

Recently approved cholesterol medication not cost-effective; could substantially increase US health costs

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Although the recently FDA approved cholesterol-lowering drugs, PCSK9 inhibitors, could substantially reduce heart attacks, strokes, and cardiovascular deaths, they would not be cost-effective for use in patients with heterozygous familial hypercholesterolemia or atherosclerotic cardiovascular disease, with annual drug prices needing to be reduced by more than two-thirds to meet a generally acceptable threshold for cost-effectiveness, according to a study appearing in the August 16 issue of *JAMA*.

Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors were approved by the U.S. Food and Drug Administration (FDA) for use in patients with heterozygous familial hypercholesterolemia (FH; a disorder caused primarily by mutations in the low-density lipoprotein [LDL] receptor gene that causes severe elevations in levels of LDL-cholesterol [C], resulting in early atherosclerotic lesions) or pre-existing [atherosclerotic cardiovascular disease](#) (ASCVD) who require additional lowering of LDL-C despite maximally tolerated doses of statins. If clinical benefits seen in short-term trials are sustained in the longer term, PCSK9 inhibitors could become an important option for patients at high risk of ASCVD, potentially lowering [health care](#) costs through preventing ASCVD events. However, with an average U.S. price in 2015 of more than \$14,000 per patient per year, their cost-effectiveness and effect on national [health care spending](#) are uncertain.

Kirsten Bibbins-Domingo, Ph.D., M.D., M.A.S., of the University of California, San Francisco, and colleagues used the Cardiovascular Disease Policy Model, an established simulation model of ASCVD in the U.S. population, to evaluate cost-effectiveness of PCSK9 inhibitors or the cholesterol [drug](#) ezetimibe in heterozygous FH or ASCVD. The model incorporated 2015 annual PCSK9 inhibitor costs of \$14,350 (based on average wholesale acquisition costs of evolocumab and alirocumab).

Adding PCSK9 inhibitors to statins in heterozygous FH was estimated to prevent 316,300 major adverse cardiovascular events (MACE; cardiovascular death, nonfatal heart attack, or stroke) at a cost of \$503,000 per quality-adjusted life-year (QALY) gained compared with adding ezetimibe to statins. In ASCVD, adding PCSK9 inhibitors to statins was estimated to prevent 4.3 million MACE compared with adding ezetimibe at \$414,000 per QALY. Reducing annual drug costs to \$4,536 per patient or less would be needed for PCSK9 inhibitors to be cost-effective at less than \$100,000 per QALY.

At 2015 prices, PCSK9 inhibitor use in all eligible patients was estimated to reduce cardiovascular care costs by \$29 billion over 5 years, but drug costs increased by an estimated \$592 billion (a 38 percent increase over 2015 prescription drug expenditures), and was estimated to increase annual U.S. health care expenditures by about \$120 billion (a 4 percent increase from the \$2.8 trillion dollars in total U.S. health care spending in 2015).

The authors write that the high cost of PCSK9 inhibitors is uniquely challenging. "This is because PCSK9 inhibitors are meant to be lifelong therapy not only for the relatively small number of patients with FH but also for a large and growing population with ASCVD. As a result, the potential increase in [health care expenditures](#) at current or even moderately discounted prices could be staggering, despite cost savings

from averted ASCVD events."

"In the face of limited health care resources, payers must consider the potential trade-off between paying for new drug treatments like PCSK9 [inhibitors](#) and investing in interventions known to improve access, physician prescription rates, and patient adherence to statin therapy among those at high ASCVD risk."

More information: *JAMA*, [DOI: 10.1001/jama.2016.11004](https://doi.org/10.1001/jama.2016.11004)

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