

Life-extending benefits of liver cancer drug Sorafenib not realistic for many patients

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For advanced liver cancer, there's a single approved drug shown to offer patients a chance at longer life. But a new study from the University of North Carolina Lineberger Comprehensive Cancer Center shows that this drug was notably less effective in patients who likely had more extensive cancer and serious liver disease than did patients included in previous clinical trials.

In the journal *The Oncologist*, researchers reported that the median survival for a group of Medicare [patients](#) on the drug sorafenib was three months, which was significantly lower than the median survival of nearly 11 months for patients treated with the drug during a phase III clinical trial. As the drug comes with significant side effects and a cost of more than \$10,000 a month, researchers are questioning the value of the drug for all patients.

"No drug that results in a three-month survival can be thought to be offering a meaningful life expectancy," said senior author Hanna K. Sanoff, MD, MPH, a UNC Lineberger member, associate professor in the department of Medicine in the UNC School of Medicine, and section chief of the Gastrointestinal Medical Oncology Program. "This doesn't mean we shouldn't prescribe it, but we should be mindful that the broader population of [liver cancer](#) patients is sicker than the patients in the landmark trial. Our patients deserve to know that the promise of nearly a year of life may not be their reality."

The U.S. Food and Drug Administration approved sorafenib – known

commercially as Nexavar – for the treatment of advanced hepatocellular carcinoma in 2007. In a phase III clinical trial, patients with advanced liver cancer had a median survival of 10.7 months on the drug, which was 2.8 months more than patients who didn't get the treatment. But patients in that study also were in good physical condition and their level of cirrhosis, which nearly universally accompanies liver cancer, was well controlled, Sanoff said.

"This drug was tested in a clinical trial with patients with mild cirrhosis who were pretty fit," Sanoff said. "Because of concurrent cirrhosis, it may be that the gap between the trial population and the average liver cancer patient may be greater than in some other cancers."

In the new study, the researchers analyzed survival data for a group of patients insured by Medicare diagnosed between 2008 and 2011. Of the 27 percent of 1,532 patients given sorafenib, median survival from the first prescription was three months, which was not statistically longer than survival of untreated patients.

They concluded that lower survival in the Medicare population was likely due to a generally sicker population. Further analysis suggested that patients in the study with earlier stage disease might be more likely to benefit from taking the drug.

"We need to question who we prescribe this to, not only because of the cost of the drugs from a side effect perspective, but also the actual financial cost," Sanoff said.

In previous studies, researchers found that the median monthly price for the drug across all available Medicare part D plans in 2014 was \$10,811 per month, said study co-author Stacie Dusetzina, PhD, a UNC Lineberger member and assistant professor in the UNC Eshelman School of Pharmacy and UNC Gillings School of Global Public Health.

That price tag can mean thousands of dollars in out-of-pocket costs for patients, Dusetzina said, as most plans require cost sharing of at least 25 percent when filling the [drug](#)'s prescription. Even for patients who have reached the catastrophic spending level in Medicare Part D – when the amount they are expected to pay out-of-pocket decreases - they would still pay \$540 per prescription fill each month.

"This is obviously going to present financial challenges for many patients," Dusetzina said. "This underscores the fact that establishing effectiveness of therapies outside of trial settings is complicated but important, if we want to really understand the value of cancer therapies. Translating the benefits of treatments into a 'real world' setting isn't always easy."

More information: H. K. Sanoff et al. Sorafenib Effectiveness in Advanced Hepatocellular Carcinoma, *The Oncologist* (2016). [DOI: 10.1634/theoncologist.2015-0478](https://doi.org/10.1634/theoncologist.2015-0478)

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