

Cancer drugs get a new consumer guide

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In a bid to inject clarity into the fast-moving, high-stakes world of cancer drugs, a task force of cancer doctors announced Monday that it has devised a decision-making aid to help physicians and their patients weigh the pluses and minuses of newly available options for treating malignancy, including their costs.

In a trial run of the proposed system, which distills a single "net <u>health</u> <u>benefit</u>" number for <u>cancer drugs</u>, several costly new medications fared poorly. Others, despite high costs, appeared to offer major returns for <u>patients</u> with few effective options.

The panel - set to the task by the American Society of Clinical Oncology - hopes to make its proposed "Value Framework" a comprehensive and widely available resource for patients with the full range of cancers. As new cancer medications enter the American pharmaceutical market, the aid would offer easy-to-understand graphics that compare the safety, effectiveness and cost of those new medications with those of drugs that have become standard therapies after years of use.

The Value Framework awarded one medication- the <u>lung-cancer</u> drug pemetrexed (marketed as Alimta), which can cost \$9,200 per month - a 0 in a 0-to-130 rating system. That rating system assesses a drug's effectiveness in extending life for cancer patients as well as the number and severity of its side effects.

Bevacizumab (marketed as Avastin), another widely touted drug used in lung cancers, scored 16 despite its average cost of almost \$12,000 per



month. The prostate cancer drug cabazitaxel (marketed as Jevtana) also was awarded only 16 points, despite a monthly cost of \$10,700.

In contrast, the cancer drug erlotinib (marketed as Tarceva) scored a relatively high score of 44 when compared with two standard treatments for metastatic non-small cell lung cancer (cisplaten-plus-docetaxel or cisplatin-plus-gemcitabine), at a cost of about \$4,600 per month.

In treatment of advanced multiple myeloma, the new index gave high marks to the new cancer drug bortezomib (marketed as Velcade), assigning it a score of 47, with a cost of about \$7,000 per month. For prostate cancer, the drug abiraterone (Zytiga), approved just a year ago, was rated 42, with a cost of about \$7,500 a month.

Women being treated for HER2-positive breast cancer-a malignancy against which standard therapies are virtually ineffective - now have access to trastuzumab (Herceptin). When added to three standard-of-care drugs, trastuzumab scored a net health benefit of 48. But the cost of the entire course of that new regimen is \$73,166.

Though cost is not a direct factor in determining a medication's net health benefit score, it was a crucial factor in spurring the development of the decision-making aid. In recent years, costs of new medications have escalated, and insurance plans have made patients responsible for an increasing share of their treatment's cost.

A cancer patient's treatment choices can have significant financial implications - including, for some, bankruptcy. The proposed framework would give physicians and patients a single score summarizing a drug's safety and effectiveness relative to medications that have long been used to treat a given cancer type.

Published Monday in the Journal of Clinical Oncology, the proposed



decision aid was drawn up by an American Society of Clinical Oncology task force on value in cancer care. Cancer physicians and patient advocates, as well as insurance and pharmaceutical company representatives, offered input on the Value Framework.

About 80 percent of the net health benefit index is based on how many more months of progression-free survival a new cancer drug provided clinical trial participants than did standard treatments. An additional 20 percent of that score reflects the number and severity of toxicities, or unwanted side effects, seen in clinical trials.

On top of that 0-to-100 score, the authors of the decision-making aid can add as many as 30 bonus points if a new drug offers either of two benefits that are particularly valuable to many cancer patients: if, compared with standard-care treatment, the drug alleviates any cancer-related symptoms, and if it allows patients to enjoy longer intervals between treatments.

Separately, the framework would provide the treatment's monthly cost.

Dr. Lowell E. Schnipper, an oncologist who was chairman of the <u>task</u> <u>force</u>, said fellow cancer doctors whose command of the research literature is up to date may know already how the new cancer drugs stack up against established therapies in safety and effectiveness.

"But what doesn't happen now - because it's awkward both for the doctors and patients - is to bring in this question of cost," said Schnipper, a specialist in blood cancers at the Dana Farber Cancer Center in Boston. Schnipper cited survey findings in which two-thirds of patients said they would want to know how much their cancer treatment would cost them.

"Most patients don't want to be dealt with paternalistically, but as thoughtful people in need of advice," Schnipper said. "And since



bankruptcy is a reality, we feel we need to bring cost into that discussion somehow."

The proposed decision aid is in line with an increasingly important priority in medical practice: to respect the priorities of patients with life-threatening diseases in shaping their treatment. Although some patients will endure the harshest drugs to extend their lives, others would prefer to live out their lives without the toxic effects of treatment. Others may look at the cost they will bear and choose a cheaper approach, particularly if it's only a little less effective than a costly new drug.

As currently drafted, however, the new Value Framework relies heavily on medical practices and research forged in an era before "precision medicine" promised to tailor treatments to individual patients.

The single net health benefit score that is at the Value Framework's heart is based on a drug's record of safety and effectiveness in a large and undifferentiated patient population. But as scientists deepen their understanding of medical genetics, they are finding that many drugs work well only for a subset of patients whose cancers carry unique genetic mutations.

Under President Barack Obama's recent precision medicine initiative, clinical trials are expected to focus increasingly on how well drugs perform on smaller populations who are carriers of specific genetic variants. As those trials proceed, <u>cancer</u> treatments that look like a bad bet when used widely may look more promising when used in a specific population.

Schnipper was optimistic that as new clinical trials match particular patients to specific drugs, "the value of those drugs to those patients will escalate tremendously." The Value Framework, he said, will be able to keep up with the promise of precision medicine.



"We really don't want this to be a static, cast-in-stone framework," Schnipper said. "Over time, the value of certain treatment regimens may be refined."

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