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Value in Cancer Care

Those Who Pay Have a Say: A View on Oncology Drug Pricing and Reimbursement

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Disclosures of potential conflicts of interest may be found at the end of this article.

Scores of articles have been published stating that cancer therapy costs are unsustainable and unjustified, and the effect of all of those papers has been nothing but a continued escalation in the price of cancer therapies. It is time to take action rather than to simply lament the present. This article assumes that costs are too high, and it suggests four specific strategies to help lower those costs. Although some examples and data from UnitedHealthcare are used in this article, the views reflected in this essay are solely those of the author.

To better understand these recommendations, a quick review of basic economics is helpful. Price in a free market is determined by supply and demand. It is a safe assumption that pharmaceutical firms are able to manufacture unlimited supplies of medications if the demand is high enough. Demand is determined by the consumer's willingness to pay, and it is this critical component that is altered in health care purchasing decisions. The free market is an illusion, because the buyer is not the payer. The consumer, a patient consulting with a physician, makes a selection and then asks a third party, the payer, to write the check. Any rational person in this scenario would be indifferent to the price. The payer functions as a broker for the patient. The payer, however, has limited resources, and this constraint forces decisions about the value of therapies. Those decisions may be different from the patient's values, and some conflict is inevitable in this situation. An economist's solution removes the payer and allows the patient to purchase her care directly, but any oncologist—and any patient—knows that without insurance, precious few patients could afford therapy. Retaining insurers is essential for keeping the health care system intact, but it does mean that the payer must find a balance between affordability and access to therapy. Following are four strategies that could help.

Remove Coverage Mandates From State and Federal Insurance Law

Insurance regulation forces payers to pay for any FDA-approved cancer therapy in 42 states; Medicare has a similar provision. But mandatory coverage eliminates any consideration of value. The therapy could be curative or simply add one additional day of life, but the price cannot be negotiated if that therapy has an FDA-approved indication. The laws were originally well intended. As expensive therapies emerged, legislators were concerned that insurers would simply refuse to pay.

The unintended consequence of this action becomes apparent when multiple therapies are available; payers cannot make decisions based on the value of therapy and substitute one therapy for another when it is clinically appropriate. Removing this legislated requirement would force pharmaceutical manufacturers to compete on price and outcomes. The market could function normally.

The lung cancer therapy necitumumab is an excellent example of why mandates force prices beyond reason [1]. This drug was added to cisplatin and gemcitabine and compared with cisplatin and gemcitabine alone in patients with stage IV squamous cell lung cancer. Three percent of the patients receiving necitumumab suffered cardiac arrest. The difference in median progression-free survival was a mere 0.2 months (5.7 vs. 5.5), but overall survival favored the necitumumab group by 1.6 months (11.5 vs. 9.9). These results are so meager that the National Comprehensive Cancer Network assigned a level 3 recommendation to the drug—an endorsement that most insurers, including Medicare, do not cover. But the FDA approval mandates require coverage at any price. The manufacturer priced this drug at $11,430 per month. The competing regimen, cisplatin and gemcitabine, costs less than $1,000 per month. It is difficult to believe that anyone except the manufacturer would consider this to be a value, but it does not matter. The law mandates coverage and therefore price is not negotiable.

Other mandates are emerging. Several states are now considering laws to prohibit step therapy for cancer. Step therapy requires treatment with a preferred regimen before the patient is eligible for a second therapy. This strategy is useful for drugs that have similar clinical response rates because a payer can obtain competitive bids and then give preference to the lowest-cost regimen. There have been so many drug discoveries in the last decade that many cancer types now have multiple effective agents. Step therapy allows patients to obtain their treatment for a lower cost. Prohibiting

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step therapy eliminates competition, raises costs, and hurts everyone except the pharmaceutical manufacturer.

A free market determines prices based on merit, and mandates prevent free market actions. It's a lose-lose proposition for patients and payers.

Create Performance Transparency for Drug Regimens

Cancer patients are benefiting from the explosion of new therapies, and that is good news. The rapid expansion of therapeutic options creates a new problem, however. Often it is impossible to make comparisons between the available options because there are no phase III clinical trials directly comparing the regimens. Drug manufacturers have no incentives to do these trials—comparison trials produce winners and losers—unless it is the only option to win FDA approval. A rational manufacturer seeks other study designs to win FDA approval. No manufacturer gambles that their drug might lose in a direct comparison with competitors, particularly when the mandates already guarantee coverage. Without direct comparison data, new drugs use marketing techniques to win approval by physicians: the company with the best sales force is the usual winner.

Clinicians are left to compare the results of the drug's original FDA registration trial. These trials enroll patients with an excellent performance status and no comorbidities. The trials all have subtle differences in their designs that require rigorous, detailed analysis. ASCO recently attempted a value comparison between competing regimens without available phase III studies [2]. The formulas were complicated, and it took months to do the actual analysis. The practicing clinician does not have the time for this work.

The patients in the typical oncology clinic are frequently much different than in the registration trials: older, sicker, and already partially incapacitated by their comorbid diseases. It is challenging to understand how those patients will fare compared with the original trial. The clinician is left to make the best guess when multiple regimens are available for selection.

This information gap can be solved. UnitedHealthcare's prior authorization tool collects the clinical information necessary to reach a clinical decision node in the National Comprehensive Cancer Network guidelines. The oncologist selects one of the recommended regimens to obtain an approval. This operational process for claim payment also creates a patient registry with an intent-to-treat declaration. The patient's claims history is included in this registry, over time creating a longitudinal medical record describing the patient's course. These registries track hospitalization rates, total cost of care, side effects, and progression-free survival or relapse rates without any further data requirements from the physician. The tool registered more than 24,000 patients in the first 6 months of operation.

In 2017, the results of each recommended regimen in patients exactly like a given patient will be displayed when the oncologist uses the online prior authorization tool. The process of prior authorization is transformed into a helpful decision support tool. The company also plans to offer this data to consumers in a simpler form.

Comparison data enhances physician and patient discussions by informing them of the benefits and trade-offs of competing regimens. One could expect changes in prescribing: underperforming regimens would be eliminated, and comparable regimens would compete on cost or side effects. Clinical care can only improve with more data transparency.

This same data drives more rational prices from manufacturers. For example, if two regimens produce similar clinical results, but one is three times more expensive, a manufacturer could expect to see the expensive regimen contracted for a lower rate. Once again, mandates are an important barrier to this strategy. Even with the persistence of mandates, however, physicians have the information to change their prescribing, particularly as more and more payment programs consider the total cost of care as a performance measure.

Profit Margins for Administering Drugs Should Be Capped at 18%

Paradoxically, this article asks for deregulation in the first recommendation and now seeks regulation as its third strategy. One of the unfortunate consequences of provider consolidation has been the acquisition of many community oncology practices by hospital systems. Most hospital systems hold monopoly or oligopoly power in their markets, and they have linked their oncology programs to hospital services access in payer contract negotiations. Put simply, the hospitals are saying, "If you want our beds, you have to take our prices for oncology treatment." The financial effects are stunning. UnitedHealthcare's average payment for community physicians is average sales price (ASP) + 28%, but the average for hospital-owned cancer clinics is ASP + 152% for exactly the same medications. Payer negotiating power is lost, and patients are literally charged twice as much for their therapy because of the location of their treatment. This monopoly/oligopoly situation is not correctable with market forces, and thus is an appropriate situation for regulation. The actual amount is not critical for this strategy, but a reasonable, capped percentage is essential.

Through the 340B program, hospitals are often allowed to acquire drugs at a significant discount compared with physicians. That discount and the extremely large profits from negotiations create the cash flow for acquiring physician practices. It is the patient who pays this bill, and once the community practices are absorbed, the patient/consumer has no alternatives.

Hospitals argue that they need the profits from the cancer center to fund other services that operate at a loss. The author believes it is immoral to force vulnerable patients to pay triple-digit mark-ups because they have cancer. If an emergency room loses money, then the charges for emergency services should be increased rather than putting this burden on a cancer patient. Exorbitant profits encourage overutilization; hospitals that depend on their cancer program for sustaining operating margins are taking risks for the unintended consequences of overtreatment.

Place Every Patient With a Genetic Mutation in a Clinical Trial

This spring, I attended a hastily rescheduled wedding. The bride's father is dying from metastatic colon cancer, and it

became obvious he would not survive to the original wedding date. He escorted her down the aisle wearing white gloves because his hands have been desquamated for months. He cannot hug her because his peripheral neuropathy wracks his body with pain when he grasps something with his hands. These side effects were the result of an off-evidence trial of a targeted therapy. He was fully aware of the risks, but his toxicities were more severe than anticipated. The tragedy of this story is not that he will die; he was aware of his prognosis and knowingly accepted the risks. The tragedy is that his life and his experience have been wasted—no one other than his attending physician learned from my friend's experience. He was not enrolled in a clinical trial.

Oncologists are tempted every day to scan their patient's cancer genome for mutation that responds to a targeted agent in another cancer type. Ordering that therapy and not enrolling the patient in a clinical trial wastes precious resources, time, and our ability to further the science of oncology. All lives matter; no one should be denied entry into a trial or registry.

The best moonshot goal for Vice President Biden is "100,000 patients enrolled in trials in 3 years." Response signals in new cancers would direct pharmaceuticals to promising opportunities. Patients would have the opportunity to try a targeted therapy without the financial risk. Physicians would have alternatives to standard therapies that work poorly.

This is not a small undertaking, and the term "moonshot" is a deliberate description rather than a cliché. Master trials such as the Targeted Agent and Profiling Utilization Registry (TAPUR) trial sponsored by ASCO must be accessible throughout the country [3]. The trials would have to be flexible and nimble; trials need to be portable, allowing patients to be treated in their own communities. Physician time is required to locate the right trial and complete the required records. None of these changes are easy or simple, but if the profession wants to understand the value and the limitations of the genetic-directed approach to therapy, they are essential.

Conclusion

The four actions recommended above require commitment, rigor, and courage. Failure to address the problem drives the whole medical care system to a crisis point. No one involved in cancer care—pharmaceutical firms, physicians and nurses, payers, and most importantly, patients—will escape the consequences of failing to change. It is time to stop writing articles and begin doing something different.

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Editor's Note: See the related article, "Getting Past No in Cancer Care," by Michael Kolodziej, on page 782 of this issue.