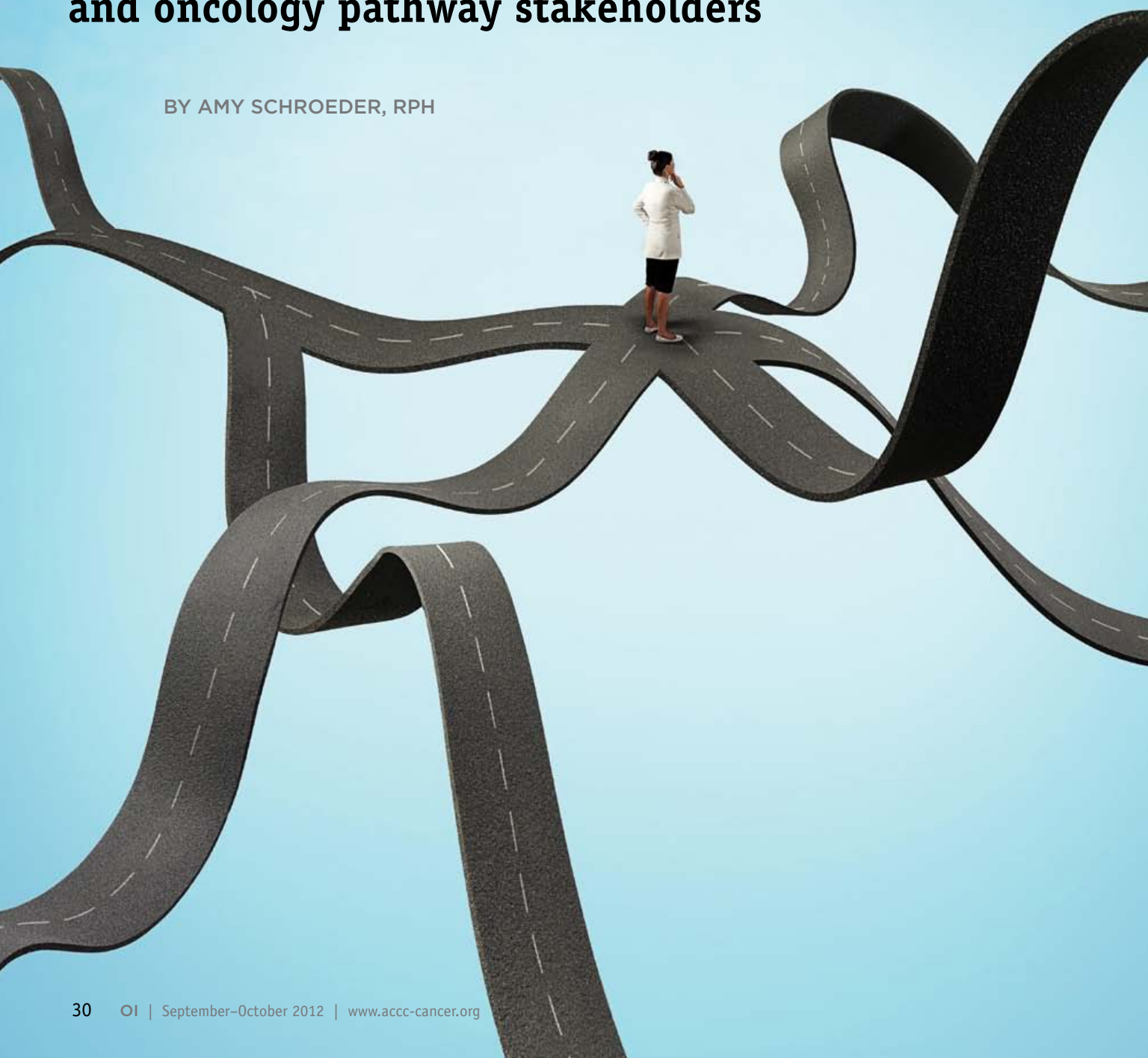
Cancer Management Systems—
Are We Heading Down the Right Road?

Results of qualitative research with payer, provider, and oncology pathway stakeholders

BY AMY SCHROEDER, RPH



In Brief

Recent articles and conferences on cancer management systems all circle around a key question—*how to simultaneously manage costs, maintain quality, and determine the value of a given treatment for both the patient and the healthcare system*. Findings from a three-phase research effort by DK Pierce & Associates, Inc. (see box on page 35), coupled with highlights from our ongoing advisory forums with payer and provider stakeholders, present a snapshot of the landscape from both the payer and provider perspectives, as well as a look at the emerging role of cancer management systems, and the options available to payers and providers for maintaining quality care while controlling costs.

Multiple factors affect the drive to create new approaches to manage the cost and delivery of cancer care, including:

- Variations in cancer care delivery[1,2]
- An increasing oncology drug spend[3]
- Evolution of employee cost-share responsibility[4,5]
- Employer application of comparative effectiveness research (CER)[6,7]
- Limitations of current clinical resources.

Oncology providers and commercial managed care organizations have indicated that currently available clinical resources do not provide enough guidance to make tailored cancer treatment choices.[8] Clinical compendia and oncology guidelines will commonly rate treatment options based on their own merit, but the guidelines generally do not provide comparisons among available options and guidance to reduce variations in care and cost. In cases where a provider does not have a set protocol, research to review all compendia options with equivalent clinical ratings can be very tedious. Additionally, these resources do not always address subset patient populations or manage decisions when preferred agents are contraindicated.

In 2012 oncology providers are looking for tools that will support efficient and valuable participation in accountable care organizations (ACOs) and patient-centered medical homes (PCMHs). Both payers and oncology providers need help in analyzing the combined implications of the cost for an oncology drug with total cost of care, efficacy, and safety. Without a valid evidence-based support process, clinically beneficial, cost-effective treatment choices for patients are difficult. The question remains: *What are the most appropriate resources for getting this information?*

Before this question can be answered, we must first look at what the research tells us. The following research findings were reported by DK Pierce & Associates, Inc., at an Oncology Stakeholder Advisory Board in October 2011.

Payer Decision Making Across Lines of Business

Commercial payers contracting with the Centers for Medicare & Medicaid Services (CMS) for managed Medicaid, Medicare Advantage, and Medicare Part D prescription drug benefits are bound to a certain extent by criteria they must follow. For example, these entities are required to submit Part D formularies to CMS for approval. However, these payers can apply utilization management criteria, such as prior authorization and step therapy at the time of prescribing, to differentiate between drugs. Under the Medicare Modernization Act (MMA), Part D formularies were to focus only on drugs that cannot be covered under Medicare Part B (essentially focusing on oral and self-administered agents), yet most benefit models of utilization management are the same in a Part D plan and in a commercial plan. Some of this similarity can be explained by the fact that dual-eligible patients (those with Medicare primary and Medicaid secondary) receive all their drugs through the Part D plan—self-administered and physician-administered. However, when a dual-eligible patient is in a nursing home, this is not always the case. An ambulatory dual-eligible is automatically assigned to a Part D plan, and physician-administered drugs may or may not be processed through the Part D benefit. If the physician-administered drug is processed through Part D, it would be shipped to the physician's office (white bagging) where the drug is administered and the patient pays a Part D co-pay. Payers surveyed noted very little difference in drug management between commercial and managed Medicaid lines of business.[9]

In the current environment, a majority of payers stated they would establish a prior authorization upon FDA approval for an oncology drug, limiting its use only to the FDA-approved label.[9] Off-label coverage could be handled on appeal following the initial denial, or by having the claim suspended for manual medical necessity review based on additional documentation submitted by the oncology provider.

Among payer medical and pharmacy benefit decision makers, regardless of the line of business, the prevalent areas of concern for oncology drugs include:

- Looking at the overall drug cost
- Determining the point for discontinuing therapy
- Managing off-label use
- Narrowing the variation among treatment options.

Many commercial payer policies refer to compendia and guidelines for guidance on coverage of cancer drugs. Some commercial payers take guidance from CMS on what compendia and literature to use; other payers use their own logic

Figure 1. Percent of Overall Practice Revenue Derived from Oncology Drugs (Oral and IV)

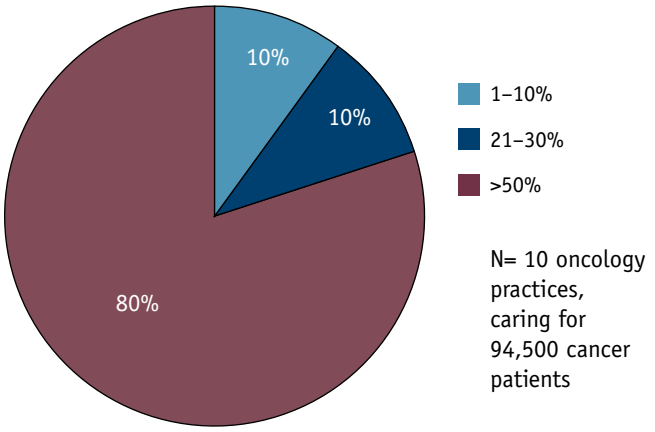
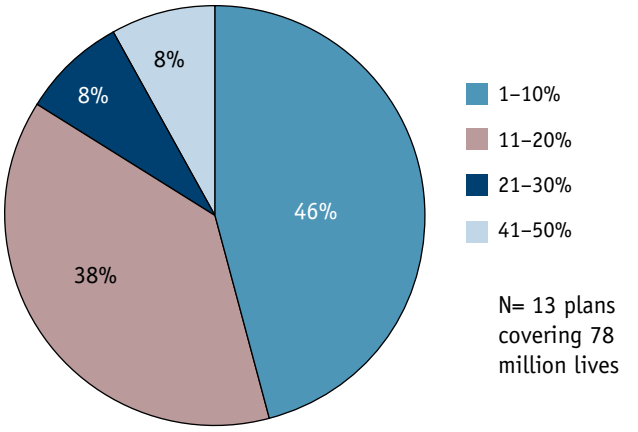


Figure 2. Portion of Overall Plan Expenditures Categorized as Oncology Drug Expense (Oral and IV)



based on references they prefer or employ a combination of options. When considering all of the variables that affect commercial payer decision making, keep in mind that payers must follow any state-based legislation that is in place.[10]

Oncology Drug Revenue & Costs

Oncology practices were asked about the percent of overall practice revenues derived from drug reimbursements. As seen in Figure 1, above, eight of ten practices still obtain greater than 50 percent of their overall revenues from drugs. Drivers for this include the addition of onsite pharmacies to manage Part D benefits for some patients. For some practices, the "buy and bill" application of in-office drug administration still serves as the primary model—even though payer reimbursements have slipped over time.

Commercial payers were asked what portion of overall plan drug expenditures were categorized as oncology drug expense. As Figure 2 above shows, 84 percent of plans surveyed reported that expenditures for oncology drugs are currently up to 20 percent of overall drug expenditures.[8]

Clinical Guidelines, Compendia & Health Technology Assessments

The majority of payers surveyed are using clinical guidelines in decision making; 92 percent report using NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) as first choice and ASCO Clinical Practice Guidelines as second choice. When choosing among clinical guidelines, 40 percent of providers report choosing pathways over or in place of guidelines.

The most popular guidelines used by both providers and payers are NCCN Guidelines. Other guidelines used include National Institute for Health and Clinical Excellence (NICE) and Cancer Clinics of Excellence (CCE) Evidence-based Treatment Protocols (ETPs).

The most popular compendium used by providers and payers is the NCCN Drugs & Biologics Compendium (NCCN Compendium®). In interviews, payers indicated that compendia are not given equal weight even when policies state more than one compendium is used. The NCCN Compendium is given more merit as the standard, based on its oncology focus and timely updates. All payers and providers who participated report using the NCCN Compendium. Fifty-four percent of payers and 80 percent of providers ranked NCCN Compendium as their first choice (see Figure 3, page 33).

If compendia and health technology assessments (HTAs) conflict in their findings, payers can choose not to cover an indication of use. Payers will review the FDA label and base initial coverage on the label. Off-label use typically will trigger an appeal or manual medical review process. Although commercial payers acknowledge the NCCN Compendium because it is recognized by CMS, payers have varying levels of respect for the NCCN Compendium and the NCCN Guidelines. This diffidence is because neither the guidelines nor the compendium provide definitive direction on the most appropriate treatment options for a given tumor at specific stages of disease.

When oncology providers were asked how they apply clinical compendia, we found that:

- 70 percent use compendia as coverage and reimbursement resources, as many of their patients have insurance policies that cite compendia criteria for coverage.
- The remaining 30 percent use compendia as coverage and reimbursement resources and as a clinical resource for initial determination of appropriate therapies.
- None of the surveyed programs use compendia solely as a clinical content decision-support tool.

Value of Peer-Reviewed Literature

Oncology providers have select oncology journals they prefer, including the *Journal of Clinical Oncology,* the *New England Journal of Medicine, Cancer,* and *Blood;* however, payers follow the broader Medicare policy oncology journal list. Both

providers and payers stated that they prefer to refer back to the original source of data, i.e., the initial clinical trial publication, although that process can be tedious.

Payers commonly approach a drug differently if there is no competitor (defined by the payer as any other treatment option within that same tumor type or stage of disease—not necessarily another drug in the same drug class). If no direct competitors exist for a drug, consideration for unmet need impacts any economic analysis. However, if multiple drugs are used to treat the same tumor type, the focus on cost increases. It is important to note that payers do not believe that there must be a head-to-head clinical trial to be able to assess cost implications.

Payers are using peer-reviewed data to help integrate other initiatives to ensure appropriate patient selection for therapies. These include:

- ***Detailed prior authorization criteria.*** Payers are commonly limiting indications of use to the FDA label and/or including ICD-9-CM diagnosis code edits, drug therapy "step edits" (documentation of prior failures, if appropriate), appropriate drug combinations, dosing criteria and term of therapy limitations, and even age-appropriateness (all based on clinical trial results).
- ***Split scripts.*** For oral anticancer drugs, some payers will dispense a 15-day supply of the drug to ensure that the patient can tolerate the medication and that dosing changes won't be required. Patients are not required to have a co-pay at each point of dispensing, but rather will pay only one co-pay per month.
- ***Novel benefit tiers.*** Select payers are rolling out tiering based on a product's "cost utility." Those drugs providing the greatest quality per adjusted life-year (QALY) savings are placed on the lower co-pay and co-insurance tiers. Other payers are developing parity benefits across both oral and injectable oncology drugs to address state-based legislation on parity of access.

Payers are mixed on their acceptance of Phase III vs. Phase II data, and acceptance is influenced by FDA approval status. If a given drug is FDA approved, then Phase II data would be accepted with cost as a driver for differentiation as compared with other available treatments. Most payers are still looking for NCCN Compendium 2A level of evidence to drive acceptance for off-label use.

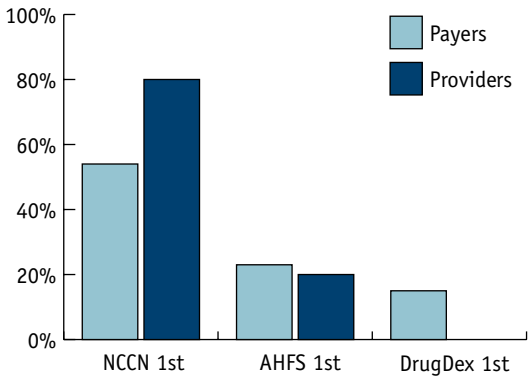
Improvement in overall survival is the *preferred* endpoint and, according to payer respondents, is likely to be the *required* endpoint in the future, as evidenced by Phase III trials. Payers may use progression-free survival (PFS) to establish prior authorization criteria, but prefer to see overall survival improvements, even in late-stage disease.

Payer respondents did not find quality of life (QOL) data relevant based on current clinical trial designs and available tools for measurement, but anticipated that physicians would value QOL data more. Cost offset, i.e., reduction in direct and indirect patient care costs, and other pharmacoeconomic findings are viewed with skepticism by payers, as these studies seem to have manufacturer bias or cannot be played out when the drug enters real-world application. However, select payers feel that these studies could be considered if a drug manufacturer was interested in applying a risk-share contract around those outcomes.

When expanding the clinical resource discussion into health technology assessment application for both oncology providers and payers, 92 percent of surveyed payers and 70 percent of surveyed providers use AHRQ, Cochrane, and/or Hayes HTAs, with a few using HTAs from NICE, the Lewin Group, or Blue Cross Blue Shield. Of surveyed oncology programs, 80 percent use HTAs, with AHRQ rated the highest, followed by Cochrane, Hayes, and the Lewin Group.

Payers are integrating other initiatives to help ensure appropriate patient selection for therapies. Compendia and guidelines provide an assessment of individual therapies, but rarely apply comparative effectiveness or guidance for how to treat outliers. Respondents expressed a need for decision-making tools to help select an appropriate therapy for an individual patient.

Figure 3. Compendia Preference



Clinical Pathway Integration

Often when the term "oncology clinical pathway" is used, the underlying thought process runs directly to payers and how they are using pathways. However, oncology clinical pathways are a significant and growing presence in oncology practices, based on provider interest in creating greater consistency and evidence-based decision making and managing the costs of cancer care. Clinical pathways are designed to demonstrate their value in terms of quality and efficiency as the market evolves with healthcare reform.

Pathways can be a packaged product from a selected vendor, or developed internally by providers or payers. Clinical pathway programs can include retrospective review of claims, comparing past medical decisions to evidence-based medicine, as well as prospective decision-making tools that help providers select evidence-based treatment options, based on

Table 1. Developing a Multidisciplinary Care Model[11]

VENDOR	FOCUS	CURRENT PATHWAYS	PATHWAYS IN DEVELOPMENT
D3/CareCore (Via Oncology)	Provider**	Bladder, Breast*, Colorectal, Esophageal*, Gastric, Head & Neck*, Lymphomas* (Hodgkin, Non-Hodgkin, Follicular, Mantle Cell/SLL, Large B-Cell, Peripheral T-Cell), MDS, Melanoma, Lung* (Mesothelioma, Non-Small Cell, Small Cell), Multiple Myeloma (Newly Diagnosed, Relapsed, Maintenance Therapy, Waldenström's Macroglobulinemia, Primary Amyloidosis, Plasma Cell, Solidary Plasmacytoma, POEMS), Ovarian, Pancreatic*, Prostate*, Renal Cell, Thyroid, Uterine, and advance care planning. Supportive care options are included in individual pathways. Most recent: CML. Radiation Oncology: Bone metastases, Brain metastases, Cervical, Endometrial, Rectal, Sarcoma, and Vulvar—now covering 90–95% of patient presentations.	Appropriate use of genetic tests or "companion" diagnostics
Cardinal Health/P4 Healthcare	Payer	Breast, Lung, Colon, Ovarian, Prostate, Renal and Multiple Myeloma Cancers: B-Cell Non-Hodgkin Lymphomas and/or Supportive Care Areas of Anemia, Neutropenia, and Anti-Emesis	Supportive Care Areas for Pathways, end-of-life care, and diagnostic testing
McKesson/US Oncology (Innovent)	Provider and Payer	Breast, CLL, Colon, Esophageal/Esophageal-Gastric Junction, Gastric, Head & Neck (3), Hodgkin, Multiple Myeloma, Non-Hodgkin Lymphoma (3), Non-Small Cell Lung, Ovarian, Pancreatic, Prostate, Rectal, Small Cell Lung, Supportive Care (4)	
ITA Partners (eviti)	Payer	1000 treatment options for 120+ cancer types, with a goal of covering 100% of patient presentations.	
New Century Health	Payer	13 major tumor types, including Breast, Lung, Colon, and Prostate, covering 75% of patient presentations	Additional pathways to meet goal of covering 90–95% of patient presentations
ION Solutions	Provider and Payer	Breast, Colon, Lung, and best supportive care	

Note: All pathways vendors consider enrollment in clinical trials as a preferred option. *Includes Medical and Radiation Oncology pathways. **D3 Oncology Solutions provides Via Oncology pathways content directly to providers. D3 and CareCore formed a joint venture in 2011 called PathForward Oncology, which is a separate entity that licenses Via Oncology content for sale to payers.

patient-specific data entries, at the site of care.

Clinical pathways can provide the majority of information requested during the prior authorization process that cannot be identified by coding, which reduces paperwork and administrative burden. Some of the information tracked by clinical pathways' algorithms includes prior therapies, lab results, performance status, comorbidities, and other agents in the combination regimen.

Clinical pathways can provide the detail that is difficult to extract from coding and medical and pharmacy claims. Many pipeline oncology agents are expected to be very costly, with clinical trials targeting only certain narrow uses or with indications for use only in small patient populations at the time of their approval. Payer respondents identified that careful attention to proper prior authorization strategies for these drugs will be important. In some cases where the pathways relationship lies with the payer, authorization of an entire protocol can be provided in real-time, incorporating the most up-to-date patient information. Clinical pathway platforms also provide methods of tracking compliance with preferred pathway regimens and other metrics, such as advance care planning.

An overview of the major clinical pathways vendors is provided in Table 1, above, including whether their primary focus is with providers or payers, what clinical pathways they have in place, and the initiatives they plan for the future.

Before establishing a contract, many pathway vendors are entering into pilot programs with payers and oncology practices to see if the relationship fits and if maintaining quality care while reducing variation and waste saves money. Several pilot programs have been completed and are in the process of publishing their results; others are currently underway. (Author's Note: DK Pierce & Associates, Inc., invited a sampling of oncology practices and payers who are using all of the pathways programs mentioned to take the survey. Due to compliance policies, some were unable to participate.)

Top findings from pathways discussions include:

- Clinical pathways are updated at regular intervals, at least quarterly.
- Pathways make decisions on three criteria: #1 efficacy, #2 safety, and then #3 cost.
- Incentives are specific to each collaboration, so there is room to negotiate how providers will be rewarded or penalized.
- Pathway compliance for the majority of programs is expected to be greater than or equal to 80 percent.
- Pathways can be integrated into provider EMR or implemented via web-based access.
- Pathways are an arm's length from drug manufacturers to minimize influence.

As mentioned above, compliance targets are generally set at 80 percent, and may be based on 1) selection of preferred regimens based on efficacy, safety, and cost; 2) number of years program has been in place; and 3) agreeing to use electronic processes vs. paper. Currently, we are seeing more voluntary participation with incentives vs. mandatory with disincentives. In some cases, adherence to pathways results in preferential payment models, i.e., higher reimbursement for complying with pathway recommendations. Some providers are contracting directly with pathways vendors and using performance data as leverage with payers. Figure 4, page 36, provides an overview of the different incentives offered for provider participation and compliance with pathway recommendations.

DK Pierce & Associates is tracking the ongoing changes in pathway vendor organization collaborations with payers, oncology societies, and providers. An excerpt of this research is documented in Figure 5 on page 36. Pins highlight contracted partnerships with payers and oncology practices, not oncologist users in payer networks.

The majority of oncology practices answering our survey use US Oncology Level I Pathways. Others use pathways programs that are created in-house or those created and run by D3 Oncology Solutions, Cardinal Health/P4 Healthcare, eviti, New Century Health, KEW Group, and ION Solutions.

Sixty-two percent of payers surveyed report that they are not using pathways programs. This finding simply means that the payer does not have a formal program with modifications on reimbursement for compliance and non-compliance.[11] At the same time, 38 percent of payers surveyed are using programs run by external (31 percent) or internal (8 percent) vendors for assessment of oncology drug utilization (see Figure 6, page 37).

For providers, 20 percent have internally designed programs with external programs as secondary support, 40 percent have programs designed by external pathways organizations, and 40 percent do not currently have programs, as illustrated in Figure 4.

Breast, lung, colon, and prostate cancers are the primary targets for those payers that do have pathways, with the first

OUR RESEARCH OBJECTIVES & METHODOLOGY

This research was developed to measure change in the market related to oncology drug management, specifically, and cancer care in general. The primary objectives were:

- To identify, from each stakeholder's perspective, key drivers that can be tracked to assess local, regional, and national change.
- To determine how payers and providers are approaching the balancing act between access and quality care for patients and the growing overall cost of cancer care.
- To outline clinical pathway initiatives.
- To build a foundation on which ongoing payer, provider, and pathway organization interviews can be layered to show market change over time.

In December 2011, DK Pierce & Associates finalized a three-phase research project that included:

Phase 1:

- Qualitative interviews with oncology pathway vendor organizations.

Phase 2:

- Online surveys with oncology programs (representing 150 oncologists caring for 94,500 patients with cancer)
- Interviews with national, regional, and local commercial payers (13 plans, covering 74 million lives).

Phase 3:

- Qualitative interviews with commercial payers focused on plans with high enrollment for Medicare Advantage, stand-alone Part D, and managed Medicaid business, and influence in oncology drug management models.

The intent of the research was to interview both large and small plans that actively manage oncology drugs, as well as to engage with those plans that are considering change for future benefit models. In terms of provider stakeholders, the research was designed to better understand evolving business models; utilization of guidelines, compendia, and pathways; and the providers' intentions concerning patient-centered medical home initiatives, etc.

Figure 4. Provider Pathway Participation Incentive Models

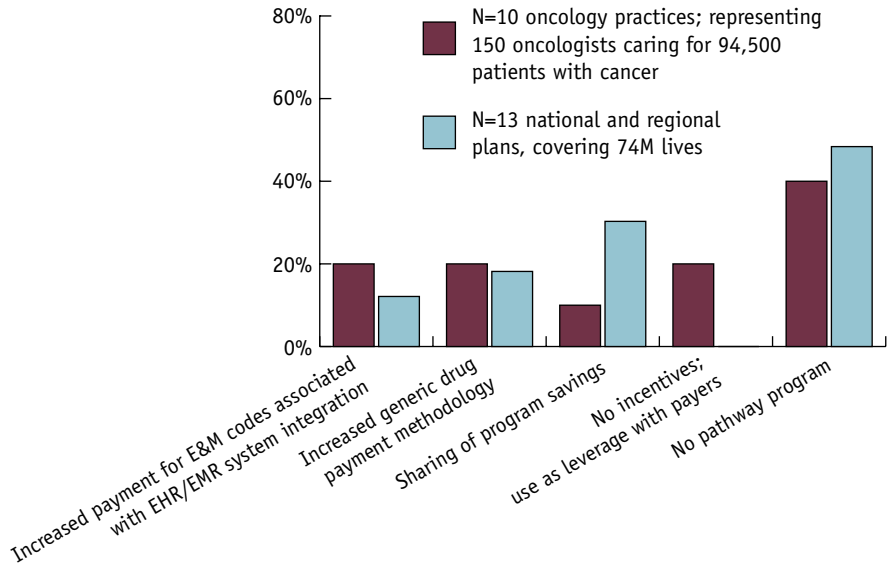


Figure 5. Oncology Pathway Collaborations

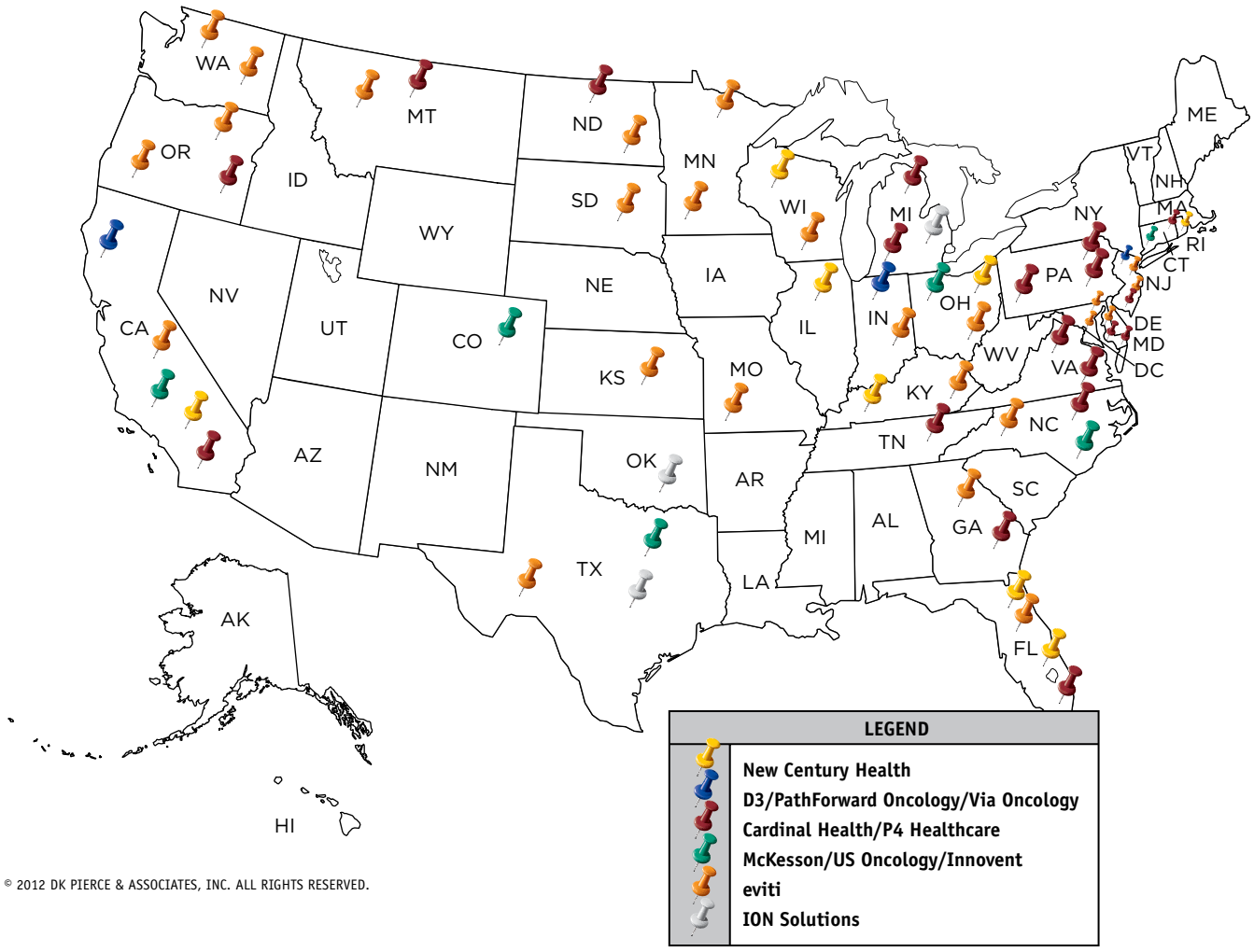
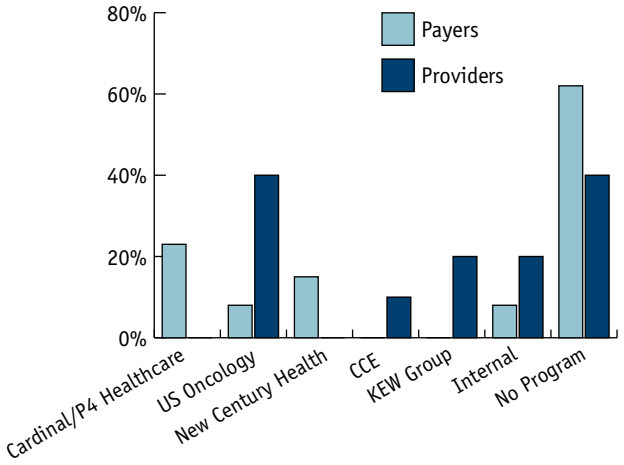


Figure 6. Use of Pathway Programs by Payers and Providers



three tumor types as the most frequent.

Lymphomas, ovarian cancer, and multiple myeloma are targets for expanded pathways used by payers in 2012. Leukemias are less of a target to date, possibly due to the inpatient treatment environment, or the fact that the hematologic malignancies do not have numerous high-cost drugs used to treat them. Multiple myeloma and lymphoma programs are already integrated into pathways used by oncology practices.

Payers are mixed on applying clinical pathways vs. conventional utilization management (e.g., prior authorizations) to manage cancers. So far, payers involved in pathways pilots have noted that cost savings are short-term and not always worth the up-front investment. Additionally, some payers are also hesitant to use pathways because of conflict with state off-label cancer drug legislation.

Going Forward

In summary, provider-focused clinical pathway programs focus on using a prospective decision-making tool to guide a provider to making the best treatment option for a given patient based on efficacy, safety, and then cost. Retrospective review of claims and medical records are used for reporting performance and compliance. Currently, providers engage in clinical pathways more as a means of documenting care quality and as leverage when contracting with payers. Payer-focused programs employ retrospective review of claims and are starting to enhance their technologies to include prospective tools that highlight preferred therapies, based on a patient's insurance plan and "real-time" authorization of those options. Payers are using pathways to cuts costs, but also as a means of showing that there is evidence supporting regimens that are preferred by the plans.

Pathways are on the road to guiding quality care and, initially, providing savings to parties involved. The question is: How long will the savings gained by following pathways continue?

The increase in oncology drug spend for patients and payers and the reliance on oncology drugs for provider revenue has led to increasing demand for measurement of quality vs. cost by payers, providers, and patients. The question yet to be answered is—What is the best way to measure for quality?

With the payer-driven cost-reduction focus, it is important for providers to know their options and make a choice, or payers will make the choice for them. Payers and providers may use cancer management systems, such as clinical pathways, for different reasons, but the important factor is that they are being used. Payers are looking for the best value to the system for the dollars they are paying out; providers are looking for the best quality and consistent care that will improve outcomes and provide leverage when negotiating contracts with payers. The market drivers are all pointing toward this same goal: How do we maintain the best value for the dollar? By identifying the best evidence-based cancer treatment options, and providing those options consistently across the U.S., we can maintain quality care and reduce costs. OI

—Amy Schroeder, RPh, is senior consultant, Oncology Strategies, DK Pierce & Associates, Inc., in Zionsville, Ind. For more information contact DK Pierce & Associates, Inc., at www.dkpierce.net/contact-us.

References

1. eviti, Inc. www.eviti.com. Last accessed July 25, 2012.

2. Goodman DC, et al. Quality of end-of-life cancer care for Medicare beneficiaries: Regional and hospital-specific analyses. The Dartmouth Institute for Health Policy & Clinical Practice. 2010 November 16. Available online at *www.dartmouthatlas.org*. Last accessed Aug. 1, 2012.

3. 2011 Medco Drug Trend Report, Vol. 13.

4. Towers/Watson National Business Group. The road ahead: Shaping health care strategy in a post-reform environment 2011. 16th Annual Towers/Watson National Business Group on Health Employer Survey on Purchasing Value in Health Care.

5. Claxton G, Rae M, Panchal N, et al. Employer Health Benefits 2011. Summary of Findings. The Kaiser Family Foundation and Health Research & Educational Trust. Available online at *http://ehbs.kff.org*.

6. Reynolds D, Martin D, Dubois RW, Westrich K. Comparative effectiveness research: do employers care? what will they do? National Pharmaceutical Council. June 2011. Available online at *www.npcnow.org/Public/Research___Publications/Publications/pub_cer/ceremployersurvey.aspx*. Last accessed Aug. 1, 2011.

7. National Business Group on Health. A guide for employers: using comparative effectiveness research. Treatments for clinically localized prostate cancer. June, 2011. Available online at: *http://businessgrouphealth.org/pdfs/FINAL_Prostate%20Guide_NBGH_AHRQ_June2011.pdf*. Last accessed July 25, 2012.

8. DK Pierce & Associates, Inc. DKP Critical Insights™: 2011 Cancer Management Survey.

9. DK Pierce & Associates, Inc. Oncology Stakeholder Advisory Board. October 2011.

10. DK Pierce & Associates, Inc. DKP Critical Insights™: 2012 State Cancer Coverage Legislative Report (with interactive map).

11. DK Pierce & Associates, Inc. DKP Critical Insights™: 2012 Clinical Pathway Vendor Organization Interviews.