

Studies show high out-of-pocket costs limit access to lifesaving specialty drugs

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"Specialty drugs" have become important treatment options for many serious and chronic diseases, and in some conditions like cancer they represent the only chance for long-term survival. But, insurers increasingly require patients to share the high costs of these medications. Two new studies led by researchers at the Perelman School of Medicine at the University of Pennsylvania have found evidence that such cost-sharing arrangements are associated with significant reductions in access to these drugs. Both papers are published online in the *American Journal of Managed Care*.

In one study, the Penn-led team conducted a review of the literature and found evidence that high out-of-pocket costs were generally associated with lower use of specialty drugs. In the second study, the team examined Medicare claims data and found that "Part D" (prescription drug plan) co-insurance policies for specialty drugs seem to be reducing or delaying use of a lifesaving class of leukemia therapies.

"High out-of-pocket costs for specialty drugs appear to pose a very real barrier to treatment," said Jalpa A. Doshi, PhD, an associate professor of Medicine in the Perelman School of Medicine.

While there is no standard definition for specialty drugs, the term typically refers to medications requiring special handling, administration, or monitoring. Many are large-molecule biologics such as monoclonal antibodies, and most are aimed at treating chronic or life-threatening diseases. Although specialty drugs typically tend to offer significant

medical advances over non-specialty drugs, they are correspondingly more expensive. In 2014, such drugs accounted for less than one percent of prescriptions in the U.S., but nearly a third of total prescription spending.

While insurers have been imposing higher cost-sharing requirements as part of their efforts to manage specialty drug spending, there has been limited information about the corresponding impact on patients. In the first of the two studies, the research team reviewed published analyses of specialty drug cost-sharing, specifically for the three conditions that attract the largest proportion of specialty drug spending: rheumatoid arthritis, cancer and multiple sclerosis.

"Although almost all the prior studies we reviewed were for privately insured patients from a time when cost-sharing levels were much lower than they are today, these studies still commonly found evidence that high out-of-pockets costs were associated with reductions in utilization of these drugs," said Doshi.

In general, the review found that increases in out-of-pocket costs seemed to have a lower impact on reducing utilization for specialty drugs as compared to the effects reported for non-specialty drugs, probably because specialty drugs often have no medically comparable alternatives, Doshi and her coauthors note. Also as compared to more consistent reductions in use of specialty drugs for rheumatoid arthritis, the review found that cost sharing -still at modest levels during the period of these earlier studies - had a lesser impact on patients' use of cancer specialty drugs.

"As a follow-up, it was particularly important to examine the extent to which the aggressive cost-sharing policies for specialty drugs seen under Medicare Part D, which are increasingly making their way into the private insurance market, adversely impact access to these treatments

even for a condition like cancer," said Doshi.

A Life-Saver Out of Reach

In the second study, published in a special AJMC supplement sponsored by the Patient Access Network (PAN) Foundation, the team did just that. They examined the impact of high specialty drug cost sharing under the Medicare Part D prescription drug benefit on patients with chronic myeloid leukemia (CML). A class of oral specialty drugs, tyrosine kinase inhibitors (TKIs), has revolutionized the treatment of CML, largely transforming it into a chronic condition and enabling many patients to have a near-normal lifespan, particularly when compared to a median survival of less than three years with prior therapies.

The team analyzed Medicare data on patients who were newly diagnosed with CML to examine whether and how quickly they initiated TKI treatment. Patients who were eligible for low-income subsidies and thus faced nominal out-of-pocket costs were compared to patients who faced average out-of-pocket costs of \$2,600 or more for their first 30-day TKI prescription fill.

Results of the study, which earlier this year won first prize in the inaugural "PAN Challenge" for research on improving access to critical medications for Americans with chronic and rare diseases, showed that patients in the latter, high-cost group were significantly less likely (45.3 percent vs. 66.9 percent) to have a Part D claim for a TKI prescription within six months of their CML diagnosis, compared to the subsidized, low cost-sharing group. Those in the high cost-sharing group also took twice as long, on average, to initiate TKI treatment.

"Medicare Part D was created to increase access to prescription drug treatment among beneficiaries, but our data suggest that current policies are interfering with that goal when it comes to specialty drugs," said

Doshi, adding that making Part D out-of-pocket costs more consistent, and limiting them to more reasonable sums would help mitigate this negative impact. "Policymakers should also consider more clinically nuanced cost-sharing policies that take medication value into account, rather than subjecting all specialty drugs to high cost sharing."

The team is currently pursuing further studies of the impact of Part D cost-sharing policies in different disease areas, and hopes ultimately to get a better understanding not only of changes in drug access but also of the long range clinical outcomes and costs associated with any delays or interruptions in treatment.

"We need to know if the current aggressive cost-sharing arrangements have adverse long-term impacts on health, and perhaps paradoxically increase overall spending due to complications of poorly controlled disease," Doshi said.

Provided by University of Pennsylvania School of Medicine

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