

DEVELOPING BEST-IN-CLASS COPAY PROGRAMS FOR OPTIMIZING GROSS-TO-NET

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INTRODUCTION

A copay assistance program is an invaluable strategic cost-saving tool that biopharmaceutical companies integrate into their patient services offering. These programs are used to support a brand's value proposition, while offsetting high-priced branded drugs, all of which can be the ultimate differentiator for a biopharmaceutical company.

Copay programs are designed to reduce patients' out-of-pocket (OOP) costs to compete with generic alternatives. These programs have many benefits for patients and health care providers. However, if not properly managed, they can become cost prohibitive. Therefore, it is critical to find the right balance between putting the patient first by designing a best-in-class copay assistance offering and maintaining fiduciary responsibility.

Throughout this discussion, the focus is on products in the specialty-lite category, including both mature (i.e., i.e. end of life cycle or loss of exclusivity) and new-to-market brands. It outlines the success factors for optimizing patient affordability, while strengthening brand and financial performance. We address below what we call the three pillars of strengthening your copay program strategy:

- Copay Program Caps: Optimizing Gross-to-Net
- Covered vs Non-Covered Programs
- Promotional Strategies

Copay programs started to emerge in the mid-2000s. The objective was to provide patients with an affordable method for obtaining branded medication, while mitigating the competitive threat of an increasing

number of generic alternatives. Patients benefit from a reduced copay on branded medications. These real-time savings are an incentive for the patient, as well as the prescribing physician, to stay on the brand product, rather than seek a cheaper alternative¹.

As a result, some of the benefits of copay programs include:

- Attracting patients to branded drugs
- Instantaneous reduction of copayment
- Therapy adherence (meaning the patient is more likely to stay on the brand and consistently refill)

For biopharmaceutical companies, copay programs put their brands closer to the more affordable tier-1 formulary OOP costs (similar to generics), rather than the more expensive traditional tier-3 price range.

There is a rigorous process by which biopharmaceutical companies design the benefit coverage of their copay programs, which is typically referred to as the Business Rule Document (BRD). The BRD comes with strict compliance and legal guidelines that biopharmaceutical companies are required to follow and explicitly communicate with healthcare providers and patients for ensuring the right patient is deemed eligible to use the copay program. We have all seen the advertisement for branded drugs that say, "pay as little as \$5 for your monthly prescription." However, the eligibility criteria are within the fine print (see example copay program terms).

EXAMPLE OF COPAY PROGRAM ELIGIBILITY CRITERIA/TERMS AND CONDITIONS:



This offer is only valid for patients with commercial insurance. This offer is not valid for any person eligible for reimbursement of prescriptions, in whole or in part, by any federal, state, or other governmental programs including, but not limited to, Medicare, Medicaid, TRICARE, or any other federal or state health care programs.

You are responsible for paying the first \$5 (or \$100 if your commercial plan does not provide coverage) for each eligible prescription fill using the coupon. The coupon has a maximum benefit, and the patient is responsible for all additional costs and expenses after maximum benefit limits are reached.

Copay programs have many benefits to patients, yet they can be costly to implement for the biopharmaceutical company. Therefore, companies must balance the financial assistance they offer to patients with the fiduciary responsibilities that copay programs require, which brings us to the topic of gross-to-net (GTN). Each prescription has a gross dollar value, which is referred to as the Wholesale Acquisition Cost (WAC). Ideally, the WAC of a brand drug is mostly (or entirely) paid for by the patient's insurance. However, payers are increasingly shifting a larger portion of this cost share on to patients. Rising deductibles and coverage restrictions more frequently delay or deny reimbursement, thus exposing patients to the full cost of the prescription, which can force a switch to a cheaper or better-covered alternative. This, coupled with increases in copay and coinsurance for branded coverage tiers, further increases the financial pressure on patients. To maintain patient adherence, this financial burden shifts to copay programs. Therefore, this widens the GTN gap and can put prescriptions at risk of simply breaking even or being underwater entirely.

We must preface that there are several different models of copay programs. Also, the competitive market and therapeutic category can drive the benefit design of the copay program. Where your brand is within its life cycle will also have an impact on how your GTN impacts the Average Sale Price (ASP).

COPAY PROGRAM CAPS: OPTIMIZING GROSS-TO-NET

Essentially, biopharmaceutical manufacturers have two main levers to optimize and control program costs. The first is to limit the total benefit or 'cap' of the copay program. The second is to choose between an

annual or monthly (per Rx) design. Other programs may leave it 'uncapped.' Overall, these two options are determined by many factors, such as managed care coverage, generic competition, or list price.

Now, let's imagine that each prescription has its own balance sheet. For a drug that has a WAC of \$1,000, this represents the gross amount of the product's cost until associated fees (e.g., managed care rebates, copay programs, wholesaler discounts, chargebacks) begin to strip away its value. Eventually, we arrive at the ASP, sometimes referred to as the Net Effective Price. In the context of GTN, ASP3 represents the difference between the list price and the net profit once all applicable fees have been accounted for (see Figure 1). As previously mentioned, those individuals within biopharmaceutical companies who are responsible for managing copay programs have a fiduciary responsibility for monitoring their GTN to ensure a favorable ASP. The gross margins of branded drugs typically fall within the 70%+ range, while generic drugs average 50%². If a copay program is uncapped, it will buy down a significant dollar amount of the patient's OOP expense after insurance is applied. An uncapped copay program can erode ASP, potentially resulting in a negative profit margin for the biopharmaceutical company.

Figure 1 depicts a GTN calculator to assess how prescription data can be used to develop a successful 'covered' copay program. 'Non-covered' copay programs will be discussed in the next section.

Figure 1: Product X[®] (covered program, uncapped benefit)

In this example, Product X[®] has a covered, uncapped benefit design. As you can see, the median WAC is \$3,213. After all fees are deducted, which amount to \$1,328, the ASP is \$1,885 – resulting in 59% profitability for each prescription. If Product X[®] were to experience a managed care loss, then the line item depicting coupons would increase to buy down the delta of that payer loss or lack of reimbursement. In this scenario, the GTN would drive ASP downward. Therefore, the success factor when managing GTN is to protect ASP based on current and unforeseen market events.

		2022			
		JAN	FEB	MAR	TOTAL
COVERED	Rx (000)	1.5	1.6	1.4	6.1
	Covered Rx - % of total Rx	82.1%	81.0%	82.5%	81.3%
	Gross Sales (\$M)	\$ 5.0	\$ 4.5	\$ 4.7	\$ 19.6
	GTN (excl Coupons) (\$M)	\$ (0.9)	\$ (0.8)	\$ (0.9)	\$ (3.4)
	Patient Benefit (\$M)	\$ (1.5)	\$ (1.1)	\$ (1.1)	\$ (4.8)
	Revenue (\$M)	\$ 2.6	\$ 2.7	\$ 2.8	\$ 11.5
	WAC (per Rx)	\$ 3,330	\$ 3,225	\$ 3,200	\$ 3,213
	GTN %	48 %	40 %	40 %	41 %
	ASP (per Rx)	\$ 1,733	\$ 1,929	\$ 1,750	\$ 1,885

An uncapped program can work well in a situation when payer coverage is strong because there's less financial risk to the program with higher payer coverage rates. For mature brands, or those that are new to market where managed care coverage is not as strong, an uncapped copay program can potentially become unprofitable over time. With that, biopharmaceutical companies must determine their threshold of what dollar amount the cap will cover without driving ASP downward and shifting the monetary risk to their patients. There are other key factors to determine – for example, at what point does the program shift from uncapped to capped? Additionally, what is the potential halo effect or perceived loss of patients that might be negatively impacted by this shift?

COVERED VS. NON-COVERED PROGRAMS:

The most common form of copay program is referred to as Covered, meaning the patient's insurance covers, or pays for a majority of the branded drug, then the copay program buys down the delta between what the payer paid, and the patient owes in OOP cost. Non-covered programs are aimed at helping patients get the branded drug in the event their insurance denies coverage of the medicine. This type of offering is more common when launching a new product. The goal here is to get patients on therapy in the interim as the brand scales and formulary coverage broadens over time.

Figure 2 depicts a non-covered program. In this example, the median WAC is \$3,133 and the non-covered benefit is buying down 95% of that WAC, resulting in a mere \$145 profit per prescription. It is also important to note that this program accounts for 21.2% of total prescriptions. In other words, more than one-fifth of all Product X® prescriptions are just slightly profitable and this benefit design is accruing a large percentage of the total prescription volume. The key question is how long to wait before determining the non-covered benefit has either become too risky, or swells to a greater share of prescriptions.

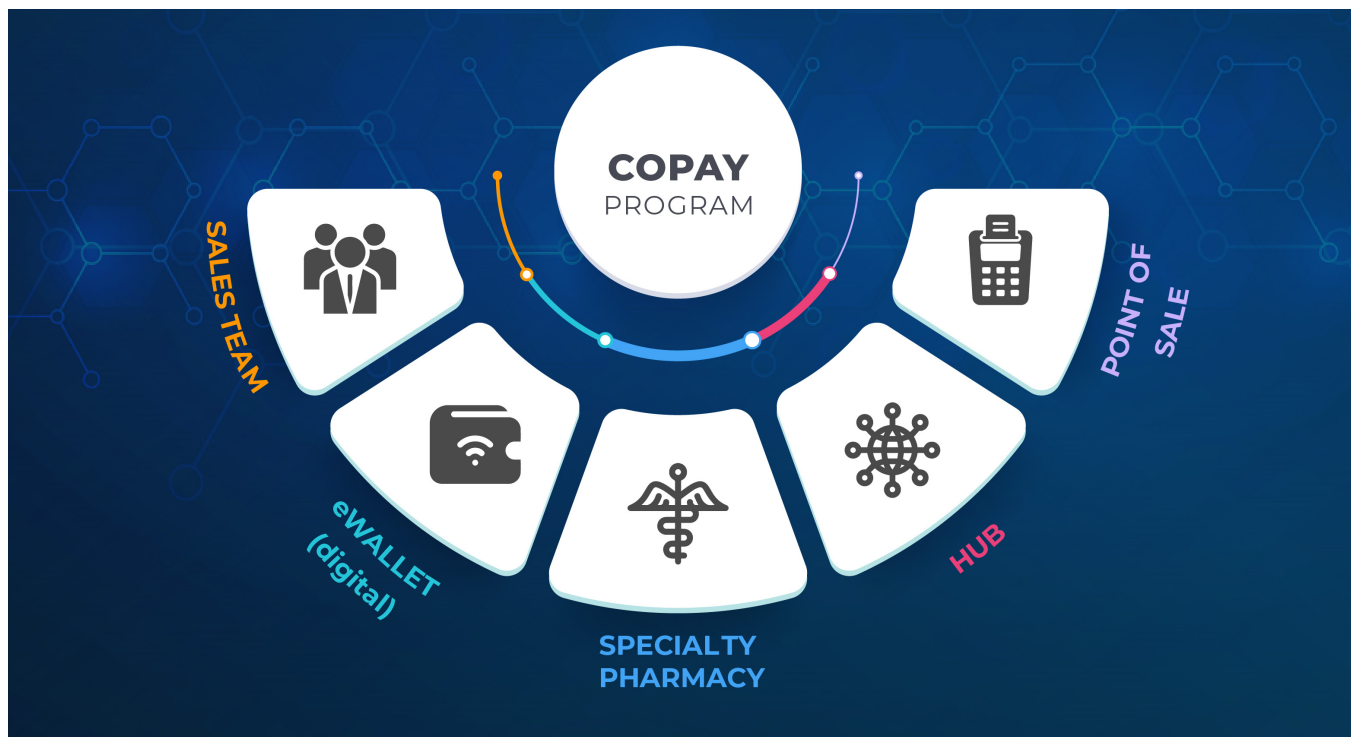
Keeping GTN and ASP top of mind, non-covered programs are, or at least should be, a short-term tactic; otherwise, the company is essentially buying their own drug over the term, which is a race to the bottom. Therefore, it would be smart to develop an exit strategy for transitioning patients off the non-covered program. Remember, Figure 2 depicts 21% of all Product X®'s prescriptions are being paid by the company at 95% of WAC. This is not sustainable for the long-term, hence the suggestion of a transition strategy beforehand.

As for offsetting the drain on ASP and possible swell of non-covered prescriptions, biopharmaceutical companies should place a limit on the total number of uses (refills) on the non-covered benefit. For instance, rather than allowing 12 refills like a covered program typically provides, the non-covered program should be limited to perhaps three uses. Lastly, rather than an OOP cost of \$5, the non-covered program might be higher, such as \$75 or \$100.

Figure 2: Product X® (non-covered, uncapped benefit)

2022					
		JAN	FEB	MAR	TOTAL
NON-COVERED	Rx (000)	0.3	0.4	0.5	1.6
	Non-Covered Rx - % of total Rx	18.0%	17.5%	19.3%	21.2%
	Gross Sales (\$M)	\$ 1.3	\$ 1.2	\$ 1.3	\$ 5.2
	GTN (excel Coupons) (\$M)	\$ (0.1)	\$ (0.1)	\$ (0.1)	\$ (0.3)
	Patient Benefit (\$M)	\$ (1.0)	\$ (1.1)	\$ (1.1)	\$ (4.6)
	Revenue (\$M)	\$ 0.2	\$ 0.1	\$ 0.1	\$ 0.2
	WAC (per Rx)	\$ 3,975	\$ 3,435	\$ 2,800	\$ 3,133
	GTN %	86 %	96 %	93 %	95 %
	ASP (per Rx)	\$ 561	\$ 134	\$ 185	\$ 145

Figure 3: Omnichannel Copay Promotion



PROMOTIONAL STRATEGIES:

Benefit design and incorporating effective GTN guardrails through the development of your business rules will ensure that you have performed proper due diligence before launching your copay program. From here, let's explore a few methods for executing a best-in-class program. For starters, an omnichannel strategy will ensure that your copay program has diverse modalities for getting to the patient. Also, the copay is not just a patient affordability resource, it is a marketing tool and part of the overall marketing strategy to help scale awareness and equity of your brand(s). Figure 3 depicts what an omnichannel strategy might include. Next, let's explore some use case examples.

- 1. Sales Teams:** Historically, biopharmaceutical companies relied on sales personnel to provide healthcare providers (HCPs) access to copay programs. However, hardcopy copay cards are costly to print and can negatively affect budgets if discarded by HCPs. Although a great source for distributing copay cards, it is important for biopharmaceutical companies to ensure salesforces are effectively trained on how to maximize the card's value proposition of when and where to provide them.
- 2. eWallet:** A digital version of the copay card is a convenient way for patients to download and store it within their smartphone. With this modality, patients never need to be concerned about losing a physical card. The other fringe benefit is reduced printing costs.
- 3. Specialty Pharmacy:** If companies have a specialty pharmacy (SP) network who distributes their brand, then they can create a separate copay program or a special offer when patients get the product from the SP network. For example, patients who go to a retail pharmacy might pay \$10 OOP, but if they obtain the brand from an in-network SP, the copay drops to \$0 or \$5. This is a useful tactic when trying to mitigate generic conversion that occurs at a retail pharmacy by shifting the patient over to the SP. Also in this scenario, the SP may automate the refill, which acts as an annuity, hence improving therapy adherence rates of the brand.
- 4. HUB:** Similar to the aforementioned benefits of the SP, if companies have a HUB that interfaces between HCPs and patients, they too should apply the copay card at the time of prior authorization approval. This ensures that patients will

automatically benefit from the reduced OOP cost, while it vertically integrates the copay into the total package of patient service programs.

5. **Point of Sale:** Vouchers, or digital forms of the copay cards can be embedded into the pharmacy workflow. For example, when a pharmacist is getting ready to dispense a brand, they will get alerted by their pharmacy software that a copay program exists. This is an important feature, as pharmacists, patients and HCPs are often unaware that copay programs exist for certain brands.

One final point. It is a best practice to create unique identification (ID) numbers for accessing each copay card method offered. By tracking digital vs salesforce distribution of copay programs, companies can better allocate budget to where there is most traction. Lastly,

a unique ID per modality can help companies track potential fraudulent copay use by pinpointing which ID is affected.

Conclusion

Copay programs for branded biopharmaceutical drugs are clearly an important and strategic tool for helping patients afford their medicine. However, they come with complex compliance checks and balances, which is why the BRD exists. Additionally, the person managing the copay program at the biopharmaceutical company must be financially astute to ensure the benefit design is aligned with the strategic marketing, budget, and forecast goals of the brand. Otherwise, a worst-case scenario would be to discontinue the copay program or reduce the patient benefits.

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