

The following information regarding generic medications is provided to you by Pharmacy Benefit Dimensions

Generic Drug Information

There are many generic medications currently available that can help prevent or lessen the risks for disease and chronic conditions such as heart disease, high cholesterol, hypertension and diabetes. These drugs are safe and effective alternatives to brand-name drugs. In fact, they're identical to their brand-name counterparts in terms of active ingredients, dosage and quality.

Generics do differ in one big way however: cost. They typically are less expensive than brand-name drugs and the savings can be significant. According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies. Due to the lower cost of generics, most are available on formularies at the lowest or Tier 1 copayment.

Why are generic drugs less expensive?

Brand-name medications are generally awarded patent protection for 20 years from the time they are discovered. By the time they are ready to be marketed and are approved by the Food and Drug Administration (FDA), they often have 10 or more years of patent protection left. This protection, which is used to help offset the high costs of research and development, provides the brand manufacturer exclusive rights to develop and market the new product without competition from other companies. When the patent expires, other drug companies can introduce competitive generic versions, but only after they have been thoroughly tested and approved by the FDA.

Generic medications have to meet the same rigid manufacturing and quality standards as the branded medication to gain FDA approval. The basic requirements for approval of generic and brand-name drugs are the same. In approving a generic drug, the generic manufacturer is required to show that a generic delivers the same amount of its active ingredient in the same amount of time as the original branded medication.

Generic manufacturers usually do not have to complete the expensive clinical trial process to prove that the active medication is effective. Instead, they are allowed to refer to the branded medication's clinical trial data which was built during the 20-year patent protection.

Following approval, both the generic and brand-name manufacturers must submit data to the FDA showing that their products continue to meet quality standards for as long as the medication is available to patients.

If you have any questions about generic medications, please speak to your doctor or pharmacist. You can also visit the FDA website at www.fda.gov/cder for more information.