

# New anti-cholesterol drugs too expensive: report

September 9 2015

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The high price of two new anti-cholesterol drugs limits the benefits patients may see from them, according to a draft report released Wednesday by a US nonprofit examining drug cost effectiveness.

The new drugs, Praluent, from French pharmaceutical giant Sanofi and Regeneron, and Repatha, from California-based Amgen, both target the enzyme PCSK9, which, when inhibited, can lead to reduced LDL-cholesterol.

The US Food and Drug Administration approved the medications earlier this year, finding they reduced cholesterol by approximately 55-60% in patients who are already on or who cannot take cholesterol-reducing statin drugs.

Wednesday's draft report from the Institute for Clinical and Economic Review (ICER) said those findings "provides moderate certainty that PCSK9 inhibitor therapy improves patient outcomes" and that the two new drugs, which it says are equally effective, may help as many as 3.5 to 15 million Americans.

But those benefits may be limited by the drugs' steep costs.

"With a list price over \$14,000 per year there are serious questions regarding the price at which these drugs would represent a sensible value to patients and to the health care system," ICER researchers said in a statement.

They said lowering that list price by 67 percent would best represent the "overall benefits" of the drugs to individual patients.

Even at that steep discount, though, the cumulative costs of those drugs on insurers and others paying for health care would drag down the full benefits of the drugs to society.

An annual price tag at or below \$2,177 is needed, ICER researchers said, "for the total costs of these new drugs to come down to a level at which doctors and insurers would not have to try to limit patient use in some way to keep overall health care cost growth within bounds."

"If the cost is more than \$2,177 a year, drug companies, doctors, insurers, and other parties may need to work together to determine ways to limit the use of these drugs, find savings in other parts of the health care system, or adopt other measures to help make these drugs more affordable," ICER president Steven Pearson said.

High cholesterol has been tied to heart disease, the most common cause of death in the United States.

Elizabeth Baxter, of Sanofi, said in a statement: "We need to better understand the ICER analysis, particularly their model and methodology, as we performed our own cost effectiveness model to help us determine the appropriate price.

"These calculations are complex and a robust and open peer-review process is essential."

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Citation: New anti-cholesterol drugs too expensive: report (2015, September 9) retrieved 25 April 2024 from <https://medicalxpress.com/news/2015-09-anti-cholesterol-drugs-expensive.html>

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