We Have a New Treatment, But You Can’t Afford It

Case Presentation

I got a call 2 weeks ago from a former patient asking for help. For the past 5 years, I’ve provided care for this gentleman, who is now in his late 70s, with slowly growing metastatic renal cell carcinoma. To make a long story short, over these years he’s undergone resection and radiation of brain metastases, at least 2 surgeries to remove local nodal deposits, and various chemotherapy trials with minor responses, and experienced a pulmonary embolus. Nevertheless, he lives a normal life. The goal he set from the very first visit was to live longer than his wife, who is chronically ill and requires his devoted attention.

His disease has progressed again. My partner recommended sunitinib—a reasonable choice given the favorable data in recent reports. However, my former patient called me for advice when he found out it would cost approximately $4000 a month. He wanted to know if I had any contacts or knew of clinical trials that would reduce the burden on his family.

I’ve tried. A search of the National Cancer Institute (NCI) web site revealed no sunitinib trials on kidney cancer outside of Japan. What about his insurance? Although he signed up for Part D of Medicare, the rules state that Medicare drug benefits do not include “off label” medication. Sunitinib was added to the NCCN Kidney Cancer Clinical Practice Guidelines in Oncology soon after the recent American Society of Clinical Oncology (ASCO) meeting, but the mandated reference compendia have yet to update their lists.

Calling Pfizer directly resulted in a referral to their FirstRESOURCE Support Program. So the patient got together with a financial counselor from the Virginia Cancer Institute and they completed the forms, enclosed the necessary tax information, and mailed the package. That was 3 weeks before this commentary was written, and the waiting began.

The Bigger Issue

Although the “off label” issue is a problem for this patient, it is really a symptom of a larger problem: huge increases in the costs of new drugs and the effects of these increases on patients. Whether it’s a 20% (or larger) copay on a $30,000-per-year drug given intravenously in the office or the 5% copay after a Medicare Part D beneficiary has spent more than $5100 on outpatient medications (amounting to a $200-per-month copay on sunitinib alone), many cancer patients are shell-shocked by their bills. (Remember that Part D does not pay any drug costs between $2250 and $5100, sometimes called the “donut hole” or “coverage gap.” The $2850 in between may be a single prescription for some expensive outpatient drugs.) USA Today recently listed the cost of care for metastatic colon cancer, calling the prices “mind-boggling.” Table 1 shows 6 real-life examples of copay issues for patients with insurance from several months at my former practice.

I don’t have the solution to this problem, but other experts are beginning to address it, and the lessons they learn might be useful. In Great Britain, the
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Table 1. Real Practice Examples of Copayment Dilemmas*†

<table>
<thead>
<tr>
<th>Example</th>
<th>Copay/Out-of-Pocket</th>
<th>Additional Costs</th>
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</thead>
<tbody>
<tr>
<td>A patient with colon cancer has Blue Cross/Blue Shield PPO. The patient is taking FOLFIRI plus bevacizumab until progression, with an average cost of treatment of $11,000 per dose. The patient is responsible for 20% of the allowed amount, approximately $2500. This continues until the patient reaches the out-of-pocket limit of $5000.</td>
<td>$2120 per month</td>
<td>$15,000 for a 1-month supply.</td>
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<tr>
<td>A patient with breast cancer has a commercial insurance. The patient is on weekly trastuzumab for 52 weeks, with an average cost for treatment of $5600 per dose. The patient is responsible for $530 per week, or $2120 per month, until the $7500 deductible is reached.</td>
<td>$530 per week</td>
<td>$5200 per dose.</td>
</tr>
<tr>
<td>A patient with colon cancer has Medicare Part A &amp; B. The patient is on cetuximab every 21 days for 6 months, with an average cost of treatment of $5200 per dose. The patient is responsible for 20% indefinitely.</td>
<td>$1040 per month</td>
<td>$5000.</td>
</tr>
<tr>
<td>A patient with melanoma has Cigna. The patient is on temozolomide 160 mg/d, with an average cost of $7000 for a 1-month supply. The patient is responsible for $3000 per month.</td>
<td>$3000 per month</td>
<td>$4500 for a 1-month supply.</td>
</tr>
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<td>A patient with pancreatic cancer has Southern Health. The patient is placed on oral capetitabine 2000 mg twice a day for 14 days, then off for 7 days. This agent is not FDA approved for pancreatic cancer; it is listed as a category 2B salvage regimen in NCCN guidelines. The cycle continues indefinitely until disease progression, with an average cost of $4500 for a 1-month supply. The patient is responsible for the full amount of the medication.</td>
<td>$4500 per month</td>
<td>$5600 per week.</td>
</tr>
<tr>
<td>A patient with myelodysplasia has prescription coverage under Medicare Part D. The patient is prescribed lenalidomide 10 mg/d for 28 days until the disease fails to respond to treatment, with an average cost of $15,000 for a 1-month supply. Some Part D benefits vary, but the norm is a $60 copay for the first month. The patient then owes $3600, and after this amount is satisfied, patient becomes responsible for 5% of the monthly amount, which in this case is $750 per month.</td>
<td>$3600</td>
<td>$530 per week.</td>
</tr>
</tbody>
</table>

* Examples courtesy of Amy Morgan, patient financial counselor at the Virginia Cancer Institute.
† In addition to the copay/out-of-pocket amounts in each example below, patients are still expected to pay a percentage of antiemetic medications and a percentage of any drug administration fees. These costs are incurred at the same time patients are expected to pay office visit copays to their doctors and for any other diagnostic tests required to manage their illness.

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As a result, routine use of trastuzumab was... nantly a research tool in the United States. The cost per year-of-life-saved (YOLS) for one intervention can be compared in a list with other interventions. The threshold of cost-effectiveness has been approximately $50,000 to 80,000 per YOLS, which is about what chronic hemodialysis, a Medicare benefit, costs society.

Most of the time, cost-effectiveness analyses show that drugs that are effective in prolonging survival are also ultimately cost-effective. In other words, the cost per YOLS was usually below $50,000 for adjuvant therapy, bone marrow transplantation, and many other common but expensive oncology interventions. However, those results preceded the entry of the very expensive biologic therapeutics into the health care system. A recent analysis of trastuzumab shows cost-effective ratios from $63,000 to $137,000 per YOLS depending on assumptions about the cost, benefit, and discount rate used in the model for metastatic breast cancer. As a result, routine use of trastuzumab was slow to enter Great Britain. However, this year, NICE approved this agent for women with HER-2 positive metastatic breast cancer. Cost-effectiveness analysis will probably not be adopted in the United States, though; explicit rationing is antithetical in our culture despite the wide variation in insurance coverage and benefits across the country.

Legislative approaches are also being considered to prevent cancer treatment from bankrupting patients with modest means. For instance, there is significant interest in limiting total copayments. This would help the patient, but not address the larger concern of drug cost and the impact of expensive oncology management on the employers who bear the brunt of cost escalation.

Role of the doctor

What role should physicians play in this area? Some doctors feel they should not intrude on personal financial decisions of their patients. They find it awkward to probe beyond the clinical and social data pertinent to the disease itself. On the other hand, a recent survey indicated that most doctors feel a duty to inform patients about the relative costs of treatment choices. Although primary care doctors frequently deal with cost issues when they face formulary restrictions for their hypertensive, depressed, and diabetic patients, oncologists are in a different boat because of the life-threatening nature of cancer, the
“mind-boggling” costs of cancer pharmaceuticals, and the lack of inexpensive substitutions (unless stopping therapy is considered inexpensive). However, the same study shows that out-of-pocket expense discussions are rare.

I suspect that the most common way to handle this issue in the real world is to guess whether a patient can afford a treatment. I know my older patient with lung cancer, who has spent a lifetime working on a fishing boat, cannot pay for apreptanit or an aromatase inhibitor. However, a retired Washington lobbyist gets the full complement of treatment choices without the financial overlay. I am not comfortable with the patronizing aspects of this approach, and although my staff tries to acquire medications from programs for indigent patients when indicated, implicit decisions are sometimes unavoidable.

What Concrete Things Can Be Done Today?

1. Create an office-based system where every patient is informed about the effectiveness of treatment and the costs. Doctors don’t have to provide cost information themselves, but are responsible for ensuring that a member of their team (eg, financial counselor, social worker, pharmacist) does this professionally. Although most patients will choose treatment even when the choice involves a small prolongation of life, a few won’t. This service should be available regardless of whether the treatment is administered in the office or requires a prescription from the pharmacy.

2. Understand the free drug programs. Many practices have honed a system for acquiring drugs for cancer patients who are unable to pay. The regulations are changing around this point, and some pharmaceutical companies have changed their rules now that Part D is active. However, the area is highly variable. Unfortunately, a significant amount of practice resources are required to arrange this service.

3. Refer patients to programs that help with copayments. Consider http://www.copays.org/, a program from the Patient Advocacy Foundation that helps eligible patients with certain kinds of cancer, as well as other disorders such as macular degeneration.

4. Hope (or lobby) that NCCN’s Drugs and Biologics Compendium is accepted by the Center for Medicare and Medicaid Services (CMS). This will increase the chances that effective treatments are listed promptly when data proves their benefit, not whenever the reference book happens to be updated.

Follow-Up

I first talked with my patient on May 31st of this year. He filled out his FirstRESOURCE (Pfizer program) paperwork but sent the wrong page of his IRS 1040. He refiled and is still waiting to see if he can get the drug. I’m glad Pfizer has this program; it just could be a little faster.

The absolute worst thing that can happen in cancer treatment is to make so much progress that only a few can afford the benefits. We have all contributed in one way or another to cancer research, most obviously in taxpayer support of NCI, and less directly in all the money paid for health care services, part of which goes to research and development. This problem requires national attention if we are to arrive at a solution that helps patients with cancer live longer and better lives.

References


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