

Managed Care Best Practices in Oncology Management

**Based on an expert-opinion roundtable discussion
held in Salt Lake City, Nov. 27, 2006**

HIGHLIGHTS

- Issues in Oncology Management
- The Current Landscape of Oncology in Managed Care
- The Process of Care
- Protocols and Working With Oncologists
- Pharmacy and Cancer Care
- Managing Oncology Agents: An HMO's Perspective

Supplement to

MANAGED
Care

*Volume 16, No. 3
Supplement 4
March 2007*

**This activity is
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**This activity is supported
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MANAGED CARE (ISSN 1062-3388) is published monthly by MediMedia USA, 780 Township Line Road, Yardley, PA 19067. This is Supplement 4 to Vol. 16, No. 3. Periodicals postage paid at Morrisville, Pa., and additional mailing offices.

POSTMASTER: Send address changes to MANAGED CARE, 780 Township Line Road, Yardley, PA 19067. Price: \$10 per copy, \$100 per year in the United States; \$120 per year elsewhere.

E-mail: editors_mail@managedcaremag.com. Phone: (267) 685-2788; fax (267) 685-2966; circulation inquiries (267) 685-2789. Copyright 2007, MediMedia USA.

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Managed Care Best Practices in Oncology Management

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Target audience

Managed care professionals, including physicians, pharmacists, medical directors, chief medical officers, pharmacy directors, and other senior managers in managed care organizations.

Purpose and Overview

These articles are derived from "Managed Care Best Practices in Oncology Management," an expert roundtable discussion in Salt Lake City, Utah, on Nov. 27, 2006.

Cancer, in its various types and presentations, is the number 2 killer in the United States. For managed care companies, access to and availability of cancer care itself and the attendant costs of such care will present an increasingly substantial management challenge.

The articles in this publication review the current landscape of oncology in managed care; the process of care; protocols and working with oncologists; pharmacy and cancer care; and managing oncology agents from an HMO's perspective. Case studies that discuss typical patients encountered in the oncology field are also presented.

The evaluations upon which coverage policies are based are often difficult and controversial for all parties involved. Collaboration and communication are key principles for ensuring the highest quality of patient care.

This publication serves as an important educational tool for managed care professionals, pharmacists, and other health care decision makers so that informed decisions can be made regarding drugs, devices, and procedures utilized when treating patients with cancer.

Educational Objectives

After reading this publication, participants will be able to:

- Describe the current oncology landscape within managed care.
- Ascertain the concerns that health plans have regarding the evolving process of cancer care.
- Focus on the importance of collaboration between the managed care industry and oncologists to strengthen cancer protocols and quality-improvement initiatives.
- Explain the challenges faced by pharmacists when evaluating the cost, effectiveness, and utilization of oncology services.
- Prepare for the future trends and cost issues that will face the oncology and managed care communities.

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ACPE Universal Program Number (UPN)

812-000-07-004-H04

Release Date: March 15, 2007

Expiration date: March 15, 2008

Medium: Journal supplement

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Disclosure information for this education activity is cited below.

Richard N. Frame, MD: consultant, Shiff Nutrition. Jeremy M. Gleeson, MD: none.

Dennis T. Harston, MD, MBA: none.

Robert F. Jaramillo, PharmD: none.

Joshua L. Mark, PharmD: grant/research support, Genentech.

Larry Pesko, MS, PhD, RPH: consultant, Genentech.

Steven Peskin, MD, MBA: none.

Michael Dalzell: none.

Amy Krajacic: none.

The Chatham Institute: none.

Program sponsorship and support

This activity is sponsored by The Chatham Institute and is supported by an educational grant from Genentech.

SUPPLEMENT TO
M A N A G E D
Care

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INTRODUCTION

Issues in Oncology Management

Cancer is the second-leading cause of death in the United States today, accounting for 23 percent of all fatalities — trailing only heart disease (27 percent) (Miniño 2006).

Mortality, however, is not necessarily the best measure of the burden imposed by cancer (or any other disease). A more meaningful metric may be the *quality-adjusted life year* (QALY) or its variant, the *disability-adjusted life year* (DALY), both of which combine mortality with nonfatal health outcomes. Such measures account for deaths occurring at younger ages that could have been delayed. A team of scientists recently examined the 20 leading causes of death and DALYs in the United States in 1996 (Michaud 2006). They determined that ischemic heart disease accounted for 23.17 percent of U.S. deaths, while the three deadliest kinds of cancer (lung, colorectal, and breast), in terms of number, accounted for 12.93 percent of deaths. In terms of DALYs, ischemic heart disease accounted for 9.5 percent of the burden and these three cancers¹ for 7.2 percent. In other words, the three kinds of cancer that caused the most deaths in 1996 were equal to 55.8 percent of the deaths from ischemic heart disease, but the DALYs attributed to these cancers were equal to 75.8 percent of ischemic heart disease DALYs. This finding has important implications for health policy decision makers, as it suggests that cancer therapies with the potential to avert the most DALYs or save the most QALYs per dollar spent may, from a societal perspective, offer the best value.

Costs versus care

Every year, oncologists acquire more tools to reduce the mortality and morbidity associated with cancer. Sophisticated imaging technologies, such as ultrasound, computed tomography (CT), positron emission tomography (PET), magnetic resonance imaging (MRI), and dual PET/CT imaging, have been developed. In addition, during the past two decades, the U.S. Food and Drug Administration (FDA) has approved a broad array of targeted biotech products for therapeutic, diagnostic, supportive, and palliative purposes. These agents include large-molecule biologics (e.g., recombinant monoclonal antibodies, such as cetuximab [Erbix] and trastuzumab

¹ Note that although prostate cancer and pancreatic cancer ranked among the top 20 causes of death (accounting for 1.58 and 1.27 percent of all deaths, respectively), they did not rank among the top 20 causes of DALYs.

[Herceptin]) along with small-molecule biologics, such as imatinib (Gleevec) and erlotinib (Tarceva), whose molecular targets were identified through the techniques of biotechnology.

MCOs have reason to be concerned about how to pay for these agents, because not only is the number of biotech products with FDA approval for oncology use increasing, but companies are also seeking to increase the utilization of agents already on the market by expanding their number of indications. For example, bevacizumab (Avastin) is a humanized monoclonal IgG1 antibody against vascular endothelial growth factor (VEGF). In 2004, it received its initial indication as first-line treatment for metastatic colorectal cancer, followed by indications in 2006 as second-line treatment for metastatic colorectal cancer and first-line treatment of non-squamous, non-small cell lung cancer (NSCLC). In 2007, a supplemental biologics license application (sBLA) is expected to be resubmitted to the FDA for the use of bevacizumab as first-line treatment for metastatic breast cancer.

Based on a phase 3 trial that found bevacizumab improved progression-free survival in patients with previously untreated advanced renal cell carcinoma, 2007 also could see the filing of an additional sBLA for bevacizumab as a first-line treatment for renal cell cancer, the most common form of kidney cancer. Beyond that, trials are in progress or planned to investigate the use of bevacizumab for the treatment of numerous other tumors, such as esophageal cancer, follicular non-Hodgkin's lymphoma (NHL), hepatocellular cancer, metastatic melanoma, ovarian cancer, pancreatic cancer, and prostate cancer.

Like many pharmaceutical products, bevacizumab's cost varies with the dose, which varies with the indication. One month of bevacizumab treatment for a patient with colorectal cancer costs about \$4,400, but 1 month of bevacizumab treatment for advanced non-squamous NSCLC costs about \$8,800, because twice the dose is required. Based on clinical trial results that led to FDA approval for this indication (specifically, first-line treatment of unresectable, locally advanced, recurrent, or metastatic non-squamous NSCLC), the average cost for a course of this therapy for patients would be about \$56,000 (Genentech 2006). What benefit does bevacizumab bring to such patients? In the clinical trial, the 1-year survival rate was 44 percent for patients receiving just chemotherapy versus 51 percent for patients receiving chemotherapy

plus bevacizumab, and the median survival was 10.3 months for patients receiving chemotherapy alone versus 12.3 months for patients receiving bevacizumab and chemotherapy (Sandler 2006). The question then becomes: Is the extra 2 months of survival worth the cost? The president of the New York Lung Cancer Alliance, a patient advocacy group, told the *New York Times* that, from a societal perspective, it is not (Pollack 2006a). But the finding of even a modest survival benefit in advanced cases spurs hopes that bevacizumab might provide a greater benefit in adjuvant and neoadjuvant settings.

Displaying sensitivity to the high costs of bevacizumab, Genentech has announced that, starting in the first quarter of 2007, it will cap the annual expenditures for bevacizumab at \$55,000 in total spending (by all payers) per eligible patient, for any FDA-approved indication. As of mid-February, eligibility criteria had not been announced, but an annual income of \$75,000 or higher was being contemplated (Pollack 2006b). Genentech also will provide \$50 million to charities that help patients with copayments, doubling the amount it previously provided for this purpose.

Other manufacturers also have shown awareness of concerns about the perceived high costs of targeted cancer treatments. After panitumumab (Vectibix) received FDA approval for the treatment of late-stage colorectal cancer not responsive to chemotherapy, its manufacturer capped a patient's annual expenditures on copayments at 5 percent of the patient's adjusted gross income (Amgen 2006). Above that amount, a patient would become eligible for an assistance program available to uninsured patients with a household income under \$75,000.

Approval of panitumumab was based on a modest improvement in progression-free survival; so far, however, improvement in disease-related symptoms or increased overall survival has not been demonstrated. Panitumumab is a monoclonal antibody against the epidermal growth factor receptor, as is cetuximab. Panitumumab was priced 20 percent below cetuximab, leading to speculation that the price of cetuximab also might decline (Pollack 2006a).

Although the creation of corporate programs to ease the pain of copayments suggests otherwise, copayments and coinsurance have shown little effect as a tool for reducing utilization when applied to cancer products (Goldman 2006). When dealing with cancer, it seems patients will pay any copayment necessary to receive the drugs they think they need. Goldman and colleagues suggest that instead of using copayments to deter utilization, insurers should strive to find ways to direct costly drug products toward patients who would derive the most benefit from them.

On the basis of molecular classifications, specific patient populations already are identified in the labeling of some products, such as trastuzumab. Trastuzumab is a monoclonal antibody against the extracellular domain of the human epidermal growth factor receptor 2 (HER2).

Under normal conditions, HER2 helps regulate cell proliferation, but when it is overly abundant, it characterizes a particularly aggressive form of breast cancer. About 25 percent of breast cancer patients have tumors that overexpress HER2, and unless a breast cancer patient is HER2-positive, trastuzumab therapy may not be warranted. The FDA has approved two tests to determine if a patient is a candidate for trastuzumab: immunohistochemical assessment (IHC), which detects overabundance of the protein, and fluorescence in situ hybridization (FISH), which detects amplification of the HER2 gene, through which overexpression of HER2 can be inferred. Because a high degree of discordance was found between local and central laboratory testing for IHC and FISH in a clinical trial of trastuzumab, the selection of patients likely to benefit from trastuzumab therapy may be enhanced if high-volume, experienced laboratories are used for HER2 testing (Perez 2006).

Likewise, the estrogen receptor (ER) status of a breast cancer patient is useful for determining whether she is a candidate for hormonal therapy; an ER-negative finding indicates that therapy is not warranted. An IHC assay is the preferred diagnostic test for ER status, but it is subject to technical variation from laboratory to laboratory, with false-negative rates ranging from 30 to 60 percent (Pusztai 2006). If clinical characteristics raise suspicion of false-negative IHC results, a second biopsy may be warranted.

When employed to treat advanced colorectal cancer, targeted therapies such as bevacizumab and panitumumab are usually provided toward the end of life. Their effects on mortality and DALYs are minimal. In contrast, therapies employed to treat patients whose cancers are in earlier stages apparently can make a substantial impact. Imatinib and trastuzumab serve as examples.

One of the most dramatic achievements shown by the new, targeted therapies is the taming of chronic myeloid leukemia (CML), recently reported in the *New England Journal of Medicine* (Druker 2006). A formerly fatal disease, CML appears to have been brought largely under control (but not cured) by the targeted drug imatinib (Gleevec). Imatinib, an orally administered small-molecule drug, was designed to inhibit the tyrosine kinase domain of an oncoprotein, BCR-ABL, which is expressed as the result of a chromosomal abnormality known as the Philadelphia (Ph) chromosome. Druker and colleagues reported that when imatinib was used as initial therapy for chronic-phase CML, the overall survival rate after 5 years of follow-up was estimated at 89 percent and the event-free survival rate at 83 percent. Only 7 percent of patients had progressed to the accelerated phase or blast crisis. Excluding patients who died from causes unrelated to CML or transplantation, the estimated survival rate at 5 years was 95 percent. Patients receiving imatinib had been treated for a mean of 50 months and a median of 60 months (indefinite treatment is recommended).

A health economics analysis using older data showed that the mean estimated survival for imatinib-treated patients with newly diagnosed, chronic-phase CML was 15.3 years compared with 9.07 years for patients treated with interferon alfa plus low-dose cytarabine (Reed 2004). Incremental discounted lifetime costs were found to be \$168,100 with imatinib, resulting in incremental cost-effectiveness ratios of \$43,100 per life-year saved and \$43,300 per QALY saved — well within the \$50,000 threshold conventionally cited for cost-effectiveness.

Meanwhile, the newest indication for trastuzumab is for adjuvant treatment of localized HER2-positive, lymph node-positive breast cancer. This indication comes on the strength of a combined analysis of data from two phase 3 clinical trials enrolling about 3,500 patients (Romond 2005). Adding 52 weeks of trastuzumab to standard adjuvant therapy reduced the risk of a primary endpoint event (recurrence of breast cancer, contralateral breast cancer, other second primary cancer, or death) by 52 percent in comparison with patients receiving only standard adjuvant therapy. After 4 years, the disease-free rates were 85 percent and 67 percent in the trastuzumab and chemotherapy-only groups, respectively, and the absolute survival rates were 91 percent and 87 percent, respectively. An editorialist for the *New England Journal of Medicine* described the results of these two trials and another trastuzumab trial reported in a separate article as “simply stunning” and “revolutionary” (Hortobagyi 2005). The editorialist noted that the only other therapy demonstrated to reduce the risk of recurrence of ER-positive breast cancer by 50 percent is tamoxifen administered for 5 years.

A broad look at the complicated landscape of oncology within the managed care world is provided in these pages. With reason, health plans have concerns about the way cancer care is evolving, particularly because the biotechnology industry is developing many new products that will benefit cancer patients but at a substantial cost. As suggested, tension exists between oncologists and payers, and is likely to increase as an aging population demands access to new anti-cancer products. In a recent survey of academic oncologists, 71 percent expected that the cost of anticancer agents would lead to rationing of the medications over the next 5 years (Nadler 2006). The importance of collaboration between the managed care industry and oncologists to strengthen cancer protocols and quality improvement initiatives intended to make the best use of resources to fight cancer is clear.

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The Current Landscape of Oncology In Managed Care

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With 17 medical oncologists and 10 clinics, Utah Cancer Specialists is the largest medical oncology group in Utah. We treat common malignancies, such as breast, colon, lung, and prostate cancer. I spend most of my time in the oncology clinic, which has become an exciting but different medical environment because of recent advances in cancer treatment. Enabling patients to live longer, these advances have raised many issues important to managed care.

In general, oncologists are aware that certain agents are very expensive. We know that the same products often have differing costs, depending on which health plan is responsible for payment. We are compelled to work first and foremost for the benefit of the patient. Whatever the cost incurred in doing so is the concern of the health plan, not the oncologist. The question of deciding what dollar value should be assigned to, for instance, an additional month of life should fall on health plans, not oncologists. We deal with the biology of cancer and the medicines used to treat it. We want to treat our patients as aggressively and as appropriately as we can. The extent to which we can do so is governed by a health plan's decision about how much it is willing to pay for treatment.

As medical oncologists, we see patients at all stages of their disease. We provide support as they progress, including bringing in hospice services when it becomes appropriate. Each case is different, driven by social expectations, cancer biology, and desire for treatment. Some patients demand aggressive care until the end of life, no matter its level of appropriateness.

Modern cancer therapy is highly individualized, so each patient sees a patient advocate employed by our practice. Patient advocates typically come from a background in social work, and they strive to eliminate confusion about payments for expensive cancer treatments. They are compassionate people, capable of delivering bad news in a sensitive way. The patient advocate is someone on whom patients can rely to walk them through the maze of paperwork — filling out insurance forms, and making sure applications are submitted in time for Medicare or Medicaid coverage if applicable.

Because of the high cost of medications, everything we

do is preauthorized. A primary responsibility of the patient advocate is to ensure that preauthorization has been acquired. Our group's pharmacist provides secondary oversight in this regard.

Oncologists realize that we live in a world with limited resources. To fit into this world, we must utilize new tools to direct the most appropriate treatment to the needs of a given patient. These tools include clinical guidelines, imaging, and genetic testing and biomarkers.



Richard N. Frame, MD

Guidelines: Treatment maps

Practice guidelines are useful tools in cancer treatment. In theory, oncologists follow guidelines. In practice, the guidelines are so broad that in many circumstances it is hard *not* to follow them. Oncology guidelines need to be flexible for the treatment of all patients. At the same time, when the guidelines are too broad, they are of little use. It is not sufficient to say that a patient is being treated by a given guideline. We need to go beyond adherence to guidelines and have the medical oncologists communicate with the insurers earlier in the treatment process. For example, after we start treating a patient with metastatic colorectal cancer, we can estimate which drugs the patient will use over the course of treatment and for how long. By predicting the treatments likely to be used, the medical oncologist can give the insurer perspective on the likely costs for that patient.

Although guidelines for treatment of disease states are broad, the guidelines for supportive care are quite useful. We know how to give drugs to manage anemia, nausea, and vomiting, for example. Although these drugs are expensive, their early-stage use can cut overall costs. Through the reduction of emergency room visits for the treatment of nausea and vomiting, and fewer admissions for neutropenic fevers, guidelines for supportive care management have emerged as a key part of oncology treatment.

The improving imaging landscape

We are rapidly approaching the time when dual-modality imaging that combines positron emission tomography (PET) with computed tomography (CT) will become a standard component of care for cancer pa-

tients. By itself, a CT scan or magnetic resonance imaging (MRI) provides morphologic information on primary tumors and metastases. In contrast, the PET/CT fusion scan constitutes an important advance in imaging because it provides not only morphologic information but also functional information on tumor metabolism. This dual data stream results in better staging and improved therapeutic regimens.

In a blind study that enrolled 98 patients with a variety of histologically proven malignancies of varying degrees of severity, full-body PET/CT scans were found to be superior to full-body MRI scans for overall tumor-node-metastasis (TNM) staging (Antoch 2003). In this study, the results of the PET/CT scan led to changes in the therapeutic regimen in 12 patients, whereas the MRI results led to changes in the management of only 2 patients.

In another blind study (N=260), PET/CT imaging was found to be more accurate for tumor staging than either CT or PET alone, or side-by-side PET and CT for TNM staging of various malignancies (Antoch 2004). In contrast, the other modalities compared with PET/CT led to few changes in therapy (side-by-side, 0 patients; CT, 2 patients; PET, 4 patients). In the 4 instances in which PET alone was more beneficial than PET/CT, the CT data resulted in false-positive diagnoses of pulmonary lesions.

Most recently, in a study of 47 patients with colorectal cancer, whole-body PET/CT colonography was found to be significantly more accurate than CT alone and at least the equivalent of side-by-side CT and PET for tumor staging (Veit-Haibach 2006). In this study, PET/CT changed the therapeutic regimen for 9 percent of the patients compared with CT alone.

In addition to better staging for a substantial proportion of patients, the PET/CT fusion scan also may reduce overall imaging costs by reducing the need for CT scans, bone scans, and MRIs. Improvements in resolution will enhance the utility of all these technologies.

Genetic testing and biomarkers

Genetic testing and biomarkers are becoming increasingly important tools for individualizing cancer treatment. Methods that enable oncologists to predict which patients are likely to respond to a given treatment clearly are important for making wise use of scarce resources.

For example, we are beginning to learn how to identify patients who might be resistant to certain chemotherapy drugs because of the way their bodies metabolize these agents. We also are beginning to develop ways to identify chemotherapy regimens likely to be highly effective in a given patient, based on specific characteristics of the tumor. In patients with node-negative early breast cancer, a signature of 70 genes has been found to be a better predictor of outcome than standard clinical and histologic characteristics (van de Vijver 2002, Buyse 2006).

Recommendations for managed care and oncology professionals

- Create patient advocates to navigate a patient's preapproval for all oncology treatments
- Invite an oncologist to sit on the pharmacy boards of managed care plans
- As new drugs become available, devise a method for their integration into clinical practice by payers and oncologists
- Adhere to guidelines, particularly for supportive care issues
- Prepare for new and urgently needed drugs
- Review CT/PT algorithms for proper use in malignant disease

Another study found a set of 76 genes in node-negative breast cancer patients that identify women at high risk of distant recurrence (Wang 2005). Such tests could be useful in guiding treatment decisions by identifying patients most likely to benefit from adjuvant systemic therapy, and by distinguishing those women who might be best served through the use of less aggressive therapies.

The Working Group on Biomedical Technology¹ has defined biomarkers as “endogenous molecules (such as proteins or metabolites) or injected agents (such as imaging agents) whose presence or state correlates with important physiological processes, disease outcomes and treatment response (including toxicity and efficacy)” (Working Group 2005). Carcinoembryonic antigen (CEA) is the biomarker with the longest history of use in cancer treatment. It is employed in the follow-up of patients with colon cancer, but it lacks sufficient sensitivity and specificity to be useful as a screening tool.

Thus far, prostate-specific antigen (PSA) is the only biomarker with FDA approval for broad use in cancer screening, used with the digital rectal examination. As a screening tool, however, PSA testing is controversial for numerous reasons. It has low specificity for prostate cancer (elevated PSA levels also are associated with benign prostatic hyperplasia and inflammation), leading to unnecessary biopsies. Also, it has been excessively used to screen elderly men whose few years of life that remain typically do not warrant treatment even if clinically significant disease is detected (Walter 2006). Moreover, in a case-control study, PSA screening has not been found to be effective in reducing mortality (Concato 2006), although another case-control study has associated PSA screening with a reduction in metastatic prostate cancer (Kopec 2005).

¹ The group was created by an ad hoc subcommittee of the National Cancer Advisory Board to advise the National Cancer Institute about the best way to use biomedical technology to transform cancer research.

In a few years, the results of the Prostate, Lung, Colorectal and Ovarian (PLCO) Screening Trial and the European Randomized Study of Screening for Prostate Cancer (ERSPC) trials should resolve questions about the actual value of PSA screening. Until then, PSA screening has, at a minimum, raised awareness of the potential value of biomarkers in cancer. The time is envisioned when invasive diagnostic and prognostic techniques will be replaced by clinic-friendly serum and blood tests to aid in making informed clinical decisions at every phase of cancer treatment (Chatterjee 2005).

Conclusion

The oncology landscape has changed dramatically in recent years, with the development of targeted therapeutics and advances in imaging technologies. In the years ahead, we can look forward to the development of genetic tests and other biomarkers to ensure that patients receive appropriate treatment.

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DISCUSSION

Imaging

LARRY PESKO, MS, PHD, RPH: Does your office perform PET scans?

RICHARD N. FRAME, MD: Yes, we do. Our clinic acquired a PET/CT fusion scanner because we believe it is very helpful in managing patients with cancer. There are numerous disease-specific protocols and algorithms for integrating the use of a PET/CT scanner. For example, with Hodgkin's disease, you give four courses of treatment and then repeat a PET/CT scan. If there is a good response, you give two more courses and repeat the scan. We have plenty of algorithms that we are willing to share and further develop. It's hard to get the long-term data, but it's building.

PESKO: I've heard that oncologists who were losing money in the area of drug delivery are looking at additional revenue streams, and so PET scanning now would become a more common entity in a practice. From an insurance company's perspective, the more revenue streams coming into a physician's office, be it drugs, diagnostics, or anything nonspecific to the practice, the more we wonder whether that usage is appropriate and necessary, or just a source of additional income.

DENNIS T. HARSTON, MD, MBA: When we look at new high-cost, high-tech imaging, we are concerned that it will be used to satisfy curiosity instead of being used for clinical purposes that would make a difference in treatment. For this reason, at our health plan, we require prior authorization for only one imaging service, PET.

JEREMY M. GLEESON, MD: Our group doesn't own one, but the hospital does, and so does a competing oncology group in town. On a clinical level, I manage a lot of thyroid cancer, and I sometimes struggle with an insurance company's unwillingness to approve PET/CT scans that I think are clinically appropriate. It is a major issue.

PESKO: The problem of self-referral has been an issue in the oncology community, first for medications and now for imaging procedures. From the standpoint of an insurance company, that is problematic. There are not many practices that self-refer, other than oncologists. To gain the confidence and trust of the insurance industry, oncologists have to get out of the self-referral business. If I were a pharmacist with the ability to write prescriptions for my patients to fill in my pharmacy, people would wonder if I were really writing those prescriptions to benefit patients or to give the pharmacy additional revenue. Medical specialties that have the ability to obtain revenue from sources other than the basic tenets of their practice become suspect in payers' eyes.

FRAME: We accept that criticism, and we live with it. We want to do the right thing, which these days includes using CT/PET fusion scanning appropriately.

The Process of Care

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Oncologists who work in a managed care environment face numerous challenges throughout the care process. Because the care of patients with cancer is a multidisciplinary undertaking, oncologists desire a barrier-free referral pattern for working with primary care physicians and surgeons, and they want to assure that all referrals for patients with malignancy are appropriately timed. Even if a smoothly operating referral process is in place, oncologists still face the problem of dealing with patients who may be reluctant to pursue treatment because of fear and lack of trust. Via the Internet, patients are becoming more informed about treatment options, and although such education may lead to fruitful discussions with the oncologist, some patients and their families may develop unrealistic expectations about what can be achieved through treatment. In such an environment, the oncologist faces increased exposure to litigation.

Direct-to-consumer (DTC) advertising, in all its forms, particularly those ads that are aired on television, also can influence a patient's thoughts on the treatment process. Some investigators have suggested that despite claims that these advertisements serve an educational purpose, they provide only limited information about disease prevalence and risk factors, and can be ambiguous about whether an individual legitimately needs a medication (Frosch 2007). Proponents of DTC advertising, however, assert that it motivates patients to learn more about medical conditions and treatment options, with the physician's role remaining preeminent (Holmer 1999).

Once the patient is amenable to therapy, the oncologist then must confront health plans' coverage limitations or authorization requirements. Because of these barriers, the oncologist's ability to use newer medications, including high-cost biologic therapies, is sometimes constrained. Even though it is common in cancer care, off-label utilization may be problematic, because MCOs tend to justify coverage decisions on whether a specific use has been approved by the U.S. Food and Drug Administration.

New models of oncology care

In oncology clinics, rapidly evolving technologies are changing the face of care. Oncologists have new options

for screening patients, such as spiral CT and virtual colonoscopy. The adoption of high-deductible health plans, however, may present a barrier to the use of these and other preventive care services. As a counterweight, pay for performance could be employed to boost cancer screening at the primary care level. For any other purpose, however, pay for performance would seem to lack utility in oncology, and will have more of an impact on primary care physicians. Concerns also exist that paying for performance will fail to reward, and possibly penalize, providers who have already achieved high levels of quality health care provision at the time of any such program's initiation (Rosenthal 2005).

The use of genetic testing to determine cancer risk and a patient's likely response to therapy appears to be on the horizon, along with the use of biomarkers for assessing treatment response. Targeted therapies, including monoclonal antibodies and intensity-modulated radiation therapy are increasingly employed. Oncologists also are making increased use of bone marrow stimulants to accelerate cancer treatment while reducing complications. In addition, less invasive treatments are becoming available, such as robotic surgery, sentinel node mapping, and nonmyeloablative stem cell transplant.

MCOs increasingly expect that oncologists who use these drugs, technologies, and techniques will follow evidence-based treatment guidelines. Some health plans also endorse specialty disease management programs to oversee patient care, or are steering cancer patients toward treatment at regional or national centers of excellence rather than local institutions. For those local oncologists and surgeons who are allowed to continue seeing cancer patients, profiles of individual practitioners and groups are being compiled on the basis of their clinical outcomes.

As an added constraint, oncologists practice today with the knowledge that legal authorities may be constructing their own profiles of physicians' utilization of controlled substances.

The following case studies illustrate how the process of care may sometimes unfold in the current managed care environment.



Dennis T. Harston,
MD, MBA

CASE STUDY 1

A 59-year-old man with a history of hypertension has noticed some blood in his stool for the past month. Because he enjoys eating red meat, he does not feel alarmed, but his wife insists that he see the family physician. A digital rectal examination reveals occult blood in the stool. In the ensuing gastrointestinal workup, the patient is found to have adenomatous polyps and a circumferential colon lesion in the descending colon. A cAMP panel revealed elevation of liver enzymes. A CT scan of the abdomen and pelvis suggests multiple lesions in the liver, and the patient is referred to a general surgeon. Preoperatively, his blood carcinoembryonic antigen (CEA) level is 22 ng/mL. The surgeon finds adenocarcinoma of the colon, Dukes stage C, where the cancer has spread to at least one lymph node. An oncologist who is consulted obtains a PET/CT fusion scan. A treatment course of 5-fluorouracil (5-FU) and levamisole ensues. Six months later, there is a rising CEA level.

This case represents a very typical patient. Today, the therapy for such a patient might be FOLFOX, a chemotherapy regimen consisting of concurrent treatment with fluorouracil, leucovorin (folinic acid), and oxaliplatin, in addition to bevacizumab (Avastin). FOLFOX is standard chemotherapy, but the regimen is aggressive and complicated, and some toxicity is associated with it. Bevacizumab is a recombinant humanized monoclonal IgG1 antibody against vascular endothelial growth factor that improves overall survival when used in conjunction with 5-FU–based combination chemotherapy.

As a result of aggressive initial treatment with FOLFOX, this patient would be likely to show a good response for 6 to 12 months, with shrinkage of the liver lesions. In a perfect world, where the size of the lesions have been reduced as much as possible with chemotherapy, this patient would be offered surgery, despite a high chance of recurrence after the lesions have been removed from the liver. The long-term, disease-free survival rate for patients with resected liver metastases is about 25 percent.

If FOLFOX/bevacizumab fails, the next step would be to add FOLFOX and cetuximab (Erbix), or irinotecan and cetuximab. Cetuximab is a recombinant chimeric monoclonal antibody that binds to the extracellular domain of the epidermal growth factor receptor (EGFR). Another possibility might be a newly approved agent, panitumumab (Vectibix), a recombinant human IgG2 antibody that binds to EGFR. A patient with this kind of tumor is a candidate for a number of high-cost agents.

CASE STUDY 2

A 34-year-old woman whose sister has a history of breast cancer has a screening mammogram. A suspicious 1 cm lesion is detected and lumpectomy is performed. A ductal carcinoma of the breast is found, with 1 of 7 nodes positive. The tumor is estrogen receptor positive and demonstrates overexpression of the HER2 protein. She undergoes a course of cyclophosphamide, methotrexate, and 5-FU, followed by radiation therapy. She then begins a course of tamoxifen. After 6 months, adjuvant treatment with trastuzumab (Herceptin) is recommended. BRCA1 and BRCA2 testing is requested, as the physician is considering recommending bilateral prophylactic mastectomy. Some problems regarding coverage by her health plan emerge: screening mammography is not recommended for the patient's age group; there is a policy against covering trastuzumab therapy as adjuvant chemotherapy; genetic testing is not a covered benefit; and preventive mastectomy in the absence of malignancy is excluded from coverage.

Genetic testing for BRCA1 and BRCA2 would be helpful in the case of this patient, and beyond the ability of the test to assess the patient's risk of ovarian cancer, the results could have implications for her entire family. If genetic testing is precluded because of its cost, the prudent oncologist would monitor her closely, paying special attention to her ovaries, and see if perhaps her health plan would cover transvaginal ultrasound. However, a negative genetic test would make the transvaginal ultrasound unnecessary, along with bilateral mastectomies and screening of family members at an early age. If the health plan were to cover genetic testing for this patient, it might prevent a substantial amount of downstream spending.

The fallback procedure for an oncologist would be to correspond with the health plan and urge reconsideration of their decision not to cover genetic testing. Health plans should have a grievance process in place to allow a specialist from outside the health plan to review the denial of coverage. An unbiased third-party review regarding coverage would be a positive approach for identifying realistic health plan policies and making sure they are applied in such a manner that they do not harm the patient population.

CASE STUDY 3

A taxi driver is found to have a small peripheral lesion in his right lung. Needle biopsy and bronchoscopic washings reveal a non-small cell lung malignancy. CT shows abnormally enlarged hilar lymph nodes.

The patient is treated with a course of radiation therapy followed by cisplatin and etoposide. The patient continues to lose weight, and after 6 months, he is unable to work. The family requests help in dealing with the strain of his progressive disability, and although hospice is discussed with them, the idea of terminal care is difficult for the family to accept. They are instead considering a trip to Mexico for additional treatments.

This case raises the important question of how health plans and oncologists can best work together to provide practical help for a patient during the last months of life. Some patients will want to press on with treatment no matter what their physicians recommend, but the earlier terminal patients are presented with the option of hospice services, the better. Hospice is now a well-known and desirable option for the terminally ill.

In their attempts to address the psychosocial aspects of cancer management throughout the process of care, many oncology offices are consolidating, incorporating social workers and counselors in a supportive team approach. Physicians are becoming more sensitive to the emotional needs of terminal patients, with a renewed focus on effective palliation and pain management. Health plans may provide dedicated case manager nurse support, and benefits are commonly offered for end-of-life care in the home and subacute settings.

Conclusion

These 3 cases span the spectrum of cancer care. First, we focused on a middle-aged patient whose prospects are less bright — but not dire — and who could look forward to several more years of relatively high-quality life. Second, we have discussed a young patient with a good probability of many years of disease-free survival. Finally, we examined the case of a man who clearly is dying.

For the middle-aged patient, treatment options include several new targeted therapies that could extend the patient's life by a modest amount of time, but at substantial cost. In the case of the young patient, her cancer is likely to be handled as though it were a chronic disease, with treatment expected to add many productive years to her life. However, numerous barriers stand in the way of ascertaining her best treatment options, and some of these obstacles may have the unintended consequence of increasing payers' expenditures in future years. From the

perspective of the health plan, financial considerations are a relatively minor factor in the third case, which involves end-of-life care. The timely provision of sensitive counseling about palliative and hospice care could spare the family from taking on a substantial financial (and emotional) burden that might be associated with the pursuit of other, nontraditional therapies.

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DISCUSSION

Dealing with novel medications

STEVEN R. PESKIN, MD, MBA: How can the dialogue about evidence-supported care be improved so that health plans can work better with oncology groups?

ROBERT JARAMILLO, PHARM D, RPH: When we get our first request for coverage of a new drug, we scramble to learn how the drug should be used. In the course of gathering all the pertinent information, it would be helpful to speak with an oncologist.

RICHARD N. FRAME, MD: When a patient needs the new medication tomorrow, this scramble is a source of anxiety, friction, and frustration. When a new drug becomes available, we struggle in trying to determine how to put it to its best use. We need a new system for dealing with novel drugs.

PESKIN: So what can be done to eliminate the scramble?

JEREMY M. GLEESON, MD: Perhaps the health plan backs off and lets the oncologist make the call.

LARRY PESKO, MS, PHD, RPH: Perhaps the scramble could be eliminated by bringing together health plan administrators and oncologists who practice within the area to discuss new products prior to their introduction to the market. This could result in an understanding of the expectations of the prescribers and the health plan before, not after, the fact. Establishing expectations before a drug is released would benefit the pharmaceutical company, the prescriber, and the payer.

Protocols and Working With Oncologists

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Lovelace Medical Group is a multispecialty medical group within an integrated health care delivery system. Unlike many health care plans, most of our oncology care is provided by a dedicated oncology group with whom there exists a highly collaborative relationship. Our structure allows for an approach that might not be appropriate elsewhere.

To obtain the depth of oncology expertise needed, it was determined that a collaboration with colleagues at the University of New Mexico would increase the depth of oncology expertise available to our patients, and also would establish a relationship to conduct clinical trials. We, therefore, decided to enter into a joint venture between the Lovelace Medical Group and the University of New Mexico Oncology Group. The oncologists see patients at Lovelace clinics, and this has turned out to be a mutually beneficial relationship. Lovelace can offer its patients oncology subspecialties that, as a plan, we did not have, and we have been able to provide the university with a patient base for clinical trials that was previously unavailable and is critical to maintaining its certification.

Managing the oncology landscape

Oncology therapy areas delineated at Lovelace include chemotherapy, novel therapies, and supportive therapies. At the plan level, we have not made much of an attempt to examine chemotherapy medications, allowing instead our oncologists to make those decisions. There is no significant review of protocols within the plan level.

Novel therapies that do not include chemotherapy go through a technology review committee, but the medical director ultimately makes the decision on coverage. Prior authorization also must be obtained. The committee includes health plan authorities and practicing physicians, and an external technology assessment is made when the capability does not exist in-house.

Managing some areas outside of chemotherapy effectively has been difficult. For example, some of the new approaches in radiation oncology have raised significant discussions — along with disagreements — about coverage for certain newer procedures. Again, final coverage decisions are left to the medical director.

Supportive therapies are evaluated through the pharmacy and therapeutics (P&T) process, and include such areas as anemia and hypercalcemia management in renal patients. P&T primarily evaluates for efficacy, safety, and

cost. This approach has been particularly instructive in the renal area, rather than oncology, because recent studies have shown that more is not necessarily better in anemia management (Drüeke 2006, Singh 2006).

Ensuring quality of care

Our close relationship with well-qualified oncologists raises our standard of care. At a plan level, there is no mechanism for actively monitoring outcomes in a pay-for-performance model in oncology. It does not seem, however, to be a challenge to assemble such a program if needed.

We follow a conventional approach to cancer screening and prevention. A plan has to follow the National Committee for Quality Assurance (NCQA) Health Plan Employer Data and Information Set (HEDIS) standards (NCQA 2007). Lovelace covers the standard screenings that are recommended — for example, a colonoscopy or sigmoidoscopy for colon cancer, PAP smears for cervical cancer, and mammograms for breast cancer. New techniques, such as whole body computed tomography (CT) scans and spinal CT scans, are not covered.

Although there is some movement in the pay-for-performance area regarding screenings, it will have more of an impact on primary care physicians, who generally perform these types of screenings, rather than oncologists, who typically do not.

Quality improvement initiatives

We are continuing to strengthen our relationship with our oncology group, and also have experienced a big push to increase our research protocol participation. Clearly, this is a major initiative that the academic oncologists are focused on. It is important to remember that many quality improvement initiatives apply at the practice level rather than at the plan level.

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DISCUSSION

Funding issues

STEVEN R. PESKIN, MD, MBA: Because you're an integrated delivery system and payer, and also doing clinical trials, how does funding take place?

JEREMY R. GLEESON, MD: Many oncology trials, of course, are poorly funded, particularly the ones that are National Cancer Institute (NCI)-sponsored trials. But participating in these protocols is considered the standard of care for a cutting-edge oncology program.

PESKIN: So the university group with which you have a contract basically absorbs the excess utilization associated with poorly funded NCI trials?

GLEESON: Yes, I think that's probably how it occurs. Of course, coverage for clinical trials in the cancer area is mandated in New Mexico, so we, as a plan, have to cover expenses that are part of a clinical trial.¹

¹ New Mexico is one of a growing number of states that has passed legislation or instituted agreements requiring health plans to pay the cost of routine medical care received during participation in a clinical trial. For a list of all of the states that have such laws or provisions, see «www.cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs.com».

Salvage therapy

DENNIS T. HARSTON, MD, MBA: Another question pertains to salvage therapy, a sort of last-chance therapy. What level of involvement does the health plan have in that, or is that also conceded to the oncologist?

GLEESON: It's typically conceded to the oncologists, with, at this point, relatively little plan oversight. Whether that's sustainable in the future as the costs go up is open to question.

PESKIN: When you enroll someone into a protocol, are they less likely to get the proverbial kitchen sink thrown at them?

RICHARD N. FRAME, MD: I think we need to differentiate between phase 1 clinical trials and phase 2 and 3 clinical trials. Phase 1 clinical trials are conducted in a university academic environment, and that's where they are kind of throwing the kitchen sink at a patient. The types of protocols that we are involved with as a clinical oncology practice, phase 2 and 3 studies, involve how long to give a drug, what's the right combination of drugs, what's the best treatment, and then following subjects for 5 years to find out which agent is better or worse. You're going to have those same costs incurred with any patient, whether they are in a study or not, and the added cost of enrolling in a study, I think, is minimal compared to what the standard oncology practice would be otherwise.

Pharmacy and Cancer Care

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At Lovelace, all pharmacy services are performed in-house, as well as contracting and management. New Mexico is 1 of approximately 17 states in the United States that mandates coverage for all chemotherapy, regardless of whether it is considered usual and customary, or if it is viewed as experimental. As a result, management of cost and utilization, at least in our plan, is limited to supported therapies, such as colony stimulating factors, anti-nausea medications, chelating agents, and low-molecular-weight heparins.

Issues can arise with some of the newer agents, such as bevacizumab (Avastin). The debate focuses on whether the medication is considered a supportive agent, or integral to the chemotherapy process. These questions can muddy the waters as to what actually falls under the heading of chemotherapy. Thus far, our approach has been to consider bevacizumab supportive therapy that we can then manage.

Evaluating the cost and utilization of oncology services

The approach taken by our facility in terms of the process of utilization management is not unique, and is probably quite standard for most health plans. We first start by establishing appropriate use guidelines through the pharmacy and therapeutics (P&T) committee. We then conduct utilization reviews by a team of clinicians to identify deviations from those established guidelines. Deviations then are grouped to determine if they are provider-specific, or if they appear to pertain to specific patient populations. Sometimes, this grouping may bring to light a large patient population that was not appropriately addressed when the review was performed, and, therefore, may require an updated assessment.

Costs associated with oncology are grouped into two general areas: the cost impact of inappropriate therapies and the cost differential of alternative therapies. The cost of inappropriate therapies is considered a quality-of-care issue, not necessarily a financial one. An example might be giving red-blood-cell stimulating factor to a pa-

tient with a hemoglobin of 13 gm/dl, or possibly not supplementing the therapy with appropriate iron. Thus, this translates into a quality-of-care issue. Conversely, the cost of an alternative therapy is considered a clinical-and-financial issue. One example might be giving a patient a dose of epoetin alfa (Procrit) instead of a dose of darbepoetin alfa (Aranesp), as several studies have found epoetin alfa to be the more cost-effective choice for chemotherapy-related anemia (Ben-Hamadi 2005, Killian 2006).

Working with oncologists

When establishing standard/best oncology care practices at Lovelace, we first look at the national clinical guidelines recommended by the major oncology organizations, then tailor those guidelines to meet our specific populations or goals. At times, we may use one guideline, and in other instances, a number of guidelines. The guidelines most commonly employed by our organization include those offered by the American Society of Clinical Oncology (ASCO) and the National Cancer Care Network (NCCN) (ASCO 2007, NCCN 2007). For example, for anemia management, we utilize NCCN guidelines — which also mirror Medicare reimbursement patterns — ensuring that our organization receives payment for the treatments we provide.

In managing chemotherapy-induced nausea and vomiting (CINV), our organization relies on several different guidelines, particularly NCCN and ASCO. An interesting aspect of the Lovelace hematology/oncology system is that the pharmacy department has taken over the management of CINV, and is working to standardize the process. The pharmacist, based on the emetogenicity of the regimen, decides which medications are appropriate for the prevention of CINV and which medications to give to the patient for treatment of delayed CINV. This is a guideline-driven, established process that has been embraced by the oncologists in our organization.

To establish these best-of-care practices, our organization uses the Pharmacy & Therapeutics (P&T) com-

mittee for discussion and to arrive at a consensus on the care of oncology patients.

An additional process that enables us to work well with oncologists is a program that we refer to as “value-added services,” such as patient chemotherapy education and chemotherapy side-effect management. These programs help to free up the oncologist’s time for other tasks, and also creates a more robust multidisciplinary care approach.

The patient chemotherapy education program is especially beneficial to patients, as it empowers them to recognize potential problems earlier in their care. By sitting down with a patient for an hour or more before treatment begins, we can educate the patient about the therapy regimen, how long he or she will be in the clinic, and about the common side effects associated with chemotherapy. Examples of potential serious side effects are presented so that the patient knows when to seek help. Our hope is to limit the number of hospitalizations, which is obviously a cost concern of the health plan.

Daily challenges

Working with oncologists from different practice settings can be a challenge. Oncologists who come from an academic setting have a bit more free reign over what medications they can use, even when they have little or no data to support the utilization. It also can be difficult to grasp the economic issues that drive the academic community. For example, we have experience with one oncologist who was using 3 chemotherapy drugs in combination — irinotecan, oxaliplatin, and cetuximab — for the treatment of cholangiocarcinoma. Data exist about the effectiveness of these agents used individually, but there are no studies that demonstrate the efficacy of all 3 medications in combination. This high-cost scenario puts a strain on a health plan, and the oncologist may not realize the economic impact of using an uncommon chemotherapy regimen. As a health care organization, it is important to provide beneficial and effective treatment to our patients, but economic ramifications also must be kept in mind.

Another strain may be what is referred to as “right now” attitudes. For the most part, this applies to patient assistance programs, or such regulated medications as lenalidomide (Revlimid) and thalidomide (Thalomid). Specialty pharmacy services represent another initiative that may strain our relationships with oncologists. These services take some responsibilities out of the hands of oncologists or other department personnel. The work is

done outside of the organization, and time delays may occur. At times, it can be difficult for oncologists to understand that the plan or the pharmacy department does not have control over third-party performance and speed.

Additional challenges include a lack of standardization, where different physicians may have different ordering practices. Communication is a barrier in any organization, and it is particularly critical in this field to ensure that patients do not receive an incorrect drug or treatment. The personality traits of team members also can complicate matters. We must find ways to work together to agree on care practices.

Improvement initiatives

Under Lovelace’s current strategy, oncologists are reimbursed using average wholesale price.

This practice may not last, but for now, it makes for a better margin for both the oncologist and the clinic. Additionally, the health plan supports payment of educational efforts, which helps bring some financial responsibility, from a pharmacy standpoint, back to the clinic, and bodes well for future work within Medicare guidelines to pay for cognitive pharmacy services.

Another improvement initiative refers to patient payment obligations. Because New Mexico state regulations mandate coverage of chemotherapy agents, our health plan does not require copayments for chemotherapy or supportive medications that are received in the treatment room. Patients pay for an office visit, but there is no immediate financial burden associated with medication cost.

Other initiatives include point-of-contact services within the hematology/oncology department. For example, the onsite pharmacy staff allows for a multidisciplinary approach toward patient care. Patients can see the face of the person who is mixing their medications, and also can get questions answered in a face-to-face interaction, which we have found to be quite valuable.

As previously noted, prior authorization for supportive and oral medications remains in the hands of the pharmacy department, freeing this task for the oncologists. Our staff members ensure that proper coding occurs so that payment is not a problem.

We also find it important that our health plan support the clinical oncology pharmacist in a department that resembles a community-setting type oncology practice. Few community-type oncology practices provide patient access to clinical pharmacy services. This approach to patient care and the support from the health plan offers our patient population the best standard of care.

The patient chemotherapy education program is especially beneficial to the patients, as it empowers them to recognize potential problems earlier in their care.

Summary

The oncology landscape is changing dramatically, with many implications for health plans and providers. To meet the coming challenges, the only effective method is to collaborate with our oncology community. A discussion of emerging issues and a long-term strategy for managing oncology agents are, therefore, critical.

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DISCUSSION

Under- and overutilization of medication

STEVEN R. PESKIN, MD, MBA: Dr. Pesko, you raised two very valid issues. You mentioned inappropriate therapy as in, perhaps, overtreating anemia associated with cancer chemotherapy or chronic disease. You also spoke of alternative therapies and instances where you can potentially obtain more cost-effective therapy. There is a third issue that you did not mention — not giving enough drugs. Do you always assume in oncology that overutilization is going to be a problem?

LARRY PESKO, MS, PHD, RPH: We want to hit the “sweet spot” every time, and I think that goal is consistent with providers and clinicians. There are reasons that an individual provider may deviate from doing the right thing. They have may have additional information that we do not, or that we failed to take into account when updating our guidelines. The individual also may lack information. But I think in general, when we look at the distribution side versus the insur-

ance side, I think oncologists’ goals are the same in terms of patient care — to provide the best, most appropriate care for the patient. We want to get involved when there is deviation from that agreement.

JEREMY M. GLEESON, MD: But I think you’re right that in the oncology area, we don’t usually think much about underutilization, as we would in, say, diabetes — and that is an area that deserves more focus.

PESKO: I think there is a potential area of undertreatment or inappropriate treatment in CINV. I’ve seen a lot of “witchcraft” used in the past in preparing various cocktails to prevent nausea and vomiting that did not work.

Working through channels

PESKIN: As a provider of care and dispenser of product, as well as a payer, if you are dealing with a compound the pharmaceutical company has elected to dispense through a channel that does not include you, how do you handle that situation?

PESKO: Well, it’s difficult, it’s constraining, and it delays therapy for the patient. The pharmacy department is put in an unenviable position, because it is the interface between the patient and the insurer. Now, we’ve identified another group that’s between the patient and the pharmacy, and that’s the specialty company or the limited distributor chosen by the manufacturer. Often, the patient, and sometimes the physician, does not understand the criteria and the constraints that this new medication distributor requires for the product. I’m not talking about specialty pharmacy, in general, but about very limited distribution systems that manufacturers have elected to contract with that takes them outside the normal route of drug distribution in the United States. It’s very difficult to explain to the physician and the patient why therapies are being delayed.

That’s probably the biggest complaint from patients and insurance companies that we get as a system. Constrained delivery systems that manufacturers have put in place are certainly troublesome.

JOSHUA L. MARK, PHARM D, RPH: One strategy we’ve used to overcome this barrier is to assign a technician who is dedicated solely to dealing with these other organizations to facilitate or expedite that process.

Managing Oncology Agents: An HMO's Perspective

ROBERT JARAMILLO, PHARM.D, RPH

Former Pharmacy Director

Altius Health Plans, South Jordan, Utah

A key to quality, cost-effective patient care for any health plan is evaluating the cost and utilization of oncology medications. Although managed care has a strong track record in evaluating medications, it has not been as adept at handling oncology agents. This deficiency must change, however, because in the next 5 years, if not sooner, oncology is going to be one of the top categories for health maintenance organizations. The overall theme for the near future will be partnership between plan managers, plan pharmacies, and care providers. In the end, the patient will benefit most from improved collaboration.

Evaluating the cost and utilization of cancer care

Rarely does just one factor guide the decision as to whether a drug will be managed. The first consideration when looking at cancer care is to identify agents for management. Between 2 and 3 years ago, Altius began to take an aggressive look at the oncology medication category. We anticipated some pushback from the oncology community if we started by looking at how we managed older, existing therapies. So, we decided to start managing new therapies as they became available on the market.

The problem we encountered was that there were so many new medications in the pipeline that it became difficult to even identify those agents and then decide on which ones we were going to manage. Many of the new medications are extremely costly, and if we had a high-cost agent with a very low impact, then maybe that was an agent that we did not want to manage. It is, thus, very important for plans to get more involved and understand the new medications that are coming into the marketplace, or will soon become available.

Other factors include the indication of use, cost of the agent, and potential off-label use, which is one of the biggest reasons we might put some type of control on a particular product. We need to ensure that there are actual data to demonstrate a drug's effectiveness in a particular disease state. Route of administration is also an important consideration, because if a drug can be dis-

pensed on the pharmacy side or be self-administered, then it is significantly easier to manage. Conversely, if the drug is infused in the physician's office or requires hospital administration, that will likely cause us to take a harder look at whether it is worth our time to manage the product.



*Robert Jaramillo,
Pharm.D, RPh*

We also look at the current treatment of care. Is this therapy better than currently available treatments, and does this improvement warrant the cost differential? This involves surveying competitive agents. It's always an advantage for a plan to steer patients to more cost-effective agents. We will examine how the medication will be distributed and reimbursed. If a pharmaceutical company decides it is going to have only 1 or 2 vendors distribute this medication, or to make it available only in physicians' offices, that will play a role in determining if this is an agent we want to manage. Lastly, we will also seek out a technology assessment to determine where this drug needs to be used and placed.

Partnering with oncology caregivers

Altius has actively sought to reach out to key opinion leaders and to get them to participate on our medical technology, medical policy, and pharmacy and therapeutics (P&T) committees. Two years ago, as we were reviewing our prior authorizations, the majority were for oncology agents, but we did not have oncology representation. Many members of our P&T committee were clearly uncomfortable about making decisions because they did not have the necessary expertise, so we sought out several providers that are now part of our team. This has proven to be a truly advantageous step for our plan.

There are cases where fast decisions need to be made, and because P&T meets only on a quarterly basis, we have reached out to oncologists who are experts in particular disease states. They will look over a policy that we have prepared regarding a medication before it is even launched as part of the plan.

Understanding standards of care is another great opportunity for collaboration. So much is happening in the oncology world today that we need to partner with these

caregivers to determine not only what they are doing now, but also how their best practices and treatment regimens may change in the near future.

We have discussions with our oncology partners before implementing policies that will have substantial impact. We also review and take into consideration compendia indication listings. Although we would like to rely solely on FDA indications, we want to be sure that strong data exist to show that these drugs are effective in particular disease states or patient populations.

We also are trying to shift the focus away from the [oncologist's] profit associated with medications, and instead place emphasis on higher payment for their administration. This has been a slow process that has taken the last few years to shift in that direction. Finally, by simply getting more oncology caregivers involved in patient case management, we inevitably strengthen our partnership.

Plan challenges

Sometimes there is a scramble for resources when new therapies come out, and we as health plans find ourselves ill prepared for or not even aware of a newly available medication. Because oncology drugs are an expensive category of medicine, budget is an important part of the picture for both the pharmacy and the plan. It is becoming harder to stay within budget, particularly when we want to be able to offer affordable premiums.

Another big challenge is integrating pharmacy and medical costs to help alleviate strained budgets. Plans tend to take a silo perspective when looking at new drugs, thinking strictly in terms of how much can be saved on the pharmacy side. We need to do a better job of incorporating the costs on the medical side so we can look at overall plan expenses pertaining to a new medication. This allows for more intelligent decisions regarding the preference of one drug over another. This is an area where I believe we need assistance, as most plans are far from having an optimal approach to this issue.

This integration also would allow us to capture the true cost of oncology treatments, something that many plans are not yet able to do. We need to look more closely at this approach if we are going to effectively manage this category.

Managing off-label usage among oncologists is another task plans face. Some oncologists give their patients varying treatment regimens, some of which do not have validated, evidence-based clinical benefit. There is an opportunity for plans to step in and decide what treatments are appropriate — not only for the patient, but also to more efficiently ascertain and manage the costs.

Integrating medical and pharmacy management is another challenge. Pharmacy tends to be both a bit more aggressive and effective at managing medications. Many plans are going to move new medications, such as infused drugs, to the pharmacy side for management. To be effective, however, this move will take planning and strategy.

There is a need for program development, particularly in the area of case management. We also have seen a huge shift in changing physician reimbursement from average wholesale price (AWP) to average sales price (ASP). It will take a lot of planning for this practice to become better accepted on the provider side. In addition, plans need to better engage their partners in the area of pay for performance.

Ethical decision making is difficult for plans. Does it make sense to pay for expensive therapy for someone to stay alive for 6 more weeks? Some patients may benefit for longer periods of time and others for less. For a health plan, this is a quandary we will face more often.

As more and more costly therapies enter the marketplace, we must be sure that we can continue to offer affordable premiums to our customers, and also to keep out-of-pocket costs affordable. Failure to do so will make insurance unattainable for some. Finally, we have to balance access to best care practices with cost management issues.

A plan clearly wants to avoid placing stumbling blocks between a patient and the best standard of care, but at the same time, it also needs to manage costs.

Oncology caregiver challenges

Oncology caregivers have been obligated to accept some of the plan's management tools, centering mainly on prior authorization. One system Altius has developed over the last several years is an injectable formulary with a tiered placement of preferred agents. As more agents become available, the formulary will be expanded, requiring ongoing communication with the oncology community.

The acceptance of movement from AWP to ASP pricing has been slow. By taking several years to implement this strategy, Altius has reached the approximate midpoint of where it wants to be. Another area that needs to gain acceptance from oncologists is the preferred distribution of medications. I believe it is going to become increasingly common that plans will more readily negotiate a better contract with a specific distributor if it is mandated that clinicians have to get the medication from a particular source, or accept the reimbursement provided. There will be a lot of pushback here from oncologists.

The facilitation of a timely response to physician appeals and challenges is important to caregivers. Although

there is an appeals process in place, often there is the mentality of “We want it done now,” and I think with more resources, we are going to work toward that goal in a more timely fashion. Concurrently, physicians will need to be more accepting of the fact that it takes time to review the information that they have provided to us.

Finally, oncologists will need to balance ethics with access to the new medications and the management of their costs, and, of course, they will want to be adequately reimbursed for their services.

Challenges from a patient’s perspective

As more of costly therapies emerge, one concern is being able to offer patients access to the best care. A plan clearly wants to avoid placing stumbling blocks between a patient and the best standard of care, but at the same time, we also need to manage costs. We must do a better job of educating our patients about the tools we use to manage oncology drugs.

Obviously, patients want affordable premiums and out-of-pocket costs. It is important that our membership see what plans pay as we distribute higher costs across the board. Patients also need to understand that sometimes a medication is a last-salvage effort, and that while it is understandable that they are trying to seek out what they may perceive to be the most extensive care for themselves, or for an ailing relative, these drugs may not be effective. Getting patients to understand that is a huge challenge.

We also have to engage patients in their own disease management, especially since research has suggested that a patient’s influence is pervasive, affecting care at different points along an episode of illness (Kravitz 2003). We struggle with this step constantly, and I still do not know the best tools to achieve this goal. Patients need to have an understanding of our policies — prior authorization, injectable and oral formularies, and the distribution of medications.

Finally, a true understanding of therapy costs would be of great value to patients. Many patients think that a drug costs only the \$10 copayment they pay at the pharmacy. They do not realize the true cost of the therapy and why the plan is taking the steps it is.

Strategies to improve patient care

As we move forward, we need to continue to develop communication efforts with our oncology groups and single providers. I think this is critical for the success of Altius, and also to achieving a great working relationship with oncologists. We need to increase our oncologists’ participation on our advisory committees, and to provide them with input into our policies. I think we must increase payment for the administration of medications, and reduce reimbursements for the medications themselves. In this way, we can feel secure that providers are

doing what is truly best for the patient and not trying to drive them toward a more profitable treatment model.

I believe that rewarding physicians for following the plan’s policies through a pay-for-performance program is a positive step, as is paying for medications for investigational studies. Plans also should be flexible when contracting fee schedules. I do not think this can be done all at once, but through give and take, we might all be able to get on the same page. Increased contracting of facilities and services to improve patient access is also important, as is a focus on best practices when developing our policies. Rather than not understanding the full scope of how a medication is being used, we need to raise our knowledge level.

The development of physician report cards is a good way to partner with a practitioner, and gives providers an understanding of how we think they are doing, but also offers them a chance to provide input on the plan’s strengths and weaknesses. Creating oncology case management programs may be as simple as examining adherence rates to determine if patients are taking their medications, and also looking at polypharmacy can ensure that no medication is being overlooked in the spectrum of care.

Summary

The only way to accomplish the goals discussed is for health plans to collaborate more constructively with the oncologist community. We have reached out to providers, but there is still plenty of room for improvement. It is critical for both our success and that of the oncology community, because no one benefits from an adversarial relationship. We have not really sat down as partners with care providers to talk about what both parties see as emerging issues and how to best address them. We are at a point in oncology where we have this opportunity.

Reference

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DISCUSSION

Keeping up with the pharmaceutical pipeline

STEVEN R. PESKIN, MD, MBA: Do you formalize how you keep abreast of the very rapidly changing oncology pipeline?

ROBERT JARAMILLO, PHARM D, RPH: Yes, we try to tap into several different sources. We use the pharmaceutical industry heavily, because we have its representatives come talk to us about what is out and what is going to be out in maybe 6 months. We also look to our pharmacy benefits manager to let us know what’s on

the horizon. That has been a great resource for us. We also look to oncology organizations to give us information about what they see coming through the pipeline.

PESKIN: How do you engage in dialogue with the oncology organizations?

LARRY PESKO, MS, PHD, RPH: Getting updates in terms of examining the pipeline for new drugs that may hit the marketplace is helpful.

JARAMILLO: What's been helpful, too, is when this is conducted in an environment where your peers are there, because there are some things that maybe another plan may think of that will perhaps lay seeds in your head as to "maybe that's something we'd like to try" or "does it make sense really to manage this particular product?"

PESKIN: So you're open to the companies coming in and giving you a preview of the next 9 months to a year?

PESKO: Yes, especially for a product that may already be on the market, but is looking at expanded indications. To understand what studies are in place and the criteria used to measure outcomes is very important to us. Likewise, it is valuable to sit in a room with your colleagues and hear their impressions and responses to this information. It gives you insight for developing strategies that will be employed when those agents hit the market.

PESKIN: I guess Lovelace has another early warning system that most pure payers would not have, given that you are — as Dr. Gleeson informed us — involved in clinical trials. Through this sort of collaboration with the university, it gives you another early warning, I would think.

JEREMY M. GLEESON, MD: Yes, it does. Sometimes we get information about what's coming down the pike. Whether we utilize that information effectively may be another matter.

Oral versus injectable agents

DENNIS T. HARSTON, MD, MBA: We continue to have a benefit differential for the oral medications. They have a pharmacy copayment that is usually considerably less than the coinsurance that goes with the injectables. Hopefully, the doctor and the patient are going to be geared toward the oral, which is a pharmacy benefit.

JARAMILLO: If there is ever a situation where maybe an injectable therapy is more cost effective and more effective in our criteria, say, as we perform prior authorization, we may create a step therapy. There are definite ways that we can do this, but again, we have not yet gone in that direction. I think Altius is very open to looking at those opportunities.

CONTINUING MEDICAL EDUCATION ASSESSMENT/EVALUATION/CERTIFICATE REQUEST
Managed Care Best Practices in Oncology Management

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EXAMINATION: Place an X through the box of the letter that represents the best answer to each question on page 21. There is only ONE correct answer per question. Place all answers on this form:

	A.	B.	C.	D.
1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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15.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PROGRAM EVALUATION

So that we may assess the value of this self-study program, we ask that you fill out this evaluation form.

Have the activity's objectives, listed below, been met?

- Describe the current oncology landscape within managed care.
 Yes No
- Ascertain the concerns that health plans have regarding the evolving process of cancer care.
 Yes No
- Focus on the importance of collaboration between the managed care industry and oncologists to strengthen cancer protocols and quality improvement initiatives.
 Yes No
- Explain the challenges faced by pharmacists when evaluating the cost, effectiveness, and utilization of oncology services.
 Yes No

- Prepare for the future trends and cost issues that will face the oncology and managed care communities.
 Yes No

Was this publication fair, balanced, and free of commercial bias?
 Yes No

If no, please explain: _____

Did this educational activity meet your needs and contribute to your personal effectiveness? Please indicate your level of agreement:

- Strongly agree.....5*
- Agree4*
- Neutral.....3*
- Disagree2*
- Strongly disagree.....1*

Did it improve your ability to:

Treat/manage/support patients?	5	4	3	2	1	N/A
Communicate with patients?	5	4	3	2	1	N/A
Manage your practice?	5	4	3	2	1	N/A
Other _____	5	4	3	2	1	N/A

Effectiveness of this method of presentation:

	<i>Very</i>				
	<i>Excellent</i>	<i>good</i>	<i>Good</i>	<i>Fair</i>	<i>Poor</i>
	5	4	3	2	1

What other topics would you like to see addressed? _____

Comments _____

CONTINUING EDUCATION POST-TEST

Managed Care Best Practices in Oncology Management

Please tear out the combined answer sheet/evaluation form on page 20. On the answer sheet, place an X through the box of the letter corresponding with the correct response for each question. There is only one correct answer to each question.

- 1. Cancer accounts for what percentage of fatalities in the United States?**
 - a. 21 percent.
 - b. 23 percent.
 - c. 25 percent.
 - d. 27 percent.
- 2. What is the average cost for a course of therapy for a patient with advanced lung cancer?**
 - a. \$44,000.
 - b. \$48,000.
 - c. \$52,000.
 - d. \$56,000.
- 3. About what percentage of breast cancer patients have tumors that overexpress human epidermal growth factor 2?**
 - a. 15 percent.
 - b. 20 percent.
 - c. 25 percent.
 - d. 30 percent.
- 4. Under the model designed by Utah Cancer Specialists, the patient advocate has all but which of the following responsibilities?**
 - a. Help to reduce confusion about payment for cancer treatments.
 - b. Research latest treatment and medication options.
 - c. Handle paperwork, such as insurance forms and applications to Medicare or Medicaid.
 - d. Ensure that preauthorization has been acquired.
- 5. Carcinoembryonic antigen has the longest history of use in cancer treatment and has high sensitivity and specificity levels for use as a screening tool.**
 - a. True.
 - b. False.
- 6. Prostate-specific antigen (PSA) testing is controversial for all but which of the following reasons?**
 - a. It has low specificity for prostate cancer, resulting in unnecessary biopsies.
 - b. It has been used excessively to screen elderly men whose life expectancy does not typically warrant treatment, even in the face of clinically significant disease.
 - c. It has failed to raise awareness about the potential value of biomarkers in cancers.
 - d. It has not been found effective in reducing mortality rates.
- 7. If genetic testing for BRCA1 and BRCA2 is precluded because of its cost, which of the following steps should an oncologist take when treating a patient with breast cancer?**
 - a. Monitor her closely, with special attention paid to her ovaries.
 - b. Determine if transvaginal ultrasound is covered.
 - c. Urge the health plan to reconsider its decision.
 - d. Inform the patient that she needs to find another oncologist to treat her.
- 8. The long-term, disease-free survival rates for patients with resected liver metastases is approximately:**
 - a. 15 percent.
 - b. 20 percent.
 - c. 25 percent.
 - d. 30 percent.
- 9. At Lovelace Medical Center, the pharmacy and therapeutics process does not evaluate which of the following?**
 - a. Cost.
 - b. Efficacy.
 - c. Safety.
 - d. Feedback.
- 10. Lovelace Medical Center utilized which organization's guidelines when constructing its own anemia management guidelines?**
 - a. National Cancer Care Network.
 - b. American Society of Clinical Oncology.
 - c. Oncology Nursing Society.
 - d. Society of Surgical Oncology.
- 11. Which of the following is not a benefit of "value-added services"?**
 - a. A more robust multidisciplinary care approach.
 - b. Less paperwork.
 - c. Patient empowerment.
 - d. More time for oncologists to focus on other tasks.
- 12. Irinotecan, oxaliplatin, and cetuximab each have shown individual activity for the treatment of cholangiocarcinoma, but no studies have demonstrated their efficacy in combination.**
 - a. True.
 - b. False.
- 13. Which of the following aspects of point-of-contact services with the hematology/oncology department at Lovelace Medical Center is untrue?**
 - a. Patients can have their questions answered in a face-to-face interaction.
 - b. Fewer individuals are involved in patient care.
 - c. Patients can decide what treatment regimen they would like to receive.
 - d. Prior authorizations are no longer required.
- 14. Which of the following is one of the biggest reasons why health plans put some type of control around a particular agent?**
 - a. Potential off-label usage.
 - b. Cost of the agent.
 - c. Indications of use.
 - d. Route of administration.
- 15. From the health plan perspective, three of the following types of patients are considered challenging. Which one is not, or at least, less so?**
 - a. Those who have a desire to seek out the best possible care, regardless of whether the drug is effective for their specific condition or a last-salvage effort.
 - b. Those who lack of understanding regarding the health plan's policy.
 - c. Those who fail to realize what their therapy truly costs.
 - d. Those who are overly involved in their own disease management.

