

UK medical group rejects new skin cancer treatment

October 15 2011, By MARIA CHENG , AP Medical Writer

(AP) -- An independent British medical watchdog says the first treatment proven to help people with the deadliest form of skin cancer is too expensive to be used by the U.K.'s health care system, a recommendation critics called a potential death sentence.

The drug, Bristol-Myers Squibb's Yervoy, has offered some hope to people with advanced skin cancers, though a study of patients with advanced, inoperable [melanoma](#) showed it extended survival only four months on average.

The National Institute for Clinical Excellence, or NICE, advised Friday that at a cost of 80,000 pounds (\$126,600) Yervoy "could not be considered a cost-effective use" of health funds. A final decision is expected next month after a public consultation.

In the U.K., most medicines are paid for by the government, as long as they're recommended by the cost-efficiency watchdog. The agency commonly rejects expensive drugs, including recently advising against new treatments for [prostate cancer](#), [breast cancer](#), and multiple sclerosis, though patients and doctors are increasingly protesting the decisions.

The government usually adopts NICE's recommendations, meaning doctors in the government-funded health service cannot prescribe Yervoy without NICE's approval.

In its decision, NICE said it was not convinced by the evidence, saying

the data for Yervoy, which works by stimulating the immune system to fight [cancer](#), did not compare it to older drugs used to treat melanoma. NICE also said the trial was too short to know how long the drug's effects would last and raised concerns about the drug's side effects, including diarrhea, rash, fatigue and nausea, which they said could affect a patient's quality of life.

"We need to be sure that new treatments provide sufficient benefits to justify the significant cost (the [health care system](#)) is being asked to pay," said Sir Andrew Dillon, NICE's chief executive, in a statement.

[Patient groups](#) and charities slammed the decision, labeling it a "[death sentence](#)" for people with advanced skin cancer.

"The breakthrough that patients and clinicians throughout the U.K. have been waiting for arrived in the form of this drug," said patient advocacy group Factor 50 and the [skin cancer](#) charity SKCIN, in a statement. "To have come so close to a breakthrough and to be told no at this stage is truly devastating."

Drugmaker Bristol-Myers will provide additional evidence in hopes that the agency "will reconsider this decision so that all patients with metastatic melanoma can access this potentially life-extending treatment," European vice president Amadou Diarra said in a statement.

NICE does not usually approve any treatments that cost more than 30,000 pounds (US\$47,492) to buy an extra healthy year of life, though it does occasionally make exceptions for lifesaving therapies.

In recent years, NICE has been forced to overturn a number of its original judgments after public outcry. "They actually reverse their decisions quite a lot," said Aparna Krishnan, a senior health care and pharmaceutical analyst at IHS Global Insight in London.

In 2005, the agency refused to recommend Alzheimer's drugs including Aricept. Public protests forced a reconsideration, and the drugs were finally recommended to all Alzheimer's patients last year. In addition, NICE has reversed its decisions on drugs including the kidney cancer drug Sutent, the flu drug Relenza, Velcade for blood cancer, and Herceptin for stomach cancer.

NICE has also been criticized for taking too long to recommend drugs. After Herceptin was first approved for breast cancer, the agency had to scramble to speed up its evaluation process after several women sued their hospitals to get treatment before advice was issued.

Some analysts said the spiraling cost of specialized cancer drugs would mean fewer hospitals and insurers willing to pay for them - particularly those with cash-strapped public health systems.

"Drug companies, meet reality," said Erik Gordon, an analyst and professor at University of Michigan's Ross School of Business. "There isn't enough money to pay \$100,000 for therapies that don't show massive benefits, unless there is a politically powerful patient advocacy group behind it."

Analyst Krishnan said she wasn't sure if patient and doctor protests would ultimately convince NICE to recommend Yervoy, but acknowledged it was a possibility. "They are in a very difficult position," she said. "They are increasingly just looking at the cost, but the pressure from the public can be very powerful."

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