

A sharp increase in the price of gout drug colchicine led to lower use and poorer disease control, research suggests

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Due to a policy decision in 2010 by the U.S. Food and Drug Administration (FDA), the price of a prescription for the therapeutic gout drug colchicine increased nearly 16-fold from \$11.25 in 2009 to \$190.49 in 2011. Out-of-pocket costs for patients who took the drug jumped more than four-fold from \$7.37 to \$39.49 over the same period.

Use of colchicine dropped 17% during this time and 27% over the following decade. Patients turned to alternative medications for <u>gout</u> such as allopurinol and corticosteroids. However, <u>disease control</u> appeared to worsen, as emergency department use by patients with gout increased by 39.8% and rheumatology doctor visits increased by 10.5% over the following decade.

Prior to 2010 the FDA had not formally approved colchicine for any particular clinical condition. That year, however, under its Unapproved Drug Initiative, the FDA approved Colcrys after its manufacturer conducted a clinical trial, and it removed other, much lower-priced, versions of colchicine from the market.

The researchers analyzed 2007–2019 data for more than 2.7 million patient-years from MarketScan (IBM), which comprises a large sample of people with either employer-sponsored health insurance or employer-sponsored Medicare supplemental plans.

The researchers note some limitations to the study. They include a lack of a control group, the patient mix could have changed over time, gout severity and functional impairment among patients were not known, possible use of over-the-counter medications such as <u>nonsteroidal antiinflammatory drugs</u> (NSAIDs) could not be determined, and the findings may not be applicable to people without employer-sponsored health coverage.

The findings of this case study, now published in JAMA Internal



Medicine, may have implications for other drugs that undergo large price increases and can serve as a useful data point for policies that could affect the price of drugs.

"A rather unique FDA policy resulted in the loss of competitors to colchicine from the market, which led to an enormous increase in its price," said study lead Dr. Dan Ly, assistant professor of medicine in the division of general internal medicine and health service research at the David Geffen School of Medicine at UCLA. "As a result, use of colchicine dropped.

"While patients with gout turned to other medications to treat their gout, such medications didn't do exactly what colchicine did and had different side effects, possibly limiting their use. And therefore it appears, based on the increase in number of emergency department and specialist visits for <u>patients</u> with gout, that their disease control got worse. This case of colchicine speaks to the possible clinical consequences of other policies and manufacturer decisions that result in significant jumps in the prices of other drugs."

More information: Changes in Prescription Drug and Health Care Use Over 9 Years After the Large Drug Price Increase for Colchicine, *JAMA Internal Medicine* (2023). DOI: 10.1001/jamainternmed.2023.0898

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