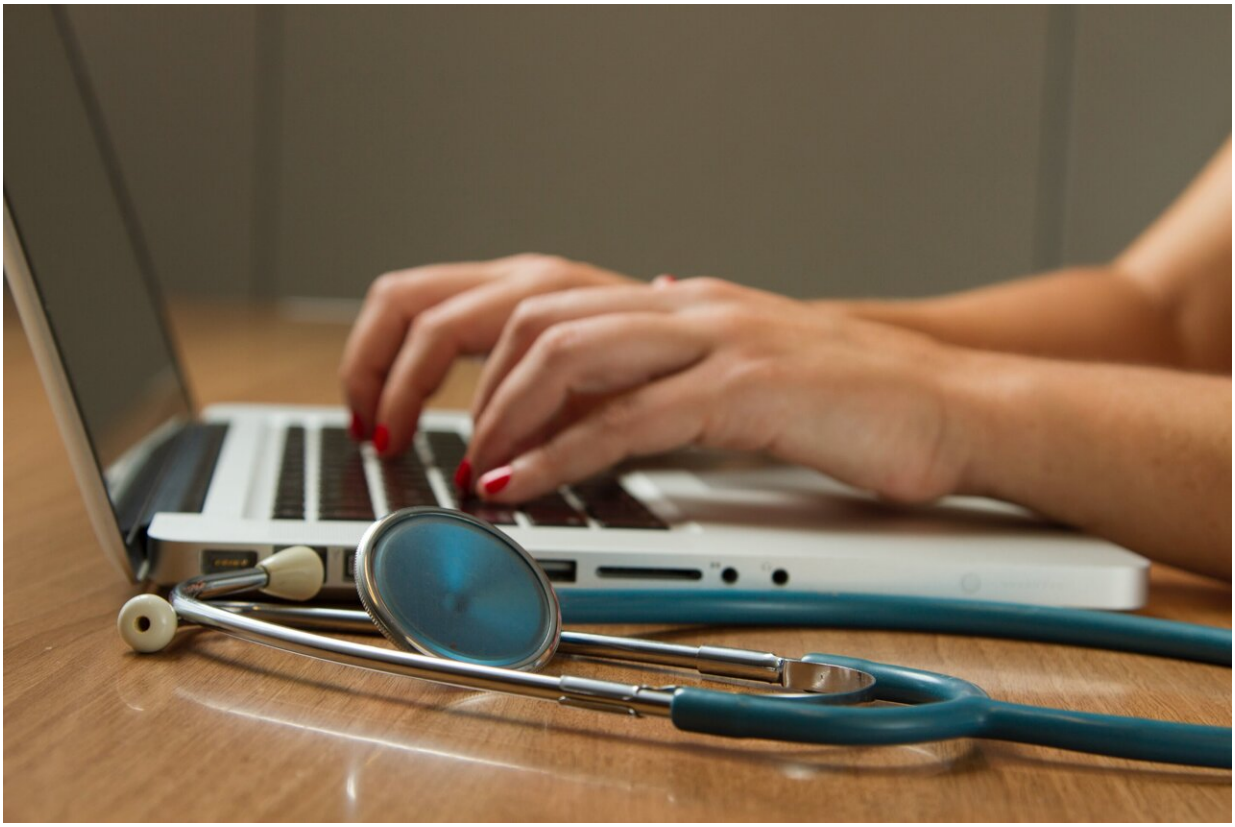
Preapproval requirement for oral anticancer drugs may interfere with treatment

December 13 2023, by Dennis Nealon



Credit: Unsplash/CC0 Public Domain

The use of prior authorizations by insurance companies for certain oral cancer drugs can lead to significant delays in patients' obtaining the medication and make it more likely that some would discontinue the

drug, according to a new study from Harvard Medical School researchers.

The research, conducted by co-authors Michael Anne Kyle and Nancy L. Keating of the Department of Health Care Policy in the Blavatnik Institute at HMS, was published on Dec. 12 in the *Journal of Clinical Oncology*.

The study reviewed Medicare Part D claims data from 2010 to 2020 to examine the consequences of a new prior-authorization policy on delayed prescription fills or discontinuation of oral anticancer drugs. Medicare covers 18% of the U.S. population, primarily adults older than 65. The median age of people diagnosed with cancer is 66 years, giving Medicare a prominent role in cancer care coverage policy.

Prior authorization is used by insurance companies to verify a patient's medical need for a given treatment. The practice has been on the rise over the past decade, drawing concerns from clinicians, patients, and regulators that it may create a hurdle to treatment access.

Harvard Medicine News spoke with Kyle about the implications of the research.

HMNews: What was the impetus for this study?

Kyle: Prior authorizations are a common utilization review measure used by insurance providers. They require that a proposed treatment be submitted to the insurance provider for review before the insurer agrees to pay for it. Clinicians, patients, and regulators have identified it as a common frustration and, at times, a barrier to access.

Financial factors—such as high out-of-pocket costs for patients—are well-known barriers to accessing prescription medications, but there is

little evidence about nonfinancial factors such as the administrative burden created by the requirement to get prior authorization before getting a medication. So we wanted to study this aspect.

Patients may find prior authorization confusing, frustrating, and burdensome for a variety of reasons. For example, people vary in their language fluency, in their ability and willingness to negotiate bureaucratic conflict, and in the amount of time available during work hours to be on the phone regarding insurance coverage. People with complex health conditions also generally face more administrative hurdles.

Some people may shrug off these annoyances, but I am concerned that the same set of events can communicate a different message to someone who regularly encounters discrimination. It could be impossible to distinguish a systems failure from structural discrimination or targeted discrimination, or some combination thereof.

What were your central findings?

The bottom line is that prior authorization requirements can delay access to medications and even discourage people from continuing a medication.

Specifically, we found that for patients enrolled in the federal Medicare Part D program who filled an oral anticancer drug prescription regularly, the introduction of a new prior authorization policy on that drug increased the likelihood of stopping the medication within 120 days. We also found an average delay of 10 days in refilling the first prescription after the policy change, compared with Medicare beneficiaries whose plans did not change the prior authorization policy on those drugs.

What are the implications of these results?

Our results underscore two major concerns: delayed access to drugs and forgoing medication due to prior authorization requirements. We found prior authorization primarily served to introduce delays into established drug regimens, which most patients ultimately resumed. The clinical implications of discontinuations or delayed fills likely vary by drug. Our findings show that prior authorization wasted time and undermined access to care and oral anticancer drug adherence for patients who were regular users of a particular medication.

However, it's important to note that prior authorization is not all bad and it may play a role in discouraging the use of expensive drugs with uncertain benefit. Our study focused only on established, effective treatments, for which prior authorization may have limited advantages and notable disadvantages.

There may be situations where prior authorization is warranted. Cancer drugs have increasingly been approved with provisional evidence of efficacy and can remain on the market after failure of confirmatory trials. When drug approval processes do not clarify a drug's therapeutic value, the task of figuring this out falls upon medical plans and individual clinicians. The ongoing presence of unproven or disproven drugs in the market suggests there are important and necessary applications of prior authorization to protect patients from costly, low-value care, which is care that is expensive but whose benefits remain unclear.

What are the takeaway messages for policymakers, physicians, and patients

Policy efforts around prior authorization broadly circle back to larger

dynamics around pricing and value in health care that we know all too well. One of the challenges with utilization management is that it is disproportionately responsible for containing high prices. As the FDA approval processes grow more flexible, the job of assessing efficacy is also increasingly shifted to clinicians and insurers to make what we call point-of-care coverage decisions. Many countries have centralized health technology assessment processes, but the U.S. does not. Perhaps the growing frustration with utilization management will make such approaches more appealing.

The other important point here is that administrative burden is, at least in part, a feature rather than a bug of prior authorization, but process improvements such as standardized electronic forms are an important policy priority to alleviate the burden on a stressed health care workforce.

Disorganized, fragmented processes burden prescribers, which is particularly concerning with clinician burnout dramatically on the rise. There are several ongoing state and federal efforts to reform prior authorization processes, including here in Massachusetts. Our findings offer important clarifications and evidence that can inform regulatory decisions.

More information: Michael Anne Kyle et al, Prior Authorization and Association With Delayed or Discontinued Prescription Fills, *Journal of Clinical Oncology* (2023). DOI: 10.1200/JCO.23.01693

Provided by Harvard Medical School

requirement-oral-anticancer-drugs.html