost would require "adherence to existing statins, reserving the new drugs primarily for patients with rare conditions."

Deutsche Bank analyst Robyn Karnauskas expects Repatha to reach peak sales of about $3.5 billion by 2022. Credit Suisse analyst Vamil Divan estimates the entire PCSK9 class of drugs—including drugs from Sanofi and Pfizer—will reach global sales of $10 billion by 2019.

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