## **Amgen Announces Major Price Cut For Its Breakthrough Cholesterol Drug**

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The Trump administration continues to work overtime to lower prescription drug



costs for consumers. In response, some pharmaceutical companies have announced rollbacks of price increases, cuts in prices, price freezes, or other ways to improve affordability for patients. In the latest example, Amgen, a leading biologics company, is stepping forward to bring down prices through a market-oriented solution that breaks through the opaque and complex drug pricing maze with a simpler pricing model.

The company <u>announced</u> today it is creating much lower pricing categories for its innovative biologic, Repatha, reducing the list price by 60%—from the current \$14,600 to \$5,850 a year. Repatha is used to treat patients who have excessively high levels of cholesterol but who do not respond to traditional statins.

These patients are at a high risk of heart attacks, stroke, or even death from cardiovascular disease and too often have a family history of heart attacks at a young age. Repatha is a biologic in a new class of PCSK9 inhibitors that dramatically lower cholesterol levels in these patients—and can have a meaningful impact on patients' lives.

The problem has been the cost. Amgen said in the company's news release that the price reduction "will improve affordability by lowering patient copays, especially for Medicare patients." The initial list price of \$14,600 reflected the billions of dollars Amgen invested to research, test, and bring this innovative product to market, but after rebates and discounts, the actual payment the company received was significantly less.

**"The science behind these drugs is astonishing,** but the price is also astonishing," Dr. Steven Miller,

chief medical officer at Express Scripts, told *The New York Times.* "With a new lower list price for Repatha, Amgen is taking an important step forward to help payers be better positioned to provide breakthrough medicines and help people achieve better outcomes," Miller told Amgen. That's an important indication that payers are listening.

Patients for whom traditional statins are ineffective too often are often blocked from accessing this new drug that could help them avoid heart attacks or disabling strokes. Insurers have been requiring inordinate testing and paperwork for doctors to document the need for the drug, and these <u>barriers</u> have been high hurdles to access. Even patients who are successful in getting approval the first time often have to repeat the process to get subsequent doses of the medicine. Others faced co-payments that put the drugs out of reach.

Steve Forbes <u>explained</u> the result: "Much attention of late has been made about patients who have picked up prescriptions at the pharmacy counter only to find the costs under their insurance plan are sky high—and rising even higher. That's because Pharmacy Benefit Managers (PBMs)—middlemen that negotiate discounts and rebates from drug manufacturers—and health plans don't always pass along those savings, sometimes up to 50 percent, to patients. This unfairly inflates drug costs."

Medicare patients, more than seven million of whom suffer from coronary artery disease, are at a high risk of going untreated. "The losers are the patients who have gone to the pharmacy counter and have not been able to get the medicine they need and that's what we need to address as a company, as an industry, and as a society," said Amgen Chairman and CEO Robert A. Bradway. A recent <u>study</u> published in *JAMA Cardiology* showed "abandonment rates ranging from 7.5% for those with \$0 copay to more than 75% for copays greater than \$350." Because of the maze of contracts and rebates between drug makers, insurers, and governments, it's almost impossible for ordinary consumers to know the actual price of a drug. There are built-in impediments to lowering drug prices. Many PBMs that negotiate lower costs in exchange for higher volume have been reluctant to give up their rebates, which generally are based upon a percentage of the negotiated price. Lower prices mean lower rebates.

So we have patients desperately in need and a drug that could likely help millions of them and save many times more in hospital costs by preventing serious events, who are often blocked from getting it.

**Something clearly had to change.** Cardiovascular disease is the number one killer in the U.S., with one death every 40 seconds from heart attacks or stroke. An estimated 10 million Americans could benefit from PCSK9 inhibitors.

Amgen and Sanofi/Regeneron both offer a PCSK9 inhibitor in the U.S. marketplace. Sanofi/Regeneron took the more traditional approach to solve access challenges for their patients—<u>announcing earlier</u> <u>this year</u> discounts of up to 69% in exchange for insurers and pharmacy-benefit managers expanding coverage to more patients.

Amgen had earlier begun individual negotiations with insurers, reducing the price of Repatha to the Harvard Pilgrim health plan, for example, and agreeing to refund the cost of the drug to any patient that went on to have a heart attack or stroke. While these announcements received positive attention, they were done within the confines of a flawed rebating system that the Trump administration has been working hard to shake up and reform.

The announcement by Amgen today takes a different approach, one consistent with the Trump administration's policy objectives of delivering savings to patients at the pharmacy counter. By creating new pricing categories, patients who pay a share of the list price through co-insurance can see immediate savings. The company says it hopes that insurers will see the value of adjusting their formulary tiers to include the drug and make it more accessible and affordable to patients.

**It would disrupt multi-year contracts** to simply lower prices across the board, so Amgen developed this work-around. It is requesting new drug payment codes (National Drug Codes or NDAs) for Repatha so it can immediately reduce list prices for those plans that participate. The older, more-expensive codes will stay on the books for existing multi-year contracts but expire by 2020.

In a <u>speech</u> earlier this month to the National Academy of Medicine, Health Secretary Alex Azar talked about 17 of the steps the administration is taking to lower drug prices, and he identified this problem: "List prices are meaningful to every American senior on Medicare Part D who pays coinsurance for drugs as a share of the list price...they can often pay thousands of dollars toward the list price of a drug before their insurance kicks in."

Amgen's announcement addresses that issue directly by significantly reducing the list price. It is a market-based solution, not a destructive government-imposed price control. It's part of the <u>complex, surgical approach</u> that is much more likely to succeed in lowering drug prices while allowing investments in research for new innovative therapies to continue.

Amgen CEO Bradway said: "Repatha can help to address this significant public health issue, but concerns over out-of-pocket costs have proven to be a barrier to its use for too many patients. We want to make sure that every patient who needs Repatha gets Repatha."

Amgen quoted a grateful patient in its release: "Since turning 65 and going on Medicare I have had to make one of the hardest decisions of my life – can I afford to stay on Repatha, the only thing, even after nine stents and numerous statins, that has worked to lower my cholesterol?" says Repatha patient Bob C. from Boca Raton, Fl. "Given my family history of heart disease, today's announcement means that I can continue taking a therapy that has been so effective for me."

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