Workers' Comp

The Difference Between Specialty Drugs, Biologics, and Biosimilars

October 14, 2018
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In the world of workers' comp pharmacy benefit management, understanding generics vs. brand name drugs, narcotics, muscle relaxants, and compounds now seems relatively simple as compared with the latest pharmacy terminology: specialty drugs, biologics, and biosimilars. These terms are making the headlines with increased frequency, and while some think they are interchangeable, there truly are distinctions between them.

Specialty Medications Specialty drugs are generally defined as high-cost medications that require a more complex method of administration, han¬dling, and storage. Most of these drugs are administered by way of injection and infusion or through oral intake and inhalation. They also require enhanced patient monitoring and ongoing therapy, which can translate into higher costs. Today, most specialty drugs treat complicated diseases, such as cancer, which are not often seen in workers' compensation. However, specialty drugs are being prescribed with increasing frequency for rheumatoid arthritis, osteoarthritis, and blood clots, which can arise in workers' compensation claims. The development and utilization of these medications is projected to grow exponentially by 2020. In 2013, the FDA began granting Breakthrough Therapy Designations, which could further fast-track new medicines, accelerating approval from eight to ten years down to just two. **Biologics** Biologic drugs are relatively new to the market. They fall under the specialty drug class and structurally mimic compounds found in the body. Biologics are created by biological processes in contrast to traditional medications created through chemistry. They are usually larger in size and have more complex molecules than their prescription drug counterparts, which tend to have small molecules. **Biosimilars** A biosimilar, as the name indicates, is similar but not identical to a brand-name biologic medication. Biosimilars are costly to produce in part because of the extra effort required to gain FDA approval compared with chemical generic drugs. The Affordable Care Act laid out a framework for how biosimilar and interchangeables could win FDA approval and maintain periods of exclusivity (an interchangeable is a biosimilar that can be substituted for a branded product without authorization from the prescriber.) The regulations require biosimilars to show there are no material differences in safety, purity, and potency from the branded product. In March 2015, the FDA approved Zarxio, the first biosimilar to be approved in the United States. Although Zarxio is not expected to impact workers' compensation, its approval opens the door for lower cost biosimilars in other therapeutic classes that may. Zarxio® is used to treat patients who lack certain white blood cells caused by cancer, bone marrow transplant,

chemotherapy, or other conditions. Although the approval of Zarxio® did not include the interchangeability status, it still signified a broader move by the industry. Several companies are working on development of biosimilars and so-called interchangeables. An increase in biosimilars should spur market competition and, perhaps, curb the rising cost of biologics. While sometimes it may seem difficult to keep up with the latest pharmacy benefit management lingo, it is important to maintain familiarity with the latest names and terms being tossed about. This awareness will pay off as bills are being reviewed and pre-authorization requests are being considered.



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