A Cholesterol Drug Tug-of-War

Patients struggle for insurance approvals of PCSK9 inhibitors, powerful drugs that lower bad cholesterol when statins don’t work.

By Sumathi Reddy

SLIM AND ATHLETIC, Carlyn Cirrincione doesn’t look like someone who should be worried about a heart attack. But Ms. Cirrincione, 45, who has a rare genetic disorder called familial hypercholesterolemia (FH), was diagnosed four years ago with the condition that causes high cholesterol because the liver is unable to remove excess LDL, the bad type of cholesterol. At the time of her diagnosis was off the blacklist.

Form or over $14,000 a year before her cholesterol at the Food and Drug Administration, documents estimated the target price tag. Nearly two years after the battle for insurance approval of PCSK9 inhibitors was successful less than half the time, according to several recent studies.

What she does need, according to her doctor, is powerful new drugs known as PCSK9 inhibitors that can dramatically lower LDL, or bad cholesterol levels when statins, which she has been on for years, can’t do the job.

There’s a vast problem the price tag. Nearly two years after the drugs were approved by the Food and Drug Administration, doctors and patients say getting insurance to pay for the drugs, which list for more than $14,000 a year before rebates or discounts, is a battle that requires endless appeals, applications and battles for insurance approval of PCSK9 inhibitors and will continue less than half the time, according to several recent studies.

Ms. Cirrincione hasn’t yet approved after she and her doctor’s numerous applications and efforts. She was diagnosed four years ago with familial hypercholesterolemia (FH), a genetic disorder often called the “silent killer,” because the liver can’t remove cholesterol from the blood stream. At the time of her diagnosis was off the blacklist. With a total of 28 mg/dL, and an LDL level more than four times what doctors recommend for patients, at 203 mg/dL

High levels of cholesterol, a fat-like substance, can build up in the arteries and slow down or block blood flow to the heart and brain, causing strokes. Doctors typically recommend LDL levels no higher than 100 mg/dL for healthy individuals and less than 70 mg/dL for those with a coronary disease risk.

Most people with high cholesterol have a combination of a healthy diet, exercise and drugs known as statins, such as atorvastatin (brand name Lipitor) and rosuvastatin (Crestor). But these drugs can’t remove the LDL levels low enough for FH patients. And for some, like Ms. Cirrincione, the medicines won’t work. Some doctors believe PCSK9 inhibitors could be a solution for millions of heart disease patients and could transform treat- ment for the most difficult case- patients with FH, as well as those with a history of heart disease or stroke for whom statins and other therapies are inadequate. Drug therapy to FH patients in 15 million Americans. But other doctors say that until drug companies can prove PCSK9 inhibitors will reduce the number of deaths caused by heart disease, and just their ability to reduce heart attacks and strokes, the drugs aren’t worth the high price.

The two PCSK9 inhibitors currently on the market were approved in 2015: Amgen Inc., makes the drug Repatha (evolocumab), which has a price tag of about $14,536 a year. SanofiA and Regeneron Pharmaceuticals Inc. makes Praluent (alirocumab), which has a list price of $14,000 a year. The medicine is new enough in a group of extremely needy patients that have cropped up in recent years.

Doctors, consumers and lawmakers have spoken out against escalating drug prices. The crisis has triggered hearings in Congress. A public letter from the FH Foundation and doctors and patients in a group of extremely needy patients that have cropped up in recent years.

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