Rx Update: Looking Beyond the Trends to **Prepare for What's Next**

It's no secret that prescription drug costs have been out of control for a while.

As they become a bigger percentage of employers' overall benefits spend the key is to stay proactive and be ready to adapt.

For most companies, rising prescription drug costs are a serious concern. Utilization, pricing and new drugs mean the trend is unlikely to reverse course.

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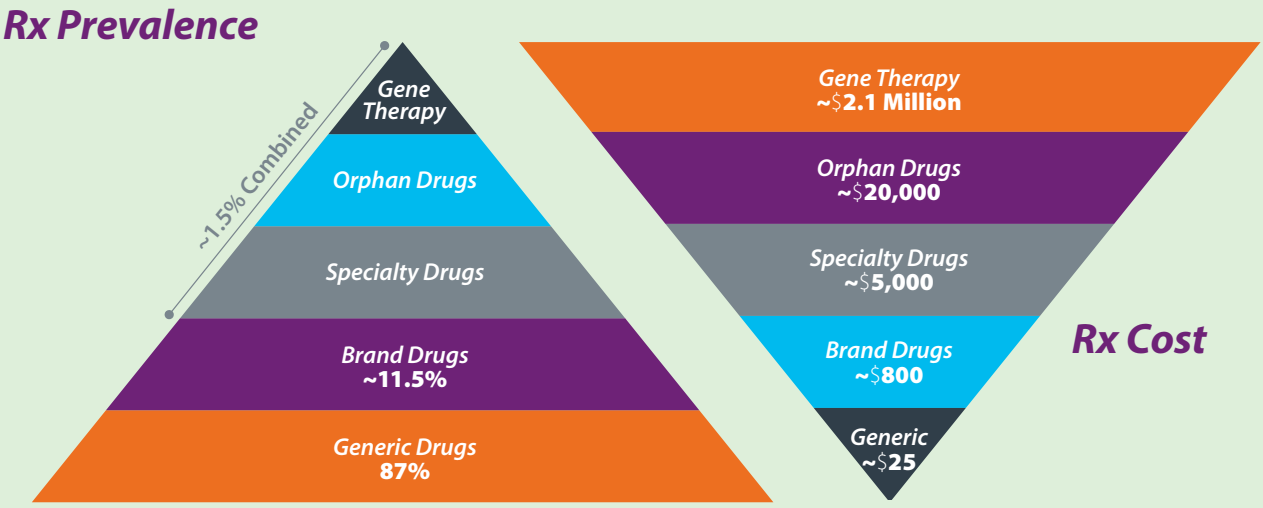


While some drugs are low in prevalence, they can account for a large portion of your pharmacy spend.

Prescription drug spending is up 5.7% to $370 billion and is projected to accelerate over the next decade.[1] By 2025, the "global medicine spend" is predicted to be $1.6 trillion — with about 60% of it estimated to be for specialty medicines in the top ten developed markets.[2]

Specialty is the fastest-growing part of the pharmacy benefit. For the first time, more than half of pharmacy spend was on specialty drugs. While only 2% of prescriptions, specialty drugs represent almost 51% of total costs.[3] Even if utilization slows, inflation and other price-related factors ensure the overall spend for specialties is likely to rise. So what can companies do about it? Before getting into the specifics, let's look at some developments in the Rx landscape.

Legislative Developments

New legislation may make it more difficult for employers to keep pharmacy spend low.

Some states are doing away with exclusivity provisions, pharmacy network steering, and prohibition of plan requirements for mandatory mail and specialty pharmacy utilization within contracts. This may cause employers to amend plan designs and set-up and increase overall plan spend. It also prohibits plan sponsors from facilitating access to clinically superior points of care, particularly for complex patients requiring specialty drugs.

Many states (CO, FL, GA, IA, IL, KY, MD, MI, MO, MS, NH, OK, SC, SD, TN, VT, WV and WY) have considered or adopted legislation targeting the pharmacy benefit manager (PBM) industry. While prior legislation also attempted to regulate the industry, the current round of legislative activity seems to be encouraged by the US Supreme Court decision in *Rutledge v. Arkansas* (2020), which found that "ERISA does not pre-empt state regulations that merely increase costs or alter incentives of ERISA plans." Observers predict similar state legislation targeting health plans and TPAs.

This could impede the ability of self-insured employers to adopt strategies to manage benefit costs and quality. Employers should consider engaging with state legislators to oppose legislation that impedes their ability to make benefit decisions, manage costs, and enhance care affordability and quality for employees.

Data** remains an essential element of prescription drug **cost containment.

Emerging Costs

The Rise of Biosimilars

With the prevalence of specialty drugs, many of which are biologics, and their impact on a company's pharmacy spend, there is some hope that biosimilars could relieve some of the cost pressure. Biosimilars are FDA-approved biologic drugs that act the same in the human body as an original (or reference) biologic drug. They can be created once the patent on the biologic expires.

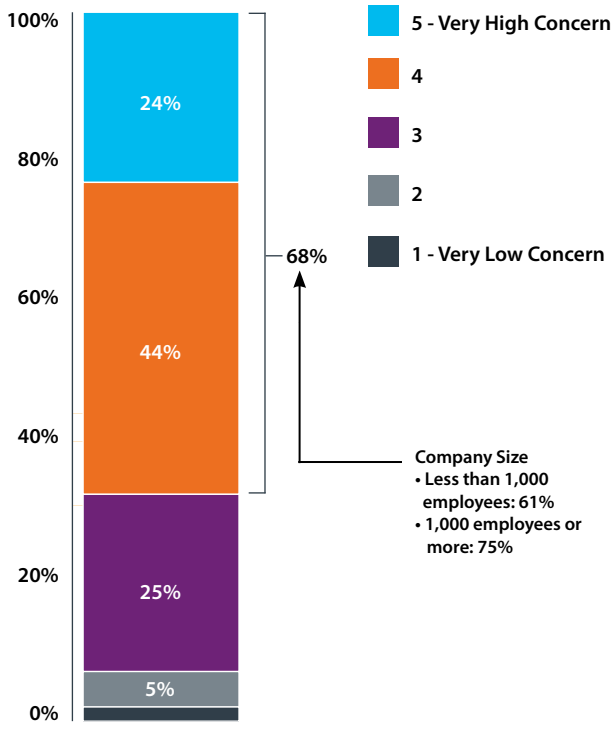
Should employers expect a big drop in their drug spend? Not necessarily. First, biosimilars are typically only 10% – 15% less in cost than the brand name drug. The impact for a single employer may not be material.

Second, PBM choices matter. If PBMs can get a better rebate from the original drug manufacturer that makes it price competitive with the biosimilar, they may keep using the original biologic.

Finally, it can often take years for a biosimilar to find its footing in the market. There is motivation to accelerate this timeline with marketing and messaging, but biologics aren't immediately added to the formulary and patients with serious conditions have to be comfortable with switching to a new brand.

So while the rise of biosimilars is a positive for cost containment, it is important to manage expectations regarding just how big the impact will be.

RX Figure 1:
Rising Cost of Prescription Drug Concern



Survey results indicate that 93% of clients are concerned at some level about rising prescription drug costs.

Gene Therapy

The global market for gene therapies is expected to reach $17.4 billion in 2023.[4] The FDA has expected to see 200 new gene therapy applications per year since 2020.[5] And some projections show that 10 – 20 gene therapies will be added to market annually by 2025.[6]

Unlike traditional drugs that are typically used to *manage* diseases, mitigate symptoms and relieve pain, gene and cell therapies target the exact cause of the disease. Some are considered curative so that there are no longer recurring symptoms, ideally after only a single treatment

Gene therapies are usually injected or infused, are made from a patient's own modified cells and are available at specific treatment centers only. Treatments target rare conditions, sometimes without any other available treatment options, and can come with a seven-figure price tag.

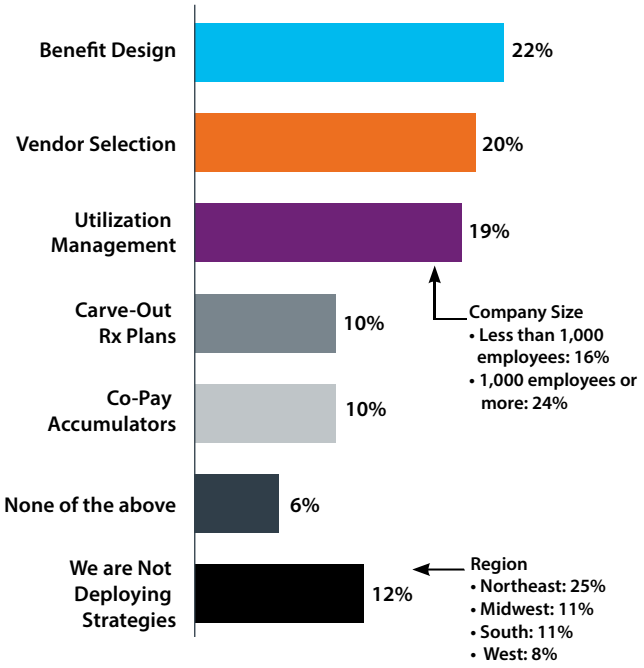
With approximately 7,000 rare conditions and many with no current treatment,[7] we should expect to see a sustained level of activity in this space for the foreseeable future.

COVID-19

Global COVID-19 vaccine spending is expected to exceed $80 billion in in 2021 and total $251 billion over six years (through 2026).[8] This is higher than earlier projections of $157 billion through 2025.[9]

For an actuarial perspective on COVID-19 testing in the context of an employer's Rx spend, refer to "Cost of COVID Testing" by NFP's Geoffrey Seibel.

RX Figure 2:
Action with Most Positive Impact on Prescription Drug Spend



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Actionable Insights

Digital Health

As seen during the pandemic, digital health can improve access to care and allow patients more flexibility. It can also improve disease management, and allow doctors and patients to base care decisions on the individual patient's data. It has become obvious that digital health will continue to be integrated into the patient experience.

However, not all digital solutions are created equal, and with more than 200 digital health solutions introduced every day navigating the landscape can be confusing, costly and time-consuming. Working with an advisor to get recommendations specific to the needs of your population will accelerate your progress toward digitally managing chronic conditions and creating measurable outcomes.

Affordable Solutions for High Cost Rx Claims

There are two primary solutions categories: PBM programs, which are available in all carve-in/carve-out structures, and cost containment programs, which are available via third parties through consultants such as NFP Rx Solutions.

Using the Data, Carving Out

Data remains an essential element of prescription drug cost containment. But not every Rx consultant has access to the right data or the ability to analyze it in ways that provide actionable insights.

One area where clients are finding success is through our Bridge Report. It allows us to look at the data and break out the expense in a client's pharmacy spend to determine if costs are being driven higher by the plan contract or because of utilization. This helps identify the strategies necessary to lower the overall spend.

One option that is gaining more attention is the possibility of carving out prior authorization, specialty or infertility prescriptions. This creates an opportunity for employers to find lower cost options for the biggest drivers of their pharmacy spend, while keeping the medical plan they want. Plans have traditionally resisted targeted carve outs, but through coalitions and ongoing negotiations, as well as demand for cost relief, this may change.

Understanding Contracts

The client-specific contract is a critical element of prescription drug cost containment strategies. Understanding the protection caveats within the contracts and the ability to objectively assess provides meaningful value to the overall Rx benefit.

PBM Programs

Specialty Rx cost control programs	**Gene therapy protection programs**	**Medical channel management programs** transfer claims from medical benefit to pharmacy benefit for discounts/rebates	**Specialty refill threshold programs** eliminate patient stockpiling

Cost Containment Programs

Manufacturer patient assistance programs where lower income patients can access the highest cost drugs for "free"	**Manufacturer copay savings cards** reduce patient copays for specialty drugs (often to $0-$10 per fill)	**Hyper-inflationary medical management** excludes drugs with hyper-inflationary price increases when alternatives are available	**Foundations/ charitable programs** provide "free" drugs
Rx importation programs allow patients to access drugs from Tier 1 countries (Canada, UK), invoiced directly from international pharmacy with no copay	**Discount/cash cards** help cash paying patients find options at pharmacies that offer lower cash prices	**Pharmacy tourism** for select specialty drugs, which can now be handled via video conferencing	**Concurrent (with PBM) prior authorization** (when allowed) provides an extra layer of scrutiny for appropriateness

One area where Rx administrators try to protect themselves is through exclusions to their commitments. It allows them to minimize the number of claims that are subject to their commitment, therefore making it easier to achieve their promise. Through our deep knowledge of market practices, removal of these caveats may be achieved through negotiation with the client's administrator. Some caveats are more impactful than others, but all play a key role in the contracting stage. This helps to reduce or contain costs throughout the duration of the agreement.

Other Actions to Consider

The complexities and variables can make meaningful progress a challenge. But at a high level, there are a variety of other actions to consider as you formulate your approach.

- **Negotiate with manufacturers** on value-based payment plans for high cost medications treating rare conditions or gene therapies. These plans can cover you and your employees and share risk with the pharmaceutical manufacturer should the drug not produce its intended effect.
- **Examine your PBM relationship** (carved-out solutions, consortium, transparent and fiduciary) to better understand the solutions they can offer in terms of cost, clinical perspective and supporting patient adherence.
- **Manage your formulary proactively** and consider a multi-tiered formulary design that separates generics, preferred, non-preferred and specialty.
- **Assess utilization management** and learn more about steps like prior authorization, step therapy or Day-1 Utilization Management (UM) Control, which guide members to safe, more cost-effective drug choices using evidence-based clinical criteria.
- **Use specialty pharmacy services**, including alternative procurement strategies, patient assistance programs, copay assistance through the drug manufacturer, or other underutilized options like accumulator adjustments that acknowledge high deductible plans and hold the integrity of the plan in place while staying compliant with the IRS.

The prescription drug landscape isn't going to get any less complicated or less costly. However you choose to move forward, it is essential to work with advisors who understand the market, can navigate complexity, and have the expertise to pinpoint problems and create the right solutions.

1 NHE Factsheet, CMS, 2021.

2 IQVIA. *Global Medicine Spending and Usage Trends: Outlook to 2025*, IQVIA.com, 2021.

3 Kelcey Blair. "What Is Drug Trend and How to Manage It," Evernorth, evernorth.com, 2022.

4 John Bergin. Genetic Modification Therapies Clinical Applications: Gene Therapies, Genetically Modified Cell Therapies, RNA Therapies and Gene Editing, BCC Publishing, BCCresearch.com, 2020.

5 Scott Gottlieb. "Statement from FDA Commissioner Scott Gottlieb, M.D. and Peter Marks, M.D., Ph.D., Director of the Center for Biologics Evaluation and Research on new policies to advance development of safe and effective cell and gene therapies," Food and Drug Administration, FDA.gov, 2019.

6 Mary Dorholt. "We're on the Verge of a Breakthrough for Gene Therapies," Evernorth, Evernorth.com, 2021.

7 Genetic and Rare Diseases Information Center. About GARD, National Institutes of Health, rarediseases.info.nih.gov.

8 IQVIA. "The Global Use of Medicines 2022: Outlook to 2026," IQVIA.com, 2021.

9 IQVIA. "Global Medicine Spending to Reach &1.6 Trillion in 2025 Excluding Spending on COVID-19 Vaccines, According to IQVIA Institute for Human Data Science Study," IQVIA.com, 2021.