KAISER
ASSOCIATES

TAKING A FRESH LOOK AT CO-PAY ASSISTANCE PROGRAMS

WHY OPTIMIZING YOUR CO-PAY PROGRAM DESIGN IS MORE IMPORTANT THAN EVER

With health plans tightening reimbursement policies across the board, many pharmaceutical companies are examining their options for increasing patient access to specialty drugs. Co-pay assistance programs, a longstanding tool for enhancing patient access, are becoming an increasingly critical and controversial lever. In this document, we summarize a new way of thinking about co-pay assistance, why it matters, and how to optimize these programs within your organization.

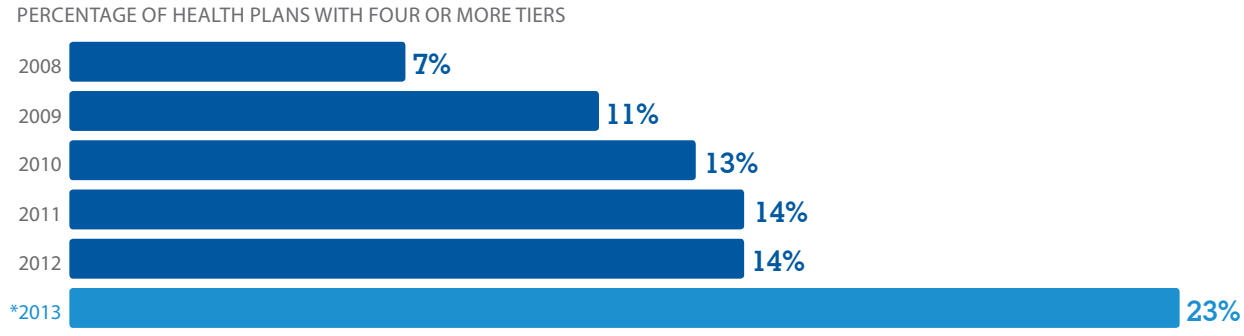
THE CURRENT LANDSCAPE

The influx of high-cost specialty drugs amid a stricter reimbursement landscape is creating new challenges for specialty drug makers. More than ever, drug companies face the difficult task of enabling patient access to new treatments in an environment of tightening reimbursement policies.

In 2013, retail co-pays increased 13% for branded drugs, and 26% for specialty medications[1]. The latest increase is part of a larger trend that has seen specialty drug co-pays increase 80% since 2006[2]. The emergence of "four-tier" drug plans is contributing to this dramatic increase, as many of these plans charge patients between 10 and 40 percent of the drug cost. The average annual cost of a tier-4 biologic exceeds $20,000 per year. The number of employers offering four-tier drug plans continues to increase, with 23% of plans now using a four-tier design *(See Figure 1).*

The downstream effects of high out-of-pocket (OOP) costs are apparent — higher barriers to patient trial, lower compliance, and increased rates of discontinuation altogether. In a study of more than 10 million prescriptions, researchers found that patients having a co-pay of $50 were nearly four times more likely to abandon a prescription at a pharmacy than patients paying $10[3]. Furthermore, physicians are considering OOP when making prescribing decisions.

FIGURE 1:
Growth in Four-Tier Health Plans, 2008 – 2013



Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2000-2013

[1] Source: Pharmacy Benefit Management Institute (PBMI): 2012-2013 Prescription Drug Benefit Cost and Plan Design Report
[2] Source: The Kaiser Family Foundation and HRET: Employer Health Benefits 2013 Annual Survey; PBMI: 2012-2013 Prescription Drug Benefit Cost and Plan Design Report
[3] Source: The Epidemiology of Prescriptions Abandoned at the Pharmacy William H. Shrank, et al. 16 November 2010

PHARMACEUTICAL COMPANIES HAVE A NUMBER OF TOOLS AT THEIR DISPOSAL TO IMPROVE ACCESSIBILITY OF PRODUCTS THAT CARRY A HIGH PATIENT OUT-OF-POCKET COST.

Most companies will agree that post-market clinical or pharmacoeconomic data generation is the most-effective tool to improve patient access – but often the least feasible due to issues with cost, timing, and execution. As a result, most Marketing and Managed Markets teams rely on pricing tools such as rebates, co-pay assistance programs, and samples to improve access. Taken together, these tools can have a meaningful impact on patient access and drug revenue. When misapplied, however, they can create excessive and often unnecessary expenses and cannibalization.

Pharmaceutical companies rarely apply the same level of resources and analytical rigor to designing co-pay programs as they do to other marketing and rebate programs — but co-pay support programs are widespread and growing in number (561 in 2014, a 34% increase since 2012[4]). The stakes are increasing as well.

In 2011, the pharmaceutical industry spent over $4 billion on co-payment assistance[5]. Co-pay assistance spending continues to increase as specialty drugs account for a higher percentage of drug costs. Amgen offers as much as $10,000 annually to help Neulasta® chemotherapy patients access the medicine. Humira®, the world's top selling drug in 2013, with monthly costs up to $2,500, provides co-pay assistance that can lower OOP expense to as little as $5 a month for eligible patients.

Although co-pay programs have recently come under fire by Pharmacy Benefit Managers and health plans, they do not seem likely to disappear anytime soon. Federal law prevents pharmaceutical companies from giving co-pay assistance to patients insured by federal programs such as Medicare and Medicaid, but the Department of Health and Human Services (HHS) recently provided guidance that this prohibition doesn't apply to health insurance offered through the state and federal exchanges mandated by the Affordable Care Act.

Co-pay assistance programs can be a particularly valuable tool when designed appropriately. In our experience, returns on co-pay programs typically range from 2 - 5 times program costs, which is equivalent to or better than many competing marketing programs. *Due to the escalating cost and potential returns of such programs, taking a fresh look at co-pay program design is warranted.*

RETHINKING CO-PAY DESIGN

Co-pay programs have traditionally followed a standard design: Pharmaceutical companies offer patients a fixed benefit amount for each course of treatment (e.g. up to a $50 benefit per prescription). This prevailing approach works well for preferred drugs obtained through a retail pharmacy, but is insufficient for specialty drugs, injectables, and high-cost non-preferred drugs. These drugs demand a far more sophisticated approach due to the variability in patient co-pay amounts, one that optimizes the multiple possible dimensions of program design. *(See Figure 2)*

Choosing the appropriate program design requires carefully defining its role within the brand strategy, quantifying the return and sources of return, projecting actual costs, and understanding the impact on patients and physicians. The process, although analytically intensive, can lead to significant incremental revenue generation and cost savings. Next we outline five key factors to consider when optimizing a co-pay assistance program, and the associated analytical needs.

(continued on page 4)

FIGURE 2:

Dimensions of Program Design

BENEFIT AMOUNT:
The monetary value associated with the program

BENEFIT TERMS:
The terms of the benefit availability (e.g., per treatment or per time period)

OFFER LENGTH:
The length of time the monetary value is offered. Examples include:
- Limited (e.g., patients' first year on therapy)
- Ongoing (e.g., no defined end-point to the benefit)
- Custom (e.g., different benefit amounts for different periods)

LOGISTICS:
The way the patient receives the benefit. Considerations include:
- Sign-up process
- Requirement for realizing benefit
- Format of program (e.g., debit card vs. coupon)
- Card restrictions (e.g., restricted to use co-pay assistance or no restrictions)

AVAILABILITY / ELIGIBILITY:
The extent to which there are restrictions on availability (e.g., available regionally vs. nationally)

[4] Source: Co-Pay Offset Monitor, Zitter Health Insights
[5] Source: Rockoff, J and Loftus, P, Branded Drugs Chalk Up a Win Under Health Law, WSJ, 3 November 2013

IN PRACTICE

Recently, Kaiser Associates worked with a client to optimize its co-pay support programs across multiple therapeutic areas.

The client had conducted an initial ROI assessment of a new program design but did not have the data to fully quantify incremental program upside and opportunity costs.

THE CLIENT:

A leading specialty pharmaceutical company.

THE CHALLENGE:

The client was examining its approach to increasing patient access to a blockbuster injectable drug used to treat multiple FDA-approved and marketed indications. Co-pay support is a critical component of its patient access strategy, with program structure varying by card value, duration, and promotional effort depending on the indication.

Objectives:

- **Complete a more thorough analysis** to determine the optimal strategies for the co-pay support program in each indication
- **Gain a greater understanding** of patient behavior within each patient group, and the factors that are most influential in patients' decisions to trial, continue, and discontinue the drug
- **Understand the influence** of patient OOP and the availability of co-pay support programs on physicians' decision to prescribe the company's drug rather than one of its competitors' drugs
- **Account for opportunity costs** and conduct in-depth research to support the program funding

Kaiser's Approach:

- **Kaiser Associates developed** and deployed quantitative surveys targeted at patients and physicians in each of the promoted indications
- **Kaiser integrated survey data** with a variety of additional inputs, including historical data around payer mix and patient OOP distribution, in order to model out expected upside (increased trial, compliance, and persistence; decreased discontinuation) and cost (opportunity cost and expected patient utilization) for the co-pay support program in each indication

Results:

Kaiser's analysis highlighted critical differences between the indications. By factoring in the unique dynamics of each indication and patient group, Kaiser Associates made customized program recommendations for each therapeutic area. Co-pay support amounts and offer duration were tailored to optimize dollar return and Kaiser identified $8-10 million in program savings across the therapeutic areas.

- **In one indication,** the drug has a clear and apparent medical benefit for a symptomatic and socially debilitating condition. For patients with this condition, out-of-pocket cost was most clearly a barrier to trial; however, once patients trialed the drug, their cost-sensitivity dropped precipitously
- **The optimal co-pay support structure** for this indication included a higher reimbursement offer for the first treatment, with the benefit expiring after the first several treatments
- **By contrast,** in a different indication without the same clear and obvious medical benefit, out-of-pocket cost was more of an influence on patients' decisions to discontinue after initial trial
- **The optimal co-pay support structure** for this indication included a slightly lower offer amount, but one that continued in perpetuity for as long as the patient was on the treatment.

Different Programs for Different Goals

ROI for Indication A: Highly Symptomatic

(1) Value of program is driven by patient trial – once patients realize medical benefit of therapy, cost-sensitivity for further treatments declines

(2) Higher reimbursement offer for first treatment

(3) Reimbursement offer declines for subsequent treatments

(4) Reimbursement offer may expire after set number of treatments

ROI for Indication B: Asymptomatic Chronic

(1) Value of program is driven by patient persistence – patient cost-sensitivity does not decline over time

(2) Reimbursement offer does not decrease over time

(3) Reimbursement offer may not expire, or may last substantially longer than for "Highly Symptomatic" indication

(4) Reimbursement offer may be tied to time period, rather than number of treatments

CONSIDERATIONS FOR DESIGNING AN EFFECTIVE CO-PAY PROGRAM

1. Defining Program Strategy and Objectives:

Pharmaceutical companies have traditionally viewed co-pay assistance programs as tools for improving patient compliance. This approach follows the traditional model seen with consumer retail loyalty cards and rewards programs. For many drug brands, this approach is shortsighted, as the benefits to a specialty drug can extend far beyond compliance improvement. In our experience, many specialty drugs actually see greater benefit when the program is designed to increase patient trial or decrease discontinuation. For example, drugs treating highly symptomatic patients have a lower need for improving compliance as patients are happy to pay for the drug once realizing its medical benefit and impact on quality of life.

Determining the right program strategy and objectives requires an up-front assessment of the magnitude and cost of patient leakage. Some drugs lose most patients prior to first fill; other drugs lose patients during the initial trial (especially if the drug takes multiple courses to achieve efficacy); still others lose patients deep into the course of therapy (particularly drugs treating asymptomatic conditions or those with delayed side effects).

A clear articulation of program strategy, objectives and expected upside is the foundation to a strong co-pay program.

2. Measuring Patient Out-of-Pocket Sensitivity:

Measuring and understanding patient co-pay sensitivity and its impact on trial, compliance, and discontinuation is the most critical input to determining optimal co-pay design. Depending on the brand and disease category, out-of-pocket sensitivity can vary widely due to patient socioeconomic demographics, burden of illness, quality-of-life impact, and availability of substitutes. Furthermore, OOP sensitivity typically varies significantly based on a patient's experience with the drug. We strongly advocate for conducting quantitative market research to understand patient OOP sensitivity across three groups:

- **Patients Naïve to Therapy:** How much of a barrier is cost to choosing the therapy?
- **Current Users:** How does cost impact compliance with the prescribed regimen?
- **Discontinued Patients:** Are out-of-pocket costs driving discontinuation?

3. Determining Quality of Coverage and Payer Mix:

Specialty drugs in particular, have high variability in the quality of coverage between health plans with patient co-pays, co-insurance, and deductibles often widely and unevenly distributed for a given drug. As a result, obtaining an accurate understanding of patient co-pay and co-insurance distribution by insurance payer type is critical when designing an assistance program.

Time of year and geography are also important considerations. In regions with a dominant health plan, the drug's coverage within that plan should be factored into program availability. Drugs with natural seasonality or a higher percentage of patients with high-deductible plans may benefit from varying co-pay assistance levels throughout the year.

Payer mix is another important consideration when modeling costs associated with co-pay programs. Due to restrictions on co-pay subsidies for Medicare and Medicaid patients, drugs with heavy commercial populations have larger patient bases eligible for co-pay assistance and therefore face higher cost exposure.

4. Acknowledging Competitive Realities

In markets with close competition, co-pay programs cannot be designed in a vacuum. In cases where there are few perceived clinical differences between brands, co-pay programs can influence physician recommendation of one product over another. In these cases, we recommend modeling the expected impact of co-pay assistance on physician and staff recommendation rate. The design of competitor co-pay programs becomes an important reference point when optimizing your own co-pay program. If a competitor offers a more generous co-pay benefit than what is optimal for your product, it becomes especially important to understand share and cost trade-offs.

5. Weighing Budget and Opportunity Costs

A final consideration involves weighing the optimal design against the realistic constraints of the business and opportunity costs of other programs. Companies will often face a choice between maximizing either incremental revenue or ROI from the program. In many cases, the optimal percentage ROI will be very different than the optimal dollar ROI. After evaluating the multiple dimensions of co-pay assistance design, the final step requires a careful analysis of budget and expected return on competing marketing programs.

CONCLUSION

With the significant increase in co-pay assistance programs and associated marketing spend, specialty drug companies stand to benefit from taking a fresh look at their co-pay assistance programs. There is more at stake than ever due to the growth in high-cost specialty drugs and insurers' corresponding steps to restrict access. Many co-pay programs are rolled out with conventional, "one-size fits all" approaches that leave significant amounts of money on the table. Informing co-pay program design with credible market research and cost analysis can allow marketing teams to understand their true impact and confidently set program design.

Kaiser Associates advises drug companies on how to optimize co-pay program design given the many complexities unique to their drugs. Using our unique research methodology and analytical frameworks, Kaiser measures the impact that programs have on acquiring new patients, improving compliance and adherence, and growing or maintaining market share. We also recognize that co-pay assistance is one tool for improving patient access and must be part of a broader, integrated strategy that incorporates rebates and sampling programs.

Who We Are

ABOUT KAISER

Founded in 1981, Kaiser Associates is an international strategy-consulting firm that serves as a key advisor to the world's leading companies. We provide our clients with the unique insight to drive critical decision-making and solve their most pressing problems. Kaiser's Healthcare Practice advises the leading Medical Technology, Pharmaceutical, and Biotechnology companies across a range of strategic, competitive and operational issues.

The foundation of Kaiser's service offering is its world-class "outside-in" methodology, which involves delivering critical facts and insights from the complex external environment to drive strategic decision making. Kaiser possesses the unique ability to generate insights across physicians, thought leaders, patients, competitors, partners, regulators, suppliers, and payers. Kaiser uses its deep industry experience and analytical tools to synthesize this diverse set of insights and develop high-impact solutions.

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