

Generic Drugs: Your Prescription for Savings



When it comes to generic prescription drugs, the U.S. Food and Drug Administration (FDA) requires all generic drugs to have the same quality and performance as the brand name equivalents. When a new generic drug product is approved, it has already met all of the standards established by the FDA. The only difference is the cost of the medication to the consumer.

More than half of the prescription drugs available today have a generic option for consumers.

Quality, safety and effectiveness

The FDA requires generic drugs to have the same quality and performance as brand name drugs. The only physical differences in the generic compared to the original brand are that the drug may be a different color or shape, and may have different dye or fillers.

Generic drug manufacturers must submit an abbreviated new drug application (ANDA) for approval to market the generic product. Before the FDA approves new generic drugs, the drugs are put through a rigorous, multi-step approval process that covers everything from quality and performance to manufacturing and labeling. To gain approval a generic drug must:

- Contain the same active ingredients as the brand name drug
- Be identical in strength, dosage form, and route of administration
- Have the same use of indications
- Be bioequivalent
- Meet the same batch requirements for identity, strength, purity, and quality
- Be manufactured under the same strict standards of the FDA's good manufacturing practice regulations required for brand name products

As for safety concerns, the monitoring of post-market 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.

Big price difference

How can there be that big of a difference in price between generic drugs and their brand name counterparts?

There are reasons behind the cost savings. Like any new product being developed, brand name drugs are created under patent protection. While it's in effect, the patent gives the drug manufacturer sole right to sell the drug. When the patent expires, other manufacturers then have the opportunity to apply to the FDA to sell generic versions.

Manufacturers of generic drugs don't have to repeat the costly clinical trials of new drugs, and generics aren't usually the drugs seen in advertising and promotions, which drives up the price of the brand name. Also, if multiple generic companies are approved to market a single product, competition between them often results in lower prices for consumers.

“Is there a generic for that?”

Most prescription drug plans, including the medical trusts administered by Christian Brothers Services, have a lower co-payment for generic medications because the cost of generic medications is considerably less expensive than brand name medications.

Be sure to review all of your medications with your doctor or pharmacist regularly and ask them to check for a generic substitute when you need a prescription.

Mandatory Generics

In the past, EBT Plans had a “soft” mandatory generic provision, which required the member initially to fill a generic medication. However, a member could request the brand name, even when the physician indicated it was acceptable to dispense the generic if the member paid the brand copay and the difference between the cost of the brand name and the cost of the generic. Members paid this unless the physician specifically stated to dispense the brand name with no generic substitution. In that case, no penalty was incurred.

Beginning Jan. 1, 2020, all EBT Plans will be Mandatory Generic regardless of how the physician writes the prescription. We will implement an appeal protocol through Express Scripts exempting the medication from penalty and allowing the brand name for those who cannot take a generic due to other inactive ingredients that may cause a reaction.