Oral Oncolytics: Part 2—Legislation Targeting Cost & Access, and Other Initiatives to Reduce Costs

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We examine efforts to correct cost inequities of oral anti-cancer agents through legislation, and we look at further efforts to reduce the cost of oral chemotherapy via cycle management and waste reduction.

Treating patients with oral oncolytics presents clinicians with numerous and unique challenges. In Part 1 of our discussion of these agents, we examined issues related to adherence, monitoring of side effects and interactions, and safe handling. We discussed costs in Part 1, but principally as they affected patient adherence. Here, in Part 2, we take a more in-depth look at cost inequities resulting from the confluence of changed management paradigms that have accompanied the proliferation of oral anti-cancer agents, and certain features of the way US health insurance policies are structured. We examine efforts to correct these inequities through legislation, and we look at further efforts to reduce the cost of oral chemotherapy via cycle management and waste reduction.

The Rise of Oral Oncolytics and the Shift in Costs

As oral chemotherapy has become more common, inpatient medical costs have decreased, and costs associated with pharmacy benefits have increased. The advent of high-cost chemotherapy began with the introduction of capecitabine for the treatment of advanced breast cancer. Progress in the field of genetics has given rise to a “golden age” of antineoplastic agents, many of which are products of the new focus on the molecular aspects of cancer—and many of these newly developed agents are oral.
The first of the molecularly targeted agents was imatinib mesylate, which dramatically altered the management of patients with chronic myelogenous leukemia (CML).[1] Formerly, CML patients would have been given interferon, but almost all eligible patients would go on to stem cell transplant. By contrast, patients whose CML was treated with imatinib had a very high response rate, resulting in a decrease in the overall number of transplants. Analysis of the cost of 2-year treatment of CML has shown that the use of imatinib was less costly and more efficacious than bone marrow transplant.[2] However, in addition to an overall decrease in cost, the introduction of imatinib also resulted in a significant cost shift. The costs of inpatient chemotherapy and procedures, both of which were covered by patients’ medical insurance, were decreased; much of the decreased cost was transferred to patients’ pharmaceutical insurance coverage. The development of other oral molecularly targeted agents has pushed additional patients who might have been treated with inpatient biochemotherapy to oral treatment instead. Other therapies on the horizon may defer the use of inpatient chemotherapy or stem cell transplant options. These changes add up to a paradigm change for patients, with increasing numbers utilizing their outpatient prescription benefit rather than their medical coverage for the treatment of specific oncologic disease states.

The Problem of Coverage Inequity

With an increasing number of oncolytics coming to market in an oral formulation, the way in which insurance policy benefit plans are structured becomes critically important. Today, there is typically a distinct separation between the portion of the policy that covers medical treatment—which includes treatment with chemotherapy drugs that are either infused or injected—and the part of the policy that covers prescription drugs. In fact, the prescription drug plan may be an entirely separate entity, and is coverage that not everyone has secured.
The prescription drug plan provides coverage for the oral medications prescribed for patients. Oral cancer medications, and specifically those that do not have infusible or injectable counterparts that gain them Medicare coverage, fall under this umbrella. Typically, any single agent that costs more than $600 is routinely placed in the tier of the plan that has the highest cost-sharing; the majority of...
currently available oral oncolytics fall into this category. The result of that tier placement often correlates directly with a patient’s ability or inability to secure needed cancer medications. As was documented in a recent Community Oncology Alliance–sponsored Avalere study,[3] out-of-pocket costs play a significant role in determining the likelihood that a patient will abandon the first fill of an oral oncolytic agent. One in four patients filling prescriptions with cost-sharing amounts over $500 abandoned their prescription and did not follow up with another oncology medication within 90 days. (Drug therapy/complexity [ie, prescription activity/burden] is also a significant driver of abandonment of oral oncolytic agents).

**Legislation Surrounding Access and Affordability**

Currently, when a patient diagnosed with cancer is prescribed an infusional or injectable therapy, the therapy is covered under the patient’s medical plan. However, if a patient with cancer is prescribed an oral therapy, that drug regimen may or may not be covered under his or her prescription plan—assuming the patient even has prescription drug coverage. Because of this gross inequity of coverage, there has been a movement in many states to level the playing field for people with cancer who need oral medications. This has resulted in what is known as oral parity legislation. The first oral parity law was passed in Oregon in 2008; that bill stipulates: “A benefit plan that provides coverage for chemotherapy treatment must provide coverage for orally administered anticancer medications on a basis that is no less favorable than intravenous or injected medications.” This means that if a patient is privately insured (the law does not apply to Medicare or ERISA plans), and his or her plan covers chemotherapy, then an orally administered drug that has been approved by the US Food and Drug Administration should have the same out-of-pocket costs for the patient as the intravenously administered drug.

Since 2008, 26 states (including Oregon) and the District of Columbia have enacted oral chemotherapy parity access laws. There continues to be a fair amount of activity with regard to oral parity legislation, with more states pursuing laws in their respective legislatures. New state laws that have recently been passed have stipulations much like that in the Oregon law quoted above. Further, efforts are being made to ensure that oral cancer medications will not be subject to any prior authorization, dollar limit, copayment, deductible, or other out-of-pocket expense that does not apply to intravenously administered or injected cancer medications, regardless of formulation or benefit category determination by the health insurance issuer; and that the health insurance issuer will not reclassify or increase any type of cost-sharing to the covered person for anti-cancer medications in order to achieve compliance with the law. One state in particular, Louisiana, took its law a step further: it limits the total amount paid by a covered person through all cost-sharing requirements to no more than $100 per filled prescription for any orally administered anti-cancer medication (cost-sharing includes copayments, coinsurance, deductibles, and any other amounts paid by the covered person for that prescription).

In addition, Congressman Brian Higgins (D–New York) introduced a bill (H.R. 2746; reintroduced in April 2013 as H.R. 1801) into the first session of the 112th Congress to amend the Employee Retirement Income Security Act of 1974, the Public Health Service Act, and the Internal Revenue Code of 1986 to require group and individual health insurance coverage and group health plans to provide for coverage of oral anticancer drugs on terms no less favorable than the coverage provided for intravenously administered anticancer medications. Currently, this bill has 58 cosponsors in the House of Representatives, although its future is uncertain.

**Access Issues Related to the Affordable Care Act Insurance Exchanges**

Although the Affordable Care Act (ACA) will fundamentally alter the health insurance landscape, the prospects of mandatory healthcare do not necessarily equate to comprehensive healthcare. The implications of this fact for the oncology community are significant.

Every state, beginning in 2014, will have a health insurance exchange where consumers can comparison shop from their computer desktop and purchase health insurance. Any insurer who chooses to sell on a state’s exchange must meet a set of state requirements—unless the plan being offered is a multistate plan. There is also a mandatory set of 13 criteria that all plans must meet, including the removal of the pre-existing condition clause—an important stipulation for those with a cancer diagnosis. Some states may go beyond the basic criteria. California, for example, has instituted additional criteria (although these don’t hold for multistate plans, which are guaranteed a spot on the exchange even if the coverage they offer is less than ideal, simply because they are expanding their reach beyond a single state).
The real concern with these plan offerings will be their formularies. Currently, the ACA states that prescription drug coverage must include six protected classes (immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics) and must offer at least one drug in every class on the formulary.

Having only one cancer drug in a formulary will clearly cause life-threatening access issues for persons who require treatment with oral oncolytics. The Department of Health and Human Services’ proposed one-drug-per-class minimum requirement for such pharmacy benefits gives insurance companies substantial flexibility when designing formularies that meet those federal standards—but with this comes the potential for significant plan differences, state to state, and clearly access issues for cancer patients. (Ironically, the Centers for Medicare and Medicaid Services have stipulated that Medicare Part D plans must cover “all or substantially all” drugs in the antineoplastic class, as well as in the other five protected classes, in order to ensure uninterrupted treatment for vulnerable Medicare beneficiaries.)

In the face of the impending insurance exchanges and plan offerings, current opinion is that state-passed laws will supersede the plan requirements that currently apply to those state exchanges. However, time will tell. For now, all should remain vigilant so as to assure our patients access to all life-saving cancer medications, regardless of the formulation.

**Oral Chemotherapy Cycle Management and Waste Reduction**

There are a variety of cost-containment plans that can potentially be implemented to decrease the cost of oral chemotherapy. These include measures designed to encourage a shift among prescribers and healthcare providers toward being more mindful of costs and resource allocation. In particular, several programs have been developed to reduce overall costs by improving the management of chemotherapy cycles and reducing oral chemotherapy waste—in order to lessen the institutional and overall healthcare cost burden without sacrificing quality or access. Chemotherapy cycle management has been utilized by numerous institutions and managed care pharmacies to reduce the overall costs of oral chemotherapy. The typical cost of a 1-month supply of oral chemotherapy can be exorbitant, ranging from several hundred to several thousand dollars. In some cases, these drugs may go to waste, as patients may be discontinued from drug therapy; may have their medication held; may be switched to another regimen because of side effects; or may be changed to an alternative regimen because of disease progression, treatment failure, or poor compliance. In some cases, the expiration periods of drug therapies may also be a factor in the waste of therapies that are compounded for patients.

Cycle management programs provide a means for reducing expenses from medication waste, while maximizing efforts to help with patient management issues during treatment. The programs provide a partial supply of medication, and then evaluate patients with a mid-cycle assessment before continuation of treatment. If a patient has noticeable side effects or difficulty in tolerating the dose, the patient may have his or her medication held until these issues resolve. In cases where a patient is able to tolerate the oral chemotherapy, the patient will be able to receive the second part of the treatment through either a mail-order or a specialty pharmacy. A retrospective cost-comparison analysis recently evaluated a cycle management program offered through Walgreens; the program was found to save $1,374 per patient in medication costs, with additional savings on indirect costs, such as hospitalization.[4]

**Conclusion**

Oral administration is an increasingly common mode of delivery for chemotherapy drugs; this trend differs sharply from the practices of previous decades, in which IV formulations of antineoplastic agents were the norm. Oral formulations make it easier for patients to administer their drugs, but the benefits of oral agents are often limited by numerous issues in areas of insurance coverage and cost. New legislation has been adopted in many states that may promote better cost-sharing ideas that will drive down patient costs and make continued treatment with these medications more feasible.
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