Benefits Toolkit:

Prescription Drug Benefits

Provided by ECG Insurance

ECG INSURANCE

Table of Contents

Introduction

As health care costs continue to rise, many employers struggle to provide their employees with health coverage at an affordable price. Prescription drug benefits are a highly utilized component of health coverage and a significant cost driver for employers. Prescription drug coverage is typically administered by a pharmacy benefit manager (PBM) and includes generic drugs, brand-name drugs and specialty drugs, such as biologics and biosimilar drugs.

A report from Segal, a benefits and HR consulting firm, found that the projected cost trend for prescription drug benefits for 2023 is almost 10%, which exceeds all other health benefit cost trend estimates for the year. This cost increase is attributable to a variety of factors, including price inflation for prescription drugs, the introduction of costly new drug therapies and the increased use of specialty biologic drugs. It can be difficult for an employer to understand the specific factors driving its prescription drug costs due to a lack of transparency in the prescription drug market.

To address rising prescription drug prices, plan designs for prescription drug benefits have become increasingly complex. Most prescription drug benefits have multiple tiers of coverage with different cost-sharing requirements (deductibles, coinsurance and copayments) at each level. Health plans also commonly use medical management techniques to help control costs, such as prior authorization, step therapy and mandatory generic substitution.

Employers seeking to lower their prescription drug spending should start off by educating their employees on how to maximize their benefits and lower their out-of-pocket drug costs. By explaining the importance of using generic drugs when they are available, comparison shopping for the best price and finding manufacturers' coupons, employers can encourage employees to become better health care consumers.

This Benefits Toolkit serves as a guide to prescription drug benefits. It outlines common plan designs for these benefits, including the use of formularies and coverage tiers. It also summarizes different strategies employers can use to control their prescription drug costs.

Prescription Drug Benefits

Prescription drug benefits are an essential component of employers' health plan coverage. According to a Kaiser Family Foundation (KFF) survey from 2022, nearly all covered employees (98%) work for employers that offer prescription drug coverage as part of their largest health plan.

Prescription drug benefits are also one of the most utilized and costly elements of an employer's health plan. Another KFF survey from 2022 found that 6 in 10 adults (62%) take at least one prescription drug, and 25% take four or more prescription medications.

Rising Cost of Prescription Drug Benefits

A recent survey from the Business Group on Health found that virtually all large employers are concerned about rising prescription drug costs and that prescription drugs account for 21% of employers' health care costs, with over 50% of those costs attributable to specialty drugs.

Regardless of whether a health plan's prescription drug benefits are fully insured or self-funded, they can be a source of confusion and frustration for both employers and employees. A lack of transparency in the pharmaceutical industry makes it difficult to understand how prescription drug benefits drive up costs for a specific health plan.

To help control rising costs and steer employees toward the most cost-effective drug options, the design of prescription drug benefits has become increasingly complex, often utilizing multiple cost-sharing tiers and various medical management techniques.

It is important for employers to understand how their prescription drug benefits work to make informed decisions and help employees understand their coverage. After all, when employees understand their coverage options, it can help lower costs, lead to better health outcomes and improve satisfaction with the employer's benefits package.

Pharmacy Benefit Manager

For most health plans, the PBM is the **central figure in the design and administration of the plan's prescription drug benefits.** Fully insured health plans usually come with their own PBMs selected by the issuer. Self-funded employers typically use the PBM selected by their third-party administrator (TPA). However, in some situations, employers may carve out their prescription drug coverage and contract with their own PBM.

PBMs typically perform the following key functions:

- Develop and maintain the prescription drug formulary, including coverage tiers and related cost-sharing requirements
- Create and maintain pharmacy networks
- Negotiate discounts and rebates with drug manufacturers

- Process and pay prescription drug claims
- Administer drug utilization programs, such as prior authorization and step-therapy programs
- Provide customer service support and educational resources to covered employees.

PBMs shape employees' access to medications by determining what drugs will be covered by the plan and how much employees will be required to pay in out-of-pocket costs. They can also reduce plan costs by negotiating with drug manufacturers and pharmacies, implementing utilization programs and encouraging employees to consider cost-effective drug options.

The PBM market is highly concentrated, with three PBMs (CVS Caremark, Express Scripts and OptumRx) controlling approximately 80% of the market share.

PBMs make a profit by charging fees for their services. They can also make money by retaining rebates received from drug manufacturers. In general, a rebate is a payment made by a drug manufacturer to a PBM for an expensive drug, such as a brand-name or specialty drug. Rebates are used to increase market share for a particular drug by encouraging PBMs to give it a prominent placement on their drug formularies.

There is a lot of debate surrounding the lack of transparency over drug manufacturer rebates, whether PBMs should be allowed to keep any portion of the rebates and the overall impact of rebates on prescription drug costs. In some situations, the availability of rebates may give PBMs an incentive to favor higher-priced drugs over more cost-effective ones. Another controversial way that PBMs make money is through spread pricing, which occurs when PBMs keep the difference between actual pharmacy charges and the higher negotiated payments from health plans.

Prescription Drug Formulary

A formulary is a comprehensive list of prescription drugs covered by a specific health plan. **A health plan's formulary is the cornerstone of its prescription drug coverage.** The formulary typically includes both brand-name and generic drugs that have been approved by the U.S. Federal Drug Administration (FDA) and are expected to meet the medical needs of most patients while offering the greatest overall value.

A drug formulary can be open or closed, although closed formularies are commonly used because they provide more control over a health plan's prescription drug spending.

- **Open formulary**—Generally, all FDA-approved drugs are covered with an open formulary. It may have some specific drug exclusions, but all therapeutic classes are covered by the formulary. Drugs may fall under tiers of coverage, requiring different cost sharing from plan participants, but no classes are completely excluded from coverage.
- **Closed formulary**—With a closed formulary, only prescription drugs that are on the formulary list are covered. Drugs that are not on the formulary are not paid for (or reimbursed) by the health plan. Drugs may be excluded from coverage for various reasons, such as if the drug has a generic

version, is considered less effective than similar drugs, or is as effective as similar drugs but costs significantly more. Health plans with closed formularies generally use an exception process to provide coverage for non-formulary medications in certain situations, such as medical necessity.

Drug formularies are typically created and maintained by a committee of health care professionals set up by the PBM. This committee reviews medications based on certain standards—including efficacy, safety and cost—and decides which prescription drugs to include on the formulary. The committee regularly updates the formulary to add or remove drugs based on the latest medical guidance and FDA approvals.

Prescription Drug Tiers

Most health plans use a tiered design for their prescription drug coverage. Under this approach, prescription drugs in the plan's formulary are assigned to a tier based on their cost-effectiveness. This approach can help control prescription drug spending and encourage covered individuals to use lower-cost medications whenever possible. According to a KFF survey from 2022, 84% of covered workers are in a health plan with at least three tiers of cost sharing for prescription drugs.

Health plans typically have three to five tiers of coverage, each with a different level of cost sharing (that is, deductible, copayment or coinsurance) for drugs within that tier. The amount of cost sharing increases for each tier, with drugs in the lowest tiers having the least amount of cost sharing and drugs in the higher tiers having the most cost sharing. Also, cost sharing and coverage may vary based on whether the provider is in-network or out-of-network.

Note that not all prescription drugs on a plan's formulary are subject to cost sharing. Prescription drugs considered preventive care under the Affordable Care Act (ACA) must be covered without cost sharing when provided by in-network health care providers. Examples of these drugs include immunizations, contraceptives, certain supplements, tobacco cessation products, bowel preparation (colonoscopy) and breast cancer primary prevention.

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Drug formularies and coverage tiers vary from plan to plan. The following are examples of different prescription drug coverage tiers:

Example: Three-tier Plan

	Type of Drug	Cost Sharing
Tier One	Generic drugs	$20 copayment
Tier Two	Brand-name drugs (including preferred and nonpreferred brand-name drugs)	$40 copayment
Tier Three	Highest-cost drugs	$80 copayment

Example: Four-tier Plan

	Type of Drug	Cost Sharing
Tier One	Lower-price generic drugs	$15 copayment
Tier Two	Higher-price generic drugs and lower-price brand-name drugs	$25 copayment
Tier Three	Higher-price brand-name drugs (or nonpreferred brand-name drugs that may have an available generic version)	$50 copayment
Tier Four	Highest-cost drugs, including specialty drugs	20% coinsurance

Example: Five-tier Plan

	Type of Drug	Cost Sharing (In-network)
Tier One	Lower-price generic drugs	$15 copayment
Tier Two	Higher-price generic drugs	$20 copayment
Tier Three	Lower-price brand-name drugs	$40 copayment
Tier Four	Higher-price brand-name drugs and some specialty drugs	10% coinsurance
Tier Five	Highest-cost drugs, mostly specialty drugs	25% coinsurance

Types of Drugs

To understand how prescription drug benefits work, it is important to become familiar with different categories of prescription drugs.

Generic Drugs	Generic drugs are those that are no longer covered by patent protection and may be produced and sold by multiple drug companies. Generics have the same active ingredients, strength, dosage form and route of administration as their brand-name counterparts. Because their development costs are less, generic drugs are often priced substantially lower (according to the FDA, 80%-85% less) than brand-name drugs.
Brand-name Drugs	These are drugs that are marketed and sold under a specific name and protected by a patent. Brand-name drugs are typically more expensive than their generic versions. Common brand-name medications include Lipitor, Zofran, Singulair and Zocor.
Specialty Drugs	These are drugs (often biologics) that may require special handling or ongoing medical monitoring and may be administered through injection or infusion. Specialty drugs are usually the most expensive drugs on a formulary. They are typically used to treat chronic conditions such as blood disorders, cancer or arthritis.
Biologic Drugs	Biologics are high-cost drugs that are made in a living system, such as microorganisms, plant cells or animal cells. They are usually administered via injection or infusion and used to treat cancer or other complex conditions.
Biosimilar Drugs	Biosimilar drugs are a lower-priced alternative to biologic drugs. A biosimilar drug is very similar to, but not exactly the same as a biologic drug. Due to the lack of meaningful differences between the drugs, biosimilars are considered as safe and effective as their biologic versions.
Preferred Drugs	These are drugs included on a formulary's preferred drug list due to their cost-effectiveness (for example, a brand-name drug without a generic substitute).
Non-preferred Drugs	These are drugs not included on a formulary's preferred drug list because they are not more cost-effective than other available drugs (for example, a brand-name drug with a generic substitute).

Medical Management Programs

In addition to drug formularies and coverage tiers, health plans often have medical management programs in place to help control costs and ensure the safe and effective utilization of prescription drugs. These programs may include:

Prior authorization—Health plans may require certain drug therapies to be approved by the health plan's PBM before they are covered.

Step therapy—This type of enhanced prior authorization requires individuals to start drug therapy for a medical condition with the safest, most cost-effective drug available before progressing to newer or more costly therapies.

Quantity limits—Health plans generally impose limits on how often an individual can get a refill of a specific drug and how much of the drug can be dispensed at one time (such as a 30-day supply).

Generic substitution—Health plans may require generic substitutions where pharmacists replace brand-name prescribed drugs with generic equivalents. If individuals insist on the brand-name drug, they may be charged the price difference between the brand-name drug and the generic equivalent, plus any applicable cost-sharing for the brand-name drug.

Maintenance drug benefit—Health plans may offer a 90-day maintenance drug benefit through a mail-order pharmacy or an in-network retail pharmacy for better pricing discounts. This benefit can save money while allowing individuals to receive a 90-day supply (versus a 30-day supply) of their maintenance medications.

Employer Considerations

Prescription drug coverage is a highly valued benefit for employees. However, as a well-utilized benefit, such coverage comes with a significant price tag. Numerous factors contribute to the high cost of prescription drug coverage, many of which are not within an employer's ability to control. However, there are some strategies employers can implement to help deliver cost-effective prescription drug coverage for their employees.

Evaluate Plan Design

To help mitigate the financial burden of rising prescription drug costs, employers should evaluate the plan design of their prescription drug benefits each year and consider making any appropriate changes. This process will be different for each employer, depending on plan setup and employee population, but may include the following:

- Formulary management—Employers can ask if there are different formulary options available for their plans and consider whether a more limited formulary could save money without negatively impacting patient care.
- Use of biosimilars—With specialty drugs making up a significant portion of prescription drug spending, biosimilars can be discussed with issuers, TPAs or PBMs (as applicable). The use of biosimilars can also be encouraged on the plan's formulary.
- Strategic cost sharing—Employers should keep cost sharing low for generic drugs to encourage patients to use these lower-priced drugs when they are available. Employers can also consider using coinsurance (instead of a fixed copayment) for higher-priced drugs to more easily keep up with medical inflation.
- Medical management programs—Employers should consider implementing the following medical management techniques:
    - Requiring prior authorization for specific prescriptions or categories of drugs to direct patients to more cost-effective options
    - Using a step therapy program so patients must try lower-priced drugs, mainly generics, before moving to more costly alternatives
    - Placing quantity limits on prescriptions, especially within specific time frames, to help avoid unnecessary costs
    - Requiring substitution of brand-name drugs for generic equivalents, where available and appropriate
    - Implementing a 90-day maintenance drug benefit through a mail-order pharmacy or in-network retail pharmacy for better drug discounts

Select the Right PBM

Most employers do not have a direct relationship with the PBM for their health plan's prescription drug benefit. Typically, an employer's health insurance issuer or TPA selects a PBM for the health plan and controls the relationship with this service provider. However, some employers may carve out their

prescription drug coverage and choose their own PBM. This can give an employer more control over their prescription drug coverage and provide them with the opportunity to demand more price transparency.

However, due to the complexity of prescription drug benefits and lack of market transparency, selecting the right PBM can be a difficult process for employers and should involve consideration of a wide range of factors. Key topics to cover during this process include:

- Formulary development and management
- Benefit design and coverage tiers, including the cost-sharing requirements at each tier
- The PBM's network of pharmacies and distribution of specialty drugs
- Medical management programs, such as step therapy, quantity limits and prior authorization
- Administrative fees and other sources of revenue, including the PBM's use of drug rebates
- Reporting capabilities
- Claims processing and payment systems
- Employee support, education and communications

Help Employees Become Better Consumers

To help reduce prescription drug spending, employers should take steps to educate employees about their prescription drug coverage and the best ways to reduce their out-of-pocket spending. Prescription drug costs can be a source of stress for many employees, so they may appreciate an employer's efforts to help them understand their options and save money. When employees choose the most cost-effective drug option, it can lower their out-of-pocket costs and also reduce the employer's prescription drug spending.

Prescription drug coverage has become increasingly complex over the years. Employers should explain their health plan's prescription drug benefit to employees, including the different types of drugs (for example, brand-name versus generic) and the plan's coverage tiers. As part of this process, employers can provide examples of expensive prescriptions and how employees can save money.

The prescription drug market is also more diverse than ever. In addition to their regular network pharmacies, employees should consider large retail stores, mobile apps and manufacturer's coupons to get the best savings on their prescriptions.

Encourage Employees to Use Generic Drugs

Generic medications save the U.S. health care system $3 billion every week and more than $150 billion annually., according to the FDA. Boosting the use of generic medications can potentially save money for employers and employees. To maximize generic use, keep employees up to date on the newest approved generic medications through this FDA resource or by utilizing the FDA's Orange Book, which allows employers to search for generic drugs

Employers should also consider providing practical tips such as the following to help employees lower their out-of-pocket prescription drug spending:

Ask if there is a **generic version available** when a doctor prescribes a brand-name drug.

Ask about the **availability of a biosimilar option** for employees using biologic drugs.

Do not assume that a neighborhood in-network pharmacy offers the lowest price on a medication. **Some large retail stores and grocery store chains offer discounts** on popular medications to drive traffic to their stores. Employees should shop around to get the best price for their medications.

Utilize a prescription drug mobile app or website to **compare prices and discounts**. GoodRx is an example of this type of service. These companies identify prices and discounts for specific medications at local or mail-order pharmacies to help individuals comparison shop and make the best buying decisions.

Search for manufacturer coupons before filling a prescription. Prescription drug manufacturers often offer **discounts and coupons for their drugs**. To find these coupons, search the internet, use a mobile app or contact the drug manufacturer.

Ask for a **90-day supply of maintenance drugs**, which can generate better discounts and reduce an individual's cost sharing.

Prioritize Preventive Care and Wellness

Another way for employers to reduce health care spending, including expenditures on prescription drug benefits, is to prioritize preventive care and wellness. According to the Centers for Disease Control and Prevention, chronic diseases are the leading drivers of the nation's $4.1 trillion in annual health care costs, with 6 in 10 adults in the U.S. having a chronic disease and 4 in 10 adults having two or more. Chronic diseases include, for example, heart disease, cancer, diabetes, chronic lung disease, stroke and chronic kidney disease.

Interventions to prevent and manage chronic diseases can have significant health and economic benefits. Preventive care helps detect or prevent diseases and medical problems before they become more serious. Preventive care benefits can help keep employees healthy and, in turn, help organizations save on prescription drug costs.

Under the ACA, most employer-sponsored health plans are required to cover certain recommended preventive services without any cost sharing when they are administered by in-network health care

providers. These services include, for example, regular checkups, cancer screenings, cholesterol screenings, diabetes screenings, vaccines and immunizations.

Employers should encourage employees to utilize their preventive care benefits to help control health care spending on chronic conditions. Making employees aware of preventive care is the first step. Employees should be educated on the free preventive care services the health plan offers, their potential risk factors and the benefits of preventive medicine.

After educating employees on their preventive care benefits, employers should take steps to increase access to preventive care opportunities. Employers should actively encourage employees to use their preventive care benefits and consider the following ways to encourage employees to receive preventive care and make it as easy as possible:

- Review benefits to ensure that telehealth options are available.
- Consider bringing preventive services on-site (for example, flu shot clinics and mobile vans for vaccinations and screenings).
- Provide paid time off (PTO) or flex hours for employees to receive preventive care.
- Offer other incentives (for example, gift cards or additional PTO) for receiving preventive care.

In addition, employers can implement wellness programs to encourage healthy lifestyle choices. A wellness program can help employees with high-risk factors make lifestyle changes to improve their quality of life and reduce their health care costs while helping employees with fewer risk factors stay healthy.

Keep in mind that offering wellness programs and incentives linked to health care may require an employer to satisfy certain federal requirements for voluntary and nondiscriminatory wellness programs. To avoid compliance problems, employers should consult with experienced legal counsel before offering these programs or incentives.

Appendix

This appendix features valuable information about prescription drug benefits, including infographics and FDA resources. Speak with ECG Insurance if you have any questions about these resources.

Printing Help

There are many printable resources in this appendix. Please follow the instructions below if you need help printing individual pages.

1. Choose the "Print" option from the "File" menu.
2. Under the "Settings" option, click on the arrow next to "Print All Pages" to access the drop-down menu. Select "Custom Print" and enter the page number range you would like to print or enter the page number range you would like to print in the "Pages" box.
3. Click "Print." For more information, please visit the Microsoft Word printing support page.

Helping Employees Control Prescription Drug Spending

To help reduce prescription drug spending, employers should take steps to educate employees about their prescription drug coverage and the best ways to reduce their out-of-pocket spending. Prescription drug costs can be a source of stress for many employees, so they may appreciate an employer's efforts to help them understand their options and save money. When employees choose the most cost-effective drug option, it can lower their out-of-pocket costs and also reduce the employer's prescription drug spending.

Employers should also consider providing employees with these practical tips to become better health care consumers and lower prescription drug costs:

Ask if there is a generic version available when a doctor prescribes a brand-name drug.

Ask about the availability of a biosimilar option for employees using biologic drugs.

Shop around for the best price. Do not assume that a neighborhood in-network pharmacy offers the lowest price on a medication. Some large retail stores and grocery store chains offer discounts on popular medications to drive traffic to their stores.

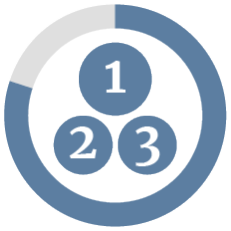
Utilize a prescription drug mobile app or website to compare prices and discounts. GoodRx is an example of this type of service. These companies identify prices and discounts for specific medications at local or mail-order pharmacies to help individuals comparison shop and make the best buying decisions.

Search for manufacturer coupons before filling a prescription. Prescription drug manufacturers often offer discounts and coupons for their drugs. To find these coupons, search the internet, use a mobile app or contact the drug manufacturer.

Ask for a 90-day supply of maintenance drugs, which can generate better discounts and reduce an individual's cost sharing.

Contact us for more information about curbing prescription drug costs.

Tips for Selecting the Right PBM



- CVS Caremark
- Express Scripts
- OptumRX

The pharmacy benefit manager (PBM) market is highly concentrated, with three companies controlling approximately 80% of the market share.

For most health plans, the PBM is the central figure in the design and administration of the plan's prescription drug benefits.

Fully insured health plans usually come with their own PBMs selected by the issuer. Self-funded employers typically use the PBM selected by their third-party administrator. However, in some situations, employers may carve out their prescription drug coverage and contract with their own PBM.

Understanding the PBM Role

PBMs typically perform the following key functions:

- **Develop and maintain the prescription drug formulary**
- **Create and maintain pharmacy networks**
- **Process and pay prescription drug claim**
- **Negotiate discounts and rebates with drug manufacturers**
- **Administer drug utilization programs, such as prior authorization**
- **Provide customer service support and educational resources to covered employees**

Selecting the Right PBM

Due to the complexity of prescription drug benefits and lack of market transparency, selecting the right PBM can be a difficult process for employers and should involve consideration of a wide range of factors, including:

- Formulary development and management
- Benefit design and coverage tiers, including the cost-sharing requirements at each tier
- The PBM's network of pharmacies and distribution of specialty drugs
- Medical management programs, such as step therapy, quantity limits and prior authorization
- Administrative fees and other sources of revenue, including the PBM's use of drug rebates
- Reporting capabilities
- Claims processing and payment systems
- Employee support, education and communications.

Contact us for more information about PBMs and health plans.

The Impact of Rising Prescription Drug Costs

Global spending on prescription drugs will reach nearly **$1.8 trillion** by 2026—and the United States alone will spend up to **$715 billion**, according to the IQVIA Institute for Human Data Science.

Furthermore, the global medicine market is expected to grow at a **3%-6%** compound annual growth rate through 2026.

As prescription drug costs continue to increase, it's important to understand the trends behind them and how to manage your organization's health care expenses better.

Why Are Prescription Drug Prices on the Rise?

Skyrocketing specialty drug costs have significantly contributed to the price of prescription drugs overall. Additionally, as the patient population expands and people age into chronic, complex diseases, increased utilization has contributed to rising costs. Other factors include:

Growth in the production of specialty drugs as the pipeline advances and expands to meet complex market needs

Failure to follow physician orders, which leads to more costly medical problems down the road

A 2023 survey from the Business Group on Health found that prescription drugs were a significant driver of health care costs in recent years. Consider the additional key takeaways:

Prescription drugs accounted for **21%** of employers' health care costs.

56% of pharmacy costs were spent on specialty medications.

Consider these six strategies to mitigate the financial burden of rising prescription drugs costs:

1. Manage usage with drug formularies.
2. Demand price transparency instead of using rebates.
3. Create prescription drug purchasing pools.
4. Support chronic disease management programs.
5. Encourage employee preventive care.
6. Foster employee health literacy to make wiser choices.

Contact us today to learn how to manage your rising prescription drug costs.

10 WAYS TO REDUCE YOUR PRESCRIPTION DRUG COSTS

The average American spends about $1,300 each year on prescription drugs. Prescription drug prices in the United States rank among the highest globally. It's no surprise that drug prices vary, so it can pay to shop around. Cutting costs on prescription drugs is easier than you may think. Consider the following strategies to help lower your bills for pills:

Go generic. If a generic drug isn't available, ask your doctor or pharmacist if there's a similar drug with a generic version.

Compare prices. Instead of running a prescription through insurance, use an app to compare and find the least expensive option.

Order a 90-day supply. Once you know a prescription works well for you, ask if there's a way to get a 90-day supply instead of a 30-day supply.

Sign up for a rewards program. Major drugstores will offer rewards programs that let you accumulate points when you fill prescriptions or use other pharmacy services, eventually resulting in coupons or other discounts.

Use a preferred pharmacy. Find a pharmacy in your network so you can secure a lower copayment and save on costs.

Call your insurance company. Every drug plan has a formulary, which refers to a list of covered drugs. If your prescribed drugs are not covered, ask if there's an alternative available.

Check for rebates. Browse manufacturer websites for coupons and rebates.

Shop around. Small and independent pharmacies tend to be less expensive than large chain alternatives.

Pay with cash. Pharmacists can tell you if you'll save money by not using your insurance and paying with cash instead.

Split pills. Tablet-splitting isn't safe for all medications, so ask your doctor if your prescription is available in a higher dose that's OK to split.

If you have prescription drug questions, talk to your pharmacist. Before paying, ask whether there's a better price available. They may know of some additional cost-cutting tips and can provide guidance.

U.S. FOOD & DRUG ADMINISTRATION

Generic Drug Facts

Generic medicines are the same high quality as their brand-name versions.

Generic drugs go through a rigorous review process to receive FDA approval. The FDA ensures a generic medication provides the same clinical benefit and is as safe and effective as the brand-name medicine that it duplicates.

Generic and brand-name medicines have the same:

- ✓ Active Ingredients
- ✓ Effectiveness
- ✓ Quality
- ✓ Safety
- ✓ Strength
- ✓ Benefits

But they can look different.

Allowable differences in size, shape, and color do not impact how medications work. Generic medicines may look different than the brand-name drugs they duplicate, but they are as safe and effective.

And they can cost a lot less money

Generic medicines tend to cost less than their brand-name counterparts because they do not have to repeat animal and clinical (human) studies that were required of the brand-name medicines to demonstrate safety and effectiveness.

When multiple generic companies market the same product, market competition typically results in prices about 85% less than the brand-name.

Learn more about generic drugs. Visit **www.FDA.gov/GenericDrugs**.

FACTS ABOUT GENERIC DRUGS

Today, nearly **8 in 10** prescriptions filled in the U.S. are for generic drugs.

SAME QUALITY &

PERFORMANCE

- FDA requires generic drugs to have the **same active ingredient**, **strength**, **dosage form**, and **route of administration** as the brand-name drug.
- The generic manufacturer **must prove its drug is the same** (bioequivalent) as the brand-name drug.
- All manufacturing, packaging, and testing sites **must pass the same quality standards** as those of brand-name drugs.
- Many generic drugs are made in the same manufacturing plants as the brand-name drugs.

ALL FDA-APPROVED GENERIC DRUGS
MUST BE EQUIVALENT TO THE BRAND-NAME DRUG.

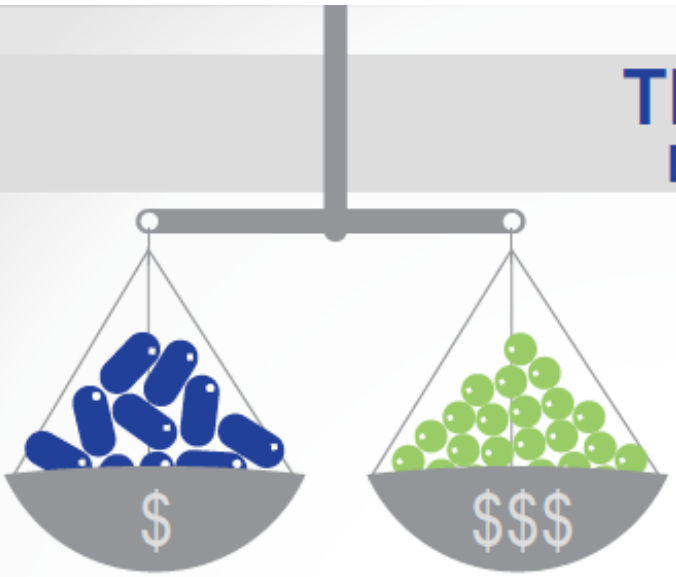
Any generic drug modeled after a single, brand name drug must perform approximately the same in the body as the brand name drug. There will always be a slight, but not medically important, level of natural variability just as there is for one batch of brand name drug compared to the next batch of brand name product.

This amount of difference would be expected and acceptable, whether for one batch of brand name drug tested against another batch of the same brand, or for a generic tested against a brand name drug.

80-85% LESS
Average cost of a generic drug vs. its brand-name counterpart

In 2010 alone, the use of FDA-approved generics saved **$158 billion.**

THE LOWER PRICE DOESN'T MEAN INFERIOR.



Generic manufacturers are able to sell their products for lower prices because they are not required to repeat the costly clinical trials of new drugs and generally do not pay for costly advertising, marketing, and promotion In addition, multiple generic companies apply to FDA to approve a generic for the same brand name drugs. Multiple generic companies are often approved to market a single product. Competition in the market place, often results in lower prices.

FDA MONITORS ADVERSE EVENTS REPORTS FOR GENERIC DRUGS.

The monitoring of adverse events for all drug products, including generic drugs, is one aspect of the overall FDA effort to evaluate the safety of drugs after approval. Many times, reports of adverse events describe a known reaction to the active drug ingredient.

Reports are monitored and investigated, when appropriate. Investigations may lead to changes in how a product is used or manufactured.

FDA IS ACTIVELY ENGAGED IN MAKING GENERIC DRUGS SAFER.

FDA is aware that there are reports that some people may experience an undesired effect when switching from a brand name drug to a generic formulation or from one generic drug to another generic drug. FDA wants to understand what may cause problems with certain formulations if, in fact, they are linked to specific generic products.

FDA is encouraging the generic industry to investigate whether, and under what circumstances, such problems occur. The Agency does not have the resources to perform independent clinical studies and lacks the regulatory authority to require industry to conduct such studies. FDA will continue to investigate these reports to ensure that it has all the facts about these treatment failures and will make recommendations to healthcare professionals and the public if the need arises.

[1]Davit et al. Comparing generic and innovator drugs:
a review of 12 years of bioequivalence data from the United States Food and Drug Administration.
Ann Pharmacother. 2009;43(10):1583-97.