

Solving America's High Drug Cost Problem: Prevent Drug Company Tactics that Increase Costs and Undermine Clinical Quality



By the Pharmacy Benefit Management Institute (PBMI)
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PATIENTS & EMPLOYERS CANNOT SUSTAIN CURRENT DRUG COST GROWTH

Prescription drug spending is projected to grow at 5.4% per year between 2021–2023 and at 5.9% between 2024–2028, faster than overall health spending, and faster than the economy is expected to grow.¹ Those responsible for bearing the burden of high drug costs — patients and payers, including employers, health plans, labor unions, and government programs — are well aware that drug costs have risen dramatically.

A Note on 2020

On March 11, 2020, the World Health Organization (WHO) declared COVID-19, the disease caused by the novel coronavirus, to be a pandemic and two days later it was declared a national emergency in the U.S. According to the Congressional Research Service (CRS), “real GDP fell at an annualized rate of 4.8% in the first quarter of 2020 (compared with a 2.1% growth rate in the fourth quarter of 2019).”² Over 20 million Americans lost their jobs in March and April alone, leading to an unemployment rate of 14.7%.³ Due to those job losses, an estimated 10.1 million Americans lost their employer-sponsored health insurance.⁴ Despite the contraction of the economy and the millions who lost their health insurance, drug manufacturers increased list prices by an average 6.8% on 857 drugs between January and June 2020, and an average 3.1% on an additional 67 drugs in July.⁵ Throughout the pandemic, PBMs have continued to provide affordable access to necessary medications for their plan enrollees.

Rising drug costs add pressure to healthcare budgets already strained by increased utilization of high-cost specialty medications and biologics. Employers and other payers are stretching to provide high-value drug benefits for their employees and other health plan enrollees.⁶ The profitability of American companies is undermined by growing healthcare costs, which may result in less job and economic growth.⁷

Pharmacy benefit managers (PBMs) helped reduce prescription drug costs for more than 266 million Americans in 2020, saving the payers who contract for their services and their covered enrollees 40 to 505 on their annual prescription drug costs compared to what they would have spent without PBMs.⁸ However, while PBMs have reduced costs and have a return on investment for payers of \$10 for every \$1 spent on PBM services,⁹ rising drug prices, especially for new specialty medications, and the tactics used by drug manufacturers threaten the financial viability of health coverage.



PATIENTS' PERSPECTIVE

Consumers understand that the prices set by drug companies directly lead to higher prescription prices and higher out-of-pocket costs. A national survey conducted by North Star Opinion Research found that most voters blame drug companies for high drug prices and out-of-pocket costs.¹⁰ This undermines drug industry campaigns that blame higher costs on employers, unions, health plans, and the PBMs they use to negotiate discounts on prescription drugs. Key findings include:¹¹

- ▶ Three-quarters of voters say the cost of prescription drugs is too high.
- ▶ By almost 3-to-1, voters blame high drug prices for increased cost-sharing.
- ▶ Only 1-in-5 voters believe drug companies' message that "rebates cause high prices."
- ▶ More than 4-of-5 voters with prescription drug coverage are satisfied with it.

In a Kaiser Family Foundation (KFF) survey, 79% of respondents said that drug costs are unreasonable, while 80% believe that "profits made by pharmaceutical companies" are a major contributing factor to those high costs.¹²

How Drug Prices Are Set

Drug companies strategically calculate drug prices to derive maximum profits. They gauge the degree of competition in the market, the cost sensitivity of target patient groups, and projected revenue goals when formulating list prices. They also account for the full spectrum of discounts and rebates they expect to issue to patients, providers, government programs, payers, and PBMs when setting prices, as well as the costs of company marketing programs like free drug samples designed to get people to begin therapy.

Drug prices were never set to recoup research and development (R&D) costs,¹³ but to extract the greatest amount of revenue possible from the health care system based on the manufacturer's internal assessment of their products' value.

While a few drug companies have pledged to limit drug price increases to single-digit increases once a year,¹⁴ the majority of companies do not embrace this pricing philosophy.¹⁵ Moreover, even single-digit increases running at three or four times the rate of inflation in the general economy can double prices in as little as ten years. Contrary to assertions otherwise, the pharmaceutical industry devotes a relatively small percentage of its funding to research and development (R&D) efforts. One researcher estimated that "Research and development is only about 17% of total spending in most large drug companies."¹⁶ Companies spend roughly one-third of their revenues on marketing, and only half as much on R&D.¹⁷

CASE STUDY

As Gilead was preparing to launch the first major potential cure for hepatitis C to the market, the drug, Harvoni, was expected to carry a high price tag: \$36,000 to treat each patient. However, over the two years leading up to the medication's launch, Gilead executives and advisers inched the number higher, to \$65,000, then \$81,000, and finally to \$84,000 — or \$1,000 a pill for the 12-week treatment — a price believed to be just below where they predicted payers would add significant formulary or access restrictions. Rather than basing prices on their R&D expenses — a frequently cited industry-wide explanation — company leaders instead set prices based on existing factors in the market to maximize revenues.¹⁸



PAYERS' SOLUTIONS

Many payers, such as employers, commercial insurers, labor unions, Medicare Part D plans, and Medicaid Managed Care plans outsource the management of their pharmacy benefits to pharmacy benefit managers (PBMs), who use clinically driven prescription drug cost-management programs designed to deliver high-quality drug benefits while targeting unnecessary costs.^{19,20} PBMs provide a number of technical and administrative functions necessary for managing the drug benefit such as developing drug formularies, creating and managing pharmacy networks, and processing and paying claims. These PBM tools are most commonly used in private insurance plans, while some of them are also used in public programs.

PBMs are critical to the delivery of quality, cost-effective healthcare. PBMs have long been recognized for their ability to create savings through negotiating rebates with drug manufacturers and discounts with retail pharmacies, offering more affordable choices of where patients can obtain their medications (e.g., pharmacy networks), providing clinical utilization management programs, and encouraging the use of generics and affordable brands.²¹

Two key functions of PBMs are essential to sustainable drug costs for employers and other payers: clinical utilization management and formulary management programs. Together, these programs ensure patient access to clinically appropriate medications while managing utilization to reduce wasteful spending.²²

Clinical Utilization Management Programs

To ensure that patients and payers receive value from specialty and other high-cost drugs, PBMs work with pharmacy and therapeutics (P&T) committees²³ and specialty pharmacies to create programs that provide prescribers and patients with evidence-based care, efficient medication delivery, clinical outcomes monitoring, and reduced costs.

PBM clinical utilization management program tools have been used over the last two decades to control traditional and specialty drug trend and assure safe and efficient medication utilization. These tools include drug utilization review, prior authorization, step therapy, pharmacy network design, and site of care management programs. Innovative strategies such as medical claims referencing and the use of genomic and other advanced molecular diagnostics are also enabling PBMs to facilitate targeted and cost-effective drug therapies for patients.²⁴

UTILIZATION MANAGEMENT PROGRAMS: STEP THERAPY AND PRIOR AUTHORIZATION

Prescription drug utilization management programs such as step therapy and prior authorization are important clinical tools to help ensure that patients receive medication that is safe and effective for their condition, helps limit off-label use of medications, promotes adherence to guidelines when they are available, and reduce costs.^{25, 26, 27} In a review of available literature, the Government Accountability Office (GAO) found that utilization management tools were associated with improved health indicators and financial savings.²⁸

Prior authorization is an administrative requirement that a physician must obtain from the insurer when prescribing certain drugs to ensure that the cost will be reimbursed. Prior authorization may require documentation, as recognized in the peer-reviewed literature that the patient has the FDA-approved indication and possibly, meets narrower requirements.

Often used in conjunction with prior authorization, step therapy is used to control costs and improve patient safety by requiring them to try one or more first-line therapies for a given condition (i.e., “steps”), and only move to a higher-line therapeutic alternative if the patient does not respond or experiences side effects.²⁹

Formulary Management Programs

A formulary is a continually updated list of prescription drugs approved for reimbursement by the PBM’s payer clients. PBMs typically develop a basic formulary and recommend it to payers, who may customize it.³⁰ The purpose of drug formularies is to encourage the use of safe, effective, and the most affordable medications. Drug formularies are not static. Rather, they are developed and continually reviewed and updated by a team of healthcare specialists, a P&T committee, and then by the PBM itself based on three primary components: clinical, financial, and other criteria such as price concessions.³¹ The first and most important component is clinical safety and efficacy, and choosing drugs with evidence of highest comparative effectiveness, which the P&T committee handles.³²

PBMs rely on P&T committees, typically made up of independent physicians, pharmacists, and other health care clinicians from multiple key disciplines, to help create formularies that include the most clinically sound prescription drugs. P&T committees

work independently of PBM trade teams and indicate whether each medication under review “must be,” “must not be,” or “may be” added to a PBM or payer’s formulary.³³ Typically, P&T committees consider only clinical factors and few consider cost, which the PBM considers after clinical criteria are addressed.³⁴ While PBMs automatically accept committees’ “must” or “must not” recommendations, PBMs use competition in the “may be included” third category to negotiate greater price concessions from drug companies.

P&T committees serve very important medication safety functions such as a review process for new drugs that uncover any safety concerns with the drug and reviews of the literature for potential safety or efficacy issues with existing drugs. These reviews are critical. One recent study found that 32% of novel drugs approved by the FDA had safety risks only discovered after the drug was approved and on the market.³⁵

Drug formularies are an important tool used by PBMs and payers not just to manage specialty and other high-cost drugs, but also to give patients financial

incentives to use generic drugs when possible. It is ultimately up to payer clients to decide based on the needs of their enrollee populations, the exact formulary that will be used in conjunction with their benefit plans, as well as the specific techniques that will be applied to encourage formulary compliance. The most effective tool for achieving formulary compliance is a benefit structure or plan design where preferred drugs have lower enrollee cost-sharing.³⁶ Drugs that do not provide sufficient

clinical efficacy or value are not given preference on formularies. Typically, in categories with multiple clinically equivalent therapies, PBMs recommend that drugs with the lowest net cost (final cost after all discounts and rebates) be placed on a formulary tier with lower cost-sharing than those with a higher net cost. PBM-recommended tiered formularies, combined with payer-determined tiered cost-sharing, have resulted in 90% of prescriptions being filled with generics.³⁷

FORMULARY EXCLUSIONS: Formulary exclusions lead to significant cost-savings and aid payers in developing and managing drug benefit designs. A recent national survey of employers found that more than half believe that formulary exclusions are an effective way to manage specialty trend. 54% of employers currently use formulary exclusions for specialty drugs, with 38% planning to add or increase the use of them in the next one to two years.³⁸ The availability of competing products on the market makes it easier for PBMs to negotiate with drug companies for deeper price concessions on behalf of payer clients.³⁹

PBMs exist to bring drug prices down to provide affordable access for the drugs patients need at the lowest net cost for payers. Without PBMs in the marketplace, payers would be left to negotiate prices on their own or pay the full costs of these drugs.



WAYS DRUG MANUFACTURERS ARE UNDERMINING PBM MANAGEMENT TOOLS

Threatened by the wide use of PBM tools that shield patients from unnecessary medications and high drug costs, drug companies are increasingly relying on revenue-boosting marketing practices to protect their market share and profit margins. These practices, including coupons and “free” drug programs,⁴⁰ entice patients to use higher-cost medications when more cost-effective, clinically appropriate alternatives exist. Many of these programs are portrayed as charitable efforts to help patients pay for expensive medication, but in reality, they are usually profit-driven marketing tactics.

Ultimately, these types of programs undermine efforts to encourage patients to take the highest-value products and drive up health care costs for everyone.

CASE STUDY

When Novartis launched Gleevec in 2001 for the treatment of chronic myeloid leukemia, the drug was priced at \$2,200 a month.⁴¹ After two competing drugs entered the market, Gleevec’s monthly price nearly doubled in 2008 to \$4,063. In the years leading up to Gleevec’s loss of patent protection, the drug’s price increased from \$6,841 to \$8,156 per month, a 19% price increase between 2013 and 2014.⁴² As Gleevec’s price climbed, so did the burden on government programs and taxpayers. Medicare spent \$996 million on the drug in 2014, up 158% from 2010, largely due to Gleevec’s significant price hikes.⁴³

To then preserve its market share despite these rising prices, Novartis deployed “free” drug, coupon, and cost sharing assistance programs to temporarily

lower out-of-pocket costs for patients with private insurance coverage.⁴⁴ Over ten years, the company additionally donated \$389 million⁴⁵ to programs that lowered patient copay levels and discouraged patients from switching to competing products once generic alternatives entered the market.

Even though patients covered by private insurance who enrolled in these programs were temporarily protected from drug price increases, payers were not shielded from price hikes. While the number of pills sold remained relatively flat over time, Gleevec’s net price increases (after rebates) drove growth in U.S. sales and propelled it to become Novartis’ biggest drug by revenue in 2015, the last year prior to Gleevec’s patent expiration.⁴⁶

MEANS-TESTED PATIENT ASSISTANCE PROGRAMS: The financial subsidy programs that drug companies rely on to increase product uptake among insured patients differ from means-tested patient assistance programs. Whereas means-tested patient assistance programs provide medications at reduced costs for low-income and uninsured patients, manufacturer-created copay assistance and “free” drug programs target patients who are already covered by insurance. By promoting drugs with sub-optimal formulary placement, these programs aim to make patients insensitive to cost and undermine payer and PBM efforts to encourage the use of the most cost-effective, clinically appropriate drugs.

Revenue-Boosting Marketing Programs

With clear exceptions for medical necessity, payers typically only cover drugs that are first validated by P&T committees, based upon clinical and cost-effectiveness measures. A growing number of pharmaceutical companies have turned to using coupons and “free” drug programs to increase the market penetration of drugs that have not received a favorable formulary placement.

Bypassing PBM formulary and utilization management processes, pharmaceutical companies provide limited quantities of high-cost drugs to patients at minimal, if any, initial cost.

Simultaneously, manufacturers link patients with manufacturer-run “hubs,” which work through any utilization management programs the patient might face to try to get the payer to cover the drug.

Unless the pharmaceutical company-run hub succeeds in convincing the payer to cover the cost of the non-formulary drug based on the grounds that the patient already started treatment — and some public programs require coverage of drugs for a month or more after the patient starts a drug — the patient will eventually become responsible for covering the cost of the drug out of pocket.

Marketing Programs that Bypass Clinically Driven Prescription Processes

TRADITIONAL PROCESS	MARKETING PROGRAM PROCESS
<ol style="list-style-type: none"> 1. Payer and PBMs add drugs to a formulary after P&T committees review drugs and recommend appropriate drugs 2. The provider prescribes a patient a high-cost specialty medication 3. Prescription is sent to a specialty pharmacy 4. The PBM conducts a PA or step-therapy review based on clinical criteria, if applicable to the drug, before the medication is approved <ol style="list-style-type: none"> a. If approved, the patient receives the medication through a specialty pharmacy b. If not approved, the pharmacy works with the physician to choose a more appropriate option 	<ol style="list-style-type: none"> 1. Drug company informs doctors of “free” drug or coupon program 2. The doctor prescribes the patient the medication and refers the patient to a drug company-owned hub processing center 3. Drug company hub enrolls the patient in the temporary marketing program and provides the patient with a limited quantity of the high-cost drug at no cost 4. Drug company hub informs the patient’s insurance company that the patient has started using the non-formulary drug 5. Drug company hub requests that the drug be covered by the insurance company <ol style="list-style-type: none"> a. Under some public programs, payers must cover drugs the patient is currently taking, or there is a transition period. b. If the payer otherwise does not approve coverage, the patient must switch drugs or pay the entire cost of the drug out of pocket.

Coupon and “free” drug programs bypass the clinically driven formulary processes and step therapy tools that PBMs use to safeguard utilization management. Drug companies use these programs to drive increased utilization of drugs that are potentially higher-cost or less well-understood instead of more clinically appropriate, cost-effective options. When payers are not involved in this process, they become obligated to address patients’ treatment options after patients have already begun taking a potentially substandard drug.

These drug company programs and tactics result in increased costs for payers and patients. While payers bear the initial burden of these unnecessarily high drug costs, patients soon face high monthly out-of-pocket costs when these time-limited programs are phased out.⁴⁷ And to the extent that the patient’s stabilization on the drug then obligates the payer to cover the drug at least for a transition period, the payer’s costs rise as well. Payers eventually share the burden of these costs with all plan enrollees through increased insurance premiums, copays, and coinsurance costs.

TACTICS PROHIBITED IN GOVERNMENT PROGRAMS

Considered illegal in federal programs due to anti-kickback laws, these tactics have long been under scrutiny by the Health and Human Services Office of Inspector General.⁴⁸ Formulary circumvention programs such as “free” drug and copay coupon programs are viewed as kickbacks as they improperly steer patients to a particular company’s drug instead of less expensive, appropriate alternatives, and encourage wasteful spending for the profit of an outside third party. One recent study estimated that relaxing the ban on manufacturer coupons in Medicare Part D would increase costs by \$48 billion between 2021-2030.⁴⁹ However, drug manufacturers attempt to get around anti-kickback laws by donating money to charities, some of which may engage in illegal practices, that help Medicare beneficiaries pay for expensive brand name drugs. The U.S. Department of Justice has been investigating these relationships between charities and drug manufacturers as potential illegal kickback schemes, including over a dozen legal actions resulting in settlements worth millions of dollars.

While not allowed within the benefit for Medicare and Medicaid,⁵⁰ these tactics and programs are still widely used in the commercial market and permitted in ACA Exchange-based coverage.

Cost Sharing Assistance and Coupon Programs

Common consumer-product brands often rely on coupon promotions instead of price reductions to lure consumers away from lower-cost competitors. Drug companies have adopted this technique and similarly use coupons to increase sales of their products. However, unlike promotions for everyday products like detergent and paper towels, these programs lead patients to start potentially life-long therapies on specialty and high-cost drugs. But because coupon programs for these high-maintenance drugs are often only temporary,

patients soon realize additional costs and burdens. Upon exhaustion of the coupons, patients become responsible for paying the full costs of treatment.

Drug company coupon programs are most often available for branded drugs that have lower-cost alternatives available on the market⁵¹ and will likely not qualify for favorable formulary placement. By definition, coupon and copay promotions only target patients who have prescription drug coverage (i.e., those who pay cost-sharing). Considered illegal

The use of copay coupons reduces the utilization of more affordable medication options, and overall prescription drug costs are continuing to rise dramatically.

in federal health programs, copay coupons are banned in Medicare and Medicaid, but allowed in the commercial market (except in Massachusetts and California, where they are allowed only for brand drugs with no generics).⁵²

Coupon programs have been highly effective and lucrative for drug companies. In 2009, coupons were available for fewer than 100 prescription medications. By 2015, the number exceeded 700 such programs.⁵³ Drug manufacturers may earn between a 4:1 and 6:1 return on investment on copay coupon programs.⁵⁴ Because insured patients are only exposed to copayment or coinsurance out-of-pocket costs, cost sharing assistance programs that temporarily lower or eliminate patient cost-sharing lure patients to choose expensive drugs over more affordable and often more clinically appropriate, options. When patients use these programs, payers are left to pay for the full amount of the drug minus the patient cost-share.⁵⁵ Overall, approximately two-thirds of prescription drug costs are paid not by patients, but instead by the employers, unions, and other payers that provide health coverage.⁵⁶

Copay assistance and coupon programs undermine payers' ability to use varying copay amounts to incent patients to take the most cost-effective drugs. Payer costs rise dramatically when enrollees choose expensive drugs over more affordable, clinically appropriate options. The use of copay coupons reduces the utilization of more affordable medication options, and overall prescription drug costs are continuing to rise dramatically.

To counteract the impact of coupon programs, many plan sponsors have implemented “copay accumulator” programs. Copay accumulator programs only count actual patient out of pocket costs toward deductible and maximum out of pocket (MOOP) limit amounts versus counting the coupon

or other copay assistance amount as if the patient had paid it with their own money. Patient advocacy groups and pharmaceutical manufacturers have pushed back against copay accumulators, arguing that coupons are essential to patients getting access to the drug they need.⁵⁷ State legislators in Arizona, Illinois, Virginia, and West Virginia have recently enacted laws restricting accumulator programs.⁵⁸ These reform measures could undermine PBM programs that try to combat the negative effect that coupon programs have on payer drug costs. For plan year 2021, CMS' Center for Consumer Information and Insurance Oversight (CCIIO) has indicated that insurers are not required to apply the value of manufacturer coupons to deductible and annual MOOP limits, in alignment with IRS guidance.⁵⁹

“Free” Drug Programs

Payers and PBMs use drug utilization management tools, such as prior authorization and step therapy, to encourage the use of lower-cost, often safer medications before progressing patients to higher-cost drugs. To evade these tools, drug companies use “free” drug programs to provide initial medication doses free of charge to patients before their insurance companies can approve the medication or determine that other medication options are more appropriate.

These programs, also known as Bridge and QuickStart Programs, entice insured patients to start specialty drug therapies at no cost out of pocket, regardless of their plan's formulary design. These programs give patients the illusion of lower prescription costs, but ultimately leave patients and payers responsible for the full cost of the drug once the program ends. These costs are ultimately borne by all plan enrollees.

Drug companies work directly with health care providers to enroll patients in these programs. As with copay coupon programs, drug companies require patients to submit confidential, personal information about their health status, disease state, previous medications, and insurance coverage. This information, otherwise difficult to obtain due to its sensitive nature, enables manufacturers to act as the patient's agent and appeal to have the drug covered by the formulary through the insurance companies on the patient's behalf.

"Free" drug programs are designed to circumvent payers' evidence-based and cost-effective specialty benefit designs. By starting patients on high-cost or specialty drugs, drug companies evade payer plan design by preventing patients from first trying less expensive and potentially more effective drug options, including generics or biosimilars. Once patients begin using these expensive drugs at no initial or low cost charge, drug companies capitalize on the opportunity to initiate prior authorization and drug coverage appeals processes with patients' insurance companies, which may be required by state law or federal regulations to approve coverage for patients stabilized on a drug.

Coupon Programs Enable Higher Drug Prices

New brand drugs introduced to the market routinely enter with higher prices than existing medications. Manufacturers of existing medications often react by increasing their own prices. This leads to higher prices across all existing drugs in the therapeutic class, even though no further clinical value is added.⁶⁰ Incremental drug price increases for existing products on the market have become a defining feature of drug company tactics.^{61, 62} Overall, list prices for brand-name medications sold in the U.S. climbed more than 14% in 2015, with no change in clinical efficacy for patients or in market demand.⁶³

In looking at nine brand name drugs with the highest sales revenue, the independent nonprofit research institute Institute for Clinical and Economic Review (ICER) found that "The total increase in spending in the US over two years due to price increases for the seven drugs found to have [clinically] unsupported price increases amounted to \$5.1 billion."⁶⁴ As a result, national drug expenditures continue to grow quickly due to these ongoing drug price increases.⁶⁵

Coupon and "free" drug programs enable drug companies to introduce high-cost drugs, sometimes with limited clinical support, to the market and gain coveted market share, while undermining step therapy and other utilization management programs designed to start patients on a lower cost, established drug and only move to more expensive medications when clinically necessary.

Revenue-Boosting Formulary Tiering Exceptions

Manufacturers also exploit requirements in Medicare Part D that allow beneficiaries to request a tier exception for a drug they are taking, based on need. Medicare has allowed beneficiaries needing a drug on a tier with higher cost-sharing to request an exception, and if the exception is granted, the plan must charge the beneficiary cost-sharing as if the drug had been placed on the lowest tier, which is typically reserved for generics. These exceptions, however, do not apply to drugs on a specialty tier.

Pharmaceutical manufacturers with very expensive drugs that Part D plans have placed in formulary tiers with higher cost-sharing can encourage and indeed help beneficiaries to request tier exceptions for lower cost-sharing, evading formulary incentives to use more cost-effective, clinically sound alternatives. The ability to challenge formulary placement, aided by manufacturer-sponsored hubs, is an ongoing concern for payers.



SOLUTIONS TO ADDRESS HIGH DRUG COSTS

During a time when drug companies are increasingly implementing coupons and “free” drug programs, payers face the challenge of providing valuable drug benefits that optimize clinical care while managing costs. Payers must especially manage the two to five% of patients who use specialty drugs since this minority of patients represents a growing, disproportionate share of overall drug and medical costs.⁶⁶

As PBMs develop clinical criteria to ensure the right drug and right dose for each patient, their clinical expertise allows them to create strategies that help physicians and patients select the optimal drug, ensuring that formularies are based on scientific evidence, not marketing tactics.

Several public policies and marketplace practices can help further address high drug costs. The key for policymakers is to avoid policies that impede effective market-based competition and tools PBMs and payers use to drive that competition.

Policy Solutions

Clarify pre-launch conversations. The FDA Modernization Act (FDAMA) of 1997, Section 114, created a regulatory safe harbor for drug companies to share health care economic information (HCEI) with a formulary committee or other similar entity. However, since the U.S. Food and Drug Administration (FDA) has never provided guidance on how to interpret or implement the statute, the distribution of HCEI is currently underutilized.

While pre-approval conversations are neither explicitly covered nor prohibited by existing legislation or regulations, the ongoing concerns about FDA’s interpretation have had a chilling effect on the industry and create a compelling need for clarification.⁶⁷

Guidance from the FDA will allow for improved communications between drug companies and payers about the real-world impacts and economic consequences of new drugs.⁶⁸ Once PBMs have access to information regarding anticipated drug indications and pricing, they can translate it earlier into recommending plan designs that will provide appropriate access and increase affordability for patients and payers.

Increase market competition. When limited competition is present in the market, drug companies can generally set and maintain high drug prices. By speeding the approval of more next-in-class brand drugs, generic drugs, and biosimilars, the FDA can facilitate competition, allowing PBMs to drive larger rebates and discounts that help offset higher drug spending trends.

Payers and PBMs are increasingly concerned about manufacturers astronomically increasing prices for off-patent drugs that are not subject to competition. After the enactment of the prescription drug user fee acts in 2017,⁶⁹ the FDA announced it would compile a list of all drugs for which market exclusivity has expired with no generic or other brand substitute products available on the market.⁷⁰ Maintaining this drug and concomitant indication indexing allows stakeholders to understand the depth of the problem better and identify which therapeutic areas are at risk for uncontested pricing models. Per the revised statute, the FDA also promotes competition for such drugs by providing an accelerated review of abbreviated new drug applications (ANDAs) for competing products, or providing other forms of regulatory flexibility to allow for more creative market solutions.

Comparative effectiveness and cost-effectiveness.

To best assess the efficacy and value that new medications provide, P&T committees need more comparative effectiveness studies. Currently, cost-effectiveness research is typically only conducted on a small scale by research organizations, payers, and government entities, and results are not always publicly accessible. Determining the true value of drugs requires rigorous, timely evidence that is applicable to large populations.

One area that would particularly benefit from this approach is specialty drugs. There is currently no uniform approach in the U.S. to measuring the value of or defining specialty drugs. An evidence base that standardizes the study of specialty drugs and clearly demonstrates the cost and effectiveness of treatment options for a variety of conditions would foster a health system that rewards providers and pharmaceutical companies for quality and value rather than purely cost and volume. Comparative effectiveness research will improve clinical decision-making, enhance the quality of care, and discourage wasteful spending.

PBMs have long been at the forefront of efforts to bring more measurement, accountability, and real-time information to the health care system. Efforts to reduce health costs without compromising clinical safety and quality have led to the development of

bundled payments, growth of accountable care models, evidence-based medicine, and payments linked to performance. These trends require PBMs and drug companies to rely on rigorous comparative effectiveness and cost-effectiveness research to create innovative approaches to measuring outcomes and assessing value.

Encourage value- and indication-based contracts.

Value-based contracts are designed to assess the performance of drugs in real-world situations, with the goal of obtaining better value, improved clinical outcomes, and lower costs. PBMs have led the industry in creating contracts that account for the value of specialty and high-cost medications. Discussions around certain government policies, such as Medicaid Best Price, are aimed at improving PBMs' ability to implement creative contracting options.

Payers prefer to provide patients with drugs that have proven outcomes and high-value propositions, so some companies are beginning to introduce products with outcome-based pricing measures instead of volume-based prices.⁷¹ One high-profile example of this has been the gene therapy drug Zolgensma. The drug manufacturer, Novartis, worked with payers to develop an outcomes-based payment over time framework, which was announced alongside the drug's FDA approval; however, the payments are still required even if the therapy fails.

Expand tools that allow plans in Medicare to negotiate price concessions on every brand drug.

Congress should reinforce price competition among brand drug manufacturers in Medicare by removing the mandate that "all or substantially all" drugs in Part D's six classes of clinical concern (the so-called protected classes) be covered. When drug companies are guaranteed drug coverage, they have no incentive to offer price concessions to payers. A recent independent study from Emory University published in the journal *Health Economics*, found that protected class status led to at least \$112–121 million per drug per year in higher U.S. sales for drugs in protected classes relative to unprotected drugs. The increased costs were driven by both higher prices and higher utilization.⁷² The author concluded that the "findings suggest that the protected class policy is quite

costly to the Medicare program and consumers. By mandating that all approved drugs be covered in these classes, the policy creates a wedge in the competitive negotiations between two parties.” MedPAC has also recommended withdrawing two classes — antidepressants and immunosuppressants — from protection. By statute, the Secretary of HHS has the discretion to designate a class as a so-called protected class, as well as to withdraw such designation. Absent congressional action, the Secretary should use this authority to remove protected class designations as appropriate or allow for the use of more PBM tools within the protected classes.

Reduce market exclusivity periods. Reducing the current period of exclusivity granted to innovator drugs can help stimulate more competition from biosimilars. Patients, employers, and taxpayers would save hundreds of billions in health spending if expensive biotech drugs faced the same generic competition as traditional brand-name drugs. The current 12 years of data exclusivity for biologics prohibits approval of 351(k) applications for biosimilars from being approved by the FDA for 12 years after the date of the first licensure of the reference product. This ensures market exclusivity for the manufacturer of the reference product for 12 years, although in practice, it is usually much longer especially with tactics used to push for longer exclusivity periods.⁷³ The result to payers and patients is that drug manufacturers of brand biologics often have monopoly pricing power.

Marketplace Solutions

Realign copay coupon use. If used with a commercial health plan’s approval as an adjunct to formulary and plan design, copay coupons can support adherence while not adding unnecessary costs to patients and the health care system. Coupons and other patient assistance programs can be used in line with tools such as formularies and clinical guidelines, to ensure clinically appropriate drug use and increase patient adherence.

Once coupons expire (generally after three months to a year, or a maximum dollar benefit), payers find it difficult to transition patients to lower-cost, clinically

equivalent medications, and patients are left to pay more out-of-pocket costs for the drug. This results in higher premiums or copays to compensate for the higher costs incurred by payers for specialty drugs, offering a coupon.⁷⁴

Since cost-sharing kickback schemes increase drug costs by undermining the formularies used by payers, they should be limited only to means-tested programs to help low-income and uninsured patients and to drugs without cost-effective alternatives.

Expand formulary exclusions. To counter manufacturer efforts to undermine formularies by subsidizing patient cost-sharing for expensive drugs typically covered on a higher cost-sharing tier, PBMs are beginning to exclude more drugs from their formularies. Exclusion lists contain drugs that offer no additional benefit over alternative treatments in the same therapeutic class; however, excluded drugs can still be covered through an appeals process. This can result in significant savings while still providing clinically appropriate access to drugs. For example, CVS Health found that patients whose plans used a selective formulary with restricted coverage of drugs saved almost \$35 on each prescription; the overall approach has saved clients \$6 billion since 2012.⁷⁵ In addition, Prime Therapeutics, in assessing the impact of moving from an open formulary to one with exclusions, found substantial pharmacy savings occurred with no associated increase in healthcare services utilization or drug therapy discontinuation.⁷⁶

Adjust cost-sharing tiers. As part of the formulary development process, payers place drugs into different patient cost-sharing tiers. Drugs in lower tiers will generally cost less or provide better value than clinically equivalent drugs in higher tiers.

Manufacturers sometimes encourage patients to override traditional utilization management rules without clinical reason by using coupons or “free” drug programs. In response, payers should be allowed to maintain incentives to use more appropriate, lower-cost drug options by preserving the cost-sharing differential between preferred and nonpreferred drugs when coupons for “non-preferred products” are used.

Support evidence-based value assessment models. Patients, providers, employers, payers, and taxpayers rightfully expect drug costs to correlate with the actual value being delivered. Without insight from organizations like the Institute for Clinical and Economic Review (ICER), it is not always possible to ensure that the value of new drugs is commensurate with the prices being charged.

ICER's mission is to help provide an independent source of analysis of the evidence on effectiveness and value to improve the quality of care that patients receive, while also supporting a broader dialogue on value in which all stakeholders can participate fully. Their aim is to provide what the health care system has long lacked: an independent, trustworthy source of information that involves the key stakeholders on value-focused discussions.⁷⁷

While manufacturers have funded organizations to discredit ICER's work and undermine its use as a resource for payers, it is critically important that both state and federal policymakers not join in efforts to keep payers from using ICER's and other group's value assessment models.

Empower patients. Patients play an important role in pharmacy decision-making and should be provided with information from payers and drug companies that help them make the best decisions for their health care. Health plans that leverage strategies such as real-time benefit tools and other forms of price transparency, educational programs, formulary management, and cost-sharing can drive patient engagement, maximize value, and lower costs.





CONCLUSION

Over the past decade, prescription drug expenditures have grown faster than any other healthcare category and represent an increasing percentage of per capita health spending. During the same period, drug companies have spent roughly one-third of their growing revenues on marketing, and only half as much on research and development.⁷⁸ Since drug prices bear little relationship to R&D costs and are set to maximize the drug company's profitability during drugs' period of patent protection, PBMs and payers should be given a stronger hand to leverage more competition among drug companies to prevent them from needlessly escalating launch and existing therapy prices. Otherwise, patients, employers, and other payers will continue to bear unnecessary costs.

Drug companies use copay assistance, "free" drugs, and similar programs to support high list prices. These programs are most often used when drugs are new to the market, do not have favorable outcomes studies, or do not provide proportionate value to other lower-cost alternatives on the market. Since these programs are time-limited, patients find it difficult to afford these high-cost medications once subsidies are stopped. Payers find it similarly difficult to transition patients to more clinically effective, higher value alternatives once these programs end. Together, these factors lead to significant concerns surrounding medication affordability and adherence, thus further affecting the health of patients and creating additional costs to the healthcare system.

PBMs have proven their ability to directly lower the nation's spending on prescription drugs while ensuring affordable access to clinically proven medications for patients.^{79, 80} Payers rely on PBMs to create strategies that encourage free-market competition, lower the high costs of drugs, and prevent wasteful spending in order not to overburden the health system. Policymakers should support policy and marketplace solutions that prevent drug companies from using tactics to evade payer formulary plan designs and add high costs to patients and payers across the healthcare system.

INTEGRATED CASE STUDY: COSENTYX®

In January 2015, the FDA approved Novartis' Cosentyx® (secukinumab) to treat adults with moderate-to-severe plaque psoriasis. One year later, Cosentyx® received approval for two new first-in-class indications, active ankylosing spondylitis, and active psoriatic arthritis.⁸¹ At the time of approval, there were already five injectable biologic drugs used to treat one or more of these three conditions on the market.

Cosentyx entered the market at a price higher than most of the existing therapeutic alternatives. To illustrate the differences in cost, a 30-day supply of the most commonly prescribed, patient-administered (e.g., self-injectable, non-infused) specialty medications used to treat plaque psoriasis, ankylosing spondylitis, and psoriatic arthritis are shown below using prices publicly available on GoodRx.com.

Pricing Comparison: Patient Administered Biologic Alternatives to Cosentyx®

Drug	Year Approved by FDA	Route of Administration	Manufacturer	Lowest Price for a 1-month supply ⁸²
Cimzia® (certolizumab pegol)	2013 ⁸³	Subcutaneous injection	UCB	\$3,762.21 (free coupon available)
Simponi® (golimumab)	2009	Syringe injection	Janssen	\$4,195.30 (free coupon available)
Humira® (adalimumab)	2005 ⁸⁴	Prefilled pens	Abbvie	\$4,538.81 (free coupon available)
Enbrel (etanercept)	2002 ⁸⁵	Sureclick injector	Amgen	\$4,539.59 (free coupon available)
Cosentyx® (secukinumab)	2015	Sensorready pens	Novartis	\$8,300.47 (free coupon available)
Stelara® (ustekinumab)	2009 ⁸⁶	Prefilled syringe	Janssen	\$9,727.26 (free coupon available)
Taltz® (ixekizumab)	2016	Autoinjector	Lilly	\$13,683.90 (free coupon available)

In response to Cosentyx's® introduction, payers established prior authorization and step therapy requirements to encourage patients to use more established treatments before progressing to this new, higher-cost medication. At the time, Aetna required patients to try at least two less costly biologic medications, including Enbrel®, Humira®, and Remicade® (which is infused, not self-administered), before starting Cosentyx®. Anthem implemented a prior authorization process that required patients

to have inadequate responses to two preferred biologic treatments in the previous six months. And, UnitedHealthCare created a step therapy program, requiring patients to use Stelara® and Humira® before advancing to Cosentyx®.⁸⁷

Novartis took a number of steps to increase utilization of Cosentyx®, including the creation of patient hubs, patient assistance programs, copay assistance and free drug programs, and a large

direct-to-consumer (DTC) campaign to encourage people living with psoriasis to ask their doctors about prescribing Cosentyx®.

Hubs

When Cosentyx® was launched, Novartis established the Cosentyx® Connect Personal Support Program hub.⁸⁸ The hub focused on helping patients and providers navigate payers' drug coverage and reimbursement support processes. In order to initiate the process, patients were required to approve the release of otherwise-protected personal health information to Novartis, including full contact information, insurance coverage details, disease state status, and prior treatment history. Once the process was initiated, the hub researched each patient's insurance benefits and prior authorization requirements and acted as the patient's agent to submit all necessary documentation and appeals forms.

Patient Assistance Programs

Through the Cosentyx® hub, Novartis provided assistance to patients experiencing financial hardship who had no third-party insurance coverage for their medicines. To qualify for this particular program, patients were required not to have prescription drug coverage (public or private) and had to meet income eligibility criteria.⁸⁹

Copay Assistance and Free Drug Programs

In comparison to the purely needs-based patient assistance programs, Novartis also established copay assistance and free drug programs to gain broader market share among patients who were

insured but had not been approved for coverage yet. Commercially insured patients who are awaiting coverage determination for Cosentyx® were given up to seven doses (about a 3-month supply⁹⁰) of the drug at no cost. Those whose insurance did not cover the drug had access to up to thirteen doses free (about an 8-month supply). Commercially insured patients who obtained insurance coverage for Cosentyx® could get up to \$16,000 worth of treatment with no cost-sharing.⁹¹

Direct-to-Consumer Advertising

Novartis invested significant resources into the drug's launch to achieve peak sales. Despite the drug's relatively small patient population, to fully drive uptake in the U.S., Novartis undertook a large DTC advertising campaign designed to target their patient base and further grow the brand.⁹² Spending \$83 million in 2015 alone on advertising Cosentyx,⁹³ Novartis tried to create demand among patients and providers, with a goal of pushing reluctant payers to cover the drug, even though most payers preferred patients first try more cost-effective, first-line treatments.⁹⁴

Thus, Novartis anticipated insurer and PBM utilization management and used programs like these to create patient demand and circumvent programs designed to ensure patients receive the most clinically- and cost-effective treatment and that payers are not subjected to unnecessary costs.

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About PCMA

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans who have health insurance from a variety of sponsors including: commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program (FEHBP), state government employee plans, managed Medicaid plans, and others.

PCMA continues to lead the effort in promoting PBMs and the proven tools they utilize, which are recognized by consumers, employers, policymakers, and others as key drivers in lowering prescription drug costs and increasing access.



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