Less than half of patients prescribed new cholesterol drug receive insurance approval

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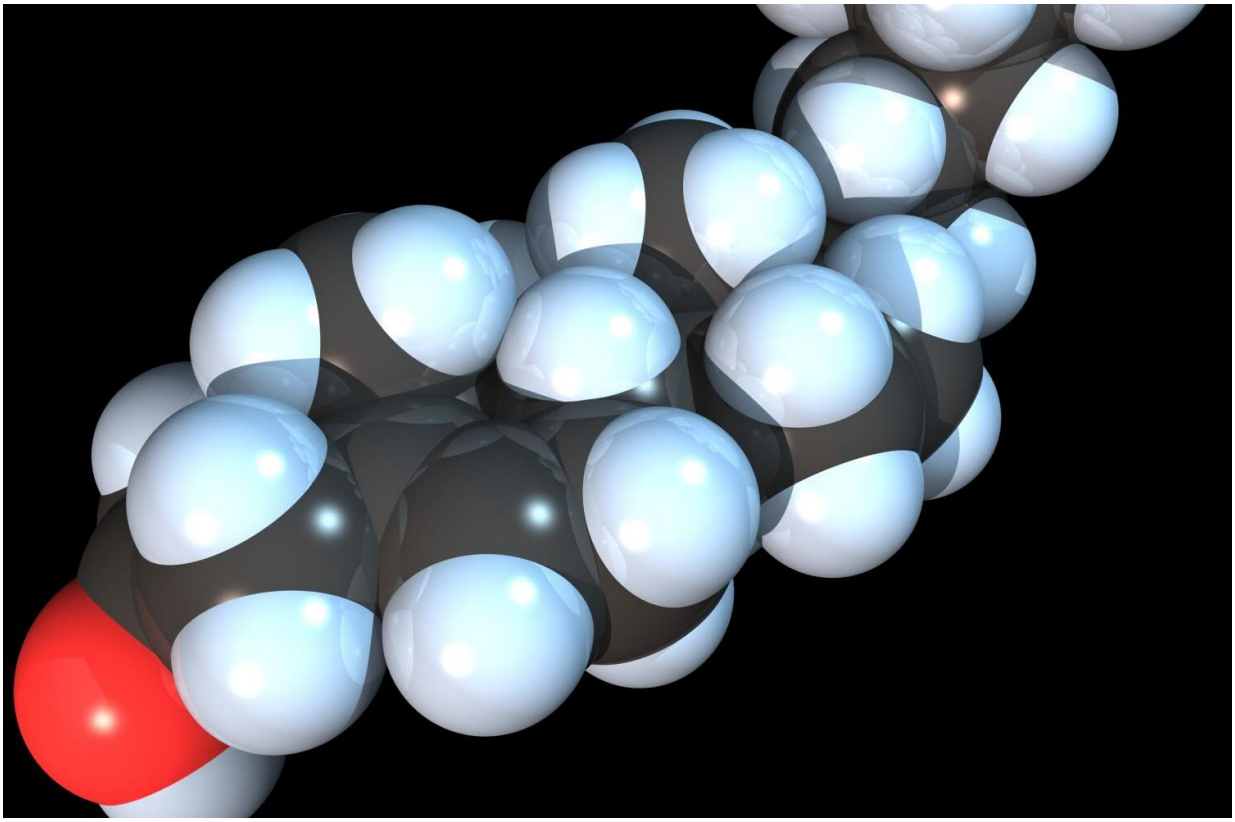

Space-filling model of the Cholesterol molecule. Credit: RedAndr/Wikipedia

Less than half of patients received their insurer's approval for prescriptions of PCSK9 inhibitors, according to new research in the American Heart Association's journal *Circulation*.

PCSK9 inhibitors, like Repatha (evolocumab) and Praluent (alirocumab), work by increasing the removal of low-density lipoprotein (LDL) or "bad" cholesterol from the blood. They have been shown to reduce LDL by 60 percent and decrease major cardiac events but cost much more than other cholesterol-lowering drugs with an average cost of $14,300 per year. Prescriptions require prior authorization by health insurance companies.

In a nationwide review of the pharmacy claims combined with electronic medical records (EMRs) lab test results of 9,357 patients prescribed the drug between July 2015 and August 2016, 4,397 (47 percent) were approved for PCSK9 inhibitor therapy and 4,960 (53 percent) were rejected. Sixty percent of those patients had a history of atherosclerotic cardiovascular disease (plaque-buildup of the arteries) while 40 percent did not.

"With the controversy surrounding whether or not these drugs were cost effective, we were anticipating that there might be some reluctance by insurance companies to cover these medications," said senior author Robert Yeh, M.D., director of the Smith Center for Outcomes Research in Cardiology at Beth Israel Deaconess Medical Center in Boston.

"However, we were surprised by the very high rate of rejection, even when prescribed to patients with known atherosclerotic cardiovascular disease, very high LDL levels and those who were intolerant of statins, for example," he said.

Researchers also found that the most significant factor associated with approval rates was insurance type, with the lowest approval rates for private insurance and the highest approval for Medicare.

"Whether or not we can agree on the cost-effectiveness of these drugs, I believe most would agree that one's access to medications should be

driven primarily by the strength of the indications for the prescription as opposed to what drug plan you happen to carry," said Yeh, who is also an Associate Professor of Medicine at Harvard Medical School. "Approximately 1 out of 3 patients who had their prescription approved did not purchase or receive the medication. Those patients who didn't purchase their medication had an out-of-pocket cost that was twice as high as those who did purchase it," said Dr. Gregory Hess, first study author and senior fellow of Health Economics at University of Pennsylvania and chief medical officer at Symphony Health.

"Approximately 1 out of 3 patients who had their prescription approved, did not purchase or receive the medication. Those patients who didn't purchase their medication had an out-of-pocket cost that was more than twice as high as those who did purchase it," said Gregory Hess, M.D., who is first author of the study and a Senior Fellow of Health Economics at University of Pennsylvania and Chief Medical Officer at Symphony Heath.

The findings are based on Symphony Health's HIPPA-compliant patient-level data from all fifty states and all payer types.

"Better education for providers prescribing these medications and more uniform guidelines by insurers about what will and will not be covered are necessary to reduce the amount of administrative waste that is created to reject prescriptions for new medications," Yeh said.

The study was a retrospective analysis and could not determine whether patients suffered any harm from the rejection of these prescriptions.

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