Circulation: Cardiovascular Quality and Outcomes

EDITORIAL

PCSK9 Inhibitors Prior Authorization

Redundant Process Due for a Redesign

See Article by Myers et al

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With rising healthcare costs, emergence of novel and expensive therapeutic options has resulted in passionate debate on strategies to guide efficient use of allocated healthcare resources. In recent years, health plans in their quest to control escalating drug costs have exponentially intensified focus on utilization management policies such as prior authorization (PA). It is not surprising that this strategy is extremely unpopular in the medical community. In a sobering American Medical Association survey, nearly 9 in 10 physicians viewed PA to have negatively impacted clinic operations and efficiency at the expense of patient care and engagement.[1] Studies have suggested an average of 20 hours/week of combined time spent by clinicians and operational staff on PA-related activities with an estimated national opportunity cost of >$31 billion for all practice interactions with health plans.[2]

In 2015, the cardiovascular community enthusiastically welcomed FDA approval of PCSK9i (proprotein convertase subtilisin/kexin type 9 inhibitors) as an additional add-on therapeutic option for managing cholesterol-related cardiovascular disease risk. However, the celebrations were short-lived. Despite approved labeling and support by consensus statements, nearly all public and private insurers placed requirements of PA for PCSK9i in response to the initial price tag of $14 000 per year. Subsequent lukewarm support from cost-effectiveness analyses further consolidated payers' position.[3]

In the last 4 years, it is now clear that these crude cost containment strategies, though effective, have not been without unintended consequences. Insights from large national insurance datasets have suggested nearly 4 initial denials for every 5 prescriptions.[4] Apart from high rejection rates, it is no secret that PA obtainment and catering to specific individual health plan requirements place heavy administrative burden on clinical practices for getting ultimate approval for nearly half of these cases. For both patients and clinicians, these barriers have been disheartening because of a lack of transparency for PA determination, especially in view of our evolving understanding that targeting the highest risk subgroups may actually be a true value proposition. While it is clear that these processes add barriers to clinical care, whether the PA rejections have consequences on patient outcomes in the real world has not been well documented.

In this issue of *Circulation: Cardiovascular Quality and Outcomes*, Myers et al[5] aim to address this specific gap in knowledge. The study highlights an important point on how access to PCSK9i translates into varying health outcomes in the real world. Myers et al using a large healthcare claims dataset, provide crude estimates of potential risk for cardiovascular adverse events in patients who were rejected for or abandoned the PCSK9i prescriptions compared with those who were approved.

Key Words: Editorials ■ cholesterol ■ cost-benefit analysis ■ drug costs ■ patient care

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Patients who rejected or abandoned (approved but did not fill the prescriptions) the drugs after limited use experienced a statistically 10% significantly higher rates of cardiovascular events than those approved for these drugs. While acknowledging the lack of generalizability of the findings and the inability to account for differences between groups despite propensity matching, higher cardiovascular disease event rates observed among those unable to receive or remain on PCSK9i are not surprising. However, at the same time, we think that 2 findings deserve further discussion.

First, the indiscriminate high rejection rates irrespective of baseline risk are disappointing. For example, it is hard to justify denying PCSK9i in every 2 out of 3 familial hypercholesterolemic patients with established ASCVD given their extremely high risk of subsequent cardiovascular events. This is an important caveat that has to be addressed. This high-risk groups represent a low hanging fruit, which the clinicians and payers can focus on. We advocate that a mere diagnosis of FH and ASCVD should suffice approval for a PCSK9i as long as LDL-C levels remain above reasonable thresholds after guideline-directed lipid lowering therapy as recommended in the most recent American Heart Association/American College of Cardiology multisociety cholesterol guideline. Easing restrictions for this high-risk population will not only bode well for mending existing distrust between clinicians and payers but likely be a cost-effective approach leading to better cardiovascular outcomes.

Second, the abandonment rate was high in the patients who were initially approved for PCSK9i. Nearly 1 in 6 patients who were approved through preauthorization did not fill the prescriptions. The average out of pocket for those not refilling approved PCSK9i was >$233/month. Prior studies have shown that prescription abandonment is proportional to average out of pocket costs. The abandonment rates range from 7.5% for those with $0 copay to 75% for patients with copays >$350.[4] Furthermore, the authors of this study found that a majority of the patients who abandoned their prescriptions were covered by Medicare and less likely to be eligible for copay assistance. These finding remind us that merely improving the PA process will not suffice. Unless we have "Just Price for PCSK9i: No less no more,"[6] cost-related medication nonadherence and financial toxicity will impede the regular access for the most vulnerable segment of our society.[7]

Moving forward, there are many important issues to consider when evaluating PA and access to PCSK9i. We think that the first and the most important determinant of this rigid PA process has been addressed to some extent. Last year, Amgen announced nearly a 60% reduction in annual cost for evolocumab, from $14 000 to $5850. High average out-of-pocket payment was cited as the primary reason driving this change. This price change once fully implemented may provide relief for both payers and patients responsible for average out of pocket payments and can be the catalyst for long overdue redesign of existing PA process.

The recent American Heart Association/American College of Cardiology cholesterol management guideline provides a practical framework for guiding healthcare providers in initiating nonstatin therapy. For example, a simplified clinical decision support algorithm following the recommended algorithm in the guideline will not only streamline selection for appropriate candidates but can also ensure attention to critical issues before prescribing PCSK9i to limit downstream denials.

Organizations such as the American Heart Association and the American College of Cardiology, apart from leading advocacy efforts to ease access barriers and providing evidence-based guidance for choosing appropriate candidates, can also take a leadership role in the development of standardized PA forms that are universally applicable, reflect recommendations from the current guidelines, and also ensure that clinicians are held accountable for appropriate prescription patterns. We think that these collaborative initiatives will play a major role in countering the prevalent resistance by payers, allowing much needed access to appropriate and deserving candidates.

Although having a standard agreed on PA documentation may hasten PCSK9i approvals, it does not absolve the significant administrative burden. For example, Saeed et al[8] reported almost 4 to 6 hours dedicated to preauthorization processes per patient. However, with shifting, emerging health payers' sentiment toward electronic PA process can reduce some of the current administrative liabilities. Would these strategies work? Recently, Kaufman et al[9] reported a 97% approval for PCSK9i, with the adoption of a standardized evaluation process, proper documentation of insurance criteria for coverage, transitioning from a paper to electronic format for insurance application, and, with time, improved communication with insurance companies in response to denials.

While we strongly advocate redesigning the PA documentation process, at the same time, we also encourage the clinical community to align prescribing practices with existing evidence-based recommendations. For example, in the current study, more than a quarter of patients prescribed PCSK9i reported no use of statin; with nearly 6 out of every 10 patients prescribed not reporting high-intensity statin therapy use in the last 12 months. While one can speculate that most of these patients may have severe statin-associated side effects allowing no use, the general consensus is that a great majority of these patients can tolerate some dose of statin therapy. Therefore, every effort should be made to document statin-associated side effects to at least 2 different statins with 1 at the lowest therapeutic daily dose of a statin before prescribing PCSK9i specifically for statin-associated side

effects in high-risk patients. These efforts can have significant downstream economic implications as well. We have recently demonstrated that maximizing and optimizing use of statins and ezetimibe could lead to a nearly 60% reduction in PCSK9i eligibility with significant cost savings to health systems.[10]

In conclusion, as the market forces have led to significant reduction in PCSK9i prices, we think that the cardiovascular community is right to question these persistent obstacles in providing the right care for the right patient. In its current form, there are clear unintended consequences of PA that are not only having a toll on patient care and satisfaction but possibly on preventable outcomes as underscored by Myers et al in the current study. At the same time, if our medical community truly aspires to overcome these blunt cost containing instruments, it is critical that clinicians are mindful of limited available resources as well as broader societal cost opportunities in our prescribing practices. Status quo is not an option anymore for parties on both sides of the aisle. We are optimistic that common-sense collaboration around value-based pricing, appropriate candidate selection, maximum use of evidence-based therapies before considering PCSK9i, streamlining, and eventual easing of PA policies will alleviate suffering for stakeholder we all care the most: our patients.

ARTICLE INFORMATION

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Disclosures

Dr Virani reports receiving grant support from Department of Veterans Affairs, World Heart Federation, and Honorarium from the American College of Cardiology (Associate Editor for Innovations, www.acc.org). The other authors report no conflicts.

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