Workers' Comp

A Deeper Look at Utilizing Generic Drugs in Workers' Comp

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According to JAMA, the Journal of the American Medical Association, during a ten-year period branded pharmaceutical products in the U.S. increased 159% by list price and 60% by net price. In a continued effort to combat rising drug costs workers' comp pharmacy benefit managers (PBMs) look to substitute equivalent generic drugs for these more costly brand versions whenever possible.

While generic substitution makes good sense it's not necessarily straight forward, and generics are not always immune to similar pricing challenges facing brand drugs. For example, market competition in the generic space that would tend to reduce costs over time is being inhibited by alleged anti-competitive behavior among generic manufacturers which is designed to reduce competition and drive-up generic drug prices.

While PBMs are doing a good job of mandating lower cost generic medications, adhering to state chosen drug lists, and developing their own formularies based on criteria that include lower-cost generic medications, new drugs continue to enter the market with manufacturers doing what they can to maintain their brand status for as long as possible.

When manufacturers develop new drugs with satisfactory results from preclinical research, the first step taken is typically to file an Investigational New Drug (IND) application with the Food and Drug Administration (FDA) to set the formal review process in motion in order to eventually secure exclusivity, often concurrently with applying for a patent with the U.S. Patent and Trademark Office that grants property rights for 20 years from the date of filing. If the IND is approved, manufacturers are able to continue along the drug development pathway and undertake clinical trials to prove safety and efficacy. Once completed, a New Drug Application is filed with the FDA, and upon review and approval, the manufacturer is permitted to produce and sell the drug with market exclusivity as a brand medication for a specified period. During this time, no other company can sell the generic version.

While this exclusivity period is designed to allow the manufacturer to rightfully recover the costs of research and development, its timeframe can vary widely depending on numerous situations including time remaining on the original 20-year patent, additional time allotted by the FDA based on certain criteria, and whether the manufacturer challenges the FDA's decision.

In addition, there are other ways to extend the market exclusivity of a drug. For example, OxyContin, which is branded oxycodone ER, has been around since the late 1990s, but it still doesn't have a true generic equivalent. OxyContin changed its formulation to be abuse deterrent in 2010, and in doing so, the oxycodone ER generic was no longer equivalent. Given this, OxyContin remains without a true authorized generic to this day. A formulation change like this is one popular example of how manufacturers can extend their market exclusivity.

With brand medications in mind, we're keeping an eye on the migraine therapeutic class at present. There is a new category of migraine medications entering the workers' comp space and according to our recent drug trends report these brand only migraine medications are driving this treatment category into the top ten therapeutic classes by spend for the first time. These drugs have an average wholesale price ranging between around $1,000 to a little north of $1,700 per script. With the average market exclusivity period being more than 12 years and additional opportunities for manufacturers to extend this exclusivity, it could be quite a while before a lower cost migraine generic for these therapies comes to market. While their script volume is relatively low, the presence of these prescriptions in the trends should raise a red flag, from a spend perspective, if they continue to increase in volume with no direct generic alternative.

While 9 out of 10 prescriptions are filled as a generic through PBM efforts, it's important to also consider that there can be valid reasons a pharmacist or doctor would choose 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.

Another possible scenario where a brand might be substituted for a generic, although rare, is in the instance of a drug shortage. 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.

Work comp PBMs continue to focus on gaining traction with available generic utilization and in our recent drug trends a slight increase was observed last year from 88.5% to 89.0%. To continuously promote generic substitution, PBMs require medications to be dispensed as generic where possible and when substitution is not restricted by the prescriber or market conditions. They also address missed generic opportunities through detailed reporting to inform claims examiners when brand drugs with a generic are available. PBMs also require point-of-sale prescriptions without dispense as written (DAW) codes with substitution availability to be dispensed as a generic at the pharmacy when possible, to further provide savings.

Physician education also plays an important role for generic education with the aim of assisting prescribers in understanding alternative therapeutic choices while maintaining optimal pharmaceutical outcomes for the injured employee. In addition, when considering lower cost therapeutic alternatives PBMs also see value in generic-to-generic conversions when addressing high-cost generics often tied to price opportunist outliers.

As you can see generic substitution can be more complex than you might think. It's the goal of the PBM to help decipher many types of scenarios for the claims examiner and to provide assistance in uncovering the appropriate medication based on each patient and to explain the reasoning behind the medications prescribed. Talk to your PBM if you have questions about generics and why they are or are not being prescribed.

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References:

https://jamanetwork.com/journals/jama/fullarticle/2762310

https://www.commonwealthfund.org/publications/journal-article/2017/sep/determinants-market-exclusivity-prescription-drugs-united#:~:text=The%20time%20remaining%20on%20a,for%20a%2020%2Dyear%20patent

https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity



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