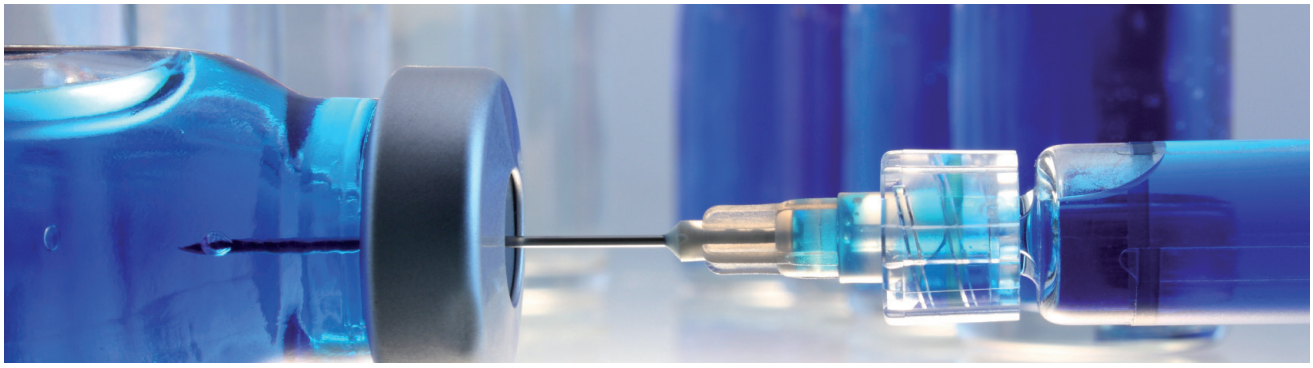
Oncology Knowledge Bulletin



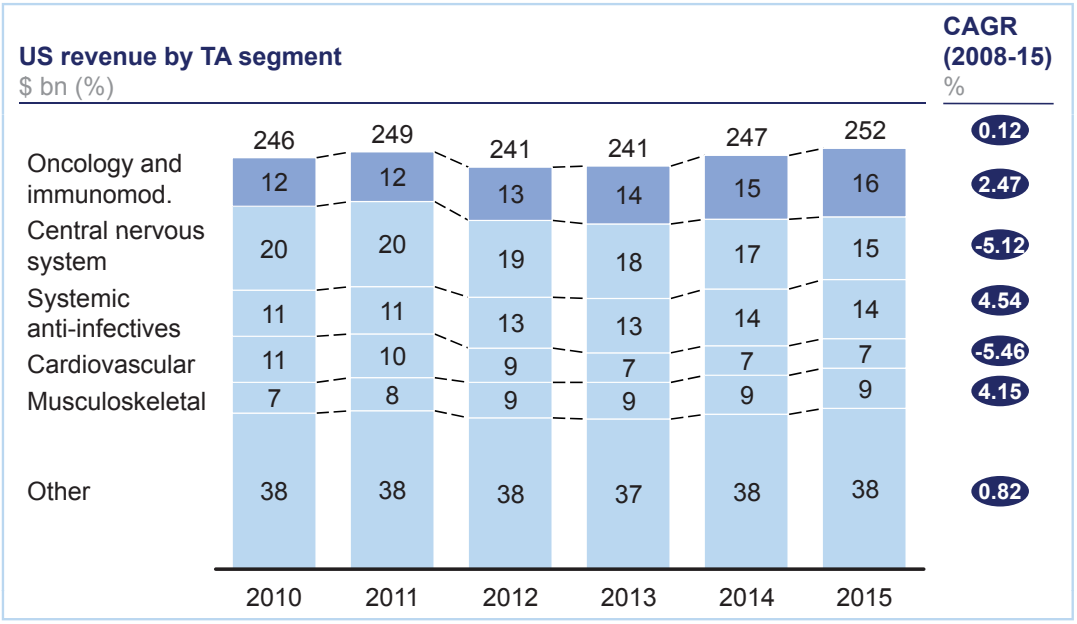
Strategies in oncology: Spotlight on clinical pathways

In response to rising healthcare costs, US payors have increased efforts to control drug costs, including through step edits or discounts for contracts. However, oncologics have been largely spared to date from such measures. Although these drugs are often very expensive, payors were reluctant to question of the value of potentially life-saving treatments for patients with few other options.

But cost pressures are intensifying, as oncologics now represent a total of 12 percent of US pharmaceutical costs, and that number is expected to rise to 16% by 2015, overtaking central nervous system (CNS) as the most costly therapeutic area (Figure 1). In addition to cost pressures, treatment trends are allowing payors to take steps to manage utilization and costs. Traditionally, most oncology drugs have been administered intravenously in healthcare facilities. Although payors often require prior authorization for intravenous treatment and may impose other restrictions, they reimburse most costs. But the number of oral oncologics is increasing, and payors are also shifting coverage of intravenous (IV) oncologics from the medical to the pharmacy benefit[1], where payors have historically been more assertive about controlling costs. Their efforts will likely extend to new oral and IV oncologics as well.

Another important trend that could further restrict reimbursement is the growth of clinical pathways, which are guidelines that describe the sequence and timing of treatments. Both payors and physicians are interested in developing pathways because the carefully selected protocols are expected to improve patient outcomes. In addition to reducing variability of treatment between facilities, clinical pathways may also reduce overall costs by decreasing the use of less effective therapies or those that cause side effects necessitating hospitalization or other expensive interventions.

Figure 1: By 2015, oncology is expected to become the largest category of pharmaceutical spend in the US



Source: Evaluate, 2011

1 NCCN Task Force Report: Specialty Pharmacy (2010)

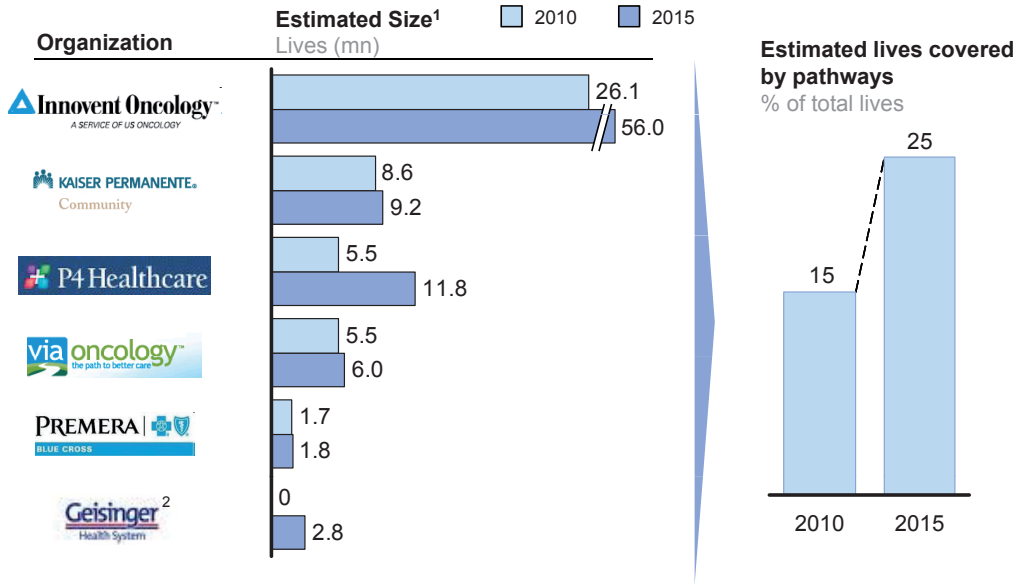
While clinical pathways will benefit both payors and patients, they could pose challenges to pharmaceutical manufacturers. If a new oncologic is not placed appropriately into a pathway, uptake of the drug may be slower and hurdles to reimbursement could be put in place. To avoid such problems, we urge manufacturers to develop strategies that will increase the likelihood their drugs hit the mark in their targeted clinical pathway.

Pathway development and adoption

Some providers have created clinical pathways independently, often using nationally recognized guidelines as a starting point and making modifications based on their own clinical insights. National clinical pathways vendors also typically begin with the same guidelines when developing pathways, but have independent advisory boards that adjust those guidelines and support creation of the pathway protocol. Many payors and providers choose to work with the national pathway vendors, including Innovent/US Oncology (acquired in 2010 by McKesson), P4 Healthcare (acquired in 2010 by Cardinal), and VIA Oncology.

Many pathways are already available, especially for cancers that are very expensive to treat, such as stage I breast cancer or stage IV lung cancer. Although only 15 percent of oncology "lives" were treated according to clinical pathways in 2010, this number could rise to 25 percent over the next five years as more and more payors establish a pathways program (Figure 2). Payors have also begun developing a few pathways for other therapeutic areas—for instance, P4 Healthcare's recently announced pathways for rheumatoid arthritis—suggesting the potential for additional growth.

Figure 2: Within five years, pathways could expand to include 25% of the oncology market.



1 Estimated
2 Pathways in development

Sources: Kaiser Permanente; Geisinger; Innovent Oncology; P4 Healthcare; UPMC/Via Oncology; Premera/Cancer Care Northwest

To date, national pathways vendors and oncology providers have been most active in pathway development. Some payors have historically restricted their efforts in this area to indirect measures, such as encouraging physician groups to adopt pathways. Other payors have launched successful pathway initiatives. For instance, Premera Blue Cross has collaborated with regional cancer centers in Washington on clinical pathway initiatives, helping to establish goals and review patient outcomes. It then ensures that its reimbursement policies reward providers for following agreed-upon pathways.

When considering what treatments should be included in a clinical pathway, as well as the order in which they should be administered and the correct dosage amounts, experts can typically choose from among many options for each step. When making decisions, experts typically focus on three questions, asked in the following order:

1. If there are multiple treatment options, which is most **efficacious**?

2. If there are multiple treatments with similar efficacy, which one is **best-tolerated**?

3. Given multiple treatments with similar efficacy and toxicity, which is the **least expensive**?

Since efficacy and tolerability trump cost in this algorithm, clinical pathways can favor expensive oncologics as the treatment of choice. Payors are generally willing to provide reimbursement for these drugs, even if lower cost alternatives are available, because the pathway protocols improve outcomes and reduce the overall cost of treatment.

Both providers and payors give physicians some leeway in terms of pathway compliance, generally considering 80 percent an appropriate number of patients to treat on-pathway. While this threshold depends on disease state and may rise in the future, compliance requirements can never be set at 100 percent because some patients will always need customized therapy.

Possible impediments to pathway adoption and use

The progress of pathways is by no means assured, and several issues may pose obstacles. The first is simple physician resistance to adding a step to their workflows, and some oncologists may perceive pathways as reducing their independent decision making. Regarding the workflow, advances in electronic medical records (EMRs) and their adoption would ideally link directly to pathways tools, e.g., clinical decision support. However, this will require broader cooperation between pathways and EMR providers.

There is also uncertainty around how multiple pathways and vendors will coexist in the marketplace. For example, if a practice has an agreement with a pathways vendor and a payor, it is unclear how additional deals with other payors would be structured. Would the next payor require different pathways, or would they accept the compliance reporting from the pathways already in place?

Providers may also hesitate to adopt pathways for financial reasons. If pathways reduce costs as expected, this translates into reduced revenues for oncologists, which is why many pathways agreements include cost-sharing between payors and practices.

Finally, for pathways to gain wide adoption, proponents will need to conclusively demonstrate both improved outcomes and reduced costs. Due to the complexity of cancer and its myriad combinations of type, stage, and personal profiles, this may be very difficult to decisively demonstrate.

Lessons learned

Given the current impact of clinical pathways, we want to highlight several issues and trends that will affect manufacturers:

1. ***Drug usage patterns:*** Clinical pathways will likely result in more prescriptions for drugs included in the guidelines. On-pathway oncologics will be in higher demand and command higher prices than off-pathway therapies for that tumor type, which will lose market share.

2. ***Factors that influence drug selection:*** While oncologics that are first-in-class or best-in-class always have always enjoyed an advantage, this benefit becomes more significant as pathways formalize preferred treatment options.

3. ***Pathway selection:*** Payors recognize that experts may have varying opinions about efficacy and tolerability, resulting in different guidelines, and so are not likely to insist that all providers follow the same clinical pathways. In the future, however, payors may become more selective about "accepted" pathways as physicians reach greater consensus about the best treatments.

4. ***Pathway growth:*** Payors are conducting retrospective analyses to compare outcomes for patients who were treated according to pathway guidelines to those who were not. If pathways clearly demonstrate improved survival rates or other endpoints, payors may adopt them more rapidly. New cost data may also influence payor attitudes, but pathways proponents will need to demonstrate cost reductions over the long term.

5. ***Pathway ownership:*** Despite the challenges, over the next four to six years we expect to see more payors requiring pathways use without partnering with a specific pathways vendor. This means that the influence of individual pathways vendors would decrease over time, though the complexity of implementing pathways programs will ensure that pathways vendors are valuable partners for the foreseeable future.

Applying the lessons

Manufacturers need to take action to ensure that they benefit from the growth of clinical pathways:

1. Manufacturers must proactively work to ensure that drugs both on-market and in development are incorporated into clinical pathways, just as they do when attempting to get drugs included in formularies. When designing clinical programs, manufacturers need to understand pathways designers' decision criteria and tailor trials to address those criteria. Follow-on assets will need to be substantially differentiated in order to displace existing treatments.

2. Understanding how pathways vendors' software solutions list and describe treatment options will instruct how manufacturers can best position their products. For example, if a physician is presented with relative cost information, how are the costs calculated? To better inform their approach, manufacturers should begin an open dialogue with pathways vendors.

3. Manufacturers should treat pathways as a preliminary comparative effectiveness tool. Healthcare reform will place more emphasis on comparative effectiveness research in coming years. Clinical pathway data provide an accurate means for making such comparisons, and manufacturers who begin to collect and analyze this information now may gain early insights into best practices for conducting comparative effectiveness tests in the future.

4. Commercial groups within biotechs and pharma companies need to understand that payors will increasingly reward physicians for following clinical pathways. As such, they must develop messaging that is appropriate for both on-pathway and off-pathway drugs. For instance, with an off-pathway drug, the message could focus on identifying patients that should not be treated according to prevailing guidelines (e.g., due to drug-drug interactions).

In summary, clinical pathways will have a long term effect on the practice of oncology. Pharmaceutical companies can realize value if they understand how pathway solutions are developed and use these insights as an input to their own R&D and commercialization strategies.

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