Orphan Oncology Drugs Part 2—

Providing Value in Patient Care

by Denise K. Pierce

In "Orphan Drugs Part 1—Patient Care to the Individual Level" (November/December 2010 *Oncology Issues*), I attempted to clarify similarities and differences between the variety of orphan drugs, with a focus on oncology drugs and biologics having the orphan classification. In Part 2, I will take a more detailed look at how payers manage oncology orphan drugs.

That being said, this article is actually about overall oncology drug management, since the approaches payers are taking do not differentiate between orphan and non-orphan, nor do they target only orphan oncology drugs. That is the good news. The ongoing challenge is that payers are increasing their oversight and management of oncology drug coverage and utilization. In response, it is vital for providers to understand the primary trends in oncology drug management and how these trends translate to ensuring patient access to care.

Why Now? Why Cancer?

The oncology community has always had a negative reaction to payer management of oncology drugs. With the understanding that cancer is a collection of diseases, providers want the flexibility to consider individual patient nuances when choosing treatment regimens. While individual consideration *is* important, today's payers want to understand the *value* that a particular treatment is bringing to the patient—and to the health system.

So, why are payers targeting cancer? Simply put, it is cost of care. In 2007 the National Institutes of Health (NIH) estimated that the direct medical costs for cancer were $89 billion.[1] This dollar amount reflected a growth of $19 billion over a two-year period. To put this into some kind of perspective, let's compare these costs to asthma, which has also been a focus of payer management. In 2007 direct medical costs for asthma were estimated at $19.7 billion.[2]

Cost aside, what should be emphasized is the many benefits cancer patients have realized in recent years and with newer treatment options. For example, the oncology community has seen significant increases in survival rates for cancer patients. Still, the challenge—from the payer perspective— is how to balance the cost of care with patient access to "appropriate" care.

What Does This All Mean for *My* Cancer Program?

What are most troublesome for the oncology specialty are the approaches payers are using to "manage" cancer treatments and how payer requirements are affecting the practice of oncology—whether care is being delivered in a practice, community-based, or academic setting. While payer administrative requirements vary across the different plans with which a program may contract, the increase in these requirements translates to greater demand on cancer center staff. A 2009 analysis specifically addressed this issue as it related to specialists, excluding internal medicine and family practice. Figure 1 on page 49 outlines the average weekly allocation of hours expended by different staff on payer-related activities to support patient access to treatment.[3]

So, the takeaway message is two-fold. First, payers are continuing their efforts to identify the "value" of cancer drugs and anti-cancer regimens. Second, the administrative requirements on the provider's end are increasing. With those two statements in mind, let's look at three different trends in payer management and what can be done to create efficiencies that lessen the time drain on cancer programs, while still supporting patient access to treatment.

Payer Oncology Drug Management Trends

Historically, oral oncology agents have been managed under a payer's pharmacy benefit, while drugs and biologics requiring physician-administration are managed under the payer's medical benefit. These diverse benefit approaches had varying payer oversight and patient cost-share. To quote singer and songwriter Bob Dylan, who could easily have been an oncology market futurist: "*The times, they are a-changin'.* " Payers are now looking to create novel oncology benefits that will ensure that "appropriate" patients get access to the "appropriate" treatments. Further, payers want to be able to more easily compare clinical and economic benefits of multiple drugs and multiple regimens.

Certain cancers are increasingly being classified as chronic diseases, which make it easier for payers to implement "conventional" approaches to oncology drug management, including:

- Formularies and drug tiers
- Prior authorization
- Increased pharmacy oversight versus medical management.

Drug Tiers and Patient Cost Share

Today, more commercial payers have pharmacy benefits with four or more tiers. Partner that finding with the fact that an increasing number of payers are considering oncology drugs (oral or infused) as "specialty" drugs, which are then placed on specialty tiers. To gain a perspective on the impact of specialty drug coinsurance cost share, we can look to a 2010 analysis of overall employer benefit prescription drug trends from the Kaiser Family Foundation.[4] The report identified that 78 percent of people with employer-sponsored health plans have benefits with a fourth or higher tier. This finding has been a significant change from even 2007, when payers may have used four tiers, but nothing beyond that. Figure 2 on page 49 shows the growth in average patient coinsurance cost share for all types of drugs that

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Figure 1: Average Weekly Hours Required to Address Payer Requirements for Drugs and Biologics

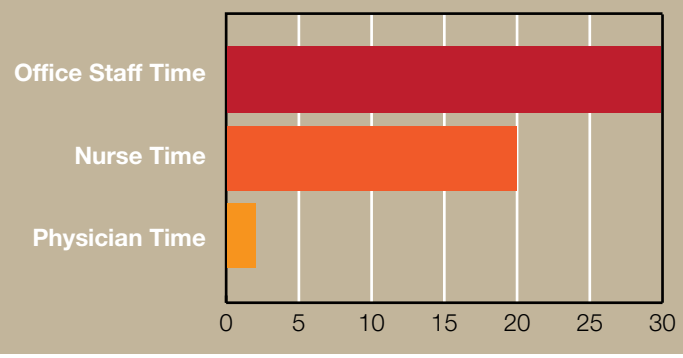
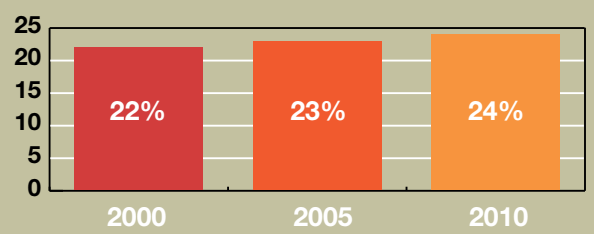


Figure 2: Average Drug Coinsurance for Fourth Tier Drugs*



*These percentages are across all prescription drugs

may be on a fourth tier. Just consider that these percentages do not even assess coinsurance requirements for those payers with *more than* four tiers.

To demonstrate this trend, let's look at the Medication Cost Integration Formulary developed by the Regence Group, a large BCBS plan in the Northwest. This particular formulary meshes coverage parameters for oral, self-injected, and infused drugs and biologics.[5] The formulary has six tiers, with tiers four, five, and six including higher-cost specialty drugs, such as oral and infused oncology drugs. Tiers four, five, and six are associated with increasing patient coinsurance levels up to 30 percent, which can result in significant patient financial impact.

Why these higher, specialty tiers? Today, specialty drugs found on the fourth tier are used to treat conditions that affect less than 5 percent of the population; however, that percent is expected to increase as new drugs are approved, and those specialty drugs on the market are used to treat an expanded array of conditions.[6] And it is these growing costs that have made payers consider making patients bear a higher financial responsibility.

So what does this mean to patients? Insurance verification and subsequent financial counseling are becoming increasingly important to help patients clearly understand the financial impact for their treatment. This time is also the point at which research into available co-pay assistance, patient assistance, and general reimbursement support programs is vital. Manufacturers of oncology drugs—orphan or otherwise—provide support resources for reimbursement. Today, many of these reimbursement and patient assistance programs have evolved to best manage the patient population size and complications brought forth by economic market conditions and the changing healthcare environment.

For more about these programs, turn to ACCC's *Reimbursement and Patient Assistance Programs: A Guide for Community Cancer Centers,* which mailed with this edition of *Oncology Issues*. Information can also be found online at websites such as: *www.needymeds.org*. Remember, identifying and applying best practices that integrate manufacturer reimbursement support resources can only synergize the time and effort undertaken by cancer center staff.

Prior Authorization

Prior authorization is not a new concept, and seems to be a consistent application used by commercial payers. Payers do not establish prior authorization requirements for every oncology drug, but they *will* do so for high-cost and high-volume agents. Again, prior-authorization efforts can include both orphan and non-orphan oncology drugs.

Conventionally, prior authorization requirements focus on FDA-approved indications, although more and more of these guidance documents are including expanded indications supported by clinical compendia such as the National Comprehensive Cancer Network's (NCCN's) *Drugs & Biologics Compendium*™ and Thomson Reuters *DrugDex*®.

Payers use prior authorization requirements to obtain support for a drug's medical necessity. Some prior authorization processes are relatively simple, only requiring a fax documenting that the drug will be used for a particular diagnosis code. However, many payer prior authorization processes can be problematic for cancer programs. For example, payers may require submission of laboratory and imaging reports, documentation of failure on prior

regimens, or a resubmission of a prior authorization review within 60- or 90-days.

Unfortunately, prior authorizations are becoming a more consistent requirement across payers. So what can oncology practices and community cancer centers do? Here are some basic strategies that can help cancer programs more efficiently process prior authorizations:

Step 1—Assess. Conduct an assessment of prior authorization criteria for the high-volume or high-cost oncology drugs that you use across the primary payers with whom you contract. Then, compare the prior authorization requirements for the same drugs across payers, and look for issues as well as opportunities to create consistent responses.

Step 2—Notify. Inform oncology drug manufacturers of any payer-specific prior authorization criteria that either 1) do not clearly match the FDA-approved labeling or 2) are creating obstacles to patient access. Most manufacturers have staff who work directly with payers, and can help shape a more appropriate process.

Step 3—Prepare. For drugs that consistently require prior authorization approval, prepare medical necessity documentation that can support quick completion of a prior authorization form and expedite patient access. Manufacturers can help provide published clinical literature or other supportive documentation that may be helpful.

"White Bagging"

Do not confuse "white bagging" with the drug management trend of "brown bagging," which bypasses the oncology practice or program and sends drugs directly to the patient, requiring them to carry the drug to the practice or program for administration. Today, payers more consistently use the "brown-bagging" method for self-administered drugs and biologics, and not for physician-administered drugs.

"White bagging" is a different model. Payers developed "white bagging" processes as a means to control drug costs by shipping drugs directly to a physician practice or program for administration to a patient. Does "white bagging" sound like the now defunct Medicare Competitive Acquisition Program (CAP)? Well, in concept "white bagging" is indeed similar to CAP, but with fewer administrative burdens.

In brief, here's how "white bagging" works. The payer negotiates special pricing with one or more specialty pharmacy organizations, therefore reducing the payer's cost of the drug. The drug is then delivered "just in time" to the practice, and is labeled for a specific patient. The patient is billed by the specialty pharmacy for the drug co-pay and/or coinsurance. The oncology provider then can bill *only for* the drug's administration to the patient, and not for the drug.

The benefits of this type of program are that the financial liability for the drug is reduced for the oncology provider, and overall drug costs are reduced for the payer. There are, however, still many challenges that need to be addressed to make "white bagging" more palatable to providers:

- While the oncology provider is still responsible for drug wastage, providers receive no compensation for that piece of drug management.
- The drug is shipped to the practice for one specific patient. If for some reason the patient can no longer receive the drug, that drug must be destroyed and cannot be used for another patient. Again, these responsibilities fall to the provider who is not reimbursed for these services.
- Providers are required to maintain separate inventory for the "white-bagged" drug, so that the provider does not bill the payer for that particular supply.
- The physician is still responsible for all payer-related medical necessity support (e.g., prior authorization) if required.

Most payers that have a "white bagging" specialty pharmacy benefit do not yet *mandate* participation—although there are select geographic areas across the U.S. where this scenario is changing. On the other hand, in some cases, if a specialty pharmacy is local and shipping is indeed timed with the patient's planned treatment, there can be benefits for the practice or cancer program.

It may be safe to say that specialty pharmacies are here to stay. So what can providers do when a payer is promoting or mandating a specialty pharmacy program benefit? Proactive oncology practices and cancer programs should consider the following three strategies:

1. Review the logistics of the program to determine how the delivery timing and administrative requirements would affect patient care.
2. Determine if there are incentives in place related to increased payment levels for drug administration.
3. Be clear on the financial implications for a patient, as the patient cost share may vary by plan.

Although the initial intent of my article was to select out orphan oncology drugs related to payer management of coverage and utilization, the message is clear that payers are looking at *all* oncology drugs in light of increasing cost of care impact. While I reviewed three major trends in oncology drug management, other trends include clinical pathways, episode of care payment mechanisms, and even comparative effectiveness trends. My take-home message—oncology practices and cancer programs must incrementally develop internal steps to better manage the increasing burdens of payer management. These steps are critical to survive in an increasingly complex reimbursement environment.

Denise K. Pierce is president of DK Pierce & Associates, Inc., in Zionsville, Ind.

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