Workers' Comp

Ask the Pharmacist: Generic Equivalent

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Are there times when it's better to dispense a brand drug instead of its generic equivalent?

Before answering that it would be good to briefly review some basic information regarding the differences between brand name and generic medications.

The Food and Drug Administration (FDA) is responsible for the approval of drugs in the U.S. In the case of a new drug, the process usually begins with "Discovery". The drug will then typically proceed into a "Preclinical Research" phase where animal testing is applied. The drug manufacturer can then apply for an "Investigational New Drug" (IND) application. If approved, the IND would allow the drug manufacturer to proceed to "Clinical Studies". All the while, the drug manufacturer is gathering data about safety (side effects, tolerance in specific patient populations, etc.) and efficacy. Once the manufacturer has enough information, a "New Drug Application" (NDA) will be filed, and if the drug is approved, it can be produced and made available for use in the U.S.

When a new drug is produced the drug manufacturers typically give it a brand name, and the FDA grants a period of exclusivity during which time the drug maker has exclusive marketing rights to that drug. Once exclusivity expires for a particular drug, generic manufacturers may begin making their versions of the brand name drug.

The generic manufacturer submits an "Abbreviated New Drug Application" (ANDA), which in essence allows them to request approval of the drug without having to include the Preclinical and Clinical Study data that the original manufacturer must supply. Instead, the generic manufacturer must prove to the FDA that the generic drug is comparable to the brand name drug in quality, purity, strength, dosage form, route of administration, efficacy, and intended use (aka, bioequivalent). That being said, the generic form will always have some differences as they cannot be exact copies of the brand, but these differences are not considered medically important in a bioequivalent drug. This abbreviated approval process allows the generic manufacturer to provide the drug at a significantly lower cost than the brand name counterpart.

To address brand usage, Pharmacy Benefit Managers (PBMs) require medications be dispensed at the pharmacy as generics where possible and when substitution is not restricted by the prescriber or market conditions. To address missed generic opportunities, outreach programs and detailed reporting can also notify the claims examiner if a brand drug with a generic available was dispensed. While 9 out of 10 prescriptions in the U.S. are filled as a generic drug, there can be reasons a pharmacist or doctor chooses to dispense a brand over its generic equivalent, ranging from clinical to financial.

The most common clinical scenario for use of brands over generics is for a group of drugs called “Narrow Therapeutic Index” drugs. The medications in this classification include anticonvulsants, which are used for treatment of seizure disorder but not pain, and blood thinners like Coumadin®. These medications are monitored via blood tests where a small change in blood concentration can affect the management of the disease. For example, if a patient is stable on a 5mg dose of Coumadin, switching to a generic warfarin may cause a small fluctuation in blood concentration and result in lower effectiveness and an increase in clotting.

Another possible scenario where a brand might be substituted for a generic, although rare, is in the instance of a drug shortage. For example, if there are limited generics available of a specific drug or there is a recall or interruption in the supply chain, the pharmacist may choose to substitute the brand in order to fill the prescription with an available medication. An even less common scenario could involve a patient being allergic to an inactive ingredient in the generic product, as the generic may contain different ingredients including additives, coloring, etc.

To find out more about brand and generic medications, visit the Food and Drug Administration (FDA) Generic Drug Facts website.

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