Insurance company requirements place heavy burden on physicians seeking to prescribe new cholesterol-lowering drugs

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A rare glimpse into the prior authorization requirements implemented by public and private insurance providers across the country has found substantial administrative burden for a new class of medications for patients with high cholesterol that places them at high risk for heart attack or stroke, according to new research from the Perelman School of Medicine at the University of Pennsylvania. So-called proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors are self-injected medications approved for individuals with a genetic condition called familial hypercholesterolemia (FH) and those with atherosclerotic cardiovascular disease (ASCVD) who have high cholesterol despite receiving traditional statin medications and other treatments. Results of the study are published today in *Circulation: Cardiovascular Quality and Outcomes*.

"As innovative yet often expensive new drugs come on the market to treat serious and/or chronic medical conditions, insurers have turned to policies aimed at ensuring appropriate use in order to manage costs," said the study's lead author Jalpa A. Doshi, PhD, a professor of General Internal Medicine. "Prior authorization - which requires a prescriber to demonstrate that a prescription is medically necessary for the patient before it is approved by the insurer - has been used for many years and is a fairly common strategy, but we found that the burden of the requirements for PCSK9 inhibitors were so high that they raise real concerns about access barriers."

The researchers analyzed data from a proprietary database containing information on prior authorization policies covering more than 275 million Americans, or more than 95 percent of those with prescription coverage. The data, which spanned 3,872 plans in the commercial, health insurance exchange, Medicare, and Medicaid segments, showed that between 82 and 97 percent of Americans were enrolled in the plans implementing prior authorization for PCSK9 inhibitors. Many required health care providers to submit actual medical records rather than simply answer questions on a form, which is more common, and to provide documentation on patient histories that may not be available if a patient has switched doctors over time.

"Of particular concern was that patients with FH, where the need for PCSK9 inhibitors is more straightforward, faced the same cumbersome requirements as did patients with ASCVD," said Michael Parmacek, MD, chair of Medicine at the Perelman School of Medicine at the University of Pennsylvania.

In addition, insurance companies often required confirmation of the FH diagnosis through genetic testing, which is not a standard test in clinical practice and typically not covered by insurance. This could place additional financial burden on patients, beyond the substantial out-of-pocket costs many would face when filling a PCSK9 inhibitor prescription.

To place these findings in context, the researchers compared prior authorization criteria for PCSK9 inhibitors to those for two other medications that would be prescribed by the same types of physicians and that shared other key characteristics (such as being more expensive than alternate treatment options). They found that prior authorization requirements for PCSK9 inhibitors were substantially more burdensome than those for the comparator drugs, involving three to 11 times the number of required items to be filled out on the prior authorization form

and more frequent demand to justify responses to individual items with medical record submissions.

Prior studies have found very high rejection rates for PCSK9 inhibitor authorization requests, and the new study may shed light on some contributing factors.

"More paperwork means more risk of errors or omissions, and the forms weren't consistent across insurance plans, so it's also juggling multiple sets of requirements and appeals when initial requests are rejected. This places particular burden on physicians in smaller practices without dedicated staff or resources to assist and could take time away from patient care. It raises the question of whether patients seen by physicians with greater administrative capacity, rather than those with the greatest medical need, are more likely to receive approval," Doshi said.

Approved in 2015, data on long-term outcomes and cost-effectiveness for PCSK9 inhibitors is still accumulating.

"It remains to be seen how payers will respond to additional evidence, and whether they will modify the prior authorization requirements," said Daniel Rader, MD, chair of Genetics at the Perelman School of Medicine. "While the concerns over the budget impact of prescribing PCSK9 inhibitors are certainly valid, there ultimately needs to be a balance between appropriate pre-approval requirements and ensuring those most in need have access to treatment."

Provided by Perelman School of Medicine at the University of Pennsylvania