MANUFACTURER FUNDING – THE UPS & DOWNS

A white paper on manufacturer funding

Why is manufacturer subsidized funding a 'big deal'?

There has been a great deal of commentary on manufacturer funding, and how plans are using the funding to do more to offset patient cost share amounts. In this white paper, we are going to give you the background on the positives and negatives of manufacturer funding, and how it can help reduce healthcare costs. At PayerAlly, we help our clients understand and make decisions that best meet their strategic goals. Manufacturer assistance and how to use it within a plan design require difficult decisions and our firm can help you make the right ones.

The focus is to educate. Dispell some of the myths. Start a discussion. Understanding payer strategy on using manufacturer funding is vitally important in controlling specialty drug costs. Specialty drugs have reached more than 50% of medication costs for payers, yet still account for only single digit percentages of claims. Also, there is no end in sight. Specialty medications currently make up 75% of the drug pipeline. Payers need real solutions to enable them to survive in an ever-increasing medication spend marketplace.

Some will have you believe that use of manufacturer funding as a way to reduce payer spend is unconscionable, yet others will tout this as the holy grail of savings mechanisms to control specialty spend. We pull from the market and provide information on the UPS & DOWNS of using manufacturer funding to offset patient and plan costs.

Different Types of Manufacturer Assistance

Manufacturer Coupons/Copay Cards – Manufacturers commonly provide copayment assistance in the way of direct assistance with the patient's intended cost share. For this example, we are going to use patient *Carla*. Carla has a $100 monthly copayment for her specialty drug. The manufacturer of that drug has a coupon or copay card that will cover the patients' cost share. The manufacturer allows cost share assistance for up to $12,000 annually (so they would have covered a copay up to $1,000). These are also called **copayment offset programs**. The use of these programs coupled with plan designs to use some of the available offset are termed Copay Maximizers, Variable Copay and other terms all used to explain programs which are maximizing the use of this type of available manufacturer funding.

Manufacturer Debit/Credit Cards – Manufacturers are now more commonly providing debit/credit cards with value to be used against the copay for a specific drug. From the manufacturer perspective, this achieves the same goal of trying to offset the patient pay amounts, while limiting the manufacturers' exposure to additional value being pulled into the payer amount owed. Again, there are programs (copay maximizers, variable copay) that find ways to ensure these available dollars become part of the benefit design.

Patient Assistance Programs (PAPs) – these are programs where based on financial need. Patients must be financially eligibile based on requirements, have no insurance, or be underinsured (denied coverage by their insurance). For this example, we are going to use patient *Patrick*. He has a commercial healthplan who has excluded coverage for the specialty drug his doctor has prescribed. Patrick's out-of-pocket is $1,000 per month with no insurance, and he is not able to afford the drug. However, the Specialty Pharmacy is able to do a benefit search for Patrick, and seeks out to gain payment for the drug through PAP. (PAPs are typically a 501(c)(3) organization ultimately funded by the manufacturer.)

PRIORITY 1

The goal of manufacturer funding should always have a primary priority of enabling patient care. How? It is intended to allow patients to seek a specialty medication, which may be unattainable due to cost. These specialty medications are typically high cost and the cost share for the member can be a barrier to access. As purveyors of healthcare, evaluating programs as to their ability to keep **PRIORITY 1** at the forefront of decisioning is crucial.

COVERAGE of SPECIALTY PRODUCTS

With the widespread availability of Patient Assistant Programs (PAPs) and copay assistance, there is big money in the decisioning on when to keep some of these specialty medication 'on benefit' or limiting their coverage. The coverage decision and strategy of how to engage with available manufacturer funding is very important in the cost of medications incurred by the payer. This is something that most payers are focused on to remain viable and keep costs down in a growing specialty drug market.

KEEPING COVERAGE

Let's talk first to those who have prioritized keeping coverage for all of these specialty medications without requiring exhausting manufacturer assistance. Keeping high-cost specialty medications on your plan design can mean better access to medications without barriers. It can also mean that you must make further decisions on how to maximize the use of manufacturer funding available to your members and to the payer. Different Pharmacy Benefit Managers (PBMs) have differing approaches to using manufacturer funding, and it also largely depends on the specialty pharmacy or network being used for dispensing.

Let's go back to *Carla* – that $100 copayment may not be that high depending on her own unique financial situtation, however, allowing her to pay that cost share personally instead of engaging with manufacturer assistance could be costly to her and her plan. Let's break it down. Carla's specialty pharmacy or prescriber informs her of a copay card that can take care of her $100 copayment. In our example, we are keeping her coverage of the medication and not requiring that Carla use or exhaust manufacturer assistance, although the manufacturer has up to $12,000 of annual copay assistance for the medication. How the Specialty Pharmacy/PBM/Plan handle that information can vary:

Option One – If the patient chooses to not particpate in the copay assistance available, Carla would be left with her $100 copay, and the plan responsible for the remainder of the cost. Although this allows for member choice, it can arguably cost the plan considerably more for the claim.

Option Two – The patient chooses to participate in the copay assistance and payer evaluates the manufacturer funding available in the marketplace and uses that analysis to change plan design only upon acceptance of the program by the patient. In our example, the payer realizes the available $12,000 annual copayment assistance on the medication Carla is taking. They create real-time plan updates to their plan design to require a $1,000 cost share at the time of dispensing.

Option Three – Knowing that Carla's expected copayment is $100 monthly ($1,200 yearly) the payer could adjust the amount on the first transaction to cover not only $100 to offset Carla's cost share, but also $10,800 of plan costs. This would leave $1,100 to continue to cover Carla's costs in the future. For the remaining months of the year, funds left would be used to offset Carla's cost share, and no additional offset of plan costs would be made.

These examples assume a full year and would be adjusted depending on when in the calendar/plan year the transaction takes place. For example, if the card has an annual limit based on the calendar year, and the patient is starting in July – the amounts would be adjusted to use all of the available funding within the calendar year. These may seem quite similar on the surface, however, they are very different depending on what happens with Carla's coverage during the year.

Although these options assume the plan doesn't require the patient to exhaust the funding, there are more aggressive management approaches that require they do.

PASSIVE CAPTURE OR AGGRESSIVE MANAGEMENT

Another big conversation in the delivery of Copay Maximizer programs and Patient Assistance Programs is whether to take a passive or aggressive approach towards the use of available copay assistance by altering or managing pharmacy benefit plan designs to maximize the use of manufacturer available funding. What do we mean? Well, in some cases the programs pushed by the payer/PBM/pharmacy include more of a ***passive capture*** approach, where they offer the program as a way to minimize patient out-of-pocket spend, yet don't require or alter benefit coverage. Others use a PBM partner or alternative funding vendor for more of an ***aggressive management*** approach, where they hold-back from coverage (either through limited coverage requiring PA coupled with management of manufacturer funding) or removal of coverage (non-essential benefit or removal of the products from the covered drug list) until the process to gain the manufacturer assistance is complete. Note, there are manufacturer programs out there that offer bridge fills and/or the member/patient may get samples of the drug from their provider.

In our case of Carla above, she may receive an offer to help pay her copay, however, worry about the process or timing and just be willing to pay the $100 out-of-pocket amount. This more ***passive capture*** approach, which was described in our Option One, Two, and Three above, could be a great deal of lost value to the payer if they could have offset any plan costs with the additional manufacturer funding if she decides to not use the copay assistance. If this more passive approach is used in order to keep high levels of member satisfaction, it comes at a cost to the payer for lost capture of funding to offset plan costs.

If during this process, Carla were required to wait and pursue copay assistance to confirm the funding availability, it's a whole different set of monitoring in which timing to dispensing becomes a relevant piece of ensuring patient satisfaction and patient compliance with intended therapy. This slow down of the process and lean into a more aggressive approach can be used by some who still display an overall passive capture approach that doesn't require patient compliance.

Finally, there is another ***aggressive management*** approach. Much like Option Two and Three above, when the payer has changed the plan design to a cost share that would maximize the manufacturer assistance available, it is done not retrospectively once the patient agrees, but instead, used plan wide to set the plan design. This means the communicated copay is no longer the $100 we saw in the more passive approach, but instead changed to $1,000 per fill when an annual limit of $12,000 was available for Option Two or even large amounts on the primary fills for Option Three.

The ***aggressive management*** approach comes in the form of limiting or declination of coverage for the medication.

LIMITING COVERAGE

Some focus on a benefit design to limit coverage through a required prior authorization process. This is aligned to widely used benefit designs today, whereby there is a clinical evaluation of the appropriateness of a medication for the therapy intended prior to coverage. However, in the world of exhausting

manufacturer funding, this is taken another step farther. How? Well, two types of practices have emerged, and understanding how your PBM, or more commonly alternative funding vendor is engaged in the prior authorization (PA) makes all the difference.

First is more of a collaboration between the prior authorization process and the alternative funding vendor, by which the medications with known alternative funding availability are going through a prior authorization (PA); first, there is a clinical review for appropriateness of coverage, and then secondarily, there is engagement with available manufacturer funding. In this collaborative approach, when a medication is prescribed, but doesn't meet the clinical criteria or is switched to another formulary product, it may never even engage to seek alternative funding. However, when the drug has passed the clinical hurdle, the PA, it engages with a team (at PBM, or more commonly the alternative funding vendor) to seek the available manufacturer assistance exhausting PAP and Copay Maximizers, before pulling from a plan payment amount. If assistance is not available, the plan would then generate the PA, and pay the claim based on the plan benefit.

A second mechanism to engage Prior Authorization (PA) can walk the line a bit more by using PA as a tool that includes applying the financially available manufacturer assistance to drive clinical decisioning. In these models, the PA is used as a stopping point for more than just the appropriate clinical use validation as it is also used to determine if the medication has available funding from PAP or copay assistance, and to require application for such funding as a precursor to approval of coverage.

Although using the PA process and having a limited coverage model can be effective and still allow for coverage, others may choose to go even more aggressive in the capture of manufacturer available funding through the complete removal of coverage for these medications.

DECLINING COVERAGE

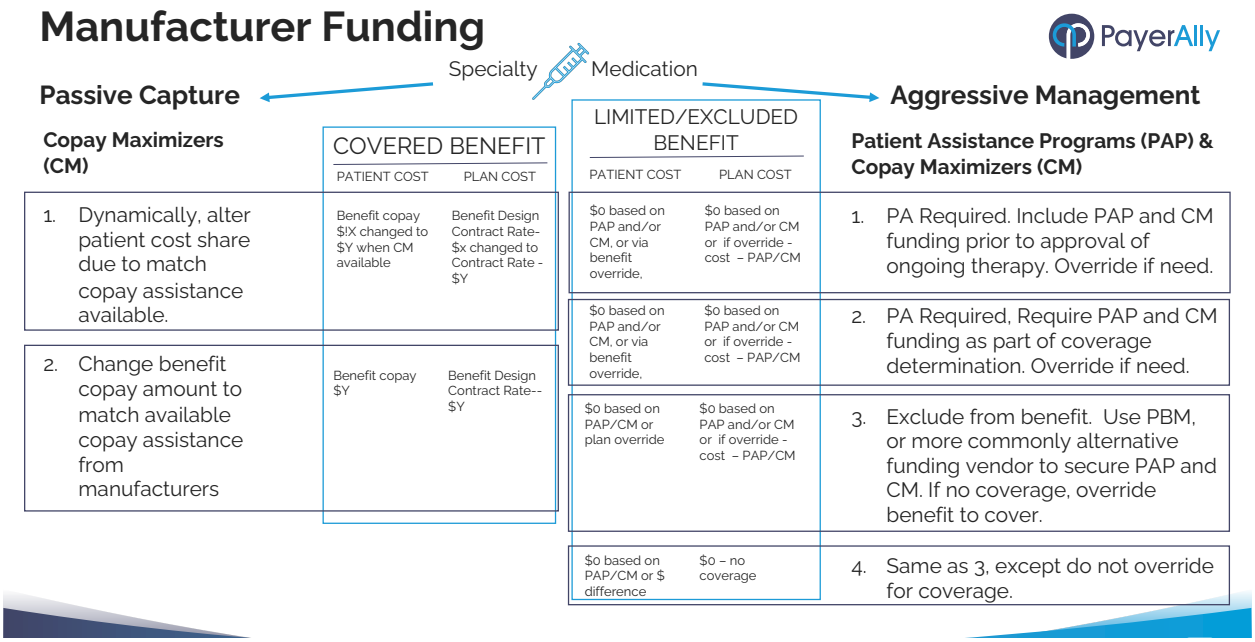
Now, let's talk to those who have made the decision to remove/restrict coverage completely for all of these specialty medications. For some payers, this becomes a tough decision, but a reality. Removing these high-cost specialty medications on the plan design can mean a barrier to access to medications, yet managing that barrier can prove to keep the patient experience a priority, and still create significant cost control. Different Pharmacy Benefit Managers (PBMs) have differing approaches on their willingness to support a benefit with complete restrictions on medication classes. There are discussions on how 'essential' it is to the plan to maintain a comprehensive drug benefit. There are arguments for and against, which need to be understood to make that informed choice.

Let's go back to *Patrick* – his payer made the decision to restrict coverage for his specialty medication because of known manufacturer funding assistance available. This could be for assistance that is the more traditional copay card or, even more likely, more aggressive available funds in a Patient Assistance Program (PAP).

First, the question of maintaining a comprehensive benefit. One could argue that because the evaluation of the availability of manufacturer assistance, and management of their patient population is aggressive to ensure the 'no patient is left behind', allows the plan to help their patients ensure continuity of care without also having to foot the bill. However, the other argument is that you are truly removing coverage for treatment for a disease, that as a comprehensive drug plan it is important to maintain coverage, and that any member that is inadvertently turned away from care because they cannot afford the full price tag, and falls through the cracks of obtaining alternative funding, could be a significant risk.

Furthermore, with these restrictions to coverage comes the question about how to manage when the manufacturer assistance is needs-based, and the patient doesn't qualify. This becomes another hurdle; to jump to manually override and restore coverage and do that all in a timely manner as to not disrupt care.

In the case where the plan restricts/removes coverage is the business model, the management of those medications outside the benefit is the area of focus for some of the **specialty carve-out** vendors. (It is important to note that the term specialty carve-out is also used in other facets of medication management; for example, prior authorization management and specialty dispensing, which are not part of this white paper.)



SCRUTINY OF PLAN BENEFIT

The use of manufacturer assistance to offset plan costs has been under a great deal of scrutiny. Articles characterize the use of manufacturer funding for plan benefit as a negative, however, with close inspection of the availability and use of programs can in many cases help everyone and keep costs down. So, in some cases, the rhetoric behind the scrutiny is more aligned to a failure to find the good in these benefits when they are properly managed and maintain PRIORITY 1 of patient-centric financial benefit as discussed earlier.

Let's maybe look at some of the fundamentals first to understanding manufacturer funding:

1. This funding is made available by manufacturers. It intended for patient use to offset their cost share, get them to begin therapy, and become compliant with the use of a manufacturer's high-cost medication.

2. Manufacturers create these funding pools to prevent loss of market share and to prevent patients from not using their medication due to high out of pocket (OOP) costs.

3. Funding allocated for copay offset is intended for patient benefit, however, when excess funding is available from the manufacturers and doesn't get used by Copay Maximizers, it adds profitability to the pharmaceutical manufacturer while not reducing any plan costs.

4. Funding for Patient Assistance Programs (PAPs) allow patients to receive the intended medication at little or no cost. It is based on economic need of the patient, the definition of which fluctuates by the manufacturers.

5. The manufacturer's funding of the Patient Assistance Program (PAP) is portrayed as good will, and therefore used as a tax write-off which allows them to recover lost funding, in whole or in part.

6. Manufacturers, in many cases, maintain the majority of their profitability from patient populations not impacted by CMs and PAPs; the Medicare and Medicaid markets. Getting patients onto their medications through funded programs can also secure those patients if they later change to a Medicare or Medicaid plan.

So, while it is important to control costs for the members, is it not appropriate to use the excess that pharmaceutical manufacturers have designated to control those costs and offset the plan costs that could ultimately also benefit members through lower premiums? Or should it just go back to the manufacturers that would support only the use of this funding to secure higher market penetration and increase their profitability?

Controlling spend is the name of the game – and yes, always with a focus on PRIORITY 1, the patients that all of us in healthcare are here to service. Understanding all of the players in the chess match, and how to create the right strategy for the payer to reduce overall spend is PRIORITY 2.

Let's take this conversation one step deeper. With intermediaries in the process to capture the manufacturer funding to offset patient and plan costs, it adds one more party to the mix. There may be less of an issue with the plans themselves offsetting their plan costs and more issues with the intermediaries using these plan funds as a revenue source. Consider the PBM role – if the PBM is operating to assist in patient access to these funds and offsetting costs to their payers, are they getting a fee share and recovering a percentage of savings, thereby reducing plan costs, but also creating a significant revenue stream for the PBM or, are they charging an administrative fee for the operational effort to do the work, but keeping the savings in a pass-through to the client arrangement? With alternative funding vendors, the same questions come into play; what value they are driving, and how are they being compensated for the work effort required to create that value?

ALL PBMS ARE NOT THE SAME

Interestingly, this is an area where PBMs greatly differ in the way they handle and even speak to manufacturer funding. They differ both in how they manage copay assistance/Copay Maximizers (CMs), and their willingness to engage with alternative funding vendors that handle Patient Assistance Program (PAP) management for excluded benefit medications.

First, let's address Copay Maximizers. One PBM uses a dynamically real-time copay change process that is seamless to members, meaning members still see their routinely established specialty drug copay, yet the copay is actually altered behind the scenes to maximize the available manufacturer copay assistance. While this version of a maximizer does great at putting the patient first, it can lag in its ability to drive results from copay assistance. Other PBMs use an altered plan design to change the patient copayment amount to match the amount of known copay assistance; this is much more effective in ensuring payers automatically have

less financial burden, and it is ultimately placed on the patient and pharmacy to secure the copay assistance or just pay out of pocket.

Next, let's touch on alternative funding vendors. One PBM has come up decisively against the use of alternative funding vendors to engage PAP recently, while other large competitors allow clients to use these vendors. Even the management of Copay Maximizer (CMs) differ from PBM to PBM. While some PBMs may claim that alternative funding doesn't work as advertised, there are just as many payers that use these vendors and would tell you otherwise. PBMs will call out the fees being charged by these vendors as being excessive, yet most clients using them see real savings that outweigh those costs. PBMs may not like these programs and vendors, which is easy to see. Using these vendors could mean removing the dispensing of the drug from the PBM's owned/operated specialty pharmacies, requiring data management to support the vendor, needing updates to a benefit design set-up, and changes to adjudication. However, many PBMs lack alternatives that can show the financial value to the client that these programs can produce.

At the end of the day, decisioning on if/when/how to use a Copay Maximizer program and Patient Assistance Programs (PAPs) to offset patient and payer costs is big business and deserves significant analysis to ensure the decisions made are best delivering on the strategy to reduce specialty drug spend.

PAYER TYPES

We almost made it to the end and didn't discuss payer types. These programs are fairly exclusive to be used for patients with non-government payers. Here are a couple of important points to be made in that regard:

First, Pharmaceutical Manufacturers supplying these alternative funding mechanisms, both copay assistance and PAPs, drive significant market share from the Medicare and Medicaid claims for which these do not apply. The manufacturer could be seeing nearly the same level of gross profit from claims which are traditionally paid less rebates, and those with assistance programs plus the tax benefit.

Second, those who use alternative funding vendors and take advantage of the PAP through limitations to their coverage for these medications falls within ERISA, which provides protection from further regulatory risk. (ERISA does not preclude a plan from carving out its specialty pharmacy benefits and applying distinct requirements to these benefits. Plans remain responsible for complying with all of ERISA's fiduciary and administrative requirements. Plans should take care to implement an alternative funding vendor in a manner that satisfies all of these requirements, including their fiduciary duties and obligations to provide an appeal process consistent with regulatory requirements.) Furthermore, the argument is that they are using the funding to offset their own costs; those costs are really going back to the employer/employee.

ANALYTIC MODELING IS KEY

Understanding the marketplace for manufacturer funding is only half the battle in creating the best strategy. The other half of the battle is creating the analytic model to make decisions on benefit design. A good analytic model must go beyond the sales modeling of the PBM (which has incentives to keep the prescriptions within their domain of control: claims management and dispensing) or that of specialty carve-out vendors (which have much to gain from keeping a portion of savings attributed to their programs).

The analytic modeling must consider all the attributes of the plan design and cost of plan management. There can be the loss of value from rebates, data management fees, channel movement to medical benefit, impact to network rates or cost-savings programs in place with PBM, expected utilization/volume changes, carve-out program management costs, and other value drivers.

Using our consultants to evaluate specialty drug spend, current benefit design, and options for using PBM or vendor directed programs to capture manufacturer funding allows for a review of all aspects of value drivers from the various programs available, and to assist directly in making a well-rounded decision on strategy.

'BIG DEAL'

Manufacturer funding will remain a 'big deal' as we enter an era of biosimilars, and as the pipeline of specialty medications matures and enters the market. Deciding not to engage or allowing decisioning based on one perspective alone can cause a payer to suffer the burden of this ever-increasing costly specialty medication marketplace. It is important to unpack all the arguments for and against the use of manufacturer available funding to offset plan costs and make sound decisions as to what is best for the payer.

Who is PayerAlly?

PayerAlly's mission is to provide cutting-edge support for our clients as they look to better manage their medication costs. We offer best-in-class clinical, financial, and consultative solutions to help better manage costs and improve performance.