Is It Time To Take a Harder Look at the QALY?

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How much should maintaining a person's health actually cost? How do you determine that number? Should high-priced biologics be covered under public and private health plans if they are not cost-effective treatment options?

These questions often are posed when analyzing the cost-effectiveness of high-priced drugs — investigations that show the relationship between the total cost of treatment and the health benefit achieved compared with not using the treatment. With cancer drugs in particular, the argument can be made that costs are very high compared with the health benefit achieved, which usually amounts to a few extra months of life.

In the United States, these questions might be asked behind closed doors, but in the nationalized health systems of the United Kingdom and Canada, they result in the formation of public policy. If drugs are not deemed to be cost-effective, patients are denied access to them through their government-sponsored health coverage. With no federal policy in the United States requiring manufacturers to demonstrate that a drug is cost-effective, payers are left to rely on economic analyses — none of which are perfect and few of which are easy to interpret. With biologics triggering calls from payers for robust cost-effectiveness evaluations, existing metrics — such as the unpopular quality-adjusted life year (QALY) — may be worth a second look.

NICE says "no"

Since 2007, these agents have failed to receive U.K. approval for the following conditions:

Advanced and/or metastatic kidney cancer
sunitinib (Sutent)
bevacizumab (Avastin)
sorafenib (Nexavar)
temsirolimus (Torisel)

Advanced metastatic breast cancer
lapatinib (Tykerb)

Colorectal cancer
cetuximab (Erbitux)
bevacizumab (Avastin)

Locally advanced or metastatic lung cancer
erlotinib (Tarceva)

Multiple myeloma
bortezomib (Velcade)*

Non-small cell lung cancer
pemetrexed (Alimta)

*The manufacturer rebates the full cost of bortezomib for people who, after a maximum of four cycles of treatment, have less than a partial response.

Source: National Institute for Health and Clinical Excellence

BREAKING NEWS

The June 25, 2008 press release read, "Because insufficient evidence was provided by the manufacturers, NICE is unable to recommend the use of the following treatments in the NHS: bevacizumab…." (NICE 2008). With that, the United Kingdom's drug watchdog agency, the National Institute for Clinical Health and Excellence (NICE), effectively denied patients in that country access to Avastin, a high-priced, but potentially lifesaving, cancer treatment. The rejection had nothing to do with the drug's efficacy, but because NICE considered it not to be cost-effective for first-line treatment for non-small cell lung cancer or breast cancer. NICE requested more data from Roche, the drug's European manufacturer, demonstrating cost-effectiveness, but the company determined that bevacizumab would not meet the agency's criteria for cost-effectiveness.

NICE's decision was one more added to a long list of high-priced drugs that have been rejected solely because they were considered too expensive (box, left).

Michael Rawlins, chairman of NICE, stated in a *Financial Times* article, "I think the drug companies are really going to have to take a hard look at the value of their products and price them accordingly. If there is a small benefit, they cannot charge premium prices. Traditionally they charged what they thought the market would bear. But we can only afford to pay when the price for innovation is in proportion to what it delivers" (Jack 2008).

After NICE's decision, Roche's U.K. spokesperson, Greg Page, retorted that "Other healthcare systems seem to think it [bevacizumab] is fairly priced" (Jack 2008).

But that may not be the case soon. Although the United Kingdom accounts for only about 3 and a half percent of worldwide pharmaceutical sales, NICE assessments often are used informally in drug price negotiations throughout the world (Office of Fair Trading 2007). With biotech drug prices escalating, a number of countries are looking at NICE's recommendations closely and discussing the introduction of high technology assessments to judge not only clinical effectiveness, but also if a drug is cost-effective.

"The FDA does not require cost-effectiveness data. Does the drug work? Is it better than a placebo? Are the side effects tolerable? If yes, then the FDA will approve it," says Mark Rubino, MHA, chief pharmacy officer with Aetna Pharmacy Management, in Hartford, Conn. Last February, a U.S. Food and Drug Administration advisory committee voted 5–4 against approving bevacizumab for advanced breast cancer because the clinical trial found that although the drug significantly slowed the progression of cancer, it did not significantly extend life. The FDA went against the panel's recommendation and approved the drug anyway, a decision that led Republican Sen. Charles E. Grassley of Iowa to ask the Government Accountability Office to investigate the decision and others regarding drugs that "appear to have little to no effect in protecting lives and increasing health."

But even if the FDA did not approve Avastin for advanced breast cancer, the way the coverage and payment system works in the United States, patients would still have access to the drug off label as long as it is listed in a compendium, a reference compiled by cancer specialists.

The Centers for Medicare and Medicaid Services has taken steps toward looking at cost-effectiveness. But no federal agency conducts rigorous evaluations for each new drug, and private technology assessments are expensive undertakings. How are payers to determine value?

HOW TO DECIDE

One cost-effectiveness metric, the Quality Adjusted Life Year (QALY), is a tool used to capture quality-of-life gains, looking beyond patient survival. Under the QALY drugs are deemed cost-effective in the sense that the overall health benefits achieved are worth the cost. For example, cholesterol-fighting drugs that cost just a few thousand dollars per QALY saved are cost-effective treatments because they can prevent future heart attacks.

In the United Kingdom, although there is not a cutoff value, NICE recommends that drugs and treatments have a QALY at or below $31,000 to $46,000. "QALYs are used by NICE in the United Kingdom and by the Canadian Agency for Drugs and Technologies," says Elan Rubinstein, principal of the consulting firm EB Rubinstein Associates, in Oak Park, Calif. But in the United States, payers, including Medicare, generally have shied away from using QALYs in making coverage decisions. Many medical directors dislike the QALY because it is difficult to relate QALY data to their responsibilities; in other words, it doesn't always tell them what they want to know.

Rubino thinks there is a better way to measure cost-effectiveness. "We look at every condition and the side effects of particular drugs, so the cost benefit may not be so much that it is more effective, but that it is more beneficial because there are fewer side effects," says Rubino. He explains that from an insurer's perspective, side effects sometimes cost just as much money as the primary disease.

"We found some of the newer drugs for rheumatoid arthritis, Crohn's disease, and psoriasis are pretty effective in treating the symptoms and preventing the onset of more severe ones, but the side effects can be significant, like very serious infections. What we are looking at is the cost of those severe side effects. Then we can rank the drugs that treat a specific disease, as well as rank them in terms of how we contract with manufacturers and how we make decisions about first-, second-, and third-line therapy."

TO QALY OR NOT TO QALY?

So is the QALY metric a good academic exercise but more or less meaningless in the real world?

"QALY is not a useless tool," says Rubinstein. "It's the best tool available to link the benefits to the costs of a drug, device, or service. It's limited because the benefits may be intermediate outcomes that not everyone agrees are valid, or may be difficult to measure, or may have different levels of importance for different audiences."

QALY limitations may arise from an economic standpoint: Why should one payer spend the money to prevent a disease that is years down the road from developing? The drug or therapy will cost them money today, but will potentially save them nothing in the future because another payer will benefit from the preventive treatments.

Another challenge in putting a price tag on the cost of one's health is that many of the high-priced cancer drugs are palliative rather than curative, prolonging the eventual worsening of the disease. Rubino says that can be a challenge, "because the cost equation is a little more difficult to get a return on, at least in the short term."

Probably the biggest difficulty in analyzing cost-effectiveness is the mixture of public and private payers in the United States, each of which have unique reasons for making formulary decisions. Without a common motivation for evaluating a drug's cost-effectiveness, the QALY may bridge enough differences to help to guide payers until a more commonly accepted tool is developed.

REFERENCE

Jack A. Dose of reality: health services curb drug costs. «http://us.ft.com/ftgateway/superpage.ft?news_id=fto062320081419096427&page=2». Accessed Sept. 3, 2008.

NICE (National Institute for Health and Clinical Excellence). NICE drug reviews terminated when manufacturers fail to submit evidence. June 25, 2008. «http://www.nice.org.uk/media/BAC/D0/2008040Terminated.pdf». Accessed Sept. 4, 2008.

Office of Fair Trading. The Pharmaceutical Price Regulation Scheme: An OFT Market Study. February 2007. «http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft885.pdf». Accessed Sept. 3, 2008.

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