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Financial Consequences of Improved Treatments for Colorectal Cancer

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Abstract

Improvements in translational research have led to improved survival in patients with both localized and metastatic colorectal cancer. However, these benefits come at high costs, and the introduction of six new agents since 1996 for colorectal cancer has resulted in much higher treatment related costs. Even insured patients may face very high treatment related costs through deductibles and co-payments. In addition, since colorectal cancer is a disease of the elderly, many patients may also be facing high treatment related costs for their other medical problems. Physicians should be aware of how these high costs may influence patients' treatment choices and adherence with therapy. This information may be important in counseling patients about the risks and benefits of systemic therapy. These challenges are not limited to patients with colorectal cancer, and physicians who take care of cancer patients across all disease sites will need to confront this increasingly complex issue.

Introduction

As described elsewhere in this issue, improvements in colorectal cancer outcomes are due in large part to improvements in systemic therapy. These advances have occurred rapidly; until 1996, the only FDA approved anti cancer drug was 5-fluorouracil. Since then, three new cytotoxic drugs (irinotecan, oxaliplatin, capecitabine) and three new monoclonal antibodies (cetuximab, bevacizumab and panitumumab) have been approved for colorectal cancer. The rapid introduction and adoption of these drugs into clinical practice has forced patients, physicians and payors to confront the impact of the high cost, in addition to potential promise, of these drugs for patients, physicians and society.

Treatment of high-risk, localized disease

As described in greater detail by Dr. Benson (page ##), adjuvant 5FU is routinely recommended for patients with Stage III colon cancer, based on clinical trial evidence that showed improved overall survival compared to patients who did not receive adjuvant therapy. The addition of oxaliplatin to infusional 5FU has been shown to improve survival compared to 5FU-based therapy alone.[1] Practice Guidelines from the National Comprehensive Cancer Network recommend six months of adjuvant 5FU (with or with oxaliplatin) for patients with stage III disease.[2]

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However, as discussed by Dr. Schrag (page ##) the role of adjuvant therapy (with or without oxaliplatin) in stage II disease is less well defined. [3–5] A systematic review published by Cancer Care Ontario in 2004 found no compelling evidence to advise the standard use of adjuvant therapy in these patients.[5] In addition, the American Society of Clinical Oncology noted that adjuvant treatment for patients with high-risk disease (i.e. obstruction, perforation) could be justified based on available data from Stage III patients. However, the guidelines panel recommends that physicians discuss the limitations of the supporting evidence and potential side effects of treatment when making treatment recommendations for patients with stage II disease.[3]

Treatment of metastatic disease

As described by Dr. Clark (page--), treatment for metastatic disease is much more complex. The National Comprehensive Cancer Network (NCCN) Practice Guidelines for Colon Cancer recommend that patients with good tolerance for intensive chemotherapy be treated initially with 5FU-based combination chemotherapy and bevacizumab.[2] The guidelines suggest additional chemotherapy and/or cetuximab or panitumumab in the second and third line settings, ultimately exposing patients to all available chemotherapy, bevacizumab and either EGFR inhibitor.[6] These treatments are rarely curative, and patients are often treated until disease progression, intolerance or death. Therefore, many patients will receive many “lines” of treatment, often for months, if not years.

Why the cost of cancer drugs is of particular concern for colon cancer patients

Since colon cancer is the third most common cancer in Americans, the widespread integration of these drugs into clinical practice has had a significant impact on health systems budgets. With the exception of 5FU, all of the approved FDA agents remain under patent protection. This can result in very high treatment costs due to drugs. Examples of treatment costs for a 70 kg man on commonly prescribed regimens are shown in Tables 1 and 2. Outpatient spending on oxaliplatin (physician and hospital outpatient clinics) in the first nine months of 2006 reached almost \$700 million, an increase of 27% over the same time period in 2005. Spending on bevacizumab during the same time period was almost \$900 million, while spending on cetuximab reached over \$300 million.[7] In total, spending on Part B drugs (physician administered drugs) by Medicare alone topped \$2.7 billion in 1997, rising steadily to \$10.9 billion in 2004.[8] It is likely that spending on these (and other) drugs will continue to rise.

Does cost of cancer care matter?

The rising cost of cancer care has drawn significant attention in both the lay press and medical literature. To address this complex topic, *The Journal of Clinical Oncology* devoted the January 10, 2007 issue to rising cancer care costs.[9] In this issue, health economist Mark Pauly argued that given the very small percentage of the Gross Domestic Product spent on cancer care (0.8% of \$13 trillion), it is unlikely that continued growth of cancer care costs will damage the economy. Instead he believes that value of continued spending in cancer care may lie in its ability to prevent premature death, suffering and fear associated with the disease.[10] On the other hand, health economist Scott Ramsey observed that society has a very “inelastic” demand for cancer care, accepting “anything at all costs.” He argues that has led to the introduction of marginally effective treatments at very high costs, which may compel insurers to curtail coverage for more interventions and to raise premiums.[11]

Even insured patients can have very high treatment costs

Although much of the focus on access to care lies in the significant uninsured population, “underinsurance” may also be a significant problem among cancer patients. Despite being “insured” through either government or employer sponsored plans, many cancer patients will still face high treatment related costs. A common definition of underinsurance is patients or families needing to spend more than 10% of their family income on out-of-pocket medical expenses for a catastrophic illness. A study of non-elderly (non-Medicare) patients in 2003 estimated that 17.1 million patients were underinsured, including 9.3 million patients with private, employment-related insurance. Cancer patients may be particularly at risk for high treatment related costs; 29% of cancer patients spent more than 10% of their family income on insurance premiums and other out of pocket health care expenses.[12]

A survey of cancer patients found that one quarter used up all or most of their savings to pay for cancer treatments, while one in 12 delayed or did not receive treatment due to cost.[13] Despite Medicare’s broad coverage, many elderly may be underinsured; one study in 2003 found that 29.3% had out of pocket expenses greater than \$5,000, while 7.3% had expenses greater than \$10,000.[14] These high out of pocket costs can have a devastating impact on family finances; half of filers from five bankruptcy courts cited medical expenses as a contributing cause, with out of pocket expenses averaging over \$11,000.[15]

Medicare coverage for cancer treatments

Since the median age of diagnosis of colorectal cancer is 72, Medicare covers the majority of these patients. Therefore, this paper will focus on insurance coverage issues related to Medicare. Coverage by private insurance plans varies widely.

Medicare Coverage

Medicare Part a covers inpatient hospital, skilled nursing facility and some home health care. For the first sixty days, Medicare pays the covered costs except for the deductible (\$1,024 in 2008). Co-payments apply for longer visits. Patients are eligible for Medicare without premiums if they or their spouse has worked 40 or more quarters of Medicare-covered employment. However, they may pay premiums if they do not meet eligibility requirements. [16]

Medicare Part B covers physician services, outpatient hospital services, certain home health services and durable medical equipment. Patients are responsible for 80% of the Medicare approved amount after meeting the \$135 annual deductible. Monthly premiums are \$96.40 per month for patients with annual incomes of up to \$82,000 per year (\$164,000 for married couples); patients with higher incomes pay higher premiums.[16] Patients may purchase additional voluntary supplemental coverage that pays a portion of the 20% co-payment.

Coverage for physician administered drugs under Medicare Part B

Medicare Part B covers 80% of intravenous and injectable agents administered in physician offices including chemotherapy and monoclonal antibodies, intravenous anti-nausea medications and other injectables (i.e. blood cell growth factors). In addition, since capecitabine is a prodrug of 5-fluorouracil, it is also covered by Medicare Part B (n.b. other oral anti cancer drugs, such as sunitinib for renal cell cancer or lapatinib for breast cancer are covered under Medicare Part D, which is discussed in greater detail below).

Changes in reimbursement for physician administered drugs

Changes at the federal level have affected how physicians are reimbursed for chemotherapy services. Prior to the Medicare Modernization Act (MMA) of 2003, physicians were reimbursed 95% of the Average Wholesale Price (AWP) for chemotherapy. The AWP was significantly higher than acquisition cost for most drugs, and practices used this “margin” to cover administration costs, such as nursing and pharmacy staff. However, in 2005, reimbursements were reduced to 106% of the Average Sales Price (ASP), with additional codes for drug administration costs. The ASP was designed to more closely reflect physicians’ drug acquisition cost. However, physicians and practices have complained that the implementation of these billing codes has been inconsistent and cumbersome.[17]

Impact of changes in Medicare reimbursements on access to chemotherapy

Early research suggests that the ASP based reimbursement system may not significantly affect access to cancer care services. A 2006 study presented by the Medicare Payment Advisory Commission (MedPAC) with partial data from 2005 found that payment changes did not affect access to chemotherapy services. A separate survey of cancer patients found that there was no significant difference in time to initiation of chemotherapy or satisfaction with chemotherapy services in patients treated before or after the ASP based pricing system.[18] However, the results of both of these studies may have been affected by an on-going Medicare Demonstration project, which may have delayed changes in care by temporarily increasing oncologist reimbursement for submitting data for quality of care monitoring. This Demonstration project has not been renewed, and the long-term impact of these reimbursement changes on access to chemotherapy services is unknown.

Of significant concern to MedPAC and other stakeholders is the impact of the MMA on the estimated 9% of patients who do not have supplemental coverage. Given the high cost of new chemotherapy agents and targeted therapies, the 20% co-payment for patients without supplemental coverage may be substantial. Furthermore, there is no annual or lifetime cap on patients’ out of pocket responsibilities.

Under the higher AWP based reimbursements, some practices were able to afford to waive co-payments for patients without supplemental coverage. However, given the lower reimbursements of the current ASP based system, practices are less likely to be able to afford to treat patients who cannot afford the co-payment. These patients face a disjointed system, with some patients treated in hospital infusion centers, which may cause disruptions in their care and pass the burden of the costs onto the hospitals. To our knowledge, there are no data on the quality of care that these patients receive.

How coverage for oral drugs through Medicare Part D affects cancer patients

Medicare Part D was introduced in 2006 to provide prescription drug coverage for oral agents. The standard plan was designed to control costs by “sharing risk” with patients through cost sharing. In 2008, the standard plan includes an annual \$275 deductible with beneficiary co-insurance of 25% until total drug spending equals \$2510, then patient payment (the “donut hole”) until the beneficiary has spent \$3216 out of pocket, after which Medicare pays 95%.

Voluntary supplemental plans may have reduced deductibles, flat co-payments, or no “donut hole” at all, and seniors are encouraged to choose plans that best accommodate their needs. However, this can be challenging for cancer patients, who are often diagnosed after they have already chosen a plan for the year. These plans are also extraordinarily complicated, making it difficult for even the most astute consumer to compare them. In addition, many plans only offer “gap coverage” for generic drugs; others offer branded “gap coverage” at a higher rate.

For example, in 2007, the premium for the “no gap coverage” plans was \$30.17. The average premium for a generic only “gap coverage” plan was \$51.11, while branded and generic gap coverage premiums reached \$93.46, over three times the premium for the “no gap coverage” plan.[17] The availability of branded drug “gap coverage” may be of particular importance for cancer patients since many new oral targeted therapies and supportive care drugs do not have generic alternatives.

Although patients will have at least 95% coverage after exiting the donut hole, it is not known if cancer patients will initially decline treatment because they are unwilling or unable to afford it because of their concerns about donut hole expenses. In addition, how Medicare Part D will affect vulnerable patients is not known. Of the 6.9 million seniors expected to enter the donut hole each year, more than one quarter are expected to have incomes below 150% of the federal poverty line and 42% are expected to be in fair or poor health.[19] It is estimated that among patients with 3 or more chronic conditions, 35% will fall into the donut hole.[20]

The “donut hole” may be of particular concern for many cancer patients; since the median age of diagnosis of colorectal cancer is 72, many patients will have other co-morbid illnesses, such as diabetes, hypertension or chronic obstructive pulmonary disease that require chronic medications. Although Medicare Part B covers all of the anti-cancer drugs for colon cancer described in this article, many cancer patients will require other supportive care medications such as narcotics, anti-emetics, and anti-coagulants that are covered by Medicare Part D. (examples in Table 3) Therefore, patients may have difficulty affording these supportive medications if they are already in the donut hole. Conversely, they may have difficulty affording their chronic disease medications if their supportive care medications place them into the donut hole. Therefore, they may be forced to choose between their supportive care medications and their medications for other diseases, decisions that may compromise their overall health.

The ability of patients to manage complications of chemotherapy and cancer may also be severely comprised if patients are unable to afford supportive medications. For example, some may have difficulty affording HT3 antagonists (i.e. granisetron or ondansetron) and consequently choose less expensive agents. This may place them at risk for chemotherapy-induced nausea and vomiting. This is particularly important for colorectal cancer patients since both irinotecan and oxaliplatin are considered moderately emetogenic.

How may cost affect discussions with patients?

Shared decision making and cancer treatment

With the availability of new agents, treatment choices in both the adjuvant and palliative setting are becoming increasingly complex. These drugs come with potential benefits, but also potential toxicities, including neuropathy (oxaliplatin), rash (cetuximab) and bleeding (bevacizumab). Although oncologists are generally adept in discussing treatment toxicities with patients, many find discussion of “economic toxicities” far more challenging. [21] Despite their discomfort with addressing the “money aspect” of their treatment recommendations, physicians should understand that cost-related concerns can be a major cause of non-compliance, and that patients are often uncomfortable initiating these conversations with their physicians.[22] It has been demonstrated in other diseases that this cost-related non-compliance may lead to adverse outcomes; studies of transplant recipients have shown that patients who are unable to afford their medications are at higher risk of reduced immunosuppression and subsequent graft failure.[23] Annual “caps” on drug benefits for the chronically ill elderly Medicare population has been associated with lower medication adherence and poorer clinical outcomes (i.e. glucose control, hypertension and hyperlipidemia).[24]

Despite the high cost of many cancer drugs, the effect of cost sharing on utilization is largely unknown. An analysis of insurance claims for specialty drugs (i.e. drugs used to treat cancer, multiple sclerosis and rheumatoid arthritis) suggests that demand for cancer drugs may be “price inelastic,” that is that the utilization did not change as cost sharing increased.[25] This analysis, which included a diverse group of cancer drugs, including monoclonal antibodies, growth factors and bisphosphonates, reviewed all drugs together, rather than looking at particular agents or indications. Although the authors did not find significant price elasticity for cancer drugs,[25] it is plausible that the results could have been affected by the heterogeneous group of drugs and indications. Another study of Medicare Part D formulary plans that evaluated the availability of a variety of cancer drugs found that most were available on most plans. Many of the brand name drugs were on higher “tiers” of co-payments, while generic drugs had lower –co-payments. Although the median co-payments of these drugs were manageable (ranging from \$5–30), the authors acknowledge that the utilization of these drugs once the patients enter the donut hole is unknown.[26]

Oncologists should be aware that as in other diseases, cost-related concerns might significantly affect cancer patients’ treatment choices as well as their compliance with treatment. Therefore, providers must be comfortable integrating a discussion about cost into the discussion of a treatment’s other risks and benefits. For example, when discussing treatment options for patients with stage II colon cancer, it is important for physicians to acknowledge the controversy surrounding the benefit of adjuvant therapy, particularly oxaliplatin based therapy. This may allow patients to weigh all of the risks (both toxicities and financial) against the potential benefit of adjuvant therapy and make an informed decision.

It is also important for physicians to understand that patients may value treatment characteristics differently; a physician may favor convenience while patients may have significant financial concerns. For example, a patient unable to afford the 20% co-payment for capecitabine should understand that intravenous 5FU will offer similar efficacy. Although intravenous treatment may be less convenient, this option may be more affordable and improve the patients’ probability of completing curative adjuvant treatment. Given these complexities, surgeons should refer all patients with stage II–IV colorectal cancer to a medical oncologist for a nuanced discussion about the risks and benefits of systemic therapy.

Patient Assistance Foundations

As a safety net option, individual pharmaceutical companies offer patient assistance programs; eligibility is often based on income and insurance status and varies by program. In addition, several foundations have emerged to assist patients with meeting co-payment responsibilities. A list of several of these foundations is provided in Table 4.

Future directions

Ongoing clinical trials are studying how to best use promising, but costly new drugs in both the adjuvant and palliative setting. Hopefully clinical trials will help to define the appropriate dose and duration of these promising medications while correlative studies identify which patients are most likely to benefit. Physicians should be encouraged to enroll patients in studies rather than treating “off study” with potentially toxic and costly medications in the setting of uncertain clinical benefits.

Patients, physicians and policymakers will need to determine how best to allocate scarce resources. One extreme approach is to continue the “anything at all cost” pattern described by Ramsey. At the other extreme is explicit rationing by the federal government. Although neither approach is appealing, the current pattern of allowing patients access to cancer treatments to be determined by their insurance coverage and their ability to pay for treatment essentially

allows private insurance plans to set social policy.[27] As progress in translational and clinical research leads to the introduction of more costly but promising drugs for different cancer sites, physicians will increasingly be forced to confront these issues.

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Table 1

Estimated cost of selected drugs and regimens based on ASP for 1.7 m², 70 kg patient

5FU/LV (Mayo Regimen, Monthly)	\$ 16
5FU/LV 400mg/m ² then 5FU 2400 mg/m ² CIV)	\$ 29
Capecitabine 1000 mg/m ² po bid × 14 days, given every three weeks (dose 1650 mg po bid)	\$ 1421
Irinotecan 350mg/m ² every 3 weeks	\$ 3,755
Irinotecan 180 mg/2 every 2 weeks	\$ 1,931
Irinotecan 125 mg/2 weekly	\$ 1,341
Oxaliplatin 85 mg/m ² every 2 weeks	\$ 2,743
Cetuximab 250mg/m ² weekly	\$ 2,117
Bevacizumab every 2 weeks	\$ 2,010

Source: http://www.cms.hhs.gov/apps/ama/license.asp?file=/McrPartBDDrugAvgSalesPrice/downloads/April08ASPbyHCPCS_032008.zip Accessed April 30, 2008

Table 2

Estimated cost per six months of commonly used regimens, based on ASP for 1.7 m², 70 kg patient

5FU/LV (Mayo Regimen, Monthly)	\$ 96
Infusional 5FU/LV (DeGramont, every 2 weeks)	\$ 352
Capecitabine 1000 mg/m ² po bid × 14 days, given every three weeks (dose 1650 mg po bid)	\$11,374
Irinotecan 350mg/m ² every 3 weeks	\$ 30,100
Irinotecan 125 mg/2 weekly ×4, every six weeks	\$ 21,460
FOLFIRI every 2 weeks	\$ 23,529
FOLFOX every 2 weeks	\$ 33,270
Bevacizumab every 2 weeks, added to a 5FU containing regimen	\$ 24,123
Cetuximab, load followed by weekly dosing, alone or in combination with irinotecan	\$ 52,080

Source: http://www.cms.hhs.gov/apps/ama/license.asp?file=/McrPartBDDrugAvgSalesPrice/downloads/April08ASPbyHCPCS_032008.zip Accessed April 30, 2008

Table 3

Costs of supportive care medications used by colorectal cancer patients

Medication	Dosage	Quantity	Price	Indication
Oxycodone controlled-release 40 mg (generic)	1 tablet every 12 hours	60 tablets	\$280	Long acting pain medication
Oxycodone 5mg (generic)	1–2 tablets every 4 hours as needed	100 capsules	\$47	Short Acting pain medication
Granisetron 1 mg (generic)	1 tablet every 12 hours as needed	6 tablets	\$126	Nausea
Odansetron 8 mg (generic)	1 tablet every 8 hours as needed	30 tablets	\$1049	Nausea
Prochlorperazine Maelate 10 mg	1 tablet every 8 hours as needed	30 tablets	\$14	Nausea
Enoxaparin	80 mg sub Q every 12 hours	60 syringes	\$3270	Anticoagulant
Warfarin	5mg daily	30 tablets	\$14	Anticoagulant
Gabapentin (generic)	300 mg 1 tablet po tid	90 tablets	\$60	Diabetic Neuropathy; used off label for patients with chemotherapy induced neuropathy
Pregabalin	50 mg po tid	90 tablets	\$180	Diabetic Neuropathy; used off label for patients with chemotherapy induced neuropathy

Source: www.drugstore.com, accessed April 15, 2008

Table 4**Patient Assistance Programs**

Organization	Contact Information	Services
HealthWell Foundation	800-675-8416 phone 282-7692 fax info@healthwellfoundation.org www.healthwellfoundation.org	Provides financial assistance to eligible patients to cover certain out-of-pocket health care costs, including: -Prescription drug coinsurance, copayments, and deductibles -Health insurance premiums -Other selected out-of-pocket health care costs
Patient Advocate Foundation, Co-Pay Relief	866-512-3861 phone 757-952-0119fax pap@patientadvocate.org www.copavs.org	Assists insured patients who are financially and medically qualified and are being treated for breast, lung, prostate, kidney, colon, pancreatic and/or head/neck cancers, malignant brain tumor, lymphoma, sarcoma, diabetes, multiple myeloma, selected autoimmune disorders and secondary issues as a result of chemotherapy treatment.
Patient Access Network Foundation	866-316-7263 phone 866-316-7261 fax contact@patientaccessnetwork.org www.patientaccessnetwork.org	Assists underinsured and assists patients who cannot afford the out-of-pocket costs associated with their treatment needs.
Patient Services, Inc.	800-366-7741 phone 804-744-5407 fax uneeedpsi@uneeedpsi.org www.uneeedpsi.org	Provides assistance with the cost of health insurance premiums associated with COBRAs, State High Risk Pools, Open enrollment, Guaranteed Issue policies, HIPAA conversion policies; and prescriptions co-payments associated with private insurance as well as with Medicare Parts B and D.