PCSK9 inhibitor access remains a significant barrier, leaving patients at risk for heart attacks and strokes

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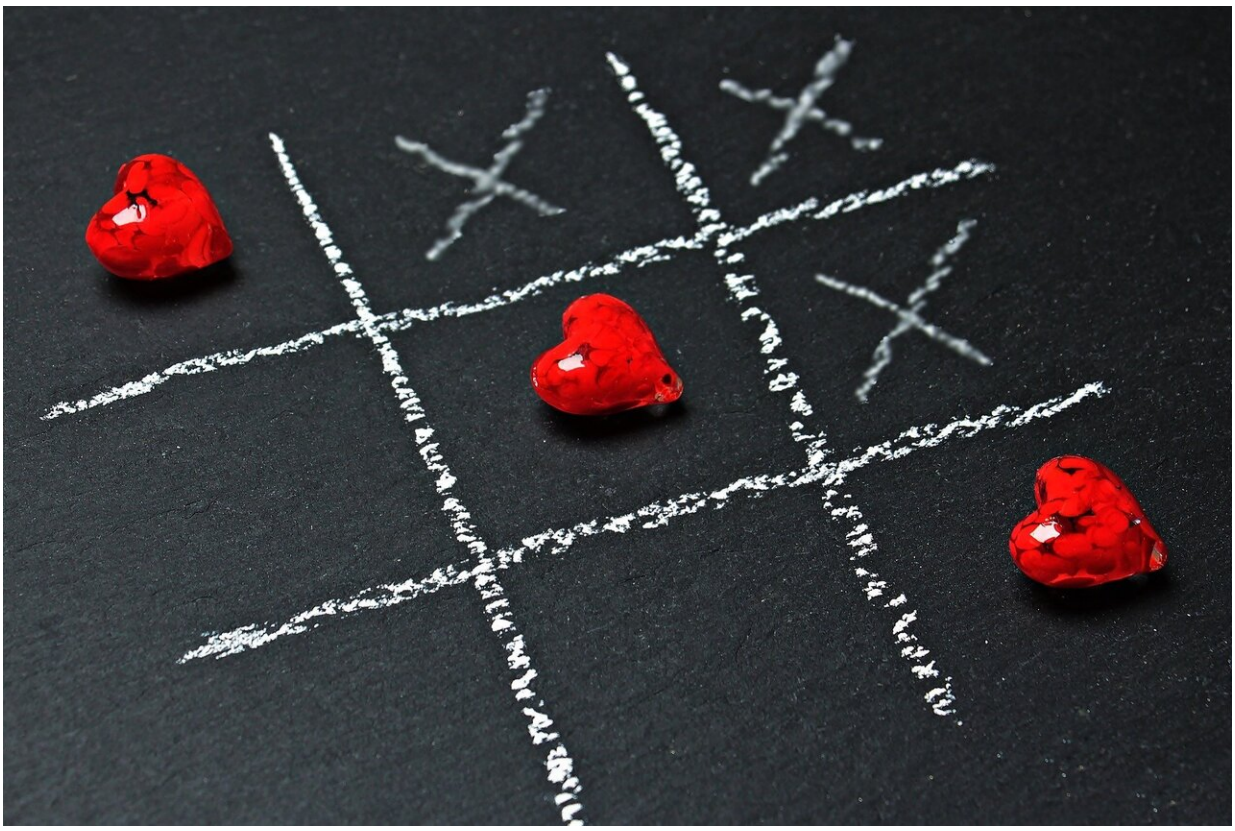

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A new study published in *Circulation: Cardiovascular Quality and Outcomes* from the Family Heart Foundation—a patient-centered

research and advocacy nonprofit organization dedicated to improving the lives of families impacted by inherited lipid disorders and LDL-cholesterol—revealed that utilization of proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9i) to reduce low-density lipoprotein cholesterol (LDL-C) remains low among high-risk patients.

Despite key developments between 2017 and early 2019 that were expected to increase appropriate utilization, rejection of prescribed PCSK9i by insurance plans remains uncharacteristically high compared to other similar therapies for cardiovascular and metabolic disease.

Since 2019, PCSK9i have had a label expansion; positive results from major outcomes trials and large studies showing the use of PCSK9 inhibitors reducing cardiac events; a 60% price reduction on PCSK9i and established clinical practice guidelines all of which were supposed to improve utilization, yet access is still a barrier leaving patients at risk for heart attacks and strokes.

The burden of cardiovascular disease, driven largely by atherosclerosis, is increasing in the United States.

High LDL-C is a major modifiable risk factor. A 2019 study by the Family Heart Foundation (formerly known as the FH Foundation) published in *Circulation: Cardiovascular Quality and Outcomes* found that compared to individuals who were able to obtain their prescribed PCSK9i, those whose prescription was rejected by insurance plans or abandoned experienced significantly more heart attacks, strokes, and other cardiovascular events within 12 months.

"The results from this new Family Heart Foundation study suggest that patients still experience substantial challenges getting the PCSK9i that have been prescribed for them by their medical team, despite guidelines recommending their use and extensive evidence documenting their role

in LDL-C reduction and the prevention of heart attack or stroke," said Diane E. MacDougall, Vice President of Science and Research at the Family Heart Foundation and co-author of the study.

"As a result, eligible patients remain at higher risk of heart attacks and other major cardiovascular events as demonstrated by the 2019 study."

Key findings from the current study showed continued barriers to PCSK9i use:

- Despite improving since 2018, 30.95% of PCSK9i prescriptions are rejected by insurance plans. This is significantly higher compared to other guideline-recommended cardiometabolic therapies with demonstrated cardiovascular benefit (rejection rates range from 3.53% to 14.61%).
- Despite developments that were expected to increase PCSK9i utilization, new PCSK9i prescriptions remained low, at 470,018 during the 2019-2021 timeframe compared with 238,704 during the 2015-2018 timeframe.
- Taking into account both rejections by insurance plans and abandonments, paid prescription rate for PCSK9i coverage was substantially lower (49.93%) than those for other guideline-recommended cardiometabolic therapies (ranging from 68.49% to 84.45%).

While statins are the first line of treatment, they may not lower LDL-C enough for high-risk patients. The 2018 ACC/AHA Multi-society Guidelines on the Management of Blood Cholesterol recommended the use of PCSK9i for appropriate patients. PCSK9i were approved by the U.S. Food & Drug Administration in 2015 as a major advancement to lower elevated LDL-C in patients with ASCVD and familial hypercholesterolemia.

After 2017, the label for PCSK9i was expanded to include reduction of cardiovascular events in ASCVD patients and reduction of elevated LDL-C in patients with primary hypercholesterolemia, based on positive data from the FOURIER and ODYSSEY Outcomes trials. In addition, PCSK9i have been similarly priced to other guideline-indicated cardiometabolic drugs since 2018.

More information: Diane E. MacDougall et al, Trends in Patient Access to and Utilization of Prescribed PCSK9 Inhibitors in a Large US Claims Database From 2015 to 2021, *Circulation: Cardiovascular Quality and Outcomes* (2024). DOI: 10.1161/CIRCOUTCOMES.123.009988

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