

Opportunities in Pharmacy Benefit Management

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FEATURING THESE LEADING PBMS:



Dear Reader:

We're delighted to share with you our "2021 Opportunities in Pharmacy Benefit Management." The disruptions caused by the pandemic and social injustice have affected every aspect of the marketplace, including pharmacy benefit management.

We assembled a group of expert advisors and, as a result, we're featuring articles on issues that are particularly important right now, and for the coming year, as well. Inside you'll find information on:

- ▶ Taking advantage of the Consolidated Appropriations Act.
- ▶ Understanding how PBMs are assigning value to the drugs employers are paying for.
- ▶ Dealing with the high-cost drugs that disproportionately drive healthcare spending.
- ▶ Getting in front of the new astronomically priced gene therapies.
- ▶ Maximizing the competitive pressure biosimilars can exert on pricing.
- ▶ Managing the disruption that comes with changing vendors or even formularies.
- ▶ Understanding the role PBMs should play in managing the mental health and health equity crises.

PBM transparency continues to dominate the conversation, and we do report on whether, and how, our three leading PBMs are demonstrating their willingness to share their contractual arrangements, act as your fiduciary agent, and permit you to audit their transactions. ***However, we'll take this opportunity to point out that there are other aspects of transparency, and that by sharing their policies, programs and results, our participating PBMs are already demonstrating a degree of transparency with our coalitions and their members.***

An important note: Purchasers bear considerable responsibility for the quality of services PBMs deliver. Require vendors to share relevant information with the PBM and the PBM to reciprocate, because pharmacy data intersects with medical, behavioral health, wellness, and other vendors serving you and your members. And use this report to help you manage performance by your current vendors and in future vendor selection. Invite Navitus, CVS, and US-Rx to participate in RFPs. Encourage/insist that your incumbent PBMs participate in our next PBM report.

PBMs are under considerable scrutiny today, but the organizations in the "2021 Opportunities in Pharmacy Benefit Management" have demonstrated a willingness to open their actions to your scrutiny. Use this to guide discussions with your current or prospective PBM, and you'll emerge better informed than ever.

John Miller
Mike Thompson
Foong-Khwan Siew
Elan Rubinstein, PharmD

PHARMACY ADVISORY GROUP

Clare Hunter, Arxcel
Chuck Gamsu, Skysail Rx
Mary Bradley, Health Transformation Alliance
Corey Belkin, (formerly from) Health Transformation Alliance
Janet McNichol, American Speech, Hearing and Language Association
John Adler, ELMC Rx Solutions
Mike Zuccarelli, CBIZ

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Midyear changes can result in member disruption, much like that during implementation, but a clinical engagement center (CEC) can easily support members who need extra help when their medication is no longer covered as a result of a formulary change. A CEC can also perform personal outreach for any clinically related benefit change, such as the implementation of new clinical programs or mail or specialty pharmacy provider changes.

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The cost of currently marketed gene therapies and the prospect of a late-stage pipeline full of gene therapies promising miracle results—at astronomical costs—has increased pressure on politicians to craft laws that would enable the government to address drug pricing—possibly with input from organizations that provide evidence-based assessment of value, such as ICER.

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The Consolidated Appropriations Act: Burden or Opportunity?

The Consolidated Appropriations Act (CAA), passed by Congress in December 2020, explicitly names employer health plans/plan sponsors as fiduciaries and establishes an array of requirements plan sponsors must now meet and report on to various federal agencies. At face value, this seems like an added burden but, on closer inspection, it can be a golden opportunity.

“Most people miss opportunity because it is dressed in overalls and looks like work.” That was easy for Thomas Alva Edison to say! After all, he never had to manage healthcare benefits in the stubbornly murky pharmacy benefits market we have today. However, unless we reconsider each challenge with clarity and determination, we will miss opportunities that present themselves as adversity. Such is the potentially golden opportunity presented as The Consolidated Appropriations Act (CAA) of 20209 (bit.ly/3EA20qv).

The act, passed by Congress in December 2020, explicitly names employer health plans/plan sponsors as fiduciaries and establishes an array of requirements plan sponsors must now meet and report on to various federal agencies. At face value, this seems like an added burden but, on closer inspection, it can be a legal remedy that provides significant leverage for employer/plan sponsors to demand transparency and accountability from their stakeholder partners. Given all our efforts, healthcare transparency has yet to be

Employers, who have increasingly looked to policy changes to disrupt the healthcare market, may find the CAA a game-changing piece of legislation, one that supports them in taking a more aggressive approach to contracting, especially regarding transparency.

accomplished, so perhaps we should welcome this change. Employers, who have increasingly looked to policy changes to disrupt the healthcare market, may find the CAA a game-changing piece of legislation, one that supports

them in taking a more aggressive approach to contracting, especially regarding transparency.

HC21 recently conducted a webinar series to educate employer members about the CAA and equip them with recommendations from subject matter experts who will help them prepare for compliance. HC21 featured Hugh O’Toole and Ned Laubache of Innovu, Shawn Gremminge of Purchasers Business Group on Health, and Renzo Luzzatti of US-Rx Care to explain the CAA requirements and best practice strategies for CAA compliance on PBM contracting and Rx reporting.

CAA Rx Requirements

The CAA requires employer plan sponsors to review contracts and eliminate gag clauses (both in medical and pharmacy contracts). Further, it establishes a series of detailed Rx reports that plan sponsors submit to various federal agencies to document the rigor of their compliance. The curiously structured law places responsibility on fiduciaries to ensure their service providers are operating in a transparent and compliant manner. This seems “roundabout” but, according to Shawn Gremminger, was a feature by design.

This feature is meant to strengthen employer negotiating power by eliminating disadvantageous terms in provider contracts. The law prohibits employers from entering into contracts that contain certain language known to disadvantage. And plan sponsors find legal cover through compliance with the reporting requirements.

Producing reports requires plan sponsors to gain access to vast amounts of data that some TPAs (and to a lesser extent PBMs) have attempted to restrict, control, or otherwise prevent the appropriate use of. As a result of the CAA, plan sponsors can now reference the law to gain necessary access to meaningful data (including rebate information). Recent hospital price transparency legislation should encourage employers that regulators intend to make more information available to the market.

The Rx reports described in the law vary from standard (PMPM Rx costs, top Rx utilization drugs, top costing drugs, etc.) to novel (impact

of rebates and coupons). Reporting the impact of rebates enhances the growing scrutiny of rebates, which critics have long blamed for distorting prices.

While the CAA has “no effective date given,” it is in effect now. Employers should be proactively reviewing contracts and eliminating gag clauses, securing data rights, and demanding information from vendors to help them comply. The responsibility for, and benefit of, compliance falls with the plan sponsors. Employers who do not take advantage of this fresh opportunity may find themselves both needlessly “grandfathering” disadvantageous gag clauses in contracts and risking fiduciary noncompliance.

With the exception of the “rebate impact” reporting, which will be due no later than 18 months after initial reports, the first suite of Rx reports is due December 27, 2021. After that, reports will be due annually before June 1 (including the first follow-up reports due before June 1, 2022).

Several years ago, when pressed by large employers to take on fiduciary responsibilities, a large PBM explicitly stipulated in its contracts that it was not a fiduciary. In other words, it was acknowledging that it would remain chiefly responsible to the interests of its organization, rather than to the customers. Recently, some smaller pass-through PBMs have agreed to align their interest with the plan sponsors’ fiduciary responsibility. It will be interesting to see if plan sponsors, encouraged by the law and the market, begin to include such “commitment language” in contracts. Employer plan sponsors should negotiate with TPAs and PBMs for greater flexibility in contracts where fiduciary concerns still exist. Terms that govern data access and use, definitions, restrictions on carve-out services, and the limiting audit rights present potential

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fiduciary conflicts for employers. Rather than accept the status quo, employers should leverage their fiduciary responsibility to cultivate more willing PBM partners.

Requirements similar to the CAA were effected in the retirement benefits market and resulted in greater transparency and savings for the fiduciary plan sponsor.

► Summary of lessons learned from the experts:

- Review contracts now.
- Get legal counsel involved early.
- Put vendors on notice that you will require information.
- Press your advantage and negotiate aggressively where fiduciary concerns exist.
- Include contract language that requires vendor partners to align themselves with your fiduciary responsibility.

- Be willing to walk away.
- Be willing to enforce contract provisions painstakingly negotiated.

NOTE: On August 20, 2021, the US Department of Labor (DOL) issued a delay on certain aspects of the CAA. Please refer to the DOL FAQ document for more information.

Jeffrey Townsend
HealthCare 21 Business Coalition
jtownsend@hc21.org
hc21.org

Biosimilars: An Opportunity for Savings

Biosimilars present an opportunity for savings now and, more important, in the future, as more biosimilars are developed. Establishing the right strategies now will contain costs tomorrow.

In August 2021, a National Alliance report, “Achieving Value: Medical Side of Drug Benefits: A Deep Dive Powered by eValue8™” (bit.ly/3pZMC2s) said: “Biosimilars represent an opportunity for savings now and, more important, in the future, as more biosimilars are developed. A Johns Hopkins study for the ERISA Industry Committee reports that if all employers who self-insure health coverage had achieved full biosimilar substitution for just the first two biologics to have biosimilars in the US, savings could have been between \$407 million and \$1.4 billion in 2018, not including the impact of undisclosed confidential rebates. Establishing the right strategies now will contain costs tomorrow.”

A recent National Alliance Action Brief (bit.ly/2ZRMSG3) outlines purchaser opportunities and strategies for using biosimilars to help control overall healthcare costs. For most marketed biosimilars, market share is lagging behind expectations. Historically the lack of biosimilars uptake reflected 1) insufficient support by health plan drug policy decisions, 2) insufficient prescriber confidence in the evidence of biosimilar equivalence, and 3) inadequate strategies to promote biosimilars to patients. The Action Brief points out that plans generally have internal policies that position biosimilars advantageously. However, strategies like formulary positioning appear to have less impact in the medical setting. Also, plans could do more to educate prescribers and patients about the effectiveness of biosimilars.

Despite slower adoption than hoped, the presence of biosimilars in the marketplace has created competition for reference products—and manufacturers have responded on a pricing basis, as shown in this study (bit.ly/3BEGjDR): “We find that, so far, the modal reaction (of manufacturers) has been to compete on price with these new (biosimilar) entrants. By aggressively cutting prices, reference biologics have been able to limit losses in volume and formulary coverage, in turn contributing to the slow uptake of biosimilars highlighted by many recent reports.” This study (bit.ly/3wcscoe) estimates that weighted average price ratios after biosimilar entry fall by an average of between 4 and 10 percentage points per biosimilar entrant.”

Market share of biosimilars has been increasing over time, and that will continue—causing lower net prices for biosimilars and for originator products, the result of market competition between these products. FDA approval of the first interchangeable biosimilar will increase attention to biosimilars generally, for PBMs, payers, prescribers, and patients. Furthermore, it may increase both confidence in and uptake of biosimilars, and may cause purchasers to more aggressively preference an interchangeable biosimilar over a biosimilar without that designation. For example, approval of the first interchangeable biosimilar will likely result in a trend over time to lower insulin prices for insulin glargine biosimilars, both interchangeable and not,

as well as for the reference product. (More below on insulin interchangeables.)

Confusion regarding terminology remains a problem. The Biologics Price Competition and Innovation (BPCI) Act defines key terms this way: A **reference product (RP)** is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared. A **biosimilar** is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. And an **interchangeable** is a biosimilar that is expected to produce the same clinical result as the reference product (RP) in any given patient, such that switching between the proposed product and the RP does not increase safety risks or reduce effectiveness compared to using the RP without switching.

The FDA has undertaken a biosimilar educational campaign which, in one of the FDA slide decks (bit.ly/3mAJ70d), includes these key takeaways:

- ▶ **Fact:** FDA’s high standards for approval mean that healthcare professionals and patients can have confidence in the safety and effectiveness of a biosimilar product.
- ▶ **Fact:** Differences between the biosimilar and reference product may be expected due to both products’ molecular complexity, but such differences are not clinically meaningful.
- ▶ **Fact:** FDA’s approval of an interchangeable biological product indicates not a higher standard of biosimilarity, but that it underwent further evaluation to allow it to be substituted for the reference product without consulting the healthcare prescriber.
- ▶ **Fact:** Patients and healthcare providers do not need to wait for a biosimilar product to “become” an interchangeable product (as there

may be business reasons a sponsor does not seek interchangeability). Biosimilars are safe and effective, just like the reference product to which they were compared.

FDA’s interchangeable designation—which does not exist in law or regulation in any other country—was established to address concerns with the potential for biosimilar immunogenicity¹ that may result due to switching between the reference product and the biosimilar. However, there is no evidence of immunogenicity for biosimilars currently on the US market.

A potential game changer in the acceptance of biosimilars was the July 28, 2021, FDA approval of Semglee® (insulin glargine-yfgn), the first interchangeable biosimilar. Semglee is both biosimilar to, and interchangeable with, Sanofi’s Lantus® (insulin glargine). Availability of an interchangeable Semglee is likely to speed the rate at which this less expensive insulin glargine increases in market share.

It is important to note that the first FDA-approved interchangeable biosimilar may bring with it a new potential for confusion: FDA interchangeability designation permits the dispensing pharmacist to interchange in place of a prescribed reference product only if, and under conditions, defined by state law. Unfortunately, there is great variation in state laws governing what the dispensing pharmacist may do vis-à-vis biosimilar interchangeability, as shown in this July 2021 Cardinal Health report (bit.ly/31eDsEY).

Some PBMs prefer a biosimilar on the formulary, and have coverage policies that require “fail first” on a biosimilar before the reference product will be approved. An FDA interchangeable designation provides PBMs and payers additional rationale for preferencing an interchangeable biosimilar

1 Immunogenicity is defined as the ability of a substance to produce an immune response. Therapeutic antibodies, enzyme therapies, peptides, and combination products can elicit an unwanted immune response that may impact their safety and efficacy.

over its reference product—and possibly over approved competing biosimilars that do not have interchangeable designation. The sales implication of this sort of preferencing may increase manufacturer interest in submitting to FDA for interchangeable designation of biosimilars.

It is important to note that the manufacturer of the first interchangeable biosimilar of a particular reference product is eligible for 12 months exclusivity before the FDA can approve another biosimilar interchangeable with that same reference product. This may further increase manufacturer interest in obtaining interchangeable designation.

According to a recently published report ([bit.ly/3nP7wie](#)) by the Midwest Business Group on Health, there are several action steps that purchasers can take to increase the utilization of biosimilars within their health plans:

1. Provide the FDA's list of approved biosimilars to your carrier and PBM for addition to your formulary, and have a discussion on how best to adopt them. Also, see the list of currently approved biosimilars in the US by administration/dispensing through the medical and/or pharmacy benefit.
 - ▶ Where a biosimilar is indicated for administration through the medical plan, talk to your carrier and consider a carve out to the pharmacy benefit to ensure equal management.
 - ▶ Where a biosimilar is indicated for dispensing through the pharmacy, talk to your PBM and ensure proper medication therapy management measures are in place (see #5 and #6).
2. Clearly define biosimilars in your contracts.
3. Ensure your contract has 100% pass-through of all rebates received and that audit rights are in place.
4. Track utilization by drug class in medical and pharmacy data to determine where the greatest opportunity exists to increase the use of biosimilars.
5. Manage the prior authorization of biologic drugs through an independent pharmacy and therapeutic committee to avoid a conflict of interest due to misaligned financial incentives to approve one drug over another.
6. If #5 is not possible or feasible, ensure the correct prior authorization or step therapy protocols are in place for each biosimilar.
7. Ask for clinical criteria, including coverage for conditions for which the biologic is approved but the biosimilar is not.
8. Consider utilization of pharmacogenetic/genomic testing prior to filling a biosimilar prescription. (If not in place for the biologic drugs, consider a wide application.)
9. Reduce the copay or coinsurance when a biosimilar is administered (consider Tier 1 or Tier 2, if your plan is multi-tiered).
10. For new prescriptions, require utilization of biosimilars first (step therapy consideration).
11. Grandfather members currently receiving the originator biologic, based on meeting consistent and established clinical criteria.
12. Consider and discuss plans for appropriate transition of the grandfathered members at a later date.
13. Talk to carriers about educating and incentivizing providers to prescribe the lowest cost, most efficacious drug first.

Elan Rubinstein, Pharm.D., MPH
EB Rubinstein Associates
elan.b.rubinstein@gmail.com
ebrubinsteinassociates.com

Improving Mental Health: Do PBMs Have a Role?

As purchasers focus on increasing access to MH/SUD care for members, PBMs should be viewed as a key ally in ensuring that associated drug cost increases do not work against this goal.

Mental health and substance use disorders (MH/SUDs) affect more than one in four Americans. While largely treatable, more than half of those with these conditions receive no care. Among those who do, care—including pharmacological treatment—is most often delivered in primary care settings where providers have limited training and resources. Further stymied by a shortage of MH/SUD providers—which existed even before COVID-19—increased access to effective MH/SUD care has become one of the top three priorities for employers nationally.

More than half of MH/SUD patients are prescribed medications designed to treat these conditions. Mental health drugs are one of the fastest-growing cost categories in outpatient managed healthcare, accounting for about a fourth of all pharmacy spending by private insurance. Among the top 20 drugs mentioned during office visits, depression and anxiety drugs are ranked third and seventh, respectively.

As efforts to increase access to MH/SUD treatment gain traction, the use—and cost—of these medications will also increase, and PBMs will become increasingly important collaborators in helping to ensure that these drugs add value and not simply cost. Here are some of the core services your PBM can offer:

Out-of-pocket Cost Management

As part of formulary development, the PBM can help determine whether a medication copay is \$10 or \$50 at the pharmacy. This can significantly impact medication adherence—one of the most critical factors in successful treatment for MH/SUD.

Medication Adherence Monitoring

MH/SUD drugs are expensive. If patients are non-adherent or only partially adherent, these medications will add little or no value for patients or purchasers, but addressing non-adherence requires first identifying it. Your PBM can monitor use of these drugs and should have well-defined action steps to take when non-adherence is detected. Even for patients who refill their medications, monitoring can show whether prescriptions are filled according to the dosing regimen. Patterns of early or late refills can suggest signs of partial/non-adherence, including self-dosing.

Patient Education

Your PBM can provide educational programs and services that supplement the information a patient receives from prescribers, covering such topics as the importance of following dosing regimens, what to expect while taking the drug(s), and potential side effects and interactions.

Clinical Collaboration

Your PBM should have clinical capabilities that can help ensure the safety and effectiveness of MH/SUD medication therapy, including:

- ▶ Monitoring for drug interactions—particularly when the patient is treated in primary care, since MH/SUDs are common co-morbidities in patients with chronic medical problems.
- ▶ Drug utilization review—to alert prescribers, pharmacists, and care managers when prescribed medications may be unsafe.
- ▶ Monitoring use of controlled substances that may be harmful and/or impede clinical improvement.

- ▶ Specialized clinical support for prescribers and other clinicians involved in the patient's treatment.

As purchasers focus on increasing access to MH/SUD care for members, your PBM should be viewed as a key ally in ensuring that associated drug cost increases do not work against this goal.

Michael Yuhas

Advisor: The Path Forward for Mental Health
nationalalliancehealth.org/www/initiatives/initiatives-national/workplace-mental-health/pathforward



Will High-cost Claims Bring an End to Self-insured Employer Healthcare?

Employers can implement strategies that result in cost reductions in the 25%–50% realm under both the medical and the pharmacy benefit—often with a focus on the fewer than 10% of plan enrollees who account for the majority of plan spending.

In an environment of continually increasing healthcare costs, the accelerating growth in the cost of specialty medications and high-tech medical treatments is particularly concerning. Specialty pharmaceutical utilization has grown 400% since 2010, to approximately \$400 billion annually; it now accounts for over 14% of total healthcare expenditures and approximately 50% of total drug spending, a figure which could double over the next 3–5 years, based on the current drug manufacturer pipelines.

The bad news: Neither the fully insured nor the stop-loss marketplace offer adequate protection from high-cost claims beyond one year for most employers.

The good news: There are many proven strategies to significantly reverse the upward cost trend that are implementable today. Employers implementing these strategies are seeing cost reductions in the 25%–50% realm under both the medical and the pharmacy benefit—often with a focus on the fewer than 10% of plan enrollees who account for the majority of plan spending. The most common strategies employers have been implementing successfully fall into three main categories:

1. Better alignment of incentives in vendor relationships to minimize cost and prevent waste in the system.

2. Risk-shifting or risk-sharing strategies that effectively move risk and costs off the plan.
3. Flexible sourcing to access needed products and services from lower-cost alternatives when available.

There are also solutions valuable for long-term sustainability and stability, such as catastrophic risk pools, value/outcomes-based pricing, and better aligning incentives with benefit administrators, providers, manufacturers, and consumers.

One additional emerging strategy for self-funded employers is the introduction of fiduciary compliance into the benefit administration equation, a primary focus of the Consolidated Appropriations Act of 2021 ([See related article.](#)) and Transparency in Coverage regulations intended to ensure that fiduciary control remains in the hands of plan sponsors.

To achieve these very attainable goals, employers may need to examine their vendor contracts to garner desired flexibility. Several strategies follow that employers have successfully implemented in recent years to mitigate or avoid high-cost claims, while still providing plan participants with affordable access to needed healthcare services and drug therapies, without sacrificing quality of care.






See the impact in the table below of these strategies successfully deployed by self-insured employers:

- ▶ Excluding unwanted “high-cost,” “low-value” drugs from formularies without penalty.
- ▶ Moving all drug management under the pharmacy benefit to consolidate and streamline prior authorization controls and clinical oversight and, at the same time, prevent inflated costs for provider-administered drugs flowing through the medical benefit.
- ▶ Implementing ERISA-compliant secondary payer strategies that leverage a multitude of options to share risk with external parties, such as offering incentives to move employees and dependents to spousal plans or leveraging Medicaid, Medicare or Exchange plans, when available.
- ▶ Incorporating flexibility to source pharmaceuticals and medical services from the lowest net-cost providers.
- ▶ Driving utilization to centers of excellence, particularly for complex and high-cost conditions, for improved outcomes and long-term cost savings.
- ▶ Carving out clinical functions, such as prior authorization and pre-certification services, to independent third parties that can ensure unbiased, clinically rigorous oversight.

- ▶ Waving copays/coinsurance and deductibles to incentivize plan participants to adopt cost-effective sources of care and embrace quality-improvement opportunities. Examples include no or lower out-of-pocket costs to plan enrollees for: high-cost chronic medications; utilization of high-quality/cost-effective providers and lowest-cost pharmacy options, including 340B pharmacies; and
- ▶ Taking advantage of drug manufacturer and charitable programs, such as copay assistance and patient assistance, to lower the overall net cost to both the plan and plan participants for drugs that otherwise would be unaffordable. Using these approaches, the plan sponsors are capturing the savings for high-cost drugs made available through these programs and waving or eliminating out-of-pocket costs to plan enrollees under the plan benefit. Cost reductions ranging from 30% to 75% net of administrator fees are possible, particularly on high-cost specialty medications.

And the list goes on. There is no one-size-fits-all option or magic bullet for every case, so the more options available to leverage under the benefit plan, the better.

To conclude with a provocative statement for self-funded employers: talk to your brokers and consultants, and tell them you would like to reduce total plan spending by 25%–50% within the next 12–18 months without reducing benefits or

Before	\$3.5MM Annually	\$194K Annually	\$248K Per Treatment	\$66K Annually	\$10.1MM Annually
	Hemophilia Cost Savings	Retail Discounts on Specialty Generics	Pharmacy Sourcing to Avoid Clinic Buy/Bill Charges	Copay Assistance Programs	Patient Assistance Programs
After	\$0.9MM Annually	\$8.8K Annually	\$15K Per Treatment	\$50K Annually	\$4MM Annually
	75.5%	95.5%	93.9%	24.2%	60.0%
					

shifting costs to plan enrollees. Don't focus solely on going out to bid for bigger discounts and drug rebates. While still important, those alone are not sufficient now. It is not enough to simply discount trend; the time has come to CHANGE the trend. Many employers have achieved 50% or greater cost reductions in their self-funded benefit plans. Every employer can, and should, be seeking and accomplishing the same.

For human resources and C-Suite management concerned about adding complexity or disrupting member access to care, neither has turned out to be the case for the many employers who have implemented the strategies described above. Other than signing off on member communications and fielding the occasional

employee question, there should be very little day-to-day involvement for the plan sponsor.

Because every high-cost case can have its own unique characteristics and circumstances, putting in place multiple options like those highlighted here will, at the end of the day, allow any employer to effectively reduce the frequency and severity of claims of all shapes and sizes, while also allowing them to better accommodate and mitigate the impact of high-cost claims when they do (and they will) occur.

Renzo Luzzatti
President
US-Rx Care
luzzatti@us-rxcare.com
us-rxcare.com

Understanding How PBMs Evaluate New Drugs and Knowing When They Can Do More

PBMs generally do tell their clients what evidence they use in their analyses through references in the coverage policies themselves. However, what role rebates and discounts play in formulary decisions, or what other business considerations they may weigh in determining access to a particular new drug, are not always discussed with plan sponsors.

“It’s a black box.” “I trust that they are using the best evidence to make decisions.” “I wish I knew more about why some drugs are covered, and some aren’t.” If you’ve ever had one of these thoughts about your PBM, you are not alone. Responsible for managing a substantial and growing part of every employer’s healthcare spending, PBMs offer purchasers clinical, scientific and administrative expertise. Staffed with pharmacists, physicians, and other experts, PBMs are tasked with judging the benefits and costs of new therapies, and managing employee access to those therapies. But what do we know about how they make those judgments? Are there ways employers can be empowered to ensure PBMs are making use of the best evidence in deciding on price and access for new therapies? Here are a few practical steps employers can take to better understand how PBMs are evaluating new therapies and how to ensure they are using the best available evidence to do so.

First, what typically happens at a PBM when a new drug is approved? It’s often a two-part process. First, a PBM team will review the existing evidence on drug safety and effectiveness (i.e., a “clinical only review”) and present a summary to

a group of external experts, known as a pharmacy and therapeutics (P&T) committee. The P&T committee is responsible for voting on whether, based on clinical evidence, the drug should be on the formulary, excluded from the formulary, or optional. Then, a different group of PBM leaders meet to integrate the P&T committee recommendation with economic considerations, factoring in negotiations over price and formulary placement with the drug maker. This separate PBM group ultimately decides formulary placement and coverage terms.

For a plan sponsor, the final outcome of this process might be the only thing to which you are privy, with notable exceptions for high-profile decisions, such as the new hepatitis C drugs, about which some PBMs were quite public with their rationale for excluding some options as part of negotiating lower prices for others. PBMs generally do tell their clients what evidence they used in their analyses through references in the coverage policies themselves. However, what role rebates and discounts play in formulary decisions, or what other business considerations PBMs weigh in determining access to a particular new drug, are not always discussed with plan sponsors.

These dynamics are a direct result of the existing market forces and an escalating arms race between manufacturers and PBMs that highlights the dysfunction in the system. The current system provides natural incentives for PBMs to negotiate for steep discounts in exchange for formulary placement, in order to keep premiums down, while manufacturers use their pricing power to jockey for favorable formulary position to drive sales.

The extensive attention on PBMs and the availability of independent analyses of drug value and pricing are starting to shift this paradigm. Now, plan sponsors can equip themselves with information that levels the playing field and affords insight into exactly what information PBMs are using for their decision-making, and how a plan sponsor can judge how the PBM is doing, all in service to the broader goal of de-escalating the prescription drug pricing arms race.

Ask what independently produced, public information your PBM is using to determine formulary placement, pricing, and patient access: The simple task of asking your PBM what information they are using to make determinations of price and access can elucidate important opportunities for improvement. If the PBM is relying solely on its own analysis, push them to incorporate value assessment reports produced from broad engagement with patients, clinical experts, and the drug's manufacturer, like those produced by the organization I work for, the Institute for Clinical and Economic Review (ICER). Relying on publicly available value assessments means the PBM is more likely to leverage comparative clinical effectiveness and cost-effectiveness information when deciding on price and access, and less likely to rely on rebates and other discounting to determine formulary placement. Value assessments help ensure that prices align with the benefits patients receive. This may mean paying more for a drug that works better, but it also means paying less for a drug that

offers marginal benefits. Using value assessments to determine price and access will ensure your employees have access to the drugs that offer them the best chance of meaningful improvement.

Ask how the PBM is ensuring access to fairly priced drugs: Using value assessment to know a fair price only helps patients if, ultimately, that fair price means better access. PBMs and other payers are now the focus of an annual assessment by ICER to see if they are ensuring fair access to drugs deemed fairly priced by an ICER analysis. Using criteria developed with drug manufacturers, patient groups, and PBMs and payers, the “Cornerstones of Fair Drug Coverage” (bit.ly/3BxfVf2) cover cost-sharing, step therapy, and prior authorization requirements, and represent an objective approach to ensuring your employees get fair access through health plans and PBMs to drugs with fair prices. When these criteria are applied successfully, employees can access and afford their medicines, and employers know that PBMs are relying on independent research to determine a fair price.

Work with benefit consultants or directly with PBM to create value-based formularies: When independent value assessments produce information about fair pricing for a class of drugs, plan sponsors have an opportunity to deploy a novel formulary design that is anchored in broad access for employees. A value-based formulary uses a “pay-up-to” approach to set the maximum payment amount for a drug at a level commensurate with the benefits it provides to patients, as determined by an independent value assessment. After setting this amount for every drug in a class, the PBM then reduces or removes utilization management criteria (and even cost-sharing) in favor of providing broad access to all therapies subject to the “pay-up-to” agreement for plan members. The success of this approach is reliant on the manufacturer agreeing to discount their price to meet the benchmark. The motivation

of the manufacturer to do so is improved volume (e.g. if patients and clinicians have less paperwork to complete for access, then manufacturers are competing for business based on how well their drugs work, not on the size of the rebate they can offer/preferred formulary placement). Broad access to all approved therapies is a win for patients and clinicians, as well as employers, because paying a value-based price for all drugs in a class will likely result in savings.

These approaches are premised on disrupting the status quo. The current system of secret negotiations, internal deliberations, and limited patient access frustrates employers and employees alike. When armed with independent value assessment, plan sponsors can start to

move the PBMs towards greater transparency. Ultimately, when employers are empowered with more information about how a PBM should be evaluating the clinical benefit and cost-effectiveness of new therapies, patients win. Employees will get better access when plan sponsors push PBMs to use independent analyses of fair pricing and fair access, and employers will see higher-value spending for the prescription drug benefit. Opening the “black box” is possible.

Sarah K. Emond, MPP
Executive Vice President and
Chief Operating Officer
Institute for Clinical and Economic Review
semond@icer.org
icer.org



Easing the Stress of Benefits Transitions

Midyear changes can result in member disruption, much like that during implementation, but a clinical engagement center (CEC) can easily support members who need extra help when their medication is no longer covered as a result of a formulary change. A CEC can also perform personal outreach for any clinically related benefit change, such as the implementation of new clinical programs or mail or specialty pharmacy provider changes.

THIS PROGRAM WAS A FINALIST FOR THE 2021 EVALU8 INNOVATIONS AWARD

Benefit transitions can be confusing and stressful for plan members, resulting in frustration and potential gaps in care. When it comes to pharmacy benefits, gaps in care can lead to poor health outcomes and drive up member costs, especially for people with chronic conditions. In fact, when seeking a new PBM partner, employers are often so concerned about member disruption that even the potential savings from switching to a new PBM may not be sufficient incentive for them to make the change.

However, providing Personalized Member Transition (PMT) support for onboarding can eliminate stress during member transitions and improve the member experience. That's why in January 2021, Navitus implemented the PMT program, offered by a newly launched clinical engagement center (CEC).

Personalized Member Transitions is based on four key steps:

1. Identification—Clinical transition analysis identifies members on maintenance medications that will not be covered or have utilization-management criteria.

2. Member Letter—The member receives a clinical transition letter.
3. Member Outreach—A CEC health professional contacts the member to discuss formulary alternatives.
4. Provider Outreach— A CEC health professional contacts the provider to obtain new a Rx.

Previously, a member going through a benefit transition would receive a mailed letter notifying them of any clinical changes (e.g., formulary changes) related to their change in PBM. But today, with the newly implemented PMT program, the CEC adds a personal phone call from a helpful clinician just a few days after the member receives the letter. Together, the Navitus clinician and the member review the letter, and the clinician helps by explaining the transition process, answering any questions, and providing follow-up as needed.

Once the CEC clinician speaks with the member regarding the transition, the clinician calls or faxes an auto-generated letter to the appropriate prescriber to initiate the prescription change. It is Navitus' goal to make CEC clinicians an integral component of the healthcare team and also to improve the prescriber experience.

This PMT program adds a more personal touch and provides an opportunity to connect

individually with members. During the process, the assigned account team will identify members whose medications will be not covered or will change tiers on the formulary as a result of the PBM transition. The team works closely with the client to develop a plan for 1) implementing any recommended changes, 2) determining a transition timeframe (e.g., 90 days), and 3) communicating the changes to members.

Every member new to the PBM can benefit from this service—it works to proactively prevent gaps in therapy, enhance savings, and increase member satisfaction. The PMT program also aims to support high-risk, high-need, and high-cost populations. For members taking medication therapy for chronic conditions, disruptions can result in hospitalizations, emergency room visits, or other high-cost interventions associated with poor health outcomes. By guiding members at risk of experiencing gaps in care through the clinical transition with the PMT program, employers experience cost avoidance and members experience improved health.

In addition to supporting members during the PBM transition, the PMT program can also be applied to midyear formulary transitions and negative tiering formulary changes. These midyear changes can result in member disruption, much like that during implementation, and Navitus' CEC can easily support members who need extra help when their medication is no longer covered due to a formulary change. With

minimal changes to the operations, the CEC can also perform personal outreach to facilitate any clinically related benefit change, such as the implementation of new clinical programs or mail or specialty pharmacy provider changes.

The PMT program is currently optionally priced per completed intervention to member and/or prescriber. Members experience no fees with this service.

Ultimately, the Personalized Member Transitions program is more personal, more human—it puts a face to the people behind the Navitus name—and is more likely to result in action on the member's part, especially with certain member populations.

Since its implementation, the PMT program has garnered positive member feedback for its exceptional service and outcomes, including:

- ▶ “Very professional, personal, and very helpful.”
- ▶ “Process works very well as is.”
- ▶ “Very good to talk to real, nice people.”

Importantly, the PMT program provides the opportunity for further discussion, questions, and for the member to get a better overall understanding of the transition process.

Brett Gadow, PharmD
Supervisor, Clinical Engagement Center
Navitus Health Solutions
ClinicalEngagementCenter@Navitus.com
navitus.com

Paying For Pharmacogenomic Medicines

The cost of currently marketed gene therapies and the prospect of a late-stage pipeline full of gene therapies promising miracle results—at astronomical costs—has increased pressure on politicians to craft laws that would enable the government to address drug pricing—possibly with input from organizations that provide evidence-based assessment of value, such as ICER.

Dramatic cost reductions in genome sequencing has fueled the discovery of genes associated with diseases and the identification of new variants. Researchers have mapped gene variations related to health, disease, and drug response, and built databases to support research and development (R+D).

To capitalize on new gene therapy development opportunities, pharmaceutical manufacturers shifted R+D focus to rare diseases, conditions that affect fewer than 200,000 people (equivalent to 0.06% of the US population). This strategy is made more enticing by the Orphan Drug Act, which provides seven years of market exclusivity following market approval, tax credits up to 25%, a waiver of prescription drug user fees, and grant programs.

The number of gene therapy candidates is booming: According to a June 2021 MacPAC¹ report (bit.ly/3bwFAK3), “Focusing specifically on therapies nearing FDA approval, 61 gene and cell therapies indicated for adults are in Phase III or later (e.g., a new drug application has been submitted).”

Because gene therapies target small clusters of individuals, manufacturer R+D costs, marketing costs, and profit are spread across a narrow target population. In addition, manufacturers of such unique therapies often address an unmet need and face no market competition—so they become monopolists in these narrow markets. This dynamic typically results in high prices—\$500,000 to \$2 million for a single course of treatment—for gene therapies.

Precision medicine includes access to genomic testing at appropriate points during a patient’s disease trajectory, data interpretation, and physician reporting to support therapeutic decision making—all prior to access to the genomic medicines themselves. An appropriate result in a genomic test (more generally referred to as a companion diagnostic) increases the likelihood that patients receiving these expensive products will benefit from them—and supports the payer’s need to establish medical necessity.

Key challenges with gene therapy are high upfront costs, budget volatility, and uncertain long-term benefit. Because rare diseases impact small populations, there is uncertainty about the number of individuals who might seek treatment

1 The Medicaid and CHIP Payment and Access Commission (MACPAC) is a non-partisan legislative branch agency that provides policy and data analysis and makes recommendations to Congress, the Secretary of the US Department of Health and Human Services, and the states on a wide array of issues affecting Medicaid and the State Children’s Health Insurance Program (CHIP).

in any given year within a particular payer’s beneficiary pool—which creates a significant risk of volatility in annual drug spending. And there is mounting payer concern about the total cost of treatment for a growing number of rare diseases—the product of high price points for gene therapies multiplied by the increasing number of people with the expanding number of rare diseases treated by these products.

To underscore the seriousness of this situation,² “With a growth rate double that of the overall pharmaceutical market, rare diseases have caught the eye of payers. Payers with a few more rare disease patients than anticipated can see challenging increases in their budgets with the approval of a new expensive treatment. Small payers can become financially insolvent with large costs from a few patients with a rare disease, while some large payers may also see 10% to 20% specialty spending on rare diseases.”

How will these therapies be paid for? Cure of a gene therapy-dependent condition may be viewed as a payer investment—yet the initial payer may not capture the benefit of this investment if there is a change in patient’s employment or a change in payer’s insurer.

Financial solutions that have been proposed include transferable multi-year annuities, targeted stop-loss, a cure fund for high-cost treatments, and a national government program to cover gene therapies, similar to the early eligibility into the Medicare program for people with kidney failure who rely on chronic renal dialysis (i.e., ESRD).³

In its report to the Congress in June 2021, MACPAC stated that is considering recommending a wholly new approach to the coverage of patients needing extremely expensive

gene therapies. Yes, this recommendation would be explicitly with respect to the public sector, but remember that the commercial marketplace often follows the government’s lead in the pricing and management of health-related services:

The TAP discussed how a new national drug benefit for cell and gene therapies could address the high up-front costs, budget volatility, and uncertainty in the long-term benefit that cell and gene therapies present. A new benefit would allow for new coverage, payment, or rebate requirements without disrupting the existing structure of the MDRP (that is, the Medicaid statutory “best price” pharmaceutical manufacturer rebate program) for all other outpatient drugs. One option would be to create a centralized, national coverage pool for these products. A federally administered program would allow standardization of coverage and payment rules across states and plans.

By consolidating gene and cell therapies into a separate drug benefit, the federal government would have increased negotiating leverage and might be able to obtain larger rebates.

Many types of outcomes-based risk-sharing arrangements have been discussed and are being tested, often based on expectations driven by evidence-based evaluations.⁴ **Finally, manufacturers touting their gene therapies as curative may be expected to warranty this outcome—and write down therapy cost if this outcome is not achieved on a case-by-case basis. Purchasers often refer to such arrangements as value-based and outcomes-based.**

2 hmpgloballearningnetwork.com/site/jcp/article/pathways-paying-rare-disease-treatments

3 newdigs.mit.edu/sites/default/files/MIT%20FoCUS%20Precision%20Financing%202019F201v023.pdf

4 hmpgloballearningnetwork.com/site/jcp/article/use-risk-sharing-agreements-manage-costs-mitigate-risk-and-improve-value-pharmaceutical and <http://newdigs.mit.edu/sites/default/files/MIT%20FoCUS%20Precision%20Financing%202019F201v023.pdf>

The cost of currently marketed gene therapies and the prospect of a late-stage pipeline full of gene therapies promising miracle results—at astronomical prices—has increased pressure on politicians to craft laws which would enable the government to address drug pricing—possibly with input from organizations that provide evidence-based assessment of value, such as ICER. Examples include laws to allow Medicare to directly negotiate drug prices and to link the prices of certain drugs to prices paid by countries that either negotiate drug prices or reference to countries that do.

Gene therapies promising miracle results but at previously unheard of prices put purchasers

in a bind. On the one hand, these therapeutic results are marvelous for patients with previously untreatable conditions. On the other hand, these new therapies—individually and especially in the aggregate—are, particularly for small and mid-sized self-funded purchasers, difficult to effectively manage, impossible to budget for, and ultimately unaffordable.

Elan Rubinstein, PharmD, MPH
EB Rubinstein Associates
elan.b.rubinstein@gmail.com
sebrubinsteinassociates.com

A Focus on PBMs

For this year's report, we asked three leading PBMs to provide insight into their operations on topics of high purchaser interest.

BUSINESS PROFILE	CVS	Navitus	US Rx
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In this section, we highlight PBM activity in outcomes-based contracts, contracting transparency and flexibility. We also discuss PBM policies on sharing data with other vendors. Also see the National Alliance Pharmacy and Medical Drugs Initiative (bit.ly/31q2XDt).

PHARMACEUTICAL MANAGEMENT	CVS	Navitus	US Rx
	● ● ● ○ ○	● ● ● ● ○	● ● ● ● ○

This section looks at PBM practices and results in prior authorization. There is increasing purchaser interest in contracting with “carve-out” specialty pharmacies, so we also highlight how PBMs can support that integration. Given the increasing expense in specialty pharmaceuticals, we also examine PBM efforts to minimize waste and to promote competition through biosimilars. (For related information, see National Alliance Report, “Achieving Value, Medical Side of Drug Benefits,” bit.ly/3pZMC2s.)

CHRONIC CONDITION RX MANAGEMENT	CVS	Navitus	US Rx
	● ● ● ● ○	● ● ● ● ○	● ● ● ● ○

2020 was a challenging year for managing chronic conditions, as many services were missed. Mental health was impacted strongly, and PBMs can play a role supporting patients. (See [article](#).) In this section we highlight how PBMs are managing behavioral and SUD drugs. Please also see the National Alliance Path Forward for Mental Health and Substance Use (bit.ly/3GJHIN6).

ENGAGING MEMBERS	CVS	Navitus	US Rx
	● ● ● ● ○	● ● ● ● ○	● ● ● ● ○

In this section, we look at how members are engaged in treatment decision-making, including the cost of drug options, and how PBMs encourage members to adhere to treatment and achieve health outcomes. This year's report highlights a topic ripped from the headlines: what PBMs are doing to collect information on their members' gender, age, race and ethnicity, and how they use that information to address health equity. Please also see National Alliance Race, Health and Equity Resources (bit.ly/31eF81e).

Overview of Findings

✓ Purchasers are increasingly interested in contracting with external specialty pharmacies, and all three PBMs can integrate the “carve-out” specialty pharmacy into their network.

✗ It’s an understatement to say that the last year has put a spotlight on health equity. This report reveals that while all the PBMs can gather primary language and gender information on their populations, they are not yet gathering race and ethnicity information, which limits their ability to improve in this important area.

✓ For the past few years, we have been reporting on PBM practices regarding low-value drugs, which drive up cost without adding significant health value. All three PBMs have essentially removed these drugs from their formularies.

✗ Mental Health is a strong priority for purchasers, especially given the impact of Covid-19, and the National Alliance’s

Path Forward for Mental Health (bit.ly/3w6KB5M) initiative is tackling this challenge in a systematic fashion. We know that PBMs can play an important role in helping patients with behavioral health and substance use needs. (See [article](#)). Our chronic disease section highlights PBM performance in this area, focusing on the basic question: Are PBMs tracking adherence for behavioral health and substance use disorder medications?

✓ It’s important that patients be rewarded for completing disease management programs, and taking their medications as prescribed. The PBMs have a full range of options to incentivize program completion and medication adherence—from adherence to guidelines (such as completing recommended tests) to meeting targeted A1c, cholesterol, and blood pressure goals—in a variety of conditions ranging from asthma to depression.

What Can Purchasers Look for in the Future?

▶ US Rx: “Exponential growth of clients looking for integrated pharmacy and medical Rx management either under the pharmacy benefit completely or managed across medical and pharmacy benefits.”

▶ CVS Health: “Several of the strategies that we are evaluating through our trade organization: 1) Indication-based rebates—Possibility to create competitive classes based on therapeutic uses rather than class of medication; 2) Value-based contracting—evaluating all indications for a given drug,

and looking for improved discounts for those indications that have lesser clinical efficacy; and 3) Risk-based contracting—providing a contracted provider network with a fixed PMPM fee.”

▶ Navitus: “Further aligning management of self-administered and provider-administered specialty medications and also expanding network options, including home infusion service/per-diem billing and value-based agreements; hemophilia and other network designs are also expected within the next year.”

Focus on PBM Performance



CVS Caremark provides a full range of PBM solutions to clients including employers, insurance

companies, unions, government employee groups, health plans, Medicare Part D plans, Managed Medicaid plans, and plans offered on the public and private exchanges throughout the United States. Our innovative tools and strategies, as well as quality client service, can help improve clinical outcomes for members, while assisting clients with managing pharmacy and overall healthcare costs. Our goal is to produce results for our clients and their plan members, leveraging our expertise in PBM services, including: plan design and administration, formulary management, Medicare Part D services, mail order, specialty pharmacy and infusion services, retail pharmacy network management, prescription management systems, clinical services, disease management, and medical spending management.

FOR MORE INFORMATION, please contact Christopher Wilson at Christopher.wilson4@cvshealth.com or 201-602-8895.

BUSINESS PRACTICES ●●●○○

At the time of this year's survey, CVS reported that it provided PBM services for 28,100,000 self-funded employer commercial lives and for 5,300,000 fully insured commercial lives through health insurers contracting with it. CVS reports having achieved all URAC accreditations.

There is growing interest among purchasers in outcomes-based contracts with pharmaceutical manufacturers. CVS reported several such contracts, including ones for diabetes, asthma and MS.

Employers are interested in greater transparency from their PBM vendors. CVS described

a new guaranteed net cost pricing model, which guarantees the client's average cost per prescription, after rebates and discounts, across each distribution channel—retail, mail order, and specialty pharmacy. Under the new model, CVS will pass through 100 percent of rebates to clients and absorb the impact of drug-price inflation and shifts in drug mix.

Of particular interest with regard to the Consolidated Appropriations Act ([See article.](#)), employers want assurance that their vendors are working in the best interests of their clients and their beneficiaries. CVS stated that it provides these services and decisions in a fiduciary-compliant manner as defined under ERISA: claims denials, Rx benefits appeals, medical necessity appeals, and UM/PA criteria and processes.

CVS allows audits that include PBM-selected amount of claims for one year; maximum allowable cost (MAC) list for generics for review against paid claims; selected access to pharmacy network contracts, payments and reconciliations; and selected access to pharmaceutical industry contracts, receivables, distributions and reconciliations. Audit rights are negotiated on a client-specific basis during the proposal process. CVS Health will permit, with thirty days' notice, an audit of mail service facilities for prescription accuracy.

Purchasers are increasingly interested in the ability to contract directly with specialty pharmacies other than the PBM's owned/contracted specialty pharmacy. CVS can integrate the specialty pharmacy into its provider network with seamless transfer of information. CVS customer care can make warm transfers for participants to the outside specialty pharmacy care teams.

PHARMACEUTICAL MANAGEMENT



Prior authorization is an important PBM service. While some argue that electronic prior authorization (ePA) leads to “rubber stamping” submissions, others say that ePA improves adherence to treatment, as patients are not delayed by the prior authorization process at the pharmacy counter. CVS’ rate of ePA approval is high, at 65%. Prior authorization approval rates for selected medication/conditions are as follows: migraine, 70%; diabetes, 61%, growth hormone deficiency, 69%.

While CVS does require genetic testing for access to appropriate specialty drugs, CVS does not require that employers cover the appropriate genetic test as a covered benefit, which could lead to unintended non-adherence.

CVS is unique in its “brick and mortar” capabilities. Their Specialty Connect program allows CVS to accept specialty prescriptions through any of the 9,900 CVS Pharmacy locations. Physicians can electronically prescribe, fax or call specialty prescriptions into a local CVS Pharmacy or patients may drop off the specialty prescription at their local CVS Pharmacy to initiate the process. After receipt of the prescription in any of these forms by the local CVS Pharmacy, patients are given the option of picking up their prescription at the local CVS Pharmacy, in addition to the option of mail delivery to the home, physician office, or alternate location.

Purchasers are interested in avoiding waste and the inappropriate use of specialty pharmaceuticals. As an example, CVS highlights its attention to hemophilia: While the industry standard is +/-10% variance between the prescribed and dispensed dose aggregated, CVS’ standard is <2%. As another example, CVS’ Synagis dosing tool predicts future dose requirements with 99% dose accuracy for the entire therapy course, resulting in a reduction of 9.7% of total Synagis spending.

Biosimilars introduce competition into the specialty drug arena. Purchasers are interested in how PBMs are promoting these alternatives, and in particular how PBMs are interacting with prescribers to achieve higher biosimilars prescribing. We asked CVS how they manage the four most prevalent biosimilars. For a new patient who has never been prescribed a biologic, CVS contacts the physician to switch from the original prescribed biologic to the biosimilar only for Retacrit. For a patient already using the original biologic, CVS does not contact physicians regarding a switch.

CHRONIC CONDITION MANAGEMENT



PBMs play an important role in helping patients manage behavioral health. (See article.) With respect to behavioral health and substance use disorder drugs, CVS monitors the most commonly and appropriately used medications. CVS also reports monitoring substance use disorders drugs for adherence. Clinician prescribing patterns are monitored, including clinician rates of prescribing multiple antidepressant medications and pain medications, once or more per year.

MEMBER ENGAGEMENT

CVS offers incentive programs to increase the completion of disease-management programs and medication adherence, including adherence to guidelines such as completing recommended tests and meeting treatment goals, such as targeted A1c, cholesterol, and blood pressure levels.

With respect to health equity, CVS captures the following demographic information at a member level: primary language, age, and gender. Although CVS did not report any efforts to improve staff cultural competency, they did describe CVS Project Health, which connects members of multicultural communities that typically have large numbers of uninsured or underinsured residents to free, comprehensive health assessments for early detection of risks for chronic conditions.



Navitus Health Solutions, LLC, owned by SSM Health and Costco Wholesale Corporation, is a full-service, URAC-accredited PBM. As a zero-spread, full pass-through PBM, Navitus aligns performance with plan sponsors’

benefit goals to deliver comprehensive clinical programs and cost-saving strategies that lower drug trend and improve member health. Navitus provides its flexible services to government entities, self-funded employers, coalitions, labor organizations, third-party administrators, and health plans, including managed Medicaid, Exchanges, and Medicare Part D.

FOR MORE INFORMATION about Navitus’ tangible solutions to the rising cost of healthcare, visit navitus.com or call 877-571-7500. Or, email us at sales@navitus.com.

BUSINESS PRACTICES ●●●●○

At the time the survey was completed, Navitus served a total of 1,327,466 self-insured commercial lives, of which 637,164 lives were contracted through employers’ health insurer or TPA and the balance contracted directly with Navitus. Navitus has URAC PBM and specialty accreditations. Navitus reports interest among purchasers in outcomes-based contracts and/or value-based contracts with pharmaceutical manufacturers, particularly in diabetes, asthma, targeted immunomodulating agents (which enhance the body’s immune response against cancer), oncology, and hepatitis C. Navitus passes all guarantee and rebate payments from pharmaceutical manufacturers back to clients.

Navitus states that it is a fiduciary solely to the extent that it exercises discretion with regard to the services provided. Navitus typically allows clients to audit its operations every two years but will accommodate annual audits. Audit against paid claims of Navitus’ maximum allowable cost (MAC) list for generics is permitted. The following are permitted for audit on an open-book

basis: pharmacy network contracts, payments, and reconciliations; sites-of-care contracts, payments, and reconciliations; and pharmaceutical industry contracts, receivables, distributions, and reconciliations. Clients may only audit periods of service not more than 18 months prior to the audit date.

With respect to sharing data with health plans, Navitus transmits the following: utilization, deductibles, accumulator file data, adherence rate, safety information (e.g., drug conflicts), potential overuse information, and complete claims data feed. Navitus states “In this time of heightened interest in health equity, Navitus can also receive demographic and cultural info such as race, ethnicity.”

PHARMACEUTICAL MANAGEMENT



Prior authorization is an important PBM service. While some argue that Electronic Prior Authorization (ePA) leads to “rubber stamping” submissions, others say that ePA improves adherence to treatment, as patients are not delayed by the prior authorization process at the pharmacy counter. Navitus reports that 16% of its prior authorizations are performed electronically. Navitus overall prior authorization approval rates for selected therapy classes are: migraine, 52%; diabetes, 56%; growth hormone deficiency, 82%.

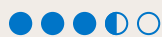
Navitus reports that it can integrate externally contracted specialty pharmacies into its provider network to provide a seamless transfer of information, and that it integrates claims data, accumulator files, deductibles, etc., for purposes of consolidated reporting. A client may include the specialty pharmacy customer number on the ID card. Navitus customer care can make warm transfers for participants to outside specialty-pharmacy care teams. Navitus will warm transfer calls as long as the vendor’s hold times are reasonable. If the vendor has excessive hold times, Navitus will provide the caller with the contact information to enable a cold transfer. Navitus

does not require genetic testing to access specialty pharmaceuticals.

Examples of ways that Navitus reduces waste and inappropriate prescribing of specialty pharmaceuticals: 1) Cosentyx—Depending on the patient’s dose, there is a potential dose-optimization savings opportunity by switching from a single-pack for 28 day supply to a two-pack for a 56-day supply. For one client, in its first year with Lumicera (Navitus’ specialty pharmacy), it experienced more than \$382,000 in savings by switching to the lower-cost package size. Through Lumicera’s consistent review of new prescriptions, this same client had more than \$189,000 in savings through Cosentyx dose optimization in its second year. 2) Gleeevec—Switching from five 100 mg tablets to one 400 mg tablet plus one 100 mg tablet results in an annual cost savings of \$12,900 per patient.

Biosimilars introduce competition into the specialty drug arena. Purchasers are interested in how PBMs are promoting these alternatives, and, in particular, how PBMs are interacting with prescribers to achieve higher biosimilars prescribing. For a prescription for an originator biologic written for a patient not previously on a biologic for which a biosimilar is available, and also for patients already using the originator biologic, Navitus may contact the prescriber to switch from the originator product to the following biosimilar products: Zarxio, Inflectra, Renflexis and Retacrit.

CHRONIC CONDITION MANAGEMENT



PBMs play an important role in helping patients manage behavioral health. (See article.) Navitus monitors several types of behavioral health drugs for adherence, including antidepressants, atypical antipsychotics, and drugs for treatment of

attention-deficit/hyperactivity disorder (ADHD), but does not monitor SUD drugs for adherence. Navitus can offer a pharmaco adherence program upon client request.

Navitus monitors the appropriateness of prescribing practices for antidepressant medications in the following ways: monitors rate of prescribing by practitioners compared to rate of depression diagnosis and investigates outliers once or more per year; monitors rates of prescribing multiple antidepressant medications once or more per year; reviews members on antidepressant to check for assessment using a standardized screening instrument once or more per year and formal drug utilization review processes once or more per year; and monitors rates of prescribing multiple antidepressant medications once or more per year. Prescribers are sent comparative performance reports.

MEMBER ENGAGEMENT ●●●●○

Navitus offers incentive programs to increase the completion of disease-management programs, including adherence to guidelines such as completing recommended tests and meeting treatment goals, such as targeted A1c, cholesterol, and blood pressure levels.

To assure that culturally sensitive, equitable and diversity competent healthcare is delivered, Navitus engaged in the following during 2020: assessed cultural needs of members, collaborated with statewide or regional pharmacy and/or medical association groups focused on cultural competency and unconscious/implicit bias issues, sponsored cultural competency training for PBM staff, required cultural competency training for PBM staff, required anti-racism and unconscious/implicit bias training of internal staff, and assessed cultural diversity of PBM staff.



US-Rx Care

offers health plan sponsors a level

of pharmacy risk management that represents a significant departure from methods and practices typically employed in the marketplace for the past twenty years. In addition, US-Rx Care operates with full transparency and without any conflicts of interest, backed up by a commitment to fiduciary standards in everything we do. Typical plan savings range from 25%–45% in total drug and administrative costs within the first 12 months of US-Rx Care service without changing benefit design. Out-of-pocket cost for covered members typically declines 30% or more. Our proprietary systems and methodologies have been developed, implemented and honed across 5 million covered lives over 20 years.

BUSINESS PRACTICES ●●●●○

In response to our survey question, US-Rx disclosed that it provides pharmacy benefit administrative services for self-funded employers, for a total of 585,000 commercial lives. US-Rx is URAC specialty pharmacy accredited. US-Rx did not have outcomes-based contracts with pharmaceutical manufacturers and expressed concern regarding such arrangements, saying, “...we see these types of performance guarantees from manufactures as being window dressing for PBM to promote the manufacturer product, water down or eliminate prior authorization criteria, boost utilization of the product, all with little or no real value or savings to the client.” US-Rx states that its contracts are 100% pass-through contracts and most do not have rebate minimums. US-Rx returns 100% of any third-party revenue, including rebates, to its employer clients. In this year’s survey, US-Rx is the only PBM that states that it does not directly use third-party analyses such as ICER in price negotiations.

US-Rx states: “We are fiduciary compliant, passing all rates and rebates 100% to our clients with no conflicts of interests. All activities are

performed on a fiduciary-compliant basis.” US-Rx permits an annual audit of: all claims processed over the life of the contract; open-book access to pharmacy network contracts, payments, and reconciliations; open-book access to sites of care contracts, payments, and reconciliations; and open-book access to pharmaceutical industry contracts, receivables, distributions and reconciliations.

US-Rx transmits deductibles, accumulator file data, and a complete claims data feed to health plans.

PHARMACEUTICAL MANAGEMENT



Prior authorization is an important PBM service. While some argue that electronic prior authorization (ePA) leads to “rubber stamping” submissions, others say that ePA improves adherence to treatment, as patients are not delayed by the prior authorization process at the pharmacy counter. USRx does not currently use electronic prior authorization (ePA), but expects to move in this direction. US-Rx reports its prior authorization rates as follows for these selected conditions: migraine, 20%; diabetes, 20%; growth hormone deficiency, 50%.

Across US-Rx’s total book of business, specialty drugs represent approximately 25% of drug spending, although US-Rx reports that it has “many clients under 10% that came to us approaching 50%.” This is significantly lower than our other two reporting PBMs.

US-Rx reports that it can integrate externally contracted specialty pharmacies into its provider network with seamless transfer of information; integrate claims data, accumulator files, deductibles, etc., for purposes of consolidated reporting; make warm transfers for participants to the outside specialty pharmacy care teams; include the specialty pharmacy customer number on the ID card; and submit third-party specialty claims for rebates. US-Rx includes genetic testing

where appropriate and part of national guidelines, and reports that those tests are regularly accessible and routinely covered items by its clients. However, US-Rx does not recommend or require genetic testing when not accepted as standard protocol for approval of a particular drug for use.

US-Rx reports that it minimizes drug waste by managing the quantities dispensed. For example, it authorizes fewer days' supply when possible, based on manufacturer packaging for oncology meds to confirm tolerability and/or efficacy before authorizing additional supply. In addition, US-Rx manages vial size as part of dose optimization to reduce or eliminate unused supplies.

Biosimilars introduce competition into the specialty drug arena. Purchasers are interested in how PBMs are promoting these alternatives, and in particular how PBMs are interacting with prescribers to achieve higher biosimilars prescribing. US-Rx contacts prescribers to switch to the biosimilar both for patients who have never been prescribed the biologic and for patients already using the originator biologic, in an effort to switch to one of the following biosimilars: Zarxio, Inflectra, Renflexis and Retacrit.

CHRONIC CONDITION MANAGEMENT ●●●●○

PBMs play an important role in helping patients manage behavioral health. (See [article](#).) With respect to drugs used in behavioral health and substance use disorder, US-Rx reports that

it does not systematically monitor adherence or compliance (i.e., medication refills), and that no commercial clients currently request these services.

US-Rx reports monitoring the rate of prescribing for depression, pain and sleep medications one or more times per year; and ongoing electronic monitoring and reporting of quantities, duration of therapy, doctor shopping, and pharmacy shopping.

MEMBER ENGAGEMENT ●●●●○

US-Rx offers incentive programs to encourage disease-management program completion and medication adherence, including adherence to guidelines such as completing recommended tests, and meeting treatment goals such as targeted A1c, cholesterol, and blood pressure levels, though US-Rx reports that it has no clients incentivizing adherence to chronic disease guidelines, or success with specific target goals for chronic disease management.

With respect to health equity, US-Rx reports that it: assesses cultural needs of members; ensures a diversity of representation on key PBM decision-making groups, such as board of directors, QI committees, member engagement committees, strategic planning committees, etc.; tailors utilization management messaging to particular cultural groups; ensures that coverage policies provide equitable coverage; and assesses the cultural diversity of its PBM staff.

Four Key Questions to Ask Your PBM or Consultant

- ▶ **What are you doing to promote greater uptake of biosimilars, both with prescribers and with patients?**

(See “Biosimilars: An Opportunity for Savings” on [page 7](#).)

- ▶ **Am I prepared for the additional responsibility of the Consolidated Appropriations Act? How can you support me?**

(See “The Consolidated Appropriations Act: Burden or Opportunity?” on [page 4](#).)

- ▶ **What are you doing to ease access to mental health medications, track adherence, and support members?**

(See “Improving Mental Health: Do PBMs Have a Role?” on [page 10](#).)

- ▶ **What strategies can I implement to address high-cost drugs?**

(See “Will High-cost Claims Bring an End to Self-insured Employer Healthcare?” on [page 12](#).)



The National Alliance of Healthcare Purchaser Coalitions is the only nonprofit, purchaser-led organization with a national and regional structure dedicated to driving health and healthcare value across the country. Our members represent more than 12,000 employers/purchasers and 45 million Americans, spending over \$300 billion annually on healthcare. Purchasers range from small and mid-sized to very large organizations, representing private and public sector, nonprofit, and union/Taft-Hartley groups.

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THE INFORMATION IN THIS REPORT IS DRAWN FROM A SUBSET OF EVALUE8, an evidence-based tool of the National Alliance of Healthcare Purchaser Coalitions. eValue8 was created by business coalitions and employers like US Bank, Ford Motor Company, General Motors, and Marriott International to define, measure and evaluate health plan performance. eValue8 asks health plans probing questions about how they manage critical processes that control costs, reduce and eliminate waste, ensure patient safety, close gaps in care, and improve health and healthcare. In addition to this report, the National Alliance performance evaluation portfolio includes analyses in mental health, oncology, medical imaging, and more.

nationalalliancehealth.org/www/initiatives/initiatives-market-assessments/evaluate8

FOR MORE INFORMATION CONTACT:

John Miller, Mid-Atlantic Business Group on Health
john.miller@mabgh.org

Foong-Khwan Siew, National Alliance of Healthcare Purchaser Coalitions
fsiew@nationalalliancehealth.org

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