

Are There Unintended Consequences of Step-Therapy Programs?

TO THE EDITOR:

As our nation struggles under the burden of healthcare costs, which are expected by 2018 to consume 20% of the gross domestic product,⁴ finding solutions that control or decrease costs without compromising quality of care is critical. For many years, pharmaceutical step-therapy programs have curbed pharmacy costs significantly,^{2,3} but questions of whether step therapy leads to unintended increases in medical costs linger. So, we applaud Mark and colleagues⁴ for examining the association between medical costs and implementation of step therapy.

However, important flaws in their methods likely have led to spurious findings. First, the authors do not present any information on how the step-therapy programs were implemented. Typically, step therapy targets individuals who are naive to therapy, representing approximately 25% of antihypertensive users (Express Scripts, internally generated data). Continuing users are not targeted. Examining all antihypertensive users rather than only those affected by the step edit makes determining which members were responsible for the increases in medical costs or utilization impossible. There is no reason to believe that implementation of step therapy would have any effect on antihypertensive users who are exempt from the edit. Inclusion of all-cause medical costs and utilization, a limitation noted by the authors, adds further to the concern of spurious findings given the nonrandomized research design used. A more appropriate approach is to evaluate those affected by the edit compared with a matched cohort of naive antihypertensive patients.

Second, the authors did not address changes in plan design between the comparison and treatment groups. Only average copayments, deemed by the authors to be “relatively constant,” were examined (personal communication TLM, March 22, 2009). Given that the study was carried out over several years, changes not only in copayments but also in formulary status between the intervention and control groups easily could explain the patterns of prescription utilization found.

We agree with the authors that more research targeting patients affected by step edits would contribute greatly to our understanding of the overall effect of step-therapy programs.

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IN REPLY:

We appreciate the support by Cox and Seiz in calling for more research on step therapy. We are optimistic that they, along with other health services researchers in the private sector and in academic research organizations, can help fill in the gaps of our knowledge about step therapy and its effect on patients.

We disagree with the assertion by Cox and Seiz that our methods may have led to false findings. The approach in our study is a standard method in observational evaluation research using an interrupted time-series design with a contemporaneous control group. The method is strengthened by the use of 2 intervention sites and 2 comparison sites and by the use of longitudinal panel data. While we agree that many step-therapy programs try to target naive users and exempt continuing users, we are not so certain that this actually is what happens in practice. For example, it is possible that prior claims history is unavailable to the step-therapy vendor because the client is new to the pharmacy benefit management or the patient recently joined a new insurance plan. We believe that the question of how step therapy affects new and continuing users is an empirical question and cannot be assumed. We agree that examining the effect of step therapy in these groups separately would be useful.

Cox and Seiz take issue with the use of total healthcare costs as an outcome measure. While we agree that evaluating hypertension-related costs would be a valuable addition, we believe that examining total healthcare costs is also critical to understand the full effect of step-therapy programs.

As Cox and Seiz point out, other alterations in benefit design such as changes in copayments may have had an effect on medication utilization. However, in our regression models, we control for overall trends and use 2 different control and intervention groups, which would minimize the effect of this potential confounder. We also note that copayment levels

for antihypertensive agents remained consistent across the period.

Finally, we would like to highlight other work that is consistent with our research in showing that drug utilization programs (such as step therapy and prior authorization that attempt to encourage the use of lower-cost medications) may decrease overall medication utilization. In particular, recent studies^{1,2} of prior authorization (a cousin of step therapy) found that prior authorization may lead to higher discontinuation rates and lower initiation rates. Additionally, a survey conducted by Cox et al³ showed that 11% of patients who tried to fill a prescription from their physicians for a proton pump inhibitor or nonsteroidal anti-inflammatory drug and were subject to step therapy never obtained any medication or obtained it at a much later date.

In an environment of unsustainable rising costs, it is critical to identify processes to encourage cost-effective treatment. However, these approaches must undergo rigorous evaluations before wide adoption to ensure that they are not having unintended consequences.

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Author Disclosure: Drs Mark and Gibson are employees of Thomson Reuters, a company that provides research services to organizations across the healthcare industry. Dr McGuigan is an employee of Pfizer, Inc, and reports owning stock in the company.

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