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MANUFACTURER FUNDING CHANGES & CHALLENGES

A white paper on the opposing thoughts on patient assistance

What is happening in the world of manufacturer funding assistance?

We previously wrote a white paper on the ups and downs of manufacturer funding assistance – read that article on our **Industy Insights** section of PayerAlly.com. Now, we are taking another step to discuss the recent **CHANGES** and on-going **CHALLENGES** of the use of manufacturer funding to offset patient and plan costs for high-cost specialty drugs. The decision on how to incorporate patient funding assistance into the medical and pharmacy plan benefit is an important one. Keeping clients informed on the perspectives of the industry, and allowing that information to drive sound decisions on their strategy is of the upmost importance. Using manufacturer funding to offset patient costs, and ensure patient access and compliance is important for some, however, using manufacturer funding to offset payer costs is not appropriate for all payers. While we are not here to be on one side or the other, we want to present an unbiased review of both sides of the argument.

So, what has recently happened that is catching the attention of payers and the media? Two manufacturers have changed the requirements in administration of their patient assistance programs to try to prevent the use of the funding beyond patient cost-share offset in order to also offset plan costs. However, there are two sides to every story, and both should be evaluated.

In the Media

Let's start with an excerpt of what has been recently reported. While there have been multiple publications calling attention to this issue, we are going to review one as a basis, then to go into the **challenges** faced by payers and managing high-cost specialty drugs and this new **change**. So, for this purpose, we have reviewed the recent article titled "Drugmakers push back on a clever tactic employers use to avoid paying for specialty medicines" from March 22, 2023[1].

In recent months, two pharmaceutical manufacturers, Abbvie and Johnson & Johnson's (J&J) Janssen unit, have changed the language in their patient assistance programs. Abbvie's new language prohibits anyone working with an outside third-party from obtaining free medication, whereas Janssen is requiring confirmation that the third-party is legally authorized (Janseen manages all manufacturer funding assistance -copay assistance and alternative funding, for J&J). This has started to "draw a line in the sand". A J&J spokesperson stated "patient assistance programs are meant to be for patients alone. Unfortunately, some companies are running programs that **divert patient assistance away from patients**." Hold on to the last part of that as we will unpack that later in this white paper.

Another part of the article summarizes the opinion of one colleague in the industry and states "**Removing insurance coverage for people who were appropriately prescribed a medicine is unethical**, though, argued Adam Fein, who heads the Drug Channels Institute, a research firm that tracks the pharmaceutical supply chain. He maintained that **people who otherwise have health insurance should not be forced into a charity program to gain access to a needed medicine**." Again, keep these quotes in mind, as we will use this information to help unpack these arguments against these programs later in this white paper.

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THE CHANGE

As you may recall from the prior white paper, "Manufacturer Funding Ups & Downs", there are two avenues where manufacturer funding is used: copay maximizer programs and alternative funding programs. Interestingly, we have seen changes that are impacting both programs.

The changes mentioned in the article called out above are happening in the **alternative funding programs** or **patient asssistance programs (PAP).** These changes are being directed by the pharmaceutical manufacturers to limit using the patient assistance programs when a payer has elected to remove coverage and engage with a third-party agency service to have their patients seek assistance and coverage through these manufacturer-funded programs.

The other change is impacting **copay maximizer programs**. These are state specific laws that are being created (largely from the lobbying efforts of pharmaceutical manufacturers) to prevent offset to patient accumulators that was gained from the use of copay offset (copay card) programs. This is common in copay maximizer programs where any money used off the copay card manufacturer assistance is removed from accumulators to keep patient out of pocket spend values to only money contributed by the patient. While some states have had a requirement in place for years, others are adding new language to follow suit. States/territories with current language include: Arizona, Arkansas, Connecticut, Georgia, Illinois, Kentucky, Louisiana, Maine, North Carolina, Oklahoma, Tennessee, Virginia, Washington, and West Virginia, as well as Puerto Rico.

THE CHALLENGE

Let's start with the main challenge: **high-cost specialty medications**. There is no lack of information out there on the ever-increasing cost of specialty medications, and there is no end in sight with the pipeline of medications being heavily weighted on specialty and gene/cellular therapies. Even though less than 2% of the population uses specialty drugs, those prescriptions account for a staggering 51% of total pharmacy spending.[2] Projected spending in the US on specialty medications by 2023 is over $500 billion.[3]

Finding mechanisms to manage the cost of these medications is a top priority for all payers. Let's also make sure we keep something in perspective; pharmaceutical manufacturers are not struggling to maintain profitability while helping to bring to market all these new high-cost medications. In fact, pharmaceutical manufacturers remain some of the most profitable organizations in the world. In 2021, the estimated revenue for pharmaceutical manufacturers was over $570 Billion.

So, let's now unpack some of these arguments and challenges.

The article reviewed article speaks to the concern of "**diverting manufacturer funding away from patients**". This is an interesting take that speaks to one side of the argument for sure, however, there is another side to the story. Many plans, who also have a strong focus on patient care, trying to manage these high-cost medications see the use of these programs as a means to an end. They establish these programs with the patient at the center; working with their PBM and vendor to ensure that the patient need is the priority. Many offer a first fill dispensing while waiting for full engagement with the PAP to allow for immediate access; they work one-on-one with the patients to ensure they complete any paperwork and follow up on accessibility, and finally when patients do not qualify, they work with them to establish coverage through overrides. There is a great deal of operational management, yet many payers find financial advantage to offsetting their ever-increasing specialty costs with the funding made available by manufacturers which they can show reduces the inflation on premiums, ultimately helping all consumers of their healthcare. We also value that this operational management is extensive, and there is

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significant analysis in the decisioning to use these programs that all payers take very seriously. Use of these programs does not always make sense as there are significant costs to the programs. Many clients don't see enough of a financial advantage to offset the costs associated with management of the programs and engagement with these vendors. The analysis is dependent on the savings which can be generated and the steep costs for the intermediary vendors and PBM for managing the program. These steep costs are also an area which requires careful evaluation and scrutiny as some of the alternative funding vendors create a cost structure with an expectation to share in the savings and do not consider the impacts of rebate loss in that calculation, which can drive more value toward the vendor and not helping the patient or plan. Others allow for an administrative fee model, which is more aligned to cover the costs of a highly operational model. Helping clients navigate those decisions falls heavily to these payers and their consultants. However, for those seeing significant cost reductions from these programs, they first focus on ensuring patient access without any cost to patient (which is usually a benefit to the patient) and offsetting plan costs leading to lower overall healthcare costs and premiums (indirectly, still a benefit to the patient). So, some may argue the reverse; these programs **'drive manufacturer funding towards offsetting patient costs both directly and indirectly'**. For many of the payers for which this is a huge asset, they are employer self-funded and the reduction in costs through the use of manufacturer funding ultimately offsets the employee costs. Ultimately, over 70% of the US population falls below the pharmaceutical manufacturer established income thresholds.

Now, let's look into another call out and challenge. There is a quite steadfast statement that these programs remove benefit coverage and that **"Removing insurance coverage for people who were appropriately prescribed a medicine is unethical"**. To unpack that, let's start with the manner in which payers manage costs. The entire plan benefits are based around creating formularies and drug lists which have exclusions to drive market share to clinically appropriate alternatives creating market advantages and lowering costs. In this case, we are looking at specific medications that are extremely high in cost for which pharmaceutical manufacturers are able to make sizeable profits once they have patients tied to the use of their medication and can create financial tax advantages by subsidizing some costs with these assistance programs. For some pharmaceutical manufacturers this is a win-win. For the pharmaceutical companies to not want to also reduce plan costs to help drive use of their product is actually counterintuitive as they already create financial advantages for payers to prefer their product in reduction of plan costs through rebate agreements.

Finally, let's unpack the quote "**people who otherwise have health insurance should not be forced into a charity program to gain access to a needed medicine"**. This, again, is specific to the PAP programs and the fact that patients whose benefit now excludes these medications requires engagement with a vendor to seek alternative funding and are required to go down this new pathway of looking for outside coverage before the plan will consider an override. If you try to look at the other side of the argument, you could also spin it that the pharmaceutical manufacturers are the ones driving this change, and the health insurance companies are just trying to stay in the game. Pharmaceutical manufacturers create a specialty medication with an extremely high price, and also fund the "charity program" to offset costs.

AT THE END OF THE DAY

Payers and the consultants that support them are deep in this conversation on a daily basis. No payer is having a conversation that reviews these programs in a flippant manner. These programs are not appropriate for every payer or all payers. These programs can be a significant answer for very specific clients with real issues in controlling specialty drug spend.

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It is all about analysis and informed decisioning on specialty cost management strategies. Payers and consultants must remain at the top of their game in understanding all the levers they can use to manage these costs.

Just like reinsurance/stop-loss is not appropriate for all payer types; where client size and employee funding enter the mix, use of PAP funding to offset payer costs is not for everyone. Ultimately, strategic management of specialty costs has many levers; all which need to be evaluated for appropriateness for the payer. When specialty costs start to decline, we can all take a breath, there is not a day that statement will likely ever be true in our lifetimes.

About 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 vendor performance.

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