Value-Based Oncology Benefits

By Michael Jacobs, RPh

Value in healthcare is defined as health outcome/dollar of cost expended.1 From a payer’s perspective, this simply means that if more resources are expended, improved health outcomes should follow within a reasonable time period. Likewise, if consistently good health outcomes can be achieved by investing a predictable amount of resources (ie, by following a narrow clinical pathway to treat a given disease or condition), payers will attempt to establish a benefit design and cost-sharing philosophy that provides those outcomes with as few barriers as possible to patients and caregivers.

Several steps must be taken in the healthcare system to provide value-based benefits in oncology. These include:

• Designing benefits that arrange cost-sharing based on the weight of scientific evidence
• Selecting networks and providers based on historic performance and delivery of desired health outcomes at financially acceptable levels
• Providing recognition (ie, compensation) for high-performing components of the healthcare system.2

Designing benefits that align the interests and incentives of all parties in oncology care is no simple task. This is partly because a number of payers do not know where, or how much, they are spending for many of these therapies.3 Some payers cover oncology therapies in the medical benefit, some cover them in the pharmacy benefit, and still others are paying for them through a coding system (J codes) that does not identify the specific therapies administered to the patients, instead listing only the charges for these therapies.

Along with these billing options, today’s patients have more choices of where to receive oncology therapies. These drugs can be provided through a hospital setting, a physician’s office, an infusion center, a specialty pharmacy provider, or a local pharmacy provider, just to name a few.

Managing Complex Care

With more than 800 new oncology pharmaceutical drug entities in development, and many of these classified as specialty medications,4 cost is becoming an increasing concern for payers. It is estimated that as many as 400 of these new therapies could cost in excess of $50,000 per course of therapy, which raises the following question for many payers: will the health outcomes produced by these expensive medications justify the added investment?

Payer concerns regarding health outcomes and healthcare costs have led many to accept the concept that following evidence-based, consensus-driven treatment protocols and pathways may be the most appropriate way to go, especially in oncology. This approach allows payers and clinicians to collect data, compare results, and identify potential care improvements as physicians begin prescribing new agents, as well as to begin achieving therapeutic predictability. With this collected information, payers can better plan benefits and share costs; identify the highest quality providers, provider networks, and distribution channels; and reward these high-quality providers for their efforts.

But payers, physicians, and patients also need to move beyond these efforts. Concerns have been raised about how to determine, with a reasonable certainty, that a given therapy will produce a positive result in a particular patient. The opposite is also true—how do we identify the patients in whom a given therapy will not produce the desired results? In some cases, pharmacogenomics can play a role. For example, women with certain breast cancer tumors possessing a genetic variant that causes overexpression of the HER2 protein will benefit if trastuzumab is part of their therapeutic regimen.5 On the other hand, women with estrogen receptor-negative/progesterone receptor-negative (ER-/PgR-) tumors will not benefit from endocrine therapy, such as tamoxifen.6 Another example of the benefit of pharmacogenetics has recently been evidenced in multiple myeloma. Even as the ability of bortezomib therapy to overcome the high-prognostic risk associated with a deletion of chromosome 13 has been relatively well documented, several studies suggest that patients who have this deletion do not benefit from thalidomide.7-10 As more information is gained regarding the molecular
Defining Value in Oncology

By Kavita V. Nair, PhD

A variety of strategies—including value-based benefit design, payment reform, and comparative effectiveness research (CER)—are being used by payers, providers, and employers to address the central issue of value in healthcare. In general, healthcare value can be defined as “improving the net ratio of benefits obtained per dollar spent on healthcare” when attempting to define value for specific disease states, oncology has been largely ignored. Under healthcare reform, however, the provision of healthcare is now a mandate, with employers required to provide health insurance, payers required to cover all individuals, and consumers required to purchase health insurance or face financial penalties. This legislation has therefore triggered an urgent need to find ways to define value in oncology for several key reasons. First, there are substantial costs associated with treating an oncology patient. A recent study of multiple myeloma costs showed that the direct medical costs for 1 therapeutic course of bortezomib, bortezomib plus dexamethasone, and lenalidomide plus low-dose dexamethasone ranged from $33,966 to $47,002. In addition, the management of complications such as hypercalcemia, anemia, bone lesions and fractures, and renal failure can themselves be quite high.

Second, there is an urgent association with treating oncology patients. The individualized and emotional nature of this disease has resulted in a “one-size-does-not-fit-all” approach to how it is currently managed. Oncologists may feel the need to treat patients with the newest (and most expensive) agents available.

The sheer complexity of oncology management has deterred many innovators from pursuing efforts to demonstrate value. That may extend survival for only a few months. The sheer complexity of oncology management has deterred many innovators from pursuing efforts to demonstrate value. The goal of this article is to provide a broad overview on how value can be defined in oncology management.

Many Means of Establishing Value

One of the first steps in defining value is to conduct CER for drug therapies, technologies, and surgical options. CER compares the benefits, risks, and costs of strategies for the treatment of a specific disease. The Comparative Effectiveness Research Act of 2009 allocated $1.1 billion in preliminary funding, and launches plans for more formal CER. Although the high cost of cancer drug therapies and treatment options make this disease area ripe for CER studies, conducting these within oncology poses challenges. The multifaceted therapy options used to treat cancer make CER complicated—it is not enough to determine if one drug is better than another; evaluations must consider whether a drug regimen may be superior to an alternative regimen or surgical option. In addition, it is unclear who will bear the cost of these evaluations. Are payers or pharmaceutical manufacturers willing to develop randomized clinical trials to gather evidence of comparative effectiveness or do oncology practices have the resources to do so within their own individual practices? Related to the issue of gathering CER data is the adoption of practice guidelines for the cost-effective utilization of oncology drugs. The manner in which drug therapies are made available to oncology patients is another defining value issue. Oncology drugs are unique in that both oncologists and pharmacy directors can acquire and dispense the drug. Oncologists employ a “buy-and-bill” approach, whereas pharmacy payers dis pense oncology drugs through specialty pharmacies and tiered formularies. Therefore, the 2 common approaches for accessing oncology drugs are through the medical benefit (typically through oncology practices) and through the pharmacy benefit. Each approach has downsides, including increased patient cost-sharing if drugs are purchased through the pharmacy benefit, and possible delayed access to therapy if patients have to wait for their physicians to acquire their medications. The unique nature of oncology drug management and the dichotomy of this distribution has prompted discussions about newer value-based benefit design options and integrated care models for oncology medication management.

Another means of establishing value in oncology management is outcomes measurement. In oncology clinical trials, the primary goal typically is to obtain evidence regarding the benefit-to-risk profile of the experimental intervention relative to an existing standard of care. Although the efficacy of oncology drugs has historically been measured by overall survival, surrogate endpoints, such as time-to-progression (TTP) and progression-free survival have been more frequently utilized over the last decade. Other end points, such as tolerability of side effects, patient quality of life, cost effectiveness of drug therapies (ie, quality-adjusted life-years and incremental rate ratios) can be utilized before starting treatment to determine the utility of using a new and expensive drug therapy. For example, the VISTA trial compared bortezomib plus melphalan/prednisone (VMP) with melphalan/prednisone (MP) in newly-diagnosed multiple myeloma patients ineligible for stem cell transplant. VMP was found to be superior to MP for TTP, the primary endpoint for the trial. VMP also provided a substantial survival benefit. An incremental cost analysis was conducted to compare lifetime health outcomes and cost effectiveness of VMP compared to MP.

References


Kavita V. Nair, PhD is associate professor and director, graduate studies (pharmaceutical outcomes research track) at the School of Pharmacy, University of Colorado, Denver.
Defining Value in... Continued from page 23

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References

Putting Multiple Myeloma on the Clinical Pathway

By Bruce Cutter, MD, MMM

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reatment of multiple myeloma (MM) has evolved rapidly in recent years, from a relatively simple, cheap, and somewhat effective regimen (melphalan hydrochloride and prednisone), to high-dose chemotherapy with autologous stem cell transplantation, to new and more effective agents. Although we are now seeing impressive responses and significantly improved survival times, this progress has not come without cost. The newer agents (eg, thalidomide, lenalidomide, and bortezomib) have their own toxicities, and considerable price tags have accompanied treatment advances. In addition, some of these agents are delivered orally, which raises unique issues regarding cost, accessibility, and system that are beyond the scope of this article.

Clinical pathways hold the promise of helping to drive fundamental change in oncology care.

Looking ahead, we need to understand how best to combine these new agents, among themselves and with older medications, and to determine the role autotransplantation will continue to play. As our understanding of MM’s cellular pathways and molecular genetics continues to improve, additional effective treatments will likely be developed. Along with the clinical challenge presented by MM, today’s clinician also must deal with matters of value and sustainability. Value (defined as quality and outcomes divided by costs) is central to the availability and success of cancer treatments; at its core, the issue is “bang for the buck.” Clinical pathways are an important means of addressing the large value deficit in oncology.

Clinical Pathways: Components and Processes

At the most fundamental level, clinical pathways represent an agreement by oncologists to treat a patient with a certain disease in a certain way; they are a tool to standardize care and reduce unexplained variation. Clinical pathways hold the promise of helping to drive fundamental change in the current system of oncology care and remedy the existing value deficit. They possess a number of beneficial qualities, including:

• Being physician (provider) developed and owned
• Being narrowly structured (ie, they are a pathway, not a menu)
• Being supportive of clinical research and knowledge advancement (eg, clinical trials are always “on pathway”)
• Being based on Institute of Medicine quality principles, including being effective (evidence-based), safe, patient-centered, timely, efficient, and equitable
• Having physician accountability as a central component
• Having an opt-out (“off pathway”) mechanism to allow for appropriate variation based on clinical needs
• Containing an ongoing review process to assist with accountability and to modify treatment as needed
• Being transparent and auditable

Addressing both the numerator and denominator of the value equation. A clinical pathway for MM (or any other cancer) would be formulated and implemented by a group of oncologists, preferably in collaboration with a health plan, who would look at the evidence for MM treatment and decide, based on clinical outcomes and other patient-centered factors (ie, toxicity and convenience), the most appropriate treatment(s) for the disease. Cost would be considered next, to help determine what treatment(s) are to be “on pathway”; cost, however, never trumps clinical criteria. The pathway would then be adopted by a practice and operationally “rolled out,” with a prospective review mechanism by physician peers to assure compliance and accountability, and to allow for the patient to be treated “off pathway” if clinical circumstances warrant (as reviewed and agreed upon by physician peers). Pathway compliance and the reasons for treating a patient “off-pathway” are documented, and retrospective data monitoring takes place to assess pathway appropriateness and accountability. A thorough pathway review is undertaken at least yearly, or more frequently if necessary, to adjust for changes in clinical practice and the literature.

The Cancer Care Northwest Pathway Experience

In our practice, Cancer Care Northwest, a pharmacy and therapeutics committee is charged with pathway development and physician accountability. The Cancer Care Northwest pathways are part of a larger quality initiative called Foundations of Quality, developed in close collaboration with Premera Blue Cross, a regional health plan, beginning in 2002. This clinical quality program has been paired with a pay-for-quality contract that created physician incentives and rewards for the value we bring to the table. Explicit in this program’s development was the belief that this model of standardizing care and reducing unexplained variation will enhance the value of care provided to our patients.

Although this belief is yet unproven, data in support of this value hypothesis are beginning to appear in the literature. So far, we have developed a “proof of concept,” in which providers and health plans collaborate in a team-based fashion to develop delivery system innovation that promises to enhance patient quality of care, address value, and promote sustainability for the system, the providers, and health plans.

Although clinical pathways can help to standardize care and reduce unexplained variation, changes necessary to address the value deficit in oncology will require fundamental culture change for providers and health plans. The major barriers to adoption of pathways and other tools to address the value deficit involve culture, leadership, and change management, not operations. Because pathways are evidence-based, quality-driven, and value-focused—in addition to being operationally viable and scalable—they speak to the needs and values of both providers and health plans. More importantly they speak to the real needs of patients.

Reference