CONTROLLING THE COST OF CARE THROUGH CLINICAL PATHWAYS

A look at how two health plans have integrated physician-developed clinical pathways into their networks.

BY BOB CARLSON, *Contributing Editor*

Clinical pathways are so new that some health plans seem uncertain about exactly what the term means. Several payers contacted for this article insisted that they had pathways when, in fact, they really meant medical policies. It's a sure bet, though, that the payer community at large will soon become diligent about clinical pathways for three compelling reasons: They reduce error, they improve the quality of care, and they reduce costs.

The concept is deceptively simple. Developed by oncologists, a clinical pathway is a management tool for standardizing the way an MCO network's physicians and other healthcare providers treat a disease. They are based on clinical guidelines or other commonly used clinical parameters. Right now, the diseases targeted by these pathways are the various cancers, but that may change as clinical pathways become more widely used.

Getting a group of physicians to do anything uniformly is almost a contradiction in terms, but at least two health plans have managed it by letting physicians themselves come up with the pathways—with a little help, of course.

CareFirst is partnering with P4 Healthcare in Columbia, Md., in an innovative pay-for-performance program using physician-developed clinical pathways. CareFirst serves Maryland, the District of Columbia, and Northern Virginia, with 3.2 million members on the medical side and 1.2 million members on the pharmacy side.

In phase 1 of the program, the pathways are for breast, colon, and lung cancer treatment and supportive care. In phase 2, which will be launched this year, the covered disease states will be expanded to include gastrointestinal, genitourinary, and hematological malignancies. Redwood City, Calif.-based Genomic Health's gene assay Oncotype DX has been included as a component of the pathway for breast cancer.

FEWER OPTIONS

"When I think of guidelines, whether they come from the NCCN [National Comprehensive Cancer Network], ASCO [American Society of Clinical Oncology], or ASH [American Society of Hematology], I think of many different approaches to treatment," says Jeffrey Scott, MD, president and medical director of P4 Healthcare. "When I think of pathways, I think of active management of those guidelines, which allows you to narrow the number of approaches in a given clinical scenario."

Scott practiced with Georgia Cancer Specialists in Atlanta for 15 years before founding P4 Healthcare, which is concluding its first year of a three-year collaboration with CareFirst.

"Our job is to facilitate the development of pathways by engaging the regional physicians, providing compliance tools, monitoring compliance, and communicating back to CareFirst and the physicians," Scott explains.

Scott's partner at CareFirst is Winston Wong, PharmD, associate vice president of pharmacy management at CareFirst, which has been experiencing 25 to 30 percent inflation rates in oncology costs. Wong classifies breast cancer, colon cancer, and lung cancer as his most expensive diseases.

"We felt like we needed to attain some control over our oncology costs," says Wong. "We could have just reduced our fee schedule, but we didn't want to make it one-sided. We wanted to make it a situation where we would have the oncologists actually working with us, and we believe we have a win-win here."

According to Wong, chemotherapy accounts for 36 percent of CareFirst's cancer care costs, and chemotherapy costs have increased 25 percent over the previous year. Breast, colon, and lung cancers, along with lymphomas and leukemias, are responsible for about 81 percent of total oncology costs. Add the cost of support-

ive care, and this figure rises to about 85 percent of care costs. With a cost trend like that, it's easy to understand why Wong likes a pathway that incorporates the Oncotype DX breast cancer assay. This molecular diagnostic assay generates a Recurrence Score (RS) based on the expression of 21 genes in breast tumor tissue. Patients with a high RS are at greater risk of recurrence and are more likely to benefit from chemotherapy.

"If pathways can help keep healthcare affordable, that's something we all need to work toward," says Winston Wong, PharmD.

"I don't want to sound like we're a marketing arm of Genomic Health, but what we see is the value of the test in terms of how it can affect cost within a patient population," says Wong. "Quite frankly, without this test, uptake would be very slow, and it is very slow right now, because a lot of physicians aren't really comfortable with the results of this test."

Scott asked a panel of nine regional oncologists and three academic oncologists to develop clinical pathways. The key driver was to identify those treatments which proved to offer the best care to patients. The physicians were tasked with using the available literature as well as national published guidelines as references in this process.

To assist the pathway development, P4 Healthcare licensed the existing pathways from the University of Pittsburgh Medical Center and the Georgia Cancer Specialists to serve as templates for the CareFirst pathways, thus incorporating aspects from multiple sources to achieve the final product. With Scott facilitating, the panel also added a pathway for treating newly diagnosed, early-stage, node-negative, estrogen receptor (ER)-positive breast cancer to the CareFirst breast cancer pathway. The new pathway incorporates the use of the Oncotype DX assay.

At one time, most women with early small, node-negative, ER-positive breast cancers were offered chemotherapy. That all changed when Oncotype DX became available in 2004. According to Genomic Health, on average, Oncotype DX changes treatment decisions 30 percent of the time when it is included in a treatment pathway.

"It's a wonderful test," says Scott, because it identifies many women who traditionally would have been exposed to chemotherapy but can now be treated with hormone therapy alone. It's also an important test, he says, because "there might be a patient who I think is at low risk of recurrence — so low that I might have considered hormonal therapy alone. Yet, when I do this test, it turns out that the risk is higher, and it might steer me toward chemotherapy."

Treatment pathways also have the potential to reduce medical errors. In an oncology practice with many physicians and nurses, several different ways of doing the same regimen clearly make for more errors than one standardized regimen.

EFFICACY, TOLERABILITY, AND COST

Developing or adding to a pathway involves evaluating efficacy, tolerability, and cost — in that order. If more than one approach is equally effective, the most tolerable wins out (in oncology, best tolerated invariably means least toxic), and if two or more options are equally tolerable, the less costly one wins. Scott emphasizes that pathways must be supported by scientific evidence and national guidelines from NCCN, ASCO, or ASH.

"Even though we're trying to control the cost of care, specifically in the oncology area, our primary focus is still to provide a quality care product to our members — people we actually live next to," says Wong, who adds that he did not participate in the pathway development discussions to avoid the appearance that CareFirst was driving the discussions and that cost was the major consideration.

Even with a molecular diagnostic assay as carefully developed and validated as Oncotype DX, some clinicians are very uncomfortable with the test, says Scott. Because oncologists are trained to believe that chemotherapy improves outcomes, they tend to prescribe it, and they may decide against ordering the test to avoid the possibility of a low RS — which would indicate that the patient is unlikely to benefit from chemotherapy.

"That's partly why we want to put Oncotype DX in a pathway, so we can eliminate that thought process," says Scott, who also facilitated the CareFirst pathway on hormone epidermal growth factor receptor 2 testing of breast cancer patients.

Wong has set the bar at a modest 65 percent oncologist compliance rate for the first year, followed by a more aggressive 80 percent rate thereafter. To make the pathway concept even more palatable, network oncologists who follow the early-stage breast cancer treatment pathway are paid at a higher rate than the standard fee schedule that the noncompliant docs receive. That's why Wong calls his initiative the oncology "pay-for-quality" program.

Scott believes Oncotype DX will save insurance companies substantial dollars because it eliminates not just the cost of chemotherapy and its ad-

For UPMC Cancer Centers, pathway care costs have increased only 1 percent annually; nonpathway costs have increased between 6 and 7 percent.

ministration, but also the cost of managing its long-term side effects. It's still too soon to tell if Wong's "pay-for-quality" program will shrink CareFirst's oncology costs, but it will almost certainly make these costs more predictable, which is not a bad start.

THE REAL SAVINGS

Right now, the clinical pathway story seems to come down to two payers: CareFirst and Highmark Blue Cross Blue Shield, based in Pittsburgh. Highmark, through the University of Pittsburgh Medical Center (UPMC) Cancer Centers, has benefited since the implementation of clinical pathways in November 2005.

The largest provider of cancer care in western Pennsylvania, with 120 medical and radiation oncologists at 40 sites, UPMC Cancer Centers has adopted 13 disease pathways so far, according to Peter G. Ellis, MD, who leads UPMC's pathway initiative. Ellis is clinical associate professor of medicine at the University of Pittsburgh School of Medicine and UPMC's director of the Medical Oncology Network.

"We take cancer care to the community," says Ellis. "We don't expect the community to come to us at our hub at the Hillman Cancer Center in Pittsburgh. We want everyone to receive the same good quality of care, and in part, we developed pathways to ensure that would happen."

It all started in 2004, when Highmark began looking for ways to control its rising oncology costs. UPMC Cancer Centers found Highmark's proposed solutions "inappropriate," as Ellis refers to it. The region's largest insurer and its largest provider of oncology services seemed deadlocked.

At about that same time, UPMC Cancer Centers had completed a study of off-label bevacizumab (Avastin) prescribing by its oncologists. The new monoclonal antibody had just been approved for metastatic colon cancer, but physicians were prescribing it for other disorders.

"We went to great lengths to limit the use of Avastin for U.S. Food and Drug Administration-labeled reasons only," Ellis says. UPMC tracked all the internal denials for every off-pathway order of Avastin and presented its findings to Highmark in March 2005. Ellis recalls how they demonstrated that Highmark's reduction of the reimbursement for the drug affects their ability to care for patients, but doesn't address the underlying drug utilization. A better model is to incentivize the appropriate drug for the appropriate patient through a program like pathways, as "that's where the real savings are."

"I believe it's impossible to manage oncology without provider and payer working together," says Peter G. Ellis, MD, of UPMC.

Real savings turned out to be a cool $1 million for just 6 months of not prescribing bevacizumab off-label. Highmark responded positively; they withdrew efforts to change the drug delivery channel and encouraged the expansion of pathways to other cancers and therapies. The payer seemed to understand that pathways ensured high quality care and helped manage their oncology spending trend.

According to Ellis, UPMC said, "OK, as long as reimbursement doesn't change and mandatory vendor impositions or specialty pharmacies aren't brought in." In the end, the largest provider of cancer care in the region partnering with the largest insurer seemed like a good idea.

UPMC Cancer Centers "opened" its first clinical pathway later that year and its most recent one last August. The pathways cover breast, colorectal, esophageal, head and neck, pancreatic, lung, ovarian, prostate, and renal cancers; lymphoma; melanoma; myeloma; and myelodysplastic syndrome.

Both Ellis and Scott agree that guidelines provide for many approaches to treatment. For Scott, a pathway means far fewer options. For Ellis, a pathway means exactly one option. "A pathway says we're going to define the best treatment for every state and stage of a given disease. We're going to pick one way, and that's going to be the UPMC way."

ECONOMIC VIABILITY

With three years and 13 pathways under its belt, UPMC Cancer Centers seems to have the pathway development and implementation process down cold. Oncology pathway development committees consist of academic and community-based oncologists, and are co-chaired by one oncologist from each group. Ellis is credited for organizing the program and for making it work, but he says it is the committees that pushed for the development of more pathways.

As program director and a practic-

Close collaboration between payers and providers is likely to become even more critical in getting the most out of limited financial resources.

ing oncologist, Ellis occasionally facilitates when "personality-driven" differences of opinion start to interrupt committee work. At this point, only 1 pathway of 13 has encountered difficulties and is being reexamined. Committees meet quarterly to update pathways in light of new evidence in the literature or to incorporate other valid real-world feedback.

Meanwhile, an oversight committee comprises Ellis; his administrator, Donald Fisher, MD, a medical director at Highmark; and vice president of pharmacy affairs Robert Wanovitch, PharmD; along with their counterparts from another major Pennsylvania insurer, UPMC Health Plan — Chief Medical Officer Anne Docimo, MD, and pharmacy director Chronos Maolis, PharmD. The committee meets quarterly to monitor provider compliance (currently at 92 percent) and cost data.

So far, internal audits have confirmed the economic viability of the pathways. According to Ellis, nonpathway care costs have increased between 6 and 7 percent annually, while pathway care costs have increased only 1 percent. Furthermore, the overall cost of care is reduced when providers comply with pathways.

It's very difficult to manage oncology because it changes very quickly, says Ellis. "I give Highmark credit for being forward-thinking enough to realize they're not oncologists."

You can do all the claims edits and utilization reviews that you want, he says, "but I believe it's impossible to manage oncology without provider and payer working together."

PERSONALIZED MEDICINE

For someone with breast cancer, colorectal cancer, or HIV, Oncotype DX, the new KRAS test, and the even newer Trofile, a co-receptor HIV tropism assay from Monogram Biosciences, can make the difference between effective treatment and disease progression. Payers and providers are starting to figure out that it pays to partner on clinical pathways so that patients are able to benefit from these new molecular diagnostics. As the portfolio of molecular diagnostics continues to grow, close collaboration between payers and providers is likely to become even more critical in getting the most out of limited financial resources.

Kimberly Popovits, president and chief operating officer at Genomic Health, sees a growing interest in pathways.

"Do we believe it's going to be the trend for the future?" Popovits asks. "I would say 'yes' as more genomic tools become available. Oncotype DX is one, but many others are in development. Recent data on the KRAS mutation with the epidermal growth factor receptor (EGFR) inhibitors in colon cancer suggest that this is another tool that can be used to direct treatment, and I wouldn't be surprised if that didn't end up in pathways."

In fact, UPMC Cancer Centers and Highmark integrated the KRAS test into their colorectal cancer pathway in the summer of 2008, and it's next in line at CareFirst. A dominant topic at the 2008 ASCO annual meeting, the test determines whether metastatic colorectal tumor tissue carries the wild-type variation of the KRAS gene or a mutated version. Patients with the wild-type KRAS gene respond to treatment with EGFR-inhibiting drugs, such as cetuximab (Erbitux) and panitumumab (Vectibix) plus chemotherapy, while those with the mutated version do not. Scott estimates that the KRAS test can eliminate $40,000 worth of drug spending in the 40 percent of patients who are nonresponders.

"This is the beginning of personalized medicine, and we're excited," says Ellis. "It is exactly where we want to be, because we've known that some cancers respond wonderfully to chemotherapy and others grow through it."

If it takes clinical pathways to reap the rewards of personalized medicine, the potential return on investment could be substantial, because so many payers and providers have yet to get on board. According to Ellis, only Houston-based US Oncology has pathways similar to those of UPMC, and only in a few markets. UPMC has been quick to capitalize on its investment.

He declines to name names, but Ellis says a large group in Texas has entered into an agreement to use UPMC pathways, and discussions are under way with groups in Michigan, Minnesota, New Mexico, New Jersey, Georgia, and Florida - all of which should be good news for patient care and cost containment.

"We're all in the game of trying to keep healthcare affordable," says Wong, "and if pathways can help, that's something we need to work toward."

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