A “Shot Heard ’Round the World” on Cancer Drug Costs?

Recently, members of the pharmacy and therapeutics committee at Memorial Sloan-Kettering Cancer Center (MSKCC) in New York reported that MSKCC will not offer ziv-aflibercept (Zaltrap, Sanofi Oncology) to patients with advanced colorectal cancer at their hospital, because the drug is too expensive. This decision was reached despite data from a double-blind, placebo-controlled, randomized trial showing that adding ziv-aflibercept to chemotherapy improved overall survival in patients with refractory colorectal cancer previously treated with oxaliplatin. And the decision was made despite the approval on August 3, 2012, by the FDA for use of ziv-aflibercept in combination with FOLFIRI chemotherapy.

Notwithstanding the trial data and FDA approval, MSKCC staff called the decision a “no brainer.” The median survival benefit with the drug was minimal (1.4 months); the drug has a similar mechanism of action to bevacizumab, which is already available for advanced colorectal cancer; and the drug price—$11,000 per month—was astronomical compared with the merely exorbitant bevacizumab at $5000 per month.

This is surely not the first formulary decision to be made with cost in mind, nor is it the first to recommend against new, expensive treatments with minimal advantage over other options. I suspect that almost every hospital and clinic formulary committee in the country has made similar decisions for all sorts of drugs, from antibiotics to chemotherapy, and for all sorts of medical equipment and devices. Of course, every business in the world chooses supplies based on cost, usefulness, and alternatives.

However, the decision at MSKCC, and more particularly its public declaration, may serve as a “shot heard ‘round the world” for voluntary limits on the use of expensive oncology drugs. And like that famous shot fired by Massachusetts minutemen at a bridge in Concord, this decision both reflects rapid cultural changes and will require far broader support and ammunition to have lasting effect.

With that understanding, several features in this decision warrant greater awareness and appreciation:

• Academic centers are becoming cost conscious. Many academic cancer centers are under increasing pressure to show value and cost awareness. Historically, they have been perceived as expensive places for treatment. Whether this characterization is fair is a different discussion. Regardless, academic hospitals are seeking ways to show that they can deliver cost-effective care. One way is to disavow expensive, relatively ineffective treatments or interventions. Academic centers are now incentivized to identify such opportunities to curtail cost without meaningfully affecting outcomes.

• Academic centers are uniquely positioned to make tough choices about appropriate use. As home to distinguished clinicians and investigators, academic oncology centers have the expertise and reputation to decide what the best treatments are, as well as where and when to incorporate novel therapies. Many academicians are also familiar with guideline or pathway development and thus have perspective on where within treatment algorithms such novel approaches belong. Finally, the nature of academic centers as non-profit institutions with salaried clinicians liberates academic hospitals and practitioners to do the right thing without undue preoccupation with personal gain. The role of arbiter for treatment choices is a tremendous value-added contribution from academic cancer centers and should be widely recognized as one of their important functions.

• Public disclosure of treatment recommendations is critical. An anonymous shot in a forest has none of the impact of the same shot fired across a public bridge. The
importance of the MSKCC decision is not so much in the decision itself, but in their public disclosure of it. This is more likely to guarantee a uniform treatment approach within the institution, as disclosure invites those who disagree with the decision to seek care elsewhere, and critically alerts regulators, third-party payers, and drug manufacturers that there are limits to what a hospital might indulge in terms of drug pricing. This disclosure should start a dialogue to define those boundaries. The New York Times will not be interested in publishing most pharmacy and therapeutics committee recommendations. But all clinics have Web sites on which they can readily post their active formulary and treatment pathways. Such clear disclosure will be an essential part of the emerging oncology marketplace.

- Conflicts of interest still matter. If institutional formulary or pathway committees are to have a larger say in the treatments that patients receive, it becomes imperative to minimize conflicts of interest. In The New York Times article, the authors disclosed that 2 of the 3 were consultants for a pharmaceutical company with a product that competes with ziv-aflibercept. Such relationships are not likely to encourage confidence in the choices made by clinical experts and could curtail bold decisions that might be needed in the future. One way around this problem would be for institutions to take seriously the importance of formulary/guideline committee work and to compensate clinical experts appropriately for their efforts. In return, the expectation would be that these specialists would refrain from commercial conflicts.

- Guidelines still matter. Strong, well-respected guidelines are an essential part of the process for making difficult decisions on optimal treatment. MSKCC was empowered in their choice by prior NCCN guidance on advanced colorectal cancer. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Colon Cancer had endorsed FOLFIRI as second-line therapy for advanced colorectal cancer, with or without ziv-aflibercept. In citing the NCCN Guidelines in their public disclosure, the MSKCC committee tacitly acknowledged the value of having guidelines such as those from NCCN to provide “cover” for withholding an expensive agent.

One decision by one hospital committee won’t save the health care system. But voluntary choices by guideline and formulary committees may be a key strategy for assuring quality clinical care while responsibly managing costs. The choices at MSKCC might be a potent shot heard loudly in many quarters.

References