ARCHIMEDES™

White Paper

Emerging Market Solutions for Specialty Drug Management

THE CHALLENGE OF SPECIALTY DRUG COSTS

In the past decade, nearly every plan sponsor has experienced the challenges that accompany a thriving biopharmaceutical market, in which specialty drugs represent about 60% of expected drug approvals in 2022[1] and more than 50% of overall drug spend, despite use by only about 2% of enrollees. Costs for specialty medications are growing at an unsustainable pace of 10%-15% per year[2] and increasingly pose a financial threat to the entire health care benefit.

The challenge is especially acute for smaller employers, which typically lack the financial resources to absorb the treatment cost of even one patient with an ultra-rare disease, which can easily exceed $1 million per year.[3] Plan sponsors need a business partner to help them maintain a specialty drug benefit that is financially sustainable. Yet, increasingly, they find it nearly impossible to achieve that goal in today's marketplace given the inherent limitations of the current PBM model, some of which include:

- Manufacturer revenue "chasing" in formulary development.
- "Spread" pricing.
- PBM pharmacy ownership.[4]

Historically, plan sponsors have relied on PBMs to manage the entire drug benefit. However, this arrangement, developed by PBMs about 25 years ago when the average monthly cost for a newly launched drug was less than $50,[5] is no longer appropriate in today's marketplace because of inherent conflicts between the business interests of the plan sponsor and the PBM. These conflicts of interest have existed for years, but they are more intense and burdensome now, when the average monthly cost of a specialty drug exceeds $7,000.[6]

Clearly, a different, less conflicted business model is needed. Yet, it may be difficult for plan sponsors to choose the best approach given the growing myriad of models that are emerging. This paper overviews the key considerations with each of the alternative market models for managing specialty drugs outside of the traditional PBM model.

NEW MARKET SOLUTIONS FOR SPECIALTY DRUG MANAGEMENT

Five major alternative models have emerged to provide improved specialty drug cost control in recent years (Table 1). For each, plan sponsors should be aware of key considerations that will affect the likelihood of achieving a sustainable, clinically appropriate benefit.

CUSTOM SPECIALTY PHARMACY NETWORK

The first of these models is a carve-out of specialty drug prescriptions from the PBM-owned pharmacy to an Custom Specialty Pharmacy Network. As a large number of specialty pharmacies emerged in this market several years ago, this approach was implemented by health plans to procure the deepest drug discounts available by leveraging competition among the growing list of pharmacies. This option has the seeming advantage of promoting competition to secure the best possible pricing. Operationally, this model is relatively straightforward and mirrors the approach that PBMs use today with owned and non-owned specialty pharmacies.

The main limitation with this option is insufficient competitive advantage for plan sponsors. With the consolidation among specialty pharmacies in recent years, competitive rates are already reflected in most PBM contracts. Thus, the incremental savings for the Custom Specialty Pharmacy Network model have lessened, ranging from 1% to 5%.

PRIOR AUTHORIZATION CARVE-OUT

Another option for plan sponsors is to carve out prior authorization (PA) reviews to an independent third party without financial ties to the PBM. The rationale for this approach is to separate the approval of the drug therapy from the PBM and the PBM-owned specialty pharmacy,[4] which have an inherent financial conflict of interest in the outcome of the approval process. This conflict is manifested in the high PA approval rates commonly seen with the traditional PBM model.

While the savings can range from 5% to 10% of plan costs, adoption of the PA carve-out model has been limited since the conflict of interest can't be removed as the vendor typically must adhere to the PBM's formulary and PA criteria to maintain the plan sponsor's rebates. Alternatively, the plan sponsor can forego its rebate guarantee in order to use a third-party PA program, which most plan sponsors have historically been unwilling to do.

THIRD-PARTY COPAY ASSISTANCE

A third option for plan sponsors to save money on specialty drugs is to implement a program that captures additional dollars from manufacturer copay assistance programs. Third-Party Copay Assistance vendors emerged a few years ago when many of the PBMs had not yet developed their own programs. In this model, the plan sponsor establishes a coinsurance amount for all specialty drugs, and the Third-Party Copay Assistance vendor enrolls members into copay assistance to ensure that the manufacturer pays most or all of the coinsurance amount. The PBM will often share claims and other client data with the vendor to support the program implementation. Third-Party Copay Assistance may also track accumulator dollars and share this information with the PBM to ensure accurate accumulator tracking.

This approach does little to solve the inherent financial conflicts that lead to inappropriate use of specialty medications due to “rebate-chasing” formularies and ineffective PAs. Thus, despite the seemingly appealing unit cost savings of 15%-20% claimed for these programs, they do little to address the root causes of unsustainable and clinically inappropriate specialty drug benefits. This approach also adds disadvantages, including administrative complexity and confusing overlap with existing PBM services as these third-party programs layer on top of PBM services and require operational coordination with the PBM. Employer demand for these programs is slowing because most PBMs now offer their own copay assistance programs, albeit often with reduced savings for plan sponsors.

ALTERNATIVE FUNDING

A fourth and frequently debated option for plan sponsors is to use a vendor that pursues Alternative Funding for specialty drugs and other high-cost brands. Alternative Funding can include charitable organizations, manufacturer patient assistance programs, manufacturer-funded foundations and/or international drug sourcing. The vendors that offer these programs vary in terms of basic program structure. Some programs require the complete exclusion of specialty drugs from coverage altogether, while others require a PA, with a denial of third-party funding before the plan provides coverage.

Adoption of Alternative Funding models is more common with mid-market employers for which even one or two high-cost specialty cases could lead to financial jeopardy. Dozens of Alternative Funding vendors have emerged in the last few years due to the growing demand from small employers. The fees are substantial and can exceed 30% of savings.

When considering an Alternative Funding vendor, it is important to recognize that savings are often inflated as the vendor analyses do not subtract rebates and copay assistance dollars (~50%) that could have been used to lower the net cost.

While Alternative Funding vendors tout significant savings (up to 60%), several challenges should be considered. First, if the patient is ineligible due to income or if program funding has been exhausted, the patient or plan will be required to pay the full cost of the drug. Second, some plan sponsors are uncomfortable with the notion of excluding coverage of specialty drugs from their benefit for legal or other reasons, such as employee relations. Third, the member experience can be disruptive, with members sometimes being caught in the middle between the Alternative Funding vendor, PBM and plan sponsor. Fourth, some stop loss plans may not cover exceptions for claims that are initially excluded and for which the vendor was unable to secure funding. Finally, these programs may not provide clinical management to monitor for appropriate prescribing, adverse drug reactions, or non-adherence.

TABLE 1

MARKET SOLUTIONS FOR SPECIALTY DRUG MANAGEMENT BEYOND THE PBM

MODEL	OVERVIEW	KEY CONSIDERATIONS	SAVINGS RANGE
Custom Specialty Pharmacy Network	Direct specialty drug prescriptions from the PBM-owned specialty pharmacy to a Custom Specialty Pharmacy Network	Provides the least amount of savings due to market consolidation and competitive specialty pharmacy pricing already reflected in most plan sponsor contracts.	1%-5%
Prior Authorization Carve-Out	Carve-out prior authorization reviews to a third-party vendor with no financial ties to the PBM	Requires the PA vendor to adhere to the PBM's rebate criteria in order to maintain the plan sponsor's rebates; adoption has been limited.	5%-10%
Third-Party Copayment Assistance	Use a stand-alone vendor that provides copay assistance programs alongside the PBM offering	Typically adopted by plan sponsors when the PBM offers no copay assistance program. Does not address clinically inappropriate use of specialty drugs. PBMs must provide some operational coordination with the vendor.	15%-20% unit cost savings
Alternative Funding	Exclude or restrict plan sponsor's coverage of specialty drugs to rely on manufacturer patient assistance or other charitable organizations for funding. Some programs include international drug procurement.	More common among smaller, mid-market employers. Does not address clinically inappropriate use of specialty drugs. Funding may not always be available, requiring the patient to pay the full cost out-of-pocket. Member experience can be disruptive. Stop-loss arrangements may be disrupted. Lack of ongoing clinical management. Stop Loss risk.	30%-60%
Specialty PBM Carve-Out	Full carve-out of all specialty drug management, including claims processing, formulary, rebates, prior authorization, copay assistance, and network management to a separate organization that specializes in the management of specialty drugs.	Provides the greatest savings while preserving coverage of specialty drugs under the pharmacy benefit; passthrough and transparent business model is the foundation, Some operational coordination with the PBM for traditional drugs is required.	25%-50%

SPECIALTY PBM CARVE-OUT

In the Specialty PBM Carve-Out model, responsibility for the entire specialty benefit—not just the pharmacy network—is carved out to a PBM with a focus on, and expertise in, management of specialty drugs. Specialty PBM Carve-Out services can incorporate all aspects of specialty drug management, including claims processing, formulary, rebates, PA, copay assistance, and specialty pharmacy network management. In addition to managing specialty drugs covered under the pharmacy benefit, specialty drug PBMs typically also offer management solutions for specialty drugs covered under the medical benefit, which can represent as much as 50% of total specialty drug expenditure for plan sponsors. Foundational to the success of this model are fully transparent reporting of plan sponsor expenditures and savings from all sources, as well as passthrough of 100% of discounts and rebates to plan sponsors.

Among those options that preserve coverage of specialty drugs under the pharmacy benefit, Specialty PBM Carve-Out provides the greatest savings (25%-50%). The program requires some cooperation from the traditional PBM to optimize member experience with the carve-out program. The remainder of this paper provides an in-depth discussion of the Specialty PBM Carve-Out Model and the market's response.

SPECIALTY PBM CARVE-OUT REVIEW

BENEFITS

While savings are typically top of mind when considering Specialty PBM Carve-Out, the model includes several key benefits that are not found among the larger PBMs, including:

Aligned Incentives

Unlike most traditional PBMs, Specialty PBM Carve-Out vendors do not need to own a specialty pharmacy and have no financial incentive to artificially promote greater or more expensive drug use through weakly enforced PA programs, auto-refills, or other tactics discussed previously. The Specialty PBM Carve-Out vendors are able to provide competitive discounts by establishing a specialty pharmacy network that incorporates best-in-class pricing.

Passthrough

Specialty PBM Carve-Out vendors earn 100% of their revenue from fees paid by their plan sponsor clients. To avoid the conflicts that occur with other models, Specialty PBM Carve-Out vendors pass through 100% of the rebates, discounts, and any other drug manufacturer payments to their plan sponsor clients.

Enhanced Clinical Care

While alignment and passthrough provide the foundation for the Specialty PBM Carve-Out model, enhanced clinical care is a key advantage of the model.

Specialty PBM Carve-Outs enhance clinical care by offering :

1. Formulary and coverage criteria that are evidence-based, with the goal of most cost-effective coverage rather than chasing rebates
2. Robust PA reviews that do not rely on physician office attestations and/or case review by pharmacy technicians, as is the common practice with PBMs
3. Verifiable case management for high cost and complex specialty patients

High-Touch Service Model

Specialty PBM Carve-Outs are designed to provide a high-touch model with greater and more customized attention to the specialty patient than the traditional PBM model. By employing highly specialized teams with the relevant clinical and operational experience, patients have the support of staff who have the in-depth knowledge of the complex clinical and purchasing aspects of specialty drugs, whether in the clinical care, member services, operations, pharmacy, or account management teams.

Specialty PBM Carve-Outs have established operational standards and processes for coordinating with the PBM for traditional drugs and with the carriers. These processes range from accumulator tracking to member services.

Savings

The savings with Specialty PBM Carve-Out can be quite substantial, with savings ranging from 25-50%.[7] Sources of savings go beyond the supply chain elements of rebates and drug discounts to incorporate benefits of the clinical and coverage model, including a more cost-effective formulary, health economics-based coverage, more rigorous PA, and more robust copay assistance programs.

savings of

25-50%

Visibility and Control

The PBM industry is notorious for being a "black box" when it comes to financial transparency. Specialty PBM Carve-Outs bring greater visibility and benefit control to plan sponsors, as a reflection of their underlying aligned business model. These benefits can take a variety of forms, ranging from drug-level rebate reporting to unencumbered audit rights, all of which are designed to provide plan sponsors with the visibility to hold their specialty drug manager accountable and to provide sufficient information to make informed decisions about their benefit.

TRADITIONAL PBM RESPONSE

Similar to health plans' response when pharmacy benefits were first carved out from the medical carrier in the 1990s, PBMs are eager to warn about consequences of these new management models for specialty drugs. While the PBMs' response is expected given their continued and growing reliance on margin from specialty drugs, their assertions represent more of wishful thinking on their part than anything resembling empirical evidence. Furthermore, PBMs fail to recognize the dramatic differences between Specialty PBM Carve-Outs and the Alternative Funding Models, the former sustaining coverage of the specialty drug benefit and providing the highest standard for clinical care and the latter passing responsibility for coverage to someone other than the plan sponsor and often removing any clinical management in the process.

In the same vein, PBMs have tried to create various obstacles to Specialty PBM Carve-Outs, which are inherently "ransom lists" to prevent plan sponsors from carving out specialty management. These ransom lists can include carve-out fees far in excess of any additional operational effort required on behalf of the PBM, threats to withhold historical data or rebates, and numerous other tactics.

As history has shown, creating artificial barriers to entry is a tired and generally ineffective strategy to protect the status quo and prevents innovation from entering the market. As illustration, despite the health plans' best efforts, carve-out of the PBM from the carrier quickly became the norm among larger employers due to the superior value proposition, with the majority of large employers carving out pharmacy benefits from their carrier by the mid-2000s.

SUMMARY

In a market riddled with conflicts of interest, new and innovative models will continue to emerge because current expenditures for specialty drugs are simply unsustainable. As employers and other plan sponsors have a growing number of market alternatives to consider in managing their specialty drug benefit, it is important that plan sponsors and their advisors are diligent in evaluating the merits of the market alternatives. To that end, this paper provided an overview and comparison of the considerations for each of the market options, recognizing that plan sponsors strive to be prudent in their efforts to provide a sustainable specialty drug benefit.

1. https://issuu.com/magellanrx/docs/mrx_pipeline_oct_proof_5?fr=sYjM5NTQzNjYyNTU
2. https://www.evernorth.com/drug-trend-report/2021-and-onward ; https://www.pharmacypracticenews.com/Policy/Article/12-21/Specialty-Drug-Approvals-A-Year-of-Firsts/65500
3. https://www.goodrx.com/healthcare-access/drug-cost-and-savings/most-expensive-drugs-period
4. At least one PBM owns a specialty pharmacy but sells the medication at cost-plus, consistent with their overall passthrough model for the PBM. This pricing model helps to mitigate the conflict of interest.
5. https://aspe.hhs.gov/price-trends-prescription-pharmaceuticals-1995-1999
6. https://press.aarp.org/2021-9-28-Average-Specialty-Drug-Price-Reached-84,442-2020-Rising-Three-Times-Faster-Prices-Other-Goods-Services
7. www.archimedesrx.com