

Can Quality-Adjusted Life Year Avoidance Help in Oncology Drug Reimbursement Decisions?



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Oncologists who advise payment authorities in Canada or elsewhere have good reasons to worry about which new therapies to fund. The last 6 or so years have seen the arrival of numerous drugs costing tens of thousands of US dollars per patient annually. Most of these drugs exploit biotechnology methods to target biological processes with exceptional specificity, often leading to therapeutics that for practical

purposes, are nearly unique in their clinical effects. Clinical and financial success begets ever faster development, so we can expect many more such drugs.¹ Moreover, combination therapy may become almost as common in oncology as in HIV therapy, raising the possibility of treating patients with more than one \$20,000 per year drug.

Payers have also discovered that many biotechnology-based oncology drugs are largely immune to traditional price controls, leaving Canadians and others paying more or less a single world price.¹ Clearly, payment agencies have to draw lines, and some patients will be denied indicated therapies. The usual line-drawing tool is a cost-effectiveness analysis, with reimbursement becoming less likely as the costs of a quality-adjusted life year (QALY) climbs beyond an implicit or explicit frontier. QALY analysis, however, is mind-numbingly mechanical, irretrievably murky, and sometimes, highly context-specific. The resulting unease is one factor in the search for alternative approaches based on ethical analysis and transparency.

In this issue of *JOP*, Browman et al² propose an imaginative example of what might be called a non-QALY component in reimbursement decisions. Inspired by the “Accounting for Reasonableness” approach advocated by Norman Daniels and others,^{3,4} Browman et al wish to integrate the experience and intuition of clinical oncologists into reimbursement decisions. Their 6-STEPPPs (Systematic Tool for Evaluating Pharmaceutical Products for Public Funding Decisions) method poses severe difficulties, but its virtues should not be dismissed lightly. Given that oncologist members of reimbursement committees are bound to exercise influence, it is better to require them to ponder trade-offs rather than permit those trade-offs to languish in obscurity. Enumerating the precise dimensions of those trade-offs—an apparently simple task that is

fraught with difficulty—will enhance the process. Getting oncologists, patients, families, and health care payers to think explicitly about what new therapies will bring to the clinic is, again, superior to the alternative scenarios of ignorance or seething frustration. This is probably true despite the threat (surely understood by the authors) of highly publicized “rescue” missions that can distort reimbursement decisions.⁴

That said, there are serious questions about how the results of 6-STEPPPs would be used, and to what end. The essential problem arises at the very beginning. In a leading example of the “Accounting for Reasonableness” approach cited by the authors,⁴ the analysts did not worry about costs until after deciding to cover a therapeutic class on the basis of “health needs.” Then they planned to exploit the price negotiations that invariably occur between payers and competing drug sellers. But for Browman et al, drug costs are the starting point, and there is little in the way of price negotiations to exploit. In this context, it makes little sense to decide on expensive new cancer therapies without regard to expenditures for nononcological conditions, as 6-STEPPPs does. The assumption of an oncology drug budget does not help. Such budgets are surely subject to change in the wake of the dynamics of drug development. Rather than deciding whether to add a new oncology therapy subject to today’s oncology budget constraint, it might be better to ask whether the arrival of a new drug merits adjustments in resource allocation among diseases and conditions.

With costs at the fulcrum of decision-making rather than an add-on, one has to worry about the mechanisms of 6-STEPPPs. It is organized around subjective 5-point rating scales. Lacking a money metric, the scales provide a weak basis for comparisons across drugs or therapeutic classes. Scores are summed across items. But the identification of items is as much art as science and is to some extent arbitrary, and the influence of core items (“clinical impact,” say) is diluted as new items are added. Annual costs are central to the final calculations, but no weight seems to be given to how many years of therapy will be necessary.

This analyst (who confesses to be an economist) will be surprised if 6-STEPPPs becomes widely used without substantial modification. Nonetheless, the ideas motivating its creators will continue as factors to be reckoned with.

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