Delivery of Innovation to Cancer Patients: Access, Communication and Coordination

Although new medicines make it possible to treat cancer more effectively and save lives, the reality is many patients don't get access to these therapies. According to a new white paper, *Securing the Future of Innovation in Cancer Treatment*, multiple challenges are keeping cancer patients from getting the most beneficial and appropriate treatments for their disease. The paper, written by the National Patient Advocate Foundation (NPAF) in concert with like-minded stakeholders, outlines several key issues and explains why addressing them is essential to achieving optimal cancer care.

Access to Oral Cancer Drugs

Today, there are more than 40 oral anticancer medications for the treatment of 54 different types of cancer and many more oral compounds are in the pipeline. Although they cannot always be used to replace injectable products, oral chemotherapy drugs are less invasive, require fewer trips to the doctor's office or hospital (an added benefit for patients who live in rural areas), and can be taken at home.

Despite these advantages to both patients and the health care system, oral chemotherapy medications are covered differently by Medicare and private insurance plans than IV or injectable cancer drugs. In the case of IV and injected drugs, because they are typically administered in a physician's office or hospital outpatient center, these drugs are reimbursed as a physician or hospital outpatient service and covered as a medical benefit. In contrast, oral medications are self-administered and obtained through a pharmacy, which means they are typically covered as a pharmacy benefit.

Why this matters is because pharmacy benefits generally carry much higher cost-sharing requirements and thus, patients are burdened with far greater copayments for oral cancer drugs. In fact, the cost differential can be substantial and devastating for patients. It is estimated that as much as 20 to 25 percent of the cost of oral anticancer medicines is shifted to cancer patients in the form of out-of-pocket costs. As a result, the American Society of Clinical Oncology (ASCO) estimates as many as 10 percent of patients do not fill oral prescriptions due to the added cost burden, thus hampering their treatment.

To correct this injustice, NPAF has joined with many cancer organizations and patient advocacy groups to help pass oral parity laws in 33 states and the District of Columbia, and more states are likely to take up legislation in 2014. These state laws require health plans to cover oral anticancer medications and injectable therapies equitably so that patients pay the same cost percentage for each type of treatment.

However, the cost disparity also applies to many patients covered through self-insured health benefit plans, which is why a national solution is required. Accordingly, the cancer community is pressing for passage of federal legislation, which has been proposed in Congress, but not enacted to date. The most recent bill, called the Cancer Drug Coverage Parity Act of 2013 (H.R. 1801), was introduced in April 2013 by U.S. Representative Brian Higgins (D-NY) and has received bipartisan support. Based on studies in states with oral chemotherapy parity laws such as Vermont, Texas and Indiana, passing the Cancer Drug Coverage Parity Act will have no appreciable effect on insurance premiums. One study found the cost to expand coverage to include oral chemotherapy for most benefit plans is under $0.50 per member per month (a mere 0.17 percent increase).

High Co-Pays for Specialty Tier Drugs

Another serious challenge for those undergoing cancer treatment is the practice by commercial health insurers to move the newer cancer therapies, and especially biologics, into the highest "specialty tier." This means that instead of being charged a fixed co-payment for their medicine, patients are required to pay a percentage of the drug's cost, from 25 percent of the cost of that drug up to 71 percent. This can cost patients thousands of dollars for a single drug that is medically necessary.

The same practice applies to Medicare beneficiaries due to Medicare Part D regulations, which allow plans to create and use formulary tiers dedicated exclusively to specialty drugs. By 2009, the Kaiser Family Foundation reported that 87 percent of stand-alone Medicare Part D Prescription Drug Plans and 98 percent of Medicare Advantage-Prescription Drug Plans employed specialty tiers. Although the Medicare Part D benefit has an out-of-pocket maximum – which is $4,550 for the 2014 plan year – the use of substantial co-insurance amounts for specialty drugs causes older cancer patients to incur a significant financial liability in a short period of time.

The impact was documented by a recent Patient Advocate Foundation analysis of almost 1,000 Medicare patients taking specialty tier drugs, which found more than one in five (23 percent) had to pay a 33 percent cost share per prescription or higher, translating into an average of $508 per prescription. Not surprisingly, this financial burden leads to non-adherence. According to a 2011 study published in the *Journal of Oncology Practice*, patients taking oncology medications with an out-of-pocket cost greater than $200 are at least three times more likely to choose not to fill their prescriptions than those with OOP costs of $100 or less.

Recognizing the devastating financial impact specialty drug tiers have on patient access to often life-saving specialty medications, NPAF and other patient organizations are working to limit patients' cost-sharing requirements through federal and state policy change. At the national level, the bipartisan Patients' Access to Treatments Act (H.R. 460), introduced in February 2013, would limit cost-sharing requirements for patients needing access to specialty drugs and enrolled in commercial health plans to no more than 10 percent above what patients are charged for medicines in Tier 3 (non-preferred brand name prescription drugs). However, since the bill does not apply to Medicare Part D plans, the cancer community is pressing for action by the Centers for Medicare and Medicaid Services (CMS) to adopt one consistent standard of cost-sharing across all tiers for Medicare beneficiaries with a limited household income. At the state level, NPAF and other advocates are working to help pass legislation regulating or prohibiting specialty tiers; to date, 23 states have considered legislation to regulate or prohibit specialty drug tiers, though not all have adopted legislation.

Impact of the Drug Utilization Review on Access

Today, decisions about a course of therapy that were once exclusively made by the doctor and patient are being questioned, and often overturned, through a drug utilization review process conducted by health plans. The external reviewer may be involved in discussions about whether a drug or service is needed, how treatment will be provided and where care will occur.

Not only is the process intrusive, it can also impose undue barriers for patients who need quality cancer care and access to more targeted, less invasive treatments. Of special concern is step therapy, or what is sometimes called "fail first," a policy used by commercial plans and the Medicare Part D program that requires patients first to attempt treatment using one particular covered drug (referred to as a step-1 drug) before payers allow coverage for the prescribed drug (referred to as a step-2 drug). Under this system, the step-2 drug will not be covered until the step-1 drug, which is less expensive, has been administered and proven ineffective.

While step therapy is intended to control costs and risk for the payer, the reality is this policy can be harmful to patients, both through exposure to potentially ineffective treatments and by delays in treatments recommended by their treating physicians. For those patients fighting life-threatening diseases, any delay to the physician-recommended course of treatment could ultimately prove fatal.

From the standpoint of the patient advocacy community, limiting patient access to needed medications and requiring time-consuming alternative courses of treatment is not an acceptable method of cost containment. Patients whose conditions are well managed on a given therapy should be protected from these kinds of cost-sharing methods throughout their tenure in a particular health plan and through any transition to a new health plan. Accordingly, NPAF is working with advocacy partners to monitor utilization review regulations in the states and will seek appropriate legislative or regulatory remedies in states where patients are treated unfairly or inappropriately.

The Need for Patient Engagement

The passage of the Affordable Care Act (ACA) resulted in numerous reforms that give patients greater ability to actively engage in policy formation and modification. Some of these new options include feedback loops so patients can provide feedback on the value of the care they receive, direct patient participation on policy boards, and opportunities for patients to participate in research and help educate the general public on coverage possibilities. NPAF seeks to increase these opportunities for patients while promoting patient awareness of existing ones.

The Institute of Medicine echoed this view when it identified patient engagement in shared decision-making as a top priority for improving quality cancer care in the U.S. In a 2013 report, *Delivering High Quality Cancer Care: Charting a New Course for a System in Crisis*, the IoM calls for supporting patients in making informed medical decisions by providing patients and their families with understandable information about the cancer prognosis and the benefits, harms and costs of treatments. The report also advocates for a "learning health care system" enabling real-time analysis of data from cancer patients in a variety of care settings to improve knowledge and inform medical decisions.

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