Reviewer’s report

Title: The impact of generic-only drug benefits on patients’ use of inhaled corticosteroids in a Medicare population with asthma

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Reviewer: Michael A Fischer

Reviewer’s report:

Overall this is a well-done study investigating an important current question in health services research. The authors examine whether introduction of a generics-only drug benefit leads to reductions in patient use of inhaled steroids for asthma. They find that patients switch from high-cost to lower-cost medications, but also that many patients fill fewer prescriptions for inhaled steroids. This finding gets at the only major additional item I would like to see in this analysis:

The authors point out the relatively low ICS use in the baseline period. This begs the question of the overall distribution of severity of illness across the study population. The adverse policy outcome that we worry about with any restrictive insurance policy is non-use of highly effective medications leading to higher health care costs (e.g. admissions for asthma because ICS were stopped). Clearly the authors do not have the data to approach this issue directly. However, I wonder if they could identify a subset of particularly vulnerable patients in their cohort to get at this question. They mention briefly the spectrum of illness. In Table 2 they identify about 12% of the population as high-risk patients, which should be about 200 or so patients. It would be of great interest to look at the high-risk patients specifically and see if they stop using ICS with the generics-only benefit. I understand that severity measures are used as covariables in the current analysis, but I would argue that there are probably two quite different populations: one group with severe asthma, using their ICS daily, getting oral steroids occasionally, and filling 10-12 ICS prescriptions per year; and a second group with milder disease. For this first group, restriction of ICS use is likely to have important clinical consequences. For the second group, restriction of ICS use may be a relatively minor matter with manageable symptoms and limited clinical consequences. If the authors can either do a stratified analysis by disease severity, or a subgroup analysis of just the highest-risk patients, they would greatly strengthen the clinical relevance of the paper.

These points are hinted at in a couple of places, particularly in the middle of page 10 when the authors note that patients with greater ICS use in 2003 had lower odds of discontinuing use in 2004 and on page 11 when they mention that patients with higher severity of disease were taking more expensive ICS.

My only other criticism was that it took me a couple of readings to get a clear
understanding of the benefit design and definitions for the two groups. A simple figure or box when the restricted and unrestricted schemes are introduced might help orient readers at the outset.

Really no other major concerns, very well done analysis.

**What next?:** Accept after minor essential revisions

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.