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Savings less than expected for generic oral chemotherapy

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A study by researchers at the University of North Carolina Eshelman School of Pharmacy and Lineberger Comprehensive Cancer Center determined the cost savings for a generic version of an orally administered cancer treatment were less than expected—a finding that questions the impact generic drugs can have on controlling health care costs.

The researchers report in the *JAMA Internal Medicine* that the cost for one fill of the generic form of the chemotherapy treatment capecitabine was $2,328 last year. That price was 36 percent lower than the projected branded drug price in 2016—a savings the researchers deemed modest compared to reductions seen for other generic drugs.

"For this oral cancer treatment, we don't see the level of price reduction that we would expect for generic drug entry," said the study's senior author Stacie Dusetzina, PhD, a UNC Lineberger member and assistant professor in the UNC Eshelman School of Pharmacy.

Dusetzina said competition from generic drugs has been an important tool for curbing medical costs and expanding treatment access. At the same time, companies may use generic price reductions as a rationale for setting higher prices for brand-name drugs, with the justification that prices will be significantly lower after generics enter the market.

Capecitabine was one of the first high-priced, orally administered cancer treatments to lose patent protection in the United States, the researchers

report. They found that increases in the price of the brand-name drug, and a smaller-than-expected reduction in the price of the generic versions of the treatment, diminished the impact of generic competition on prices three years after the brand-name drug came off patent.

"Using capecitabine as a case study for the potential effect of generic competition for orally-administered anti-cancer therapies, we found that reductions in the list price were more modest than those observed for other drugs with the same number of generic market competitors," said the study's first author Ashley Cole, MPH, a doctoral student and graduate research assistant in the UNC Eshelman School of Pharmacy.

The researchers used commercial insurance claims data to estimate prescription prices for branded and generic capecitabine between 2002 and 2016. Capecitabine lost patent protection in 2013, and according to the researchers' data, the first fill for the generic alternative was in March of 2014. The price of a standard one-month supply of generic capecitabine averaged $2,598 in 2014, only 17 percent below the projected branded drug price. By 2016, the average generic price dropped to $2,328, which was 36 percent below the projected branded drug price. Other studies have found greater savings for generic entry, even in settings with a similar number of competitors.

They also determined that brand-name drug prices increased over time, and generic prices followed suit. In 2016, the price of the generic capecitabine was similar to the list price of the brand-name drug in 2010, and it was 70 percent higher than the brand-name drug's list price in 2002.

"The price of capecitabine has more than doubled since 2002, so even after generic entry, the price paid by health plans is still higher than the branded drug's original list price after you adjust for inflation," Dusetzina said. "If prices after generic entry are ultimately higher than

original list prices, then it isn't clear that patients will have easier access to treatment following generic entry."

In this study of commercially insured patients, most patients had lower out-of-pocket costs after generic entry. However, about 10 percent of people paid more than $100 for one fill of the medication.

"As we see more patients enrolled in high deductible health plans, paying deductibles or co-insurance for their drugs, this lack of price reduction may directly impact patients," Dusetzina said.

The findings may have policy implications. Encouraging robust generic competition could help control health care costs, Dusetzina said, as the number of manufacturers offering generic products has been found to be related to price reductions.

"There's an ongoing national conversation around prescription drug prices, particularly specialty drugs, like those used in oncology," Cole said. "Some have suggested that generic price competition will be a market-based solution to this problem. Our study provides early evidence that generic competition alone may not be enough to rein in the high prices for orally administered cancer therapies."

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