What are medication switches?

Medication switches are most often thought of as changing a brand-name product to a generic drug. Switching also can mean the changing of one brand-name product for another, or the switching of a generic medication to the same drug produced by another generic manufacturer. These can be initiated by your physician or pharmacy.

Switches are done to reduce the overall cost of prescription medications. The main beneficiary may be your health plan, which for most people age 65 or older is the federally funded Medicare program. Many younger people are covered by Medicaid, which is jointly funded by the states and federal government and managed by the states. Medication switches also benefit those who have to pay part of their medication costs through a co-payment. The savings only apply to plans which have a lower co-payment for generic medications than for brand-name medications. Consumers without insurance who must pay out of pocket for their medications also benefit.

There are two types of switches: generic substitution and therapeutic substitution.

**What is generic substitution?**

Generic substitution refers to the switching of a brand-name product to a generic product with the same active ingredients. The opportunity for cost savings emerges when expensive brand-name medications lose their patent protection and several generic medications are introduced on the market. The appearance of several manufacturers of the same generic leads a healthy price competition. Within months, the use of the expensive brand-name medication typically drops and the use of its generic counterparts increases markedly. The cost of 100 tablets of the brand-name cholesterol-lowering statin drug simvastatin (Zocor) in the 20 milligram strength is advertised as $449.97 on the Web site of a large chain pharmacy. The same Web site lists the price of generic simvastatin in the same strength and amount for $82.19, a difference of $367.78. In the U.S., price reductions of 50 percent to 80 percent are common (see Chapter 17).

Most states currently permit or require pharmacists to offer generic equivalents to consumers who present prescriptions for brand-name drugs and require consumers to give consent or be informed of generic substitutions.
What is therapeutic substitution?
With therapeutic substitution, a medication previously determined to be therapeutically equivalent to a second drug, even though it is not chemically identical to the prescribed drug, is automatically dispensed by the pharmacist without contacting the prescriber for authorization. This is an accepted practice in hospitals, and most, if not all, hospitalized patients have experienced therapeutic substitution. A committee of physicians and pharmacists, usually called the Pharmacy and Therapeutics Committee, determines therapeutic equivalence and what medications can be substituted.

Therapeutic substitution is not a state- or federally regulated activity. Government health plans may require therapeutic substitution, and private sector health plans offer economic inducements for what amounts to therapeutic substitution. In private sector plans, the preferred drug in a family of drugs may be based only on the lowest-contracted price, rather than an evaluation of comparative safety and effectiveness by physicians and pharmacists. This is accomplished by offering consumers lower co-payments for preferred drugs.

What is the experience with medication switches?
Generic substitution, in particular, has been a very contentious issue over the years and it is primarily driven by economics. Brand-name drug manufacturers can lose hundreds of millions of dollars in sales when a generic equivalent of one of their products is approved for sale. Manufacturers have responded by trying to cast doubt on the safety of generic drugs.

In the mid-1990s, the pharmaceutical industry failed to convince the FDA to change the generic drug approval standard to favor protection for brand name products. The industry responded by creating a patient group that advocated making generic substitution more difficult for drugs with small differences in therapeutic and toxic doses, so-called narrow therapeutic index drugs. This advocacy group went from state to state attempting to have generic substitution laws changed.

More recently, industry-supported patient advocacy groups are conducting similar campaigns to make the generic substitution for epilepsy drugs more difficult. By the end of the decade, five top-selling anti-epilepsy drugs will lose their patent protection. These five drugs accounted for almost $6 billion in sales in 2007.

There are no well-documented therapeutic differences, including safety differences, between brand-name medications and FDA-approved generic products. Some differences in efficacy and safety may exist for long-acting formulations (see Chapter 8) as well as a few specific medications for which even small differences in blood concentrations may have significant therapeutic implications.
The advantage of medication switches is the substantial cost savings for patients and their health plans, including government plans. In some cases, switches can increase the quality of care while reducing costs. The disadvantages are that patients are given medications with different names, and packages with different tablet colors or shapes. This can be confusing to some patients and, in worst-case scenarios, influence treatment adherence (see Chapter 41).

**Where can I find information on whether an FDA-approved generic equivalent is available for a brand-name drug?**

Your pharmacist is a good source for this information. The FDA also operates a Web page called Drugs@FDA (www.accessdata.fda.gov/scripts/cder/drugsatfda/), a catalog of FDA-approved medications which provides information about FDA-approved therapeutic equivalents for brand-name drugs.

**Key messages**

- Medication switches are done to reduce the high cost of prescription drugs.
- Generic substitution means that patients prescribed an expensive brand-name medication are given a less-expensive generic equivalent in the pharmacy.
- Therapeutic substitution means switches within a drug class; a brand-name medication may be replaced by a less expensive brand-name or generic product.
- The cost savings are substantial, especially for health plans.