

Battling the High Cost of Nonadherence with Oral Cancer Therapies

By Aileen Soper, Wade Hubbard, and Tracy Foster

Nonadherence among oncology patients—particularly those taking self-administered antineoplastic agents—undermines optimal health outcomes, complicates medical decision making for physicians, and increases overall US healthcare costs. It also impacts the commercial success of pharmaceutical products.

Pharmaceutical manufacturers, particularly of oncology drugs, have a unique opportunity to offer support services that may help improve adherence. Achieving an optimal level of adherence can augment a patient's quality of life and clinical outcomes, as well as enhance the level of communication between patients and oncologists.

The Scale of the Adherence Issue

The problem of patients not adhering to prescribed therapies is widespread and impacts all socioeconomic classes and disease states. In the United States, 50 to 70 percent of patients do not take their medications as prescribed.¹ Sixty percent of patients cannot actually identify their own medications, and 30 to 50 percent ignore or otherwise compromise prescription-related instructions.² Research shows that adherence rates range between 16 and 100 percent in adult cancer patients who are

taking oral anticancer drugs—meaning that many fail to take their self-administered antineoplastic prescriptions as directed.³

The economic burden that nonadherence places on the US healthcare system is staggering, with an estimated annual cost of \$100 billion to \$300 billion.^{4,5} Another estimate states that hospital costs due to patient noncompliance amount to an \$8.5 billion annual price tag.⁶

Nonadherence has many implications for the pharmaceutical industry. Previously published reports show patient nonadherence costs the industry more than \$30 billion in lost revenue each year.⁷ On average, the indus-

try loses one in five prescriptions because between 14 and 21 percent of patients never fill their original prescriptions.⁸ That loss is compounded considering that the cost to acquire a new patient is 62 percent higher than it is to retain an existing one.⁹

Some barriers to adherence include patient forgetfulness, competing priorities, intentionally omitting doses, lack of information, or emotional factors. Surprisingly, according to a 2005 study published in the *New England Journal of Medicine*, physicians may be unknowingly contributing to the problem. That study showed that patient adherence may suffer as a result of physicians prescribing complex drug regimens, not adequately explaining the benefits and side effects of a medication, and not considering a patient's lifestyle or the drug's costs.¹⁰

The high cost of oncology medications as well as increasing patient cost-sharing for prescription therapies also negatively

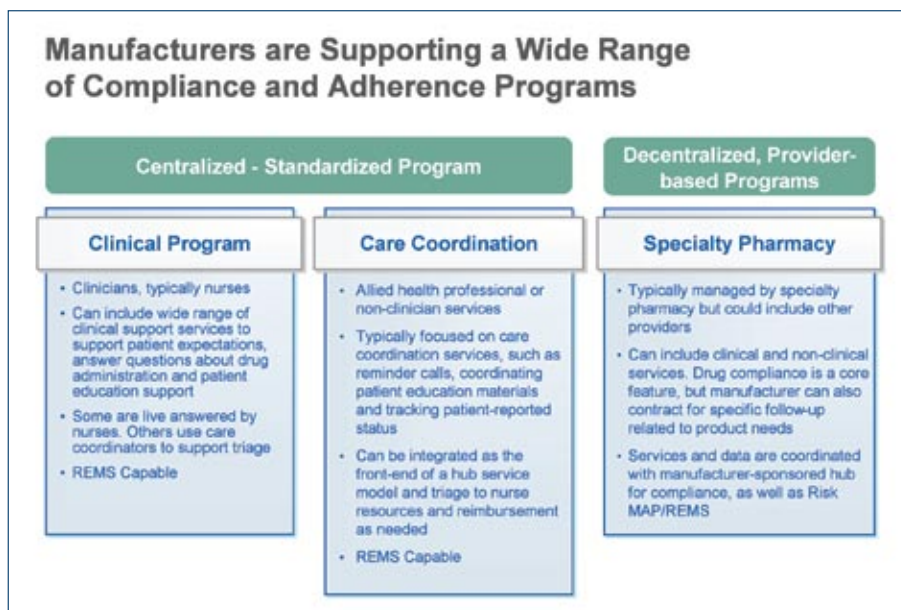


Figure 1. Program Design¹⁴ Source: AmerisourceBergen Specialty Group. Reprinted with permission.

impact adherence. Out-of-pocket spending for adults with employer-sponsored health coverage increased 34 percent between 2004 and 2007.¹¹ Studies have shown that as patient cost-sharing increases for prescriptions designed to treat chronic illness, adherence declines.¹²

Interventions to Boost Adherence

Oncologists, who are extremely busy and under a lot of pressure, have limited time and resources to devote to patient adherence. Pharmaceutical manufacturers, on the other hand, have a unique opportunity to offer supplemental resources for improving adherence and, thus, the efficacy of the chosen therapy. Independent research confirms that the type of interventions that can be offered as components of adherence and persistency programs can help increase adherence.¹³

Several types of adherence programs have been designed specifically for pharmaceutical manufacturers. The structure of these programs can vary depending on the severity of the targeted condition. Under a centralized model, the manufacturer typically utilizes nurses who offer clinical services that support patient expectations, answer questions about drug administration, and provide patient education. Such programs also typically offer care coordination, in which non-clinical staff offer reminder calls, coordinate patient educational materials, and track patient-reported statuses. These services can be integrated as the front-end of a hub model, in which program representatives can triage callers to nurses or to reimbursement support as needed.

Alternately, an adherence program can be designed as a decentralized, provider-based model that is typi-

cally administered through a specialty pharmacy. The decentralized programs include clinical or non-clinical services with drug compliance as a core feature. Services and data can be coordinated with a manufacturer-sponsored hub for compliance reporting and administration of a risk evaluation and mitigation strategy (REMS) program (Fig. 1).

Adherence Program Benefits

The benefits of adherence programs include improving patient health and extending lives as well as supplementing face-to-face interventions offered by medical providers. Benefits include disease education, compliance monitoring, and counseling by pharmacists, social workers, and/or nurses. Programs that increase adherence help to control healthcare spending by reducing hospitalizations and other costly treatment modalities. Successful programs designed to boost adherence can help manufacturers retain patients, extend prescription life, and decrease lost revenue. These programs also can reinforce and strengthen a manufacturer's public image.

Don't Lose the Data!

The best adherence programs not only achieve the objective of keeping patients on therapy as prescribed, but also capture valuable post-launch data. Pharmaceutical manufacturers can benefit from having access to the type of detailed data that may only be available from adherence pro-

grams. Examples of the data that can be captured include the percentage of patients opting into the program, rates of patients discontinuing therapy, adverse event tracking, feedback on starter kits/devices used in administration, and many others.

High-quality adherence programs are designed with an intelligence-gathering platform

that allows retention of data around the product's key value proposition (e.g., fewer side effects, reduced hospitalizations).

In order to gain appropriate coverage or garner fair pricing, oncology manufacturers will need to be able to support key value propositions with real-world data throughout the product life cycle. Both public and private payers have been reluctant to conclude that results from small, homogenous clinical trials with short assessment periods will be applicable to their large, heterogeneous populations that are subject to varied practice patterns. More and more, these payers are requiring data to support favorable drug assessment and coverage decisions. Savvy oncology manufacturers will respond to this market demand and develop resources and tools to acquire, retain, and disseminate that information to payers.

In addition to supporting value propositions, governmental initiatives are also driving the demand for adherence programs and the valuable data these programs capture. This type of

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information can be leveraged as an integral part of a product's REMS. As the federal government grapples with healthcare reform, the role of comparative effectiveness is expected to grow into a key component of drug evaluations. Without a high adherence rate, the efficacy of any drug therapy is diminished. Thus, adherence programs may actually become strategic in that they represent increased costs for later entrants to the market and, therefore, offer a competitive advantage.

It should be noted that there are some limitations to the data that can be gathered through an adherence program. Results are most often self-reported by patients, and actual medication consumption cannot easily be verified; a patient may fill a prescription, but the programs cannot always verify if the patient actually took the medication. Additionally, therapy discontinuation may be physician directed and, therefore, not an indication of poor compliance. Establishing strong relationships with patients and providers enrolled in any adherence program is key to capturing and understanding the quality of the data retained.

Conclusions

The well-documented alarming rates of patient nonadherence negatively impact patient health outcomes, increase overall healthcare costs, and can undermine a therapy's commercial success. As federal regulatory agencies and payers from both the public and private sectors increasingly demand data to support positive

product coverage and reimbursement, manufacturers must be able to collect and report actionable data that demonstrate the efficacy and overall value of their products. This type of data can be disseminated through targeted, field-based tools that help communicate a product's "story." Thus, an adherence program should be a key component of any successful market strategy for manufacturers.

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Key Benefits of an Adherence Program

- Improve patient health and extend patient lives
- Extend prescription life (decrease lost revenue), reduce overall healthcare costs
- Support comparative effectiveness and value proposition—adherence is central to accurate assessment of clinical effectiveness and cost-effectiveness of therapy
- Support Risk Evaluation and Mitigation Strategy (REMS) approach
- Differentiate product and services from competitors

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