Drug Pricing and Value in Oncology
Patricia M. Danzon and Erin Taylor

doi: 10.1634/theoncologist.2010-S1-24

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://theoncologist.alphamedpress.org/content/15/suppl_1/24
Drug Pricing and Value in Oncology

PATRICIA M. DANZON, ERIN TAYLOR

The Wharton School, University of Pennsylvania, Philadelphia, Pennsylvania, USA

Key Words. Economics • Pharmaceutical • Costs and cost analysis • Insurance • Cost-effectiveness analysis • Medicare

Disclosures: Patricia M. Danzon: Research funding/contracted research: Merck; Erin Taylor: None.

The content of this article has been reviewed by independent peer reviewers to ensure that it is balanced, objective, and free from commercial bias. No financial relationships relevant to the content of this article have been disclosed by the independent peer reviewers.

ABSTRACT

This paper examines the issue of prices, relative to value, for cancer drugs. The analysis focuses on the effects on manufacturer pricing incentives of insurance coverage, specifically, the effectiveness of patient cost sharing, incentives created by reimbursement rules for physician-dispensed drugs, and payer ability and incentives to negotiate discounts. For pharmacy-dispensed cancer drugs, both Medicare Part D prescription drug plans (PDPs) and private payers’ pharmacy benefit managers are increasingly placing these drugs on specialty tiers that offer no leverage for negotiating discounts and imply often unaffordable cost sharing for patients who lack catastrophic coverage. Simulation analysis of financial risks faced by PDPs confirms their incentives to place costly drugs on specialty tiers if more preferred formulary placement would increase use, possibly because of adverse selection risk. Faced with largely price-insensitive consumers and payers, manufacturers would rationally charge high prices. This situation is exacerbated for physician-dispensed cancer drugs, where Medicare’s average selling price plus 6% reimbursement rule favors high-priced drugs. Because U.S. payers do not require evidence on prices relative to value, U.S. data are unavailable to test whether prices are higher, relative to value, for cancer drugs than for other drugs. Evidence from the Canadian Common Drug Review on cost-utility values suggests that cancer drugs are relatively high priced, although conclusions are tentative because of very small samples and non-U.S. data. Making such outcomes-adjusted prices available in the U.S. would be helpful to physicians, payers, and patients and indirectly constrain pricing to align with value. The Oncologist 2010;15(suppl 1):24–31

INTRODUCTION

High prices for cancer drugs are a growing concern to payers and patients, given the large number of cancer drugs in development. Although new drugs may offer health benefits, their high prices raise questions of crowd-out of other services in payer budgets, affordability of copayments to patients, and concern whether the health benefits gained warrant the high cost. These concerns reflect the broader challenge of assuring value for money in health care, which is less constrained by market forces than are other sectors of the economy.

For most goods and services, we rely on standard competitive markets to align prices with value to consumers and costs to producers. If consumers are reasonably well in-
formed and spending their own money, the prices they are willing to pay reflect their valuation, and consumer price sensitivity also constrains manufacturers to charge prices that approximate costs, provided competitive alternatives are available. Thus, in well-functioning markets the “invisible hand” of the price system aligns value to consumers with cost to producers and hence assures that resources are allocated to yield maximum value.

However, health care markets in general and pharmaceutical markets in particular function less well to align value, price, and cost, because necessary conditions are weaker. Patients, payers, and even physicians often lack good information about effectiveness and risks, especially for new drugs. Patents and other market exclusivities limit competition in order to preserve incentives for research and development (R&D), but thereby also reduce competitive pressures on prices. Most important, insurance drives a wedge between the out-of-pocket prices consumers pay and the prices manufacturers receive, with the difference paid by insurance. Insurance is designed to protect consumers from financial risk and assure access to otherwise unaffordable treatments. But if insurance is paying most of the bill, consumers (and their physician agents) have less incentive to be price sensitive, which in turn creates incentives for manufacturers to charge higher prices than they would if patients were paying in full, unless payers intervene. Although most insurance requires cost sharing, to preserve some patient price sensitivity, on costly services even modest coinsurance undermines financial protection: a 30% coinsurance on a drug costing $40,000 or $12,000 may lead many patients to simply forego the treatment. For such costly services, alternative payer reimbursement and formulary strategies may be a useful addition to modest patient cost sharing, to assure prices are commensurate with value.

In this paper, we examine the reimbursement and cost-sharing rules for cancer drugs used by public and private insurances in the U.S. to determine whether current approaches provide reasonable constraints on manufacturer pricing and reasonable financial protection for patients. Ramsey provides an earlier discussion of these issues [1]. We also provide limited evidence on whether actual prices for cancer drugs are high, relative to value, compared with other drugs. Simply comparing price per dose for drugs to treat different conditions is an apples-to-oranges comparison. Meaningful comparison requires normalizing the different drug prices by their respective expected health outcomes. The most widely accepted outcomes-adjusted price metric is the cost per quality-adjusted life year gained (cost/QALY). Unfortunately, a comparison of cost/QALY for oncologics versus other drugs is not possible with available U.S. data. We therefore report Canadian data, and discuss why the Canadian data are plausibly indicative of U.S. prices. We conclude that efficiency in drug pricing and resource use for cancer could be enhanced by changes in our insurance and reimbursement systems, including reporting of outcomes-adjusted prices to enable physicians, patients, and payers to make more informed choices.

METHODS

We review the major U.S. insurance coverages for cancer drugs with a focus on their effects on manufacturer pricing. We conclude that Medicare Part B (for physician-dispensed drugs) creates incentives for manufacturers to charge high rather than low prices. Medicare Part D (for pharmacy-dispensed drugs) places prescription drug plans (PDPs) at partial financial risk and hence incentivizes them to actively manage drug spending. However, using a simulation model, we show that the Part D benefit design creates incentives for PDPs to place costly cancer and other specialty drugs on a specialty tier, with high patient coinsurance, rather than requiring manufacturers to compete through price discounts for preferred tier placement, which would reduce drug prices for payers and reduce copayments for patients, but also increase financial exposure for PDPs.

Available data on drug prices in the U.S. (for Medicare Part B, see http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/; for Medicare Part D, see http://www.medicare.gov/MPDPF/Public/Include/DataSection/Questions/GeneralQuestions.asp) report price per dose and dose-specific price per month, respectively, for a wide range of drugs. Using such data to compare prices across different types of drugs requires defining the number of doses per standard treatment course for each drug, aggregating from price per dose to price per treatment, and adjusting this treatment price by a measure of health outcome gained. Payers in many other countries review estimates of outcomes-adjusted cost per treatment, using measures such as cost/QALY, as one input to reimbursement decisions. Such data are not available for the U.S., because U.S. payers do not require them. Our review of data published by the Canadian Common Drug Review (CCDR) supports the hypothesis that cancer drugs have relatively high outcomes-adjusted prices, compared with other drugs, but conclusions are tentative because of very small sample sizes. We explain why these Canadian prices are plausibly indicative for the U.S., but such projections are necessarily tentative. We conclude with policy implications.
RESULTS

Insurance Structure and Pricing
Most cancer drugs are dispensed in physician offices and are therefore covered under Medicare Part B or by a private insurer's medical benefit, rather than Medicare Part D or the private patient’s pharmacy benefit. Prior to 2005, Medicare reimbursed dispensing physicians at 95% of average wholesale price (a list price), while manufacturers competed for market share by offering discounts to increase the physician’s margin between the reimbursement and their acquisition cost. Since 2005, Medicare Part B pays average selling price (ASP) (the volume-weighted average manufacturer selling price, lagged two quarters) plus 6%. This shift to ASP reimbursement reduced physicians’ dispensing margins and Medicare payments in the short run. But in the longer run, the ASP formula is counterproductive to value-based pricing and cost control. It creates perverse incentives for manufacturers to compete by charging high rather than low prices, because a higher price offers a larger margin to the dispensing physician and this may influence prescribing, other things equal [2]. The main impact of the perverse ASP incentives is likely in higher initial launch prices, which manufacturers can set freely, rather than large postlaunch price increases, which may squeeze physician margins because of the two quarter lag in adjusting ASP reimbursement. Because many private payers follow Medicare reimbursement, this Part B reimbursement rule and the perverse incentives it creates for manufacturers have likely contributed to high prices for oncologics and other physician-dispensed drugs. This upward pricing pressure may spill over to pricing of pharmacy-dispensed drugs, because manufacturers would rationally set similar prices of physician-dispensed and pharmacy-dispensed formulations of the same compound.

Given this price-increasing effect of Medicare’s ASP + 6% reimbursement rule, patients’ 20% cost sharing provides the only countervailing constraint on prices for Part B drugs. However, faced with the 20% cost sharing on high-priced drugs, including many oncologics, patients likely fall into two groups. Patients whose supplementary insurance—either Medigap or Medicaid—covers the cost sharing would be price insensitive, whereas those who must pay the 20% coinsurance out of pocket may forego the drug, unless they are referred to a patient assistance program or a hospital outpatient department that may waive the copayment. Thus, if most patients have supplementary insurance while those who must pay out of pocket drop out of the market at quite low prices, the coinsurance provision provides little if any constraint on manufacturer pricing because those patients who remain in the market are heavily insured and price insensitive. Of course, the manufacturer’s optimal pricing strategy depends on how many patients drop out at each price level. Documenting this would require detailed empirical analysis that is beyond the scope of this paper. However, this hypothesis suggests that Medicare Part B’s ASP + 6% reimbursement creates incentives for manufacturers to charge high prices for cancer drugs and other physician-dispensed drugs, relative to their health value, and that the 20% patient coinsurance is at most a weak constraint.

Unlike physician-dispensed drugs, for which patient cost sharing is the only potential constraint on prices, drugs that are dispensed through retail pharmacies may be actively managed by pharmacy benefit managers (PBMs) for private plans and by PDPs for Medicare Part D. These PBMs and PDPs are often operated by the same companies and use similar tiered formulary strategies to constrain drug prices. For many common drug classes, PBMs/PDPs place select “preferred” on-patent drugs on a second tier with a modest copay (about $30 per script), putting “nonpreferred” on-patent drugs on a third tier, with a significantly higher copay ($45–$60 per script). PBMs use this cost-shares for classes of drugs such as cancer drugs, if each drug has a unique therapeutic profile such that doctors and patients are unwilling to accept formulary controls over clinical choices. But as more drugs become available in such specialty classes, one might expect to see PBMs/PDPs making more use of preferred tier placement to negotiate discounts. In principle, this could improve access for patients through lower copays and reduce drug costs for PBMs and payers who receive the discounts.

In practice, however, despite the growing number of drugs in specialty classes, PDPs are increasingly placing drugs costing ≥$600 a month on a fourth “specialty” tier with a 25%–33% coinsurance rate, and PBMs are following [3, 4]. Anecdotal evidence suggests that, faced with cost sharing of hundreds of dollars, patients fall into two camps, depending on whether or not they have supplementary or catastrophic insurance. Seniors would rapidly exceed Medicare Part D’s catastrophic threshold, such that their cost share is at most 5% (zero for Medicaid eligibles), while the PDP pays 15% and taxpayers pick up the remaining 80%. Private patients with a catastrophic limit on their cost...
sharing would also face zero or minimal copayment, the
PBM’s share is zero, and most of the cost is shifted to the
health plan or the self-insured employer. Thus, for patients
with catastrophic coverage, cost sharing becomes largely
moot and they are price insensitive, whereas patients with-
out catastrophic coverage would likely not fill the prescrip-
tion or would apply for patient assistance programs.

Thus, oncology drugs illustrate the basic problem with
reliance on patient cost sharing to constrain prices for costly
services: A coinsurance percentage that is sufficient to in-
fluence manufacturer pricing is an unaffordable expense to
many patients. Catastrophic protection under public or pri-
vat programs is designed to protect patients from this risk.
But if these fully insured patients are the majority of cus-
tomers, while those who face the full coinsurance forego
the drug or apply for patient assistance programs, the coins-
urance has little constraining effect on manufacturer pric-
ing. In other words, given our current insurance systems,
which rely almost exclusively on patient coinsurance to
constrain prices, and, appropriately, also often include a cap
on patient financial exposure, the manufacturer’s optimal
strategy may be to set a high price for the highly insured
majority while offering heavy discounts or patient assis-
tance to those (at least some) who cannot afford the cost
sharing. In the absence of other payer constraints, such in-
surance does little to constrain manufacturer pricing and
may also result in nonoptimal patient care.

### Table 1. Data on cancer versus noncancer drug approvals by the Canadian Common Drug Review (CCDR)

<table>
<thead>
<tr>
<th></th>
<th>Cancer b</th>
<th>Cancer c</th>
<th>Noncancer b</th>
<th>Noncancer c</th>
</tr>
</thead>
<tbody>
<tr>
<td>n of drug indications revieweda</td>
<td>10</td>
<td>10</td>
<td>108</td>
<td>108</td>
</tr>
<tr>
<td>n of drugs with cost utility provided</td>
<td>5</td>
<td>5</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Maximum</td>
<td>$101,000</td>
<td>$80,000</td>
<td>$137,000</td>
<td>$137,000</td>
</tr>
<tr>
<td>Mean</td>
<td>$68,800</td>
<td>$60,800</td>
<td>$63,037</td>
<td>$58,448</td>
</tr>
<tr>
<td>Median</td>
<td>$71,000</td>
<td>$61,000</td>
<td>$63,000</td>
<td>$59,000</td>
</tr>
<tr>
<td>Minimum</td>
<td>$36,000</td>
<td>$36,000</td>
<td>$9,225</td>
<td>$4,919</td>
</tr>
</tbody>
</table>

Recommendation

<table>
<thead>
<tr>
<th></th>
<th>Cancer b</th>
<th>Cancer c</th>
<th>Noncancer b</th>
<th>Noncancer c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not list</td>
<td>2</td>
<td>2</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>List</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>List in similar manner</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>List with criteria/conditions</td>
<td>3</td>
<td>3</td>
<td>14</td>
<td>14</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Cancer b</th>
<th>Cancer c</th>
<th>Noncancer b</th>
<th>Noncancer c</th>
</tr>
</thead>
<tbody>
<tr>
<td>n of drugs without cost utility provided</td>
<td>5</td>
<td>5</td>
<td>83</td>
<td>83</td>
</tr>
<tr>
<td>Do not list</td>
<td>3</td>
<td>3</td>
<td>41</td>
<td>41</td>
</tr>
<tr>
<td>List</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>List in similar manner</td>
<td>1</td>
<td>1</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>List with criteria/conditions</td>
<td>1</td>
<td>1</td>
<td>27</td>
<td>27</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Cancer b</th>
<th>Cancer c</th>
<th>Noncancer b</th>
<th>Noncancer c</th>
</tr>
</thead>
<tbody>
<tr>
<td>n of drugs without cost utility provided</td>
<td>5</td>
<td>5</td>
<td>83</td>
<td>83</td>
</tr>
<tr>
<td>Do not list</td>
<td>3</td>
<td>3</td>
<td>41</td>
<td>41</td>
</tr>
<tr>
<td>List</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>List in similar manner</td>
<td>1</td>
<td>1</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>List with criteria/conditions</td>
<td>1</td>
<td>1</td>
<td>27</td>
<td>27</td>
</tr>
</tbody>
</table>

*Including all final (most recent) recommendations from the CCDR for a given indication of a drug.

*Calculated using the maximum cost utility (if there was a range provided).

*Calculated using the median cost utility (if there was a range provided).

### Empirical Evidence on Prices

Comparing prices across drugs is an apples-to-oranges ex-
ercise unless each price is normalized by some measure of
the health value it delivers. Cost-utility analysis addresses
this problem by comparing drug prices, adjusted for any
cost offsets, relative to QALYs gained. Comparison of cost/
QALY provides a reasonable measure of the value gained
per dollar spent across different drugs or health interven-
tions, provided a standardized and comprehensive method-
ology is used to measure costs and outcomes. Payers in
many countries require manufacturers to submit evidence
on the comparative effectiveness of new drugs relative to
current treatment, and/or cost/QALY, as one input in reim-
bursement review. Because U.S. payers do not require such
information, outcomes-adjusted prices are not readily
available based on U.S. data.

To provide some evidence on outcomes-adjusted drug
prices for cancer versus other conditions, we therefore draw
on data submitted to the CCDR, which is tasked to review
comparative effectiveness, prices, and value for money for
new drugs and to make (nonbinding) reimbursement rec-
ommendations to Canada’s provincial drug formularies.
Table 1 summarizes our review of the evidence on the cost-
utility ratios for cancer versus noncancer drugs, reviewed
by the CCDR from May 2004 to May 2009. Of the 10 can-
cer drug indications and 108 noncancer drug indications re-
viewed, only five and 25, respectively, include cost-utility
information (the majority of the ratios are cost/QALY, but a couple are cost per life year gained). Within the noncancer group, we excluded one drug that was an extreme outlier at $363,516 per QALY and was subsequently withdrawn from the market because of adverse events. We report results based on the maximum and the mean cost/QALY for each drug, if a range was reported.

Comparing each drug’s maximum cost/QALY, the overall mean, median, and minimum are higher for cancer than for noncancer drugs, specifically, $68,800, $71,000, and $36,000 for cancer drugs, compared with $63,037, $63,000, and $9,225 for noncancer drugs. The same conclusion holds when the comparison is based on each drug’s median cost/QALY. The CCDR’s recommendations for reimbursement provide an indication of its willingness to pay and the criteria used. The CCDR’s commentary makes clear that it considers the quality of the effectiveness evidence and other factors, not just the cost/QALY ratio. Of the 10 cancer drugs reviewed, five received some positive reimbursement recommendation (one “in similar manner” and four “with criteria/conditions”), and a similar percentage (58 of 108) of the noncancer drugs was recommended for reimbursement. Of course, any conclusions based on these data are tentative because of the small sample size. Taken at face value, this evidence suggests that there is a wide range of prices for cancer and noncancer drugs; that, on average, cancer drugs are priced higher than other drugs, normalized for value; and that payers are willing to pay these higher prices for at least some cancer therapies, which would validate the manufacturer pricing strategies.

It might be argued that these Canadian data do not necessarily shed light on drug pricing in the U.S. or the effects of U.S. reimbursement policies on pricing as outlined above. U.S. data would certainly be preferable, but unfortunately such data are unavailable because U.S. payers do not require them. We report these Canadian data as the best available and plausibly indicative of U.S. prices, given that pharmaceutical firms have strong incentives to set similar prices in closely connected markets, because payers compare drug prices across markets [6]. Given the dominant size of the U.S. market, optimal pricing for the U.S. market would rationally influence prices charged in Canada. Evidence confirms that prices for recent biologics, including cancer drugs, are quite similar across countries and more so for biologics than for other drugs [7]. Thus, if reimbursement rules led to higher prices for drugs for cancer than for most other indications in the U.S., such patterns would likely be reflected in

<table>
<thead>
<tr>
<th>Table 2. Assumptions for PDP Part D break even model</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The PDP receives 20 enrollees who are average risk (1.0 risk score)</strong></td>
</tr>
<tr>
<td><strong>Of these enrollees:</strong></td>
</tr>
<tr>
<td>When the cancer drug is on the specialty tier, only one beneficiary uses the drug(^{a})</td>
</tr>
<tr>
<td>When the cancer drug is on the preferred-brand tier, two beneficiaries use the drug</td>
</tr>
<tr>
<td>All beneficiaries enrolled in the plan take a drug that costs $114 per month (chosen to yield the average Part D monthly premium of about $30 and the plan breaks even); this drug is assumed to be on the preferred-brand tier with a copay of $30 per month</td>
</tr>
<tr>
<td>The price of the cancer drug varies in the range of $600–$15,000 per month, increasing in increments of $500 after $1,000</td>
</tr>
<tr>
<td>The PDP has no deductible, a standard initial coverage limit ($2,700), and the standard out-of-pocket threshold ($4,350)</td>
</tr>
<tr>
<td><strong>Comparison based on PDP placing the cancer drug on the specialty tier, with 33% cost sharing, versus on the preferred-brand tier, with the 2008 average cost sharing for preferred brand drugs ($30)(^{b})</strong></td>
</tr>
<tr>
<td><strong>Enrollees are not eligible for the low-income subsidy</strong></td>
</tr>
<tr>
<td><strong>All copayments are paid in full</strong></td>
</tr>
<tr>
<td><strong>Solve the model for the following:</strong></td>
</tr>
<tr>
<td>Premium the plan requires to break even when the cancer drug is on the specialty tier versus preferred-brand tier(^{c})</td>
</tr>
<tr>
<td>Fix the plan premium at ≤$35, then calculate plan loss as a function of price of the cancer drug (Fig. 1)</td>
</tr>
<tr>
<td>For the preferred-brand tier, set a loss limit and calculate the discount the plan would require to achieve that loss, while putting the drug on the preferred tier; this loss generally exceeded 30% of the drug price. The estimated loss in Figure 1 assumes no discount</td>
</tr>
</tbody>
</table>

\(^{a}\)This implies 5% of enrollees use a specialty drug, which is consistent with evidence that 4.4% of PDP enrollees used a specialty drug in 2007 [5].

\(^{b}\)Based on Medicare Payment Advisory Commission 2009 analysis [3, 4].

\(^{c}\)This was too high to be a realistic option.

Abbreviation: PDP, prescription drug plan.
prices in other closely connected markets such as Canada. But such conclusions are also tentative.

Formulary Placement and Cost Sharing for Cancer Drugs
Having examined how PDP/PBM strategies contribute to high pricing and high cost sharing, we now examine why they adopt these strategies. As discussed earlier, Medicare PDPs and private PBMs increasingly place all cancer and other specialty drugs on a specialty tier with a 25%–33% coinsurance, rather than using preferred formulary placement with lower copayments to negotiate manufacturer price discounts. This trend is prima facie puzzling at a time when the increasing number of similar drugs in specialty classes offers greater opportunity for PBMs/PDPs to seek competitive discounts in return for preferred formulary placement. The fact that Medicare PDPs adopt this strategy more often than private PBMs suggests that the PDP’s greater financial risk may play a role. Specifically, PDPs are at risk for 15% of the per-patient costs beyond the Medicare catastrophic threshold, whereas PBMs typically bear no risk for patient costs. PDPs also face greater adverse selection risk because most Medicare beneficiaries have a choice among a number of stand-alone PDPs, whereas most private employers offer employees only one PBM. Medicare permits PDPs to place drugs costing >$600 per month on a specialty tier, which also protects the PDP from tier exemption requests, which could be significant if some drugs in a class are on the nonpreferred tier while others are on the preferred tier. These administrative costs are omitted from our financial model.

In order to understand the potential impact of the financial exposure faced by PDPs on high-priced drugs, we developed a model of the net revenue (premiums minus drugs) to the PDP and the out-of-pocket costs to patients if an expensive drug is placed on a specialty tier with 33% coinsurance versus a preferred brand tier with $30 copayment, with varying levels of discount. Other assumptions are common across the two scenarios. Simulations show that the costs to the PDP and the beneficiary are essentially the same across the two scenarios, as long as the formulary placement of the expensive drug has no effect on use or on the PDP’s mix of beneficiaries. Indeed, if the PDP is able to negotiate a discount on the drug price in return for preferred formulary placement, its loss is smaller under that scenario than when it places the drug on the specialty tier (see Table 2). Critical to this neutrality result for the PDP and the beneficiary are the Medicare rules with respect to deductible, donut hole, and catastrophic corridor. These assure that patient cost sharing varies little with formulary placement provided the beneficiary uses one or more expensive drugs and hence spends through the out-of-pocket threshold early in the year. In 2009, the Part D deductible was $295, the initial coverage limit was $2,700, and the out-of-pocket threshold was $4,350. Thus, most patients using cancer drugs would exceed the out-of-pocket threshold early in the year.

However, if the PDP puts expensive drugs on a specialty tier, the beneficiary must pay a third of the price immedi-
ately on filling the prescription. This initial high out-of-pocket cost and/or misunderstanding of catastrophic protection may lead some patients to not take a drug when it is on a specialty tier, whereas they might use it when it is a preferred brand with a more modest initial copayment, although their total expected cost sharing is the same over the course of the year. Also, if one PDP offers expensive specialty drugs on a preferred tier with only $30 copayment, it may attract proportionately more high-risk patients who anticipate using these drugs, compared with competing PDPs that place all these drugs on a specialty tier. Thus, placing all expensive drugs on a specialty tier may reduce financial risk and cost for the plan, because of these use and selection effects, compared with placing one or more specialty drugs on a preferred brand tier in return for price discounts.

To illustrate these effects, we estimated the net revenue for the PDP under the assumption that placing an expensive cancer drug on a preferred tier doubles its use, that is, two in 20 patients use the drug rather than one in 20, because of either greater use by existing patients or adverse selection of more high-risk patients to this PDP. Under this assumption, the PDP incurs very significant losses as a result of placing expensive specialty drugs on a preferred tier. Moreover, there is no reasonable discount on the drug price that could offset this loss to the PDP (see Fig. 1). The loss is greater the greater the increased use of cancer drugs when they are placed on a preferred tier; the higher the cancer drug prices; and the more complementary drugs the high-risk patients use, because the PDP is at risk for 15% of all drug costs per patient beyond the catastrophic limit.

Of course, if placing some specialty drugs on a preferred tier has no effect or even a negative effect on average use, for example, because more low-risk patients select the PDP that puts specialty drugs on a preferred tier, this strategy will make money for PDPs and it would likely be the dominant strategy in the marketplace. The fact that it is not, and that there is a trend among PDPs to place increasing numbers of specialty drugs on a specialty tier, suggests that our model is illustrative of actual experience. The model ignores any higher premium the plan might receive from the Centers for Medicare & Medicaid Services for high-risk patients, which would likely reduce but not fully offset the losses the PDP would incur with the high use of specialty drugs. We did model the additional premium the PDP would need to charge beneficiaries to break even, but the implied premium was too high to make this a realistic strategy in the highly competitive PDP marketplace.

Unlike PDPs, private PBMs are not at financial risk for the drug spending of their beneficiaries. Placing expensive cancer drugs and other specialty drugs on a preferred tier does not expose them to financial risk and does not protect them from tier exemption requests. Moreover, some private PBM patients lack the catastrophic protection enjoyed by Medicare Part D beneficiaries; hence, placing expensive drugs on specialty tiers with 33% coinsurance is more likely to result in private patients foregoing these drugs. All these factors may contribute to the slower adoption of specialty tiers by private PBMs than by Medicare PDPs. Nevertheless, to the extent that private health plans and/or self-insured employers bear the cost of greater use of expensive drugs, their desire to limit their financial risk plausibly contributes to the trend. Also observed among private PBMs is placing cancer drugs on a specialty tier. Indeed, the parallel trend among private plans to move physician-dispensed drugs from their medical benefits to their drug benefits may partly also reflect the plans’ desire to limit their financial exposure, which is potentially less with the higher patient cost sharing under the drug benefit than the medical benefit.

**DISCUSSION AND CONCLUSIONS**

We have argued that our current insurance reimbursement and cost-sharing arrangements for cancer drugs creates incentives for manufacturers to set relatively high prices and for plans to shift more costs to patients. We are simply describing the rational response of various parties—patients, physicians, payers, and manufacturers—to the incentives created and imply no criticism or judgment. Rather, these trends of high pricing and cost shifting are rational responses if plans are unable, because of regulation, litigation, or other factors, to use alternative strategies rather than patient cost sharing to constrain prices paid for costly services. As R&D and new drug approvals shift increasingly to cancer drugs and other specialty drugs for which traditional PBM/PDP cost control mechanisms work poorly, it is critical that we adopt more rational and information-based approaches to measuring value for money for these drugs and other pricey therapies. If payers evaluate comparative effectiveness and cost-effectiveness and make such information available to physicians and patients, this would enable more informed decision making. If payers also use such information as one input in making coverage and reimbursement decisions, this would incentivize manufacturers to set prices commensurate with health benefit delivered. This form of flexible and indirect price constraint, which aligns prices with innovation and health benefit, provides more appropriate incentives for R&D and for efficient resource allocation than either the status quo or alternative price control mechanisms that have been proposed.
ACKNOWLEDGMENTS

No research support was received for this project.

An earlier version of this paper was presented at the NCPF/IOM Workshop on Value in Cancer Care.

AUTHOR CONTRIBUTIONS

Conception/Design: Patricia Danzon
Collection and/or assembly of data: Erin Taylor
Data analysis and interpretation: Patricia Danzon, Erin Taylor
Manuscript writing: Patricia Danzon
Final approval of manuscript: Patricia Danzon, Erin Taylor

REFERENCES

1 Ramsey S. How should we pay the piper when he’s calling the tune? On the long-term affordability of cancer care in the US. J Clin Oncol 2007;25:175–179.


4 Walsh B. The tier 4 phenomenon: Shifting the high cost of drugs to consumers.” AARP Strategic Analysis & Intelligence Briefing Report, March 2009.


This article has been cited by 2 HighWire-hosted articles:
http://theoncologist.alphamedpress.org/content/15/suppl_1/24#otherarticles