Current and New Approaches to Making Drugs More Affordable

August 2018

CVS Health

Our responsibility to our clients is to help ensure plan members take appropriate, cost-effective medications that improve health outcomes and lower overall medical costs. If price reductions by pharmaceutical manufacturers can help bring down drug costs, then we are in favor of it. However, if only a few manufacturers make such reductions, it may only affect a few medications.

At CVS Health, we have undertaken comprehensive efforts to help reduce the cost of drugs. Our pharmacy benefit management (PBM) business, CVS Caremark, employs three primary PBM techniques:

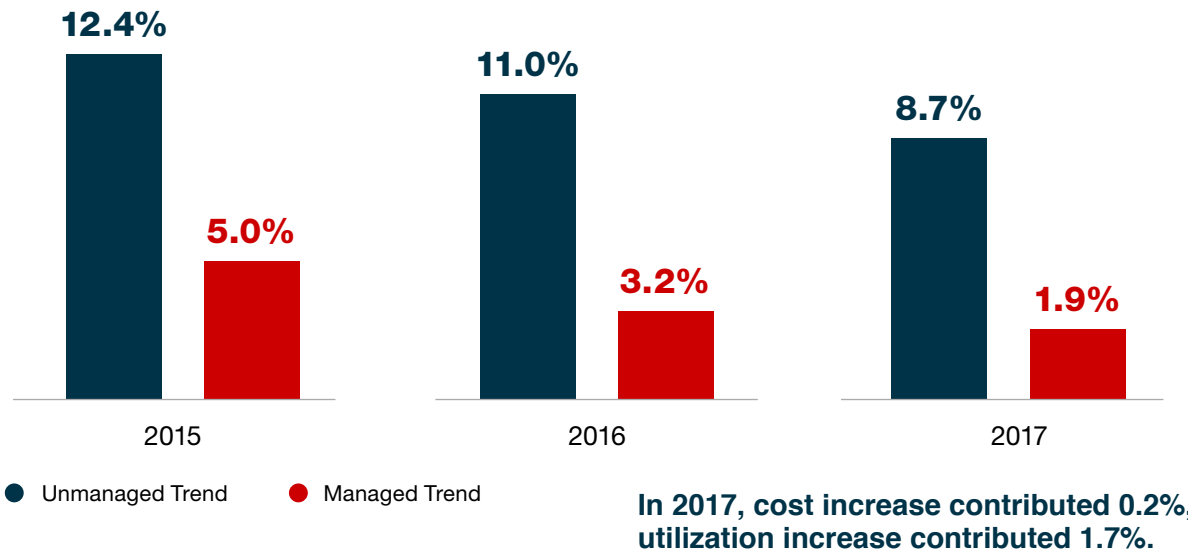
- **Encourage the use of lower-cost alternatives, such as generic medications through step therapy**
- **Use prior authorization to help ensure patients utilize appropriate medications according to evidence-based rules**
- **Obtain lower costs for drugs by using competition to determine formulary placement when more than one clinically equivalent drug is available**

However, more needs to be done and additional innovations are necessary to help bring escalating drug prices and costs under control. In this white paper we introduce some innovations that can further reduce costs and provide greater details on existing tools.

Bringing Cost Inflation Under Control

While it is often lost in the debate over who is responsible for high drug prices, CVS Caremark has been able to help improve adherence and keep drug cost inflation under control in spite of steady price increases by manufacturers. In 2017, drug price growth for PBM clients was only 0.2 percent, despite manufacturer price increases of nearly 10 percent.[1] Improvements in member adherence reduced overall health care costs for clients by $600 million. This clearly shows PBM tools are helping control costs while also promoting better health through greater adherence to medications.

PBM Strategies Kept Client Drug Costs in Check

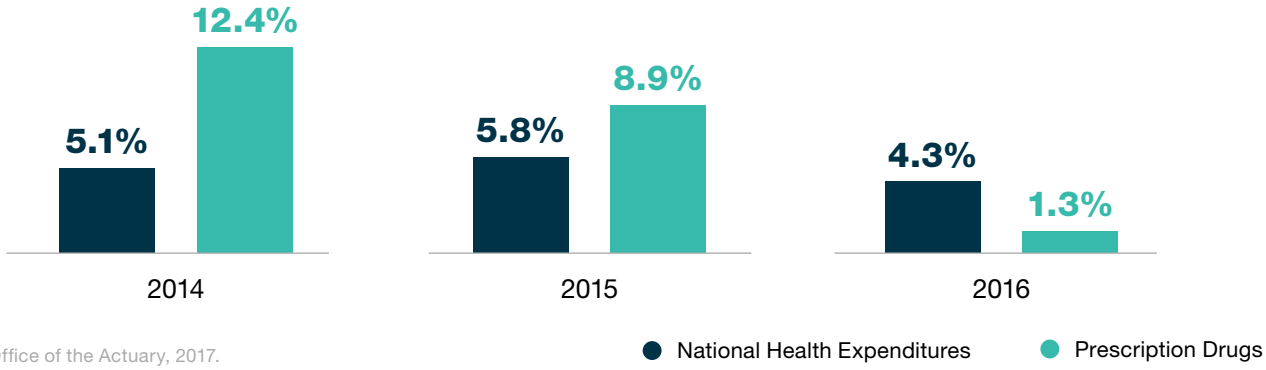


In 2017, cost increase contributed 0.2%, utilization increase contributed 1.7%.

Source: CVS Health Enterprise Analytics, 2018.

These results aren't unique to commercial clients. In fact, the Medicare Part D plans we serve have seen premium increases of less than 2.5 percent a year over the last five years. In 2016, drug prices for Medicare plans grew only 1.5 percent, according to data published by the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary.

Data from the Federal Government Also Shows Decelerating Inflation in Drug Costs



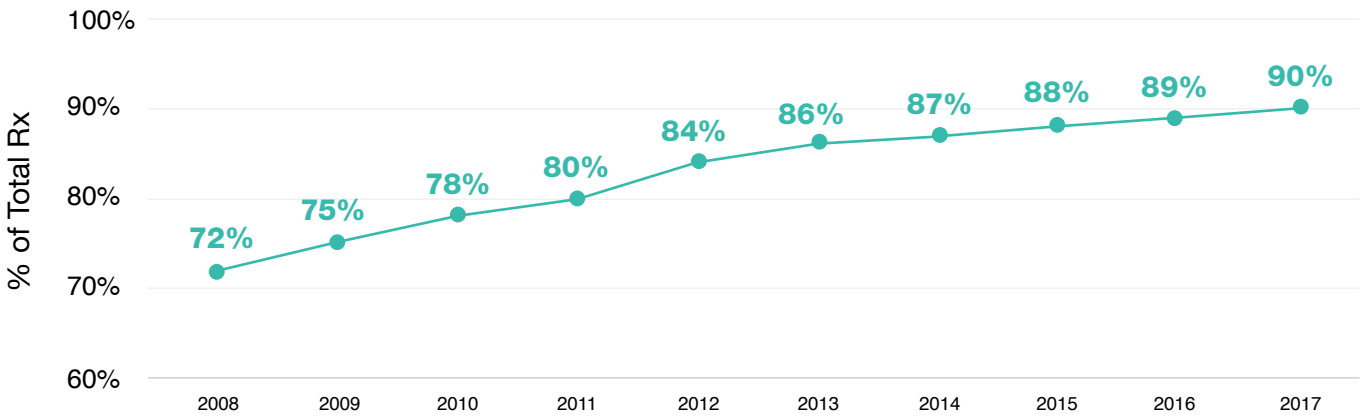
Source: CMS Office of the Actuary, 2017.

Three PBM Techniques for Managing Costs

As discussed, we use generics, prior authorization and step therapy, and formulary placement to help lower drug costs for payors. Let's look at each one more closely.

Technique One: Encouraging Greater Use of Generics

U.S. Generic Market Share as Percentage of Total Prescriptions



Source: IQVIA National Prescription Audit, Dec. 2017.

The U.S. has by far the highest use of generics in the world — nearly 90 percent — and most of this can be attributed to PBMs using step therapy. Step therapy requires that members utilize the most cost-effective, therapeutically equivalent alternatives — such as generics — first. Our research shows that use of generics actually improves outcomes and saves lives. Greater use of generics for cardiovascular disease reduced risk of hospitalization for stroke and unstable angina, and led to a 3 percent decrease in overall mortality, according to one study.[2]

U.S. generic use is nearly 90% — almost double that of the OECD

The Organisation for Economic Co-operation and Development is an intergovernmental economic organization with 37 member countries.

Generics Help Improve Adherence and Outcomes, Lower Costs

7%

improvement in downstream adherence

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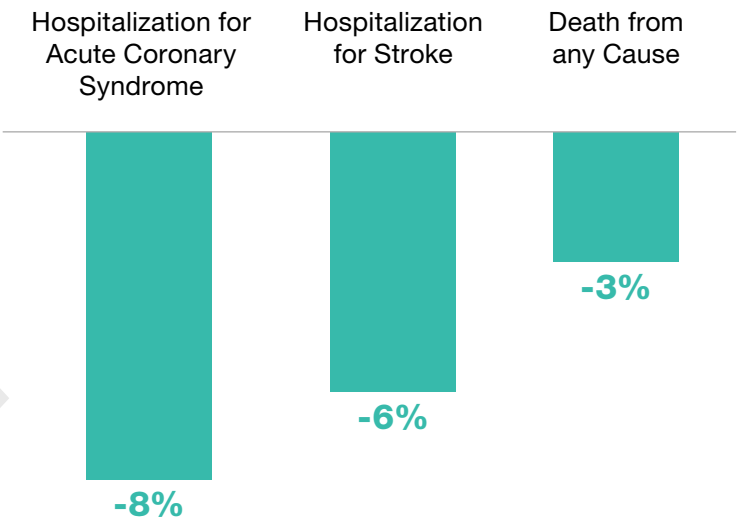
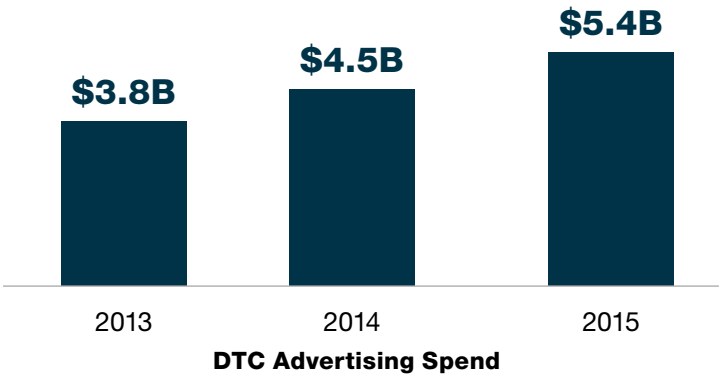
Lower rates of cardiovascular events and death



Source: Gagne et al., Annals of Internal Medicine, 2014.

Of course, this begs the question: If, as some assert, PBMs are only interested in higher prices, why do they push lower-cost generics? The answer — and simple truth — is that the PBM business model is built on getting the lowest cost for medications, encouraging the use of the lowest-cost alternatives, and helping members achieve optimal adherence to medications.

Manufacturers Use DTC Ads to Grow Sales for Expensive Branded Drugs



Source: Nielsen & Kantor DTC Spending Data, 2014-2015.

Drug manufacturers, on the contrary, fight the use of generics by promoting their drugs through physician detailing and direct-to-consumer (DTC) advertising to build brand loyalty and then raise drug prices. Use of DTC advertising for branded drugs has risen exponentially in the last several years, to nearly $5.5 billion. The poster child for this is the expensive brand drug Humira, whose list price doubled in the last six years. It's manufacturer, Abbvie, spent $429 million on promotion in 2017 alone.[3,4] The drug continues to be one of the best-selling drugs on the market.

Technique Two: Ensuring Appropriate Utilization Through Prior Authorization

Another way CVS Caremark helps reduce costs is through prior authorization requirements, which are simply a way of ensuring physicians are using the best evidence-based rules and prescribing the most cost-effective medications for patients. In 2017, the PBM reviewed 3 million prior authorization requests, saving payors more than $2.9 billion without reducing overall adherence. CVS Health has also made dramatic strides in reducing the administrative burden for providers by greatly broadening availability of electronic prior authorization.

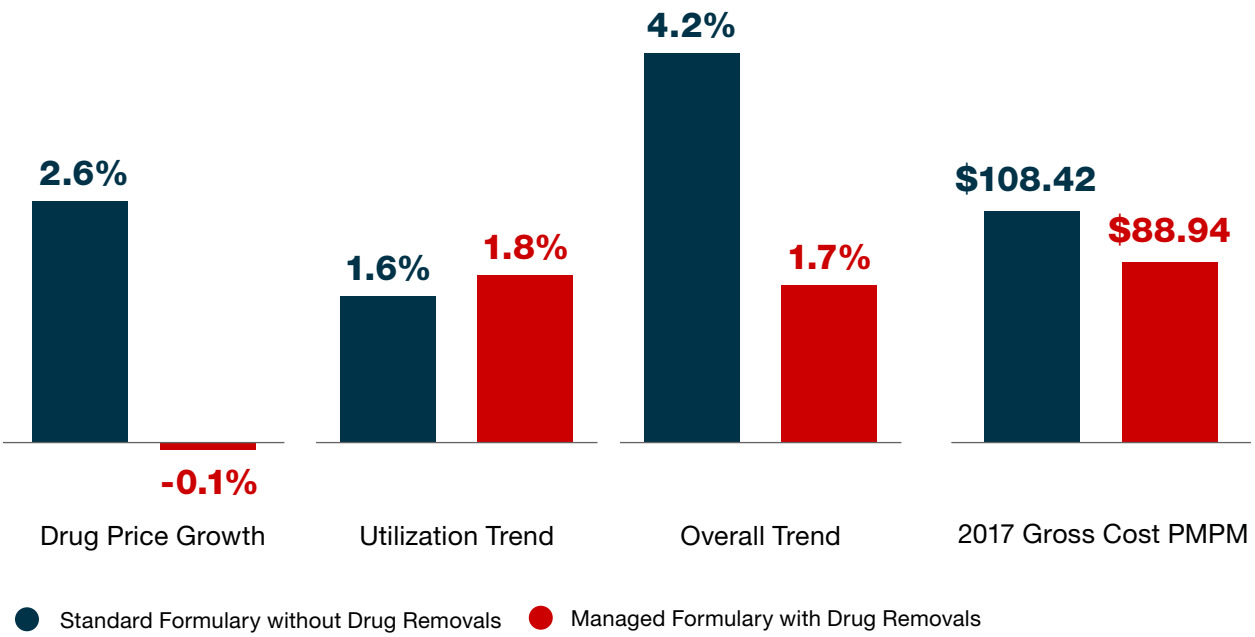
In 2017, CVS Caremark reviewed 3 million prior authorization requests, saving payors more than

$2.9B

Technique Three: Formulary Management

CVS Caremark develops formulary plan design strategies to obtain rebates and discounts from pharmaceutical manufacturers on behalf of payors, to help control costs. Most drug classes have multiple competing drugs, which clinical experts consider "clinically equivalent." When that is the case, the PBM adds the drug with the lowest net cost — that is, the manufacturer-set price minus the rebate or discount — and removes higher-cost clinically equivalent drugs within the same therapeutic class from the formulary. Drugs with lower manufacturer-set prices need smaller rebates to be competitive.

Managed Formularies with Drug Removals Helped Reduce Costs, Improve Adherence



Source: CVS Health Drug Trend Report 2017. Age-adjusted, post-rebate. CVS Health Managed Formularies: Include Standard with Opt-In to Drug Removals, Advanced Control Formulary, and Template Value Formulary.

The competition between the long-acting insulin Lantus and the new biosimilar Basaglar is a great example of this. Clinical trials have shown Lantus and Basaglar to be clinically equivalent. In 2017, Lantus was removed from our Standard Formulary in favor of Basaglar and other long-acting insulins. This resulted in 20,000 of 27,000 Lantus users across the CVS Caremark book of business moving to other more cost-effective therapies, many to Basaglar. Moving all users to Basaglar would lead to savings of more than $30 million per year.

Independently Reviewed

All of our formulary decisions are based on the best possible medical evidence, including guidelines from the leading medical specialty societies, and are reviewed by an external panel of experts, known as the Pharmacy and Therapeutics Committee. These experts are not CVS Health or CVS Caremark employees, and are also free of any financial relationship with pharmaceutical manufacturers. They approve every step therapy, every prior authorization requirement and every formulary change. Such use of an impartial, independent committee of experts by PBMs to approve business practices is unique within health care.

The Myth about Rebates and List Prices

Pharmaceutical manufacturers insist that increasing drug prices are a result of them having to pay rebates. This is simply not true. If that was the case, rebates and list prices should be highly correlated. To the contrary, our data show that in many cases list prices are increasing faster for drugs with smaller rebates than for medications with substantial rebates. Revlimid, manufactured by Celgene, is a good example. The price has tripled since 2005 to more than $18,000, yet there are almost no rebates. The simple truth is, drug manufacturers take advantage of the monopoly granted by patents whenever possible, and there is no correlation between rebates and price increases. Rebates are possible only when there are equivalent competitor medications in a class, and we can use formulary placement to drive lower costs.

There is no Correlation Between Manufacturer-Driven Price Increases and Drug Rebates

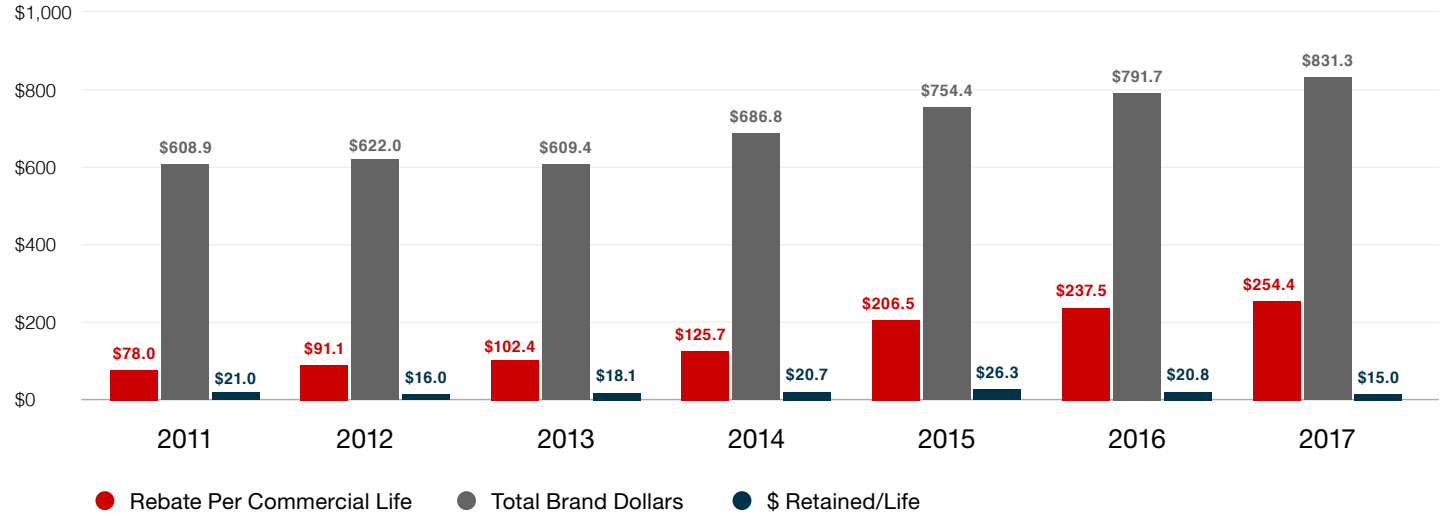
Drug Category	List Price Increase	Average Rebate
Anticonvulsants	46%	6%
Multiple Sclerosis	27%	7%
Rheumatoid Arthritis	50%	10%
Asthma/COPD	20%	25%
Overactive Bladder	39%	26%
DPP-4 Inhibitors (Diabetes)	28%	26%

COPD (Chronic obstructive pulmonary disease).

Source: CVS Health Enterprise Analytics, 2018. Cohort of commercial clients, Q2 2015-Q1 2018.

Pharmaceutical manufacturers also argue that PBMs retain the rebates they negotiate, and that higher drug prices mean more rebates and greater profits for PBMs. This is entirely false. Rebate retention also has no correlation to higher drug prices. Indeed, our data show that while branded drug spend per CVS Caremark member has increased from about $608 in 2011 to $831 in 2017, the average rebate retained by the PBM over that time is less than $20 per member. The rebates CVS Caremark obtains from manufacturers are returned to clients to lower their costs. Competition among PBMs means more and more rebates are going back to clients. This is a good thing, and it demonstrates that the market techniques used by PBMs are working.

Higher Drug Costs Have no Correlation to Retained Rebates



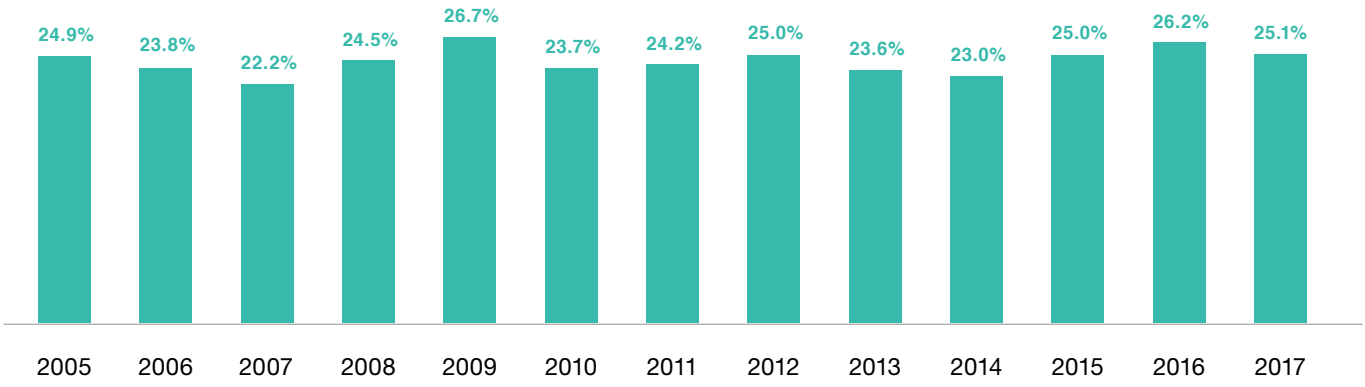
Includes commercial members in health plans, employers, Medicaid, and exchange plans.

We should be clear about what happens with rebates. CVS Caremark clients — employers and insurers — use rebates to lower the costs of providing insurance for their employees and members. For example, CVS Health, as an employer, spends $1.2 billion annually on health care benefits, of which, $250 million is for prescription drugs. As part of a standard contract, CVS Caremark returned $47 million in rebates to CVS Health. CVS Health, as an employer, requires that rebates earned should be used to help our members with their out-of-pocket (OOP) costs. CVS Caremark offers this program — known as point-of-sale (POS) rebates — to any client. The program enables the plan to apply rebates at the point of sale (the pharmacy counter) to lower the cost of the drug when a member is paying OOP or has coinsurance. Of the total rebates returned to CVS Health, $6.3 million in rebates were put toward lowering OOP costs for our members, helping improve adherence by 4 to 6 percent. The remaining rebates are used to reduce employees' cost share, and to reduce costs overall to CVS Health as the employer.

CVS Caremark retains rebates, with client approval, generally when the PBM goes "at risk" for a guaranteed level of rebates. When CVS Caremark produces deeper discounts for a client than was guaranteed, it may retain the portion above the guarantee. Some clients prefer this approach, to ensure predictable costs. However, most clients prefer total transparency and 100 percent rebate pass-through. CVS Caremark has an estimated rebate retention of approximately 2 percent thus far in 2018. By doing so, the PBM has kept drug price growth nearly flat.

However, not all PBMs and insurers are as capable, and the high prices that manufacturers charge do get paid. That's why the drug makers' playbook is to constantly raise list prices and why their margins have remained incredibly steady — and high. Only the constant increase in list prices can explain these margins, not new discovery — the new drug approvals over the last decade have averaged 32 annually, from a high of 46 in 2015 to a low of 19 in 2016.[5]

Annual Operating Margin for Top 15 Pharmaceutical Manufacturers



Source: www.macrotrends.net. Operating margins defined as operating profit divided by annual revenue in aggregate for 15 pharmaceutical manufacturers. Pharmaceutical manufacturers identified based on annual 2017 revenues.

Ongoing Innovation: Three New Strategies

The three essential PBM techniques to help reduce costs are working, as demonstrated by drug costs for clients remaining essentially flat. However, we are not standing still. CVS Caremark continues to develop and implement new initiatives to help ensure that patients can get the medications they need. We believe three recent PBM innovations will further lower the costs of medications:

- **Assistance for patients in the deductible phase of their insurance, during which they shoulder all the costs**
- **Addressing the launch price of new medications, something PBMs have not historically been able to mitigate**
- **A renewed emphasis on transparency so that members, their doctors and their pharmacists can understand the true cost of a prescribed medication**

1. Zero Out-of-Pocket Costs for Chronic Disease

For the entire cohort of CVS Caremark members, average annual OOP costs are dropping, and were down to $11.89 per-member-per-month in 2017. However, many standard insurer or employer plans increasingly use higher deductibles to reduce overall costs of providing insurance, which places more of the financial responsibility on members. Members with a chronic disease who are in high deductible health plans (HDHPs) can have large OOP payments — 2.5 percent of members have OOP costs of more than $1,000 annually. It is well known that if patients have high copayments, they are less likely to fill their prescription — referred to as prescription abandonment at the retail counter. This, of course, leads to higher overall costs for payors, because patients who do not take their medications have poor health outcomes.

Recognizing this, the federal government allowed HDHPs associated with health savings accounts (HSAs) under Internal Revenue Service (IRS) rules to create a preventive drug list, which enables plans to have zero-dollar copay for drugs that prevent disease. The definition of "preventable" is somewhat flexible — CVS Caremark encourages clients to cover all generic medications for chronic diseases as well as some key branded drugs, like insulin, under this category.

We recommend this wider "preventive" drug list for clients with any kind of HDHP, and believe that the government should broaden the definition of what is considered a preventive drug. Research we recently completed indicates that expanding preventive drug lists to the five most chronic diseases — diabetes, hypertension, hyperlipidemia, asthma/COPD, and depression — could substantially improve care and lower costs. Our analysis shows that if clients employ POS rebates and follow the CVS Caremark Standard Formulary, they can implement a zero-dollar drug list for these conditions, helping lower costs for their members while also saving money for the plan.

Adding a Zero-Copay Chronic Drug List Reduces Cost

Source: CVS Health Enterprise Analytics, 2018. Total projected health care cost savings from improved adherence per 100K commercially insured members.

Zero-dollar member OOP costs could be revolutionary for diabetes and cardiovascular care, and would certainly be welcomed by doctors and patient advocates. CVS Caremark can and does offer its zero-copay chronic drug list to employers and insurers with standard HDHPs not employing HSAs. We should note that using rebates at the point of sale is critical to this program, and we encourage PBM clients to apply POS rebates to help defray OOP costs for their employees. In summary, zero-dollar copays will lower costs for payors, and improve health for members. For IRS-regulated HDHPs with HSAs, moving to zero-dollar copays for members with a chronic disease would require changes to IRS rules to broaden the preventive drug list. However, that small change will have a profound effect on lowering costs for consumers in the deductible phase and improve health outcomes.

The rules governing HSAs should also be changed to give HDHPs the option to cover all prescription drugs — including generic and brand drugs — outside the deductible, so patients can access these drugs for little or no copay if that is how the plans want to structure their benefit.

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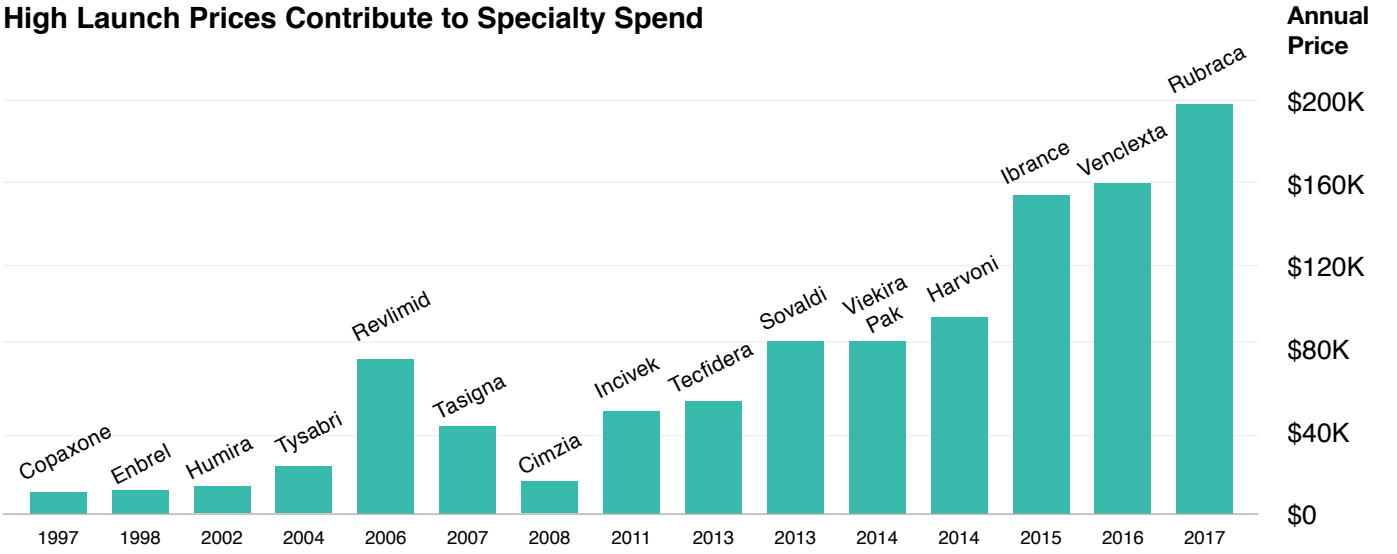
2. Reducing Launch Price Using Comparative Effectiveness

The second innovation to lower costs addresses the price at which a medication is launched — its initial price. Launch prices have been steadily rising for years, and are completely up to the discretion of the manufacturer. Quantitative methods, such as the concept of quality-adjusted life years (QALY), can help us compare the cost and effectiveness of medications. In Europe, most medications are priced initially to produce effectiveness rated at $50,000 per QALY.

The U.S. does not have any such programs. Launch prices continue to go up, into the hundreds of thousands of dollars each year, pushing costs per QALY into the $300,000-$500,000 range — costs the U.S. health care system simply cannot absorb.

High Launch Prices Contribute to Specialty Spend



~$178K **average annual price of the last three approved oral oncology drugs**

Sources: CVS Specialty analysis of Medispan data. Annual drug costs based on average wholesale price (AWP) accessed December 2017.
CVS Specialty Analytics. Drug launch cost based on wholesale acquisition cost (WAC) launch pricing accessed Spring 2018.

CVS Caremark is initiating a program that allows clients to exclude any drug launched at a price of greater than $100,000 per QALY from their plan. The QALY ratio is determined based on publicly available analyses from the Institute for Clinical and Economic Review (ICER), an organization skilled in the development of comparative effectiveness analyses. Medications deemed "breakthrough" therapies by the U.S. Food and Drug Administration will be excluded from this program, which will focus on expensive, "me-too" medications that are not cost effective, helping put pressure on manufacturers to reduce launch prices to a reasonable level.

We believe as more PBM clients adopt such programs, manufacturers will begin to moderate launch prices. No one but manufacturers have, until now, had any control over the launch price of newly patented drugs. This new approach, harnessing the power of the market, could change manufacturer behavior. CVS Caremark continues to use other PBM techniques to help lower costs for payors and their members, but lower launch prices could help bring about real deflation in drug prices.

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3. Transparency in Drug Costs

The third new strategy centers on greater transparency in drug pricing and costs. We are addressing this with a series of tools that can be used by doctors, pharmacists, and consumers to understand the real costs of drugs. The first step is to get doctors and other providers engaged in cost control at the time a prescription is written. Right now, the provider chooses a medication largely without visibility into the cost to the member.

To address this lack of visibility, we now provide real-time benefit information to doctors to help ensure they have up-to-the-minute, member-specific coverage and pricing information, as a prescription is being written. We enable prescribers to see:

- **The true cost of the drug**
- **The amount the member will have to pay**
- **A list of therapeutic alternatives and the cost of each alternative**

This is not information physicians are used to seeing, but preliminary data suggest if they have access to it, they are likely to take the right action to save patients money. For prescriptions written by physicians using real-time benefit information, when a lower-cost preferred alternative is presented, physicians are switching to the lower-cost alternative 40 percent of the time. In these cases, the member cost was $130 lower per fill compared to the original non-preferred drug selected.

The same information is also available to pharmacists at CVS Pharmacy locations through a tool called Rx Savings Finder, which enables them to quickly and seamlessly evaluate individual prescription savings opportunities and work with members and their doctors to get the lowest-cost medication prescribed. And the same information is also available to all PBM members through the Check Drug Cost Tool on the CVS Caremark app and member portal. When members use the Check Drug Cost tool to access real-time benefit information, they switch to a lower-cost alternative 20 percent of the time, saving $120 per fill. We firmly believe that transparent access to drug cost information is the best approach to reducing costs.

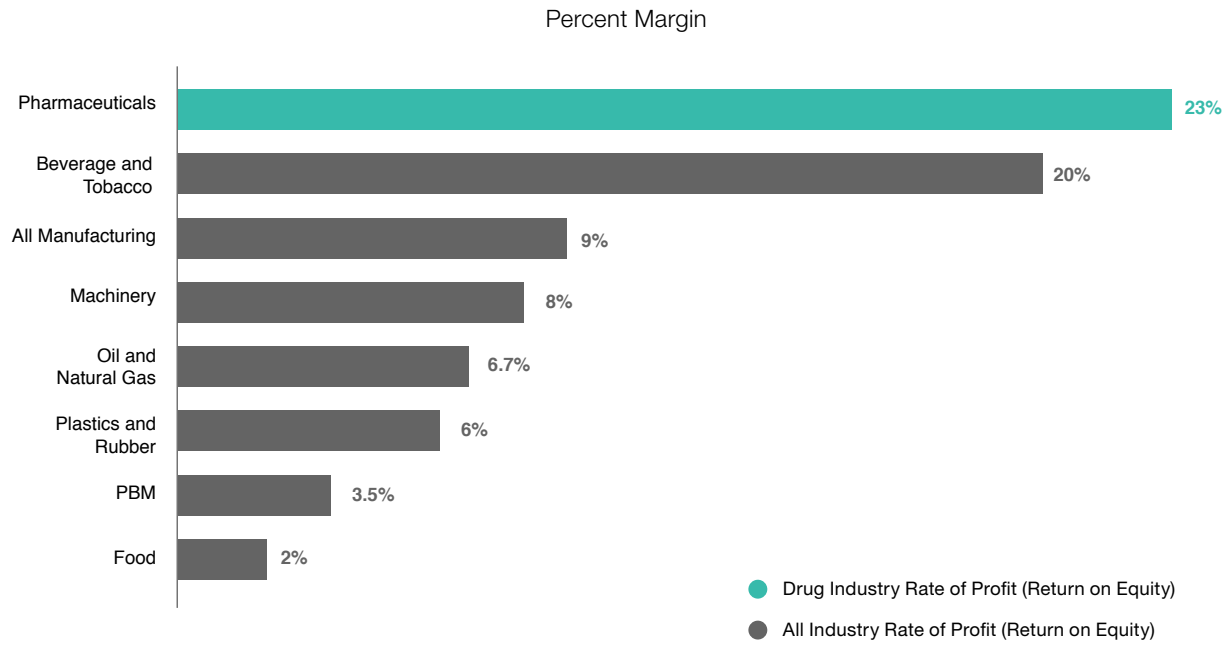
These three new strategies can help lower costs as a complement to traditional PBM tools.

Lowering Drug Prices to Improve Health

The most important thing CVS Caremark can do for PBM clients is to help ensure people take their medications — doing so improves overall health and lowers cost. But to accomplish this, medications must be affordable. The techniques we have used to this point are based on evaluating the comparative effectiveness of various medications based on clinical evidence and using market techniques to ensure the lowest possible cost. The proposed innovations build on that base of clinical evidence and health care economics to address two key aspects of the drug cost crisis: burdensome OOP payments and ever-higher drug launch prices.

These innovations will do two things: help patients afford the medications they need, and lower profit margins for pharmaceutical companies. However, lower profits should not impede discovery. Today, drug manufacturers spend more money on marketing than discovery. These marketing expenditures can be shifted, thereby refocusing the drug manufacturing industry on its primary goal — the discovery of new treatments for illness.

Pharmaceutical Manufacturers Can Afford to Lower Prices and Still Have Decent Margins



Source: U.S. Census Bureau, 2012; Public Citizen, 1999.

1. 2017 AWP trend pre-rebate was 9.2% for traditional brands, based on claims for our Commercial Cohort (employers and health plans). Calculated by CVS Health Enterprise Analytics, April 2018.
2. https://www.ncbi.nlm.nih.gov/pubmed/2522238.
3. Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher. NY Times, Jan 6, 2018. https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html.
4. https://www.mmm-online.com/commercial/dtc-pharma-ad-spending-slipped-46-in-2017-kantar/article/750421/.
5. https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.

Data Source: CVS Health internal data unless otherwise noted.

Adherence results may vary based upon a variety of factors such as plan design, demographics and programs adopted by the plan. Client-specific modeling available upon request.

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Savings will vary based upon a variety of factors including things such as plan design, demographics and programs implemented by the plan.

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