Using generic cancer drug could save many millions of dollars

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With the expiration in January of the patent on Gleevec, the drug that 15 years ago changed chronic myeloid leukemia (CML) from a death sentence to a treatable illness, insurance companies and patients have the opportunity to realize huge cost savings, new Johns Hopkins Bloomberg School of Public Health research suggests.

The researchers, publishing online this month in the *Journal of the National Cancer Institute*, say that if all CML patients were started upon diagnosis on the generic form of Gleevec, known as imatinib, the cost of treatment per patient over five years would be nearly $100,000 less than it is now. Most CML patients require lifelong, daily medication.

This means that a health insurer with 100 patients with chronic myeloid leukemia could save $9.1 million over five years. CML is a relatively rare cancer that starts inside the bone marrow. Roughly 6,000 Americans are diagnosed with it every year and up to 90 percent survive five years on drugs like Gleevec, which is manufactured and sold by Novartis Pharmaceuticals Corporation.

"If we start all patients on the generic form of Gleevec and it works, then they are on a generic for the rest of their lives," says study leader William V. Padula, PhD, an assistant professor in the Department of Health Policy and Management at the Bloomberg School. "This amounts to a huge cost savings for them and their insurers."

While Gleevec was the first drug to successfully treat CML, two other

drugs in the same category, known as tyrosine kinase inhibitors, have come on the market in recent years: dasatinib (sold as Sprycel) and nilotinib (sold as Tasinga). Generic versions of these drugs will not be available for many years; the branded versions cost roughly $75,000 each for a year's supply. In nearly 90 percent of cases, patients are now started on one of these newer drugs based on each physician's preference, but research has shown that overall five-year survival rates of all three drugs are equivalent.

Also, CML patients tend to switch drugs during the course of treatment if there are side effects or if one drug doesn't appear to be effective, meaning that over the course of five years, roughly 50 percent of patients will take Gleevec for some or all of the time.

Padula and his colleagues, including Rena M. Conti, PhD, a health economist at the University of Chicago, found that if insurers decided to only pay for Gleevec as the first line drug - instead of allowing doctors to choose - the savings would be even greater than $100,000 over five years if the patient stayed on Gleevec for the entire time. This five-year time point is significant since it is the amount of time hematologists and oncologists typically use to measure progression-free survival or overall survival from remission in CML patients. With the patent protection on Gleevec lost, the researchers estimate that the per-patient, per-month cost of imatinib will likely drop 60 to 90 percent from its current cost of nearly $60,000 a year as generic manufacturers make and sell imatinib. That could mean the drug could cost less than $6,000 a year for those who stay on it.

For the study, the researchers compared cost-effectiveness of the different medications by analyzing Truven Health Analytics MarketScan data from newly diagnosed CML patients between Jan. 1, 2011 and Dec. 31, 2012.

Last year, Gleevec lost patent protection in Canada and the price of imatinib is now 18 to 26 percent of the branded drug price. The national health insurance system has mandated the use of the imatinib first, which has resulted in large cost savings.

Despite efforts to control costs, total prescription drug spending in the United States was $374 billion in 2014, up 13 percent from 2013, the highest annual growth rate since 2001, according to IMS Health.

"There is minimal risk to starting all patients on imatinib first," Padula says. "If the patient can't tolerate the medication or it seems to be ineffective in that patient, then we can switch the patient to a more expensive drug. Insurance companies have the ability to dictate which drugs physicians prescribe first, and they regularly do. Doing so here would mean very little risk to health and a lot of cost savings."

The car industry, Padula says, bases the price of its models on how much it costs to make each one, with a little bit of profit thrown in. Drug prices have little to do with the actual cost of what goes into manufacturing and distributing their product. Drug companies argue that prices take into account the cost of research and development, as well as the value provided to the patient.

"When patent protection is lost, the prices are set closer to the true cost of the drug," Padula says. "They're making 'General Motors' profits as opposed to Pharma profits and that savings can be shared with the consumer, but only if doctors and insurers work together to make sure patients are being prescribed the more cost-effective medication."

More information: "Cost-effectiveness of Tyrosine Kinase Inhibitor Treatment Strategies for Chronic Myeloid Leukemia in Chronic Phase After Generic Entry of Imatinib in the United States" *Journal of the National Cancer Institute*, 2016.

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