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Workers' Comp

Ask The Pharmacist: Biologics and Approved Biosimilar Drugs in Workers’ Compensation

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What are biological and biosimilar drugs?

It is likely you have heard the terms biological or biosimilar drugs and wondered, “what exactly does that mean?” Or you may have heard of many of these drugs not realizing they are biologicals or biosimilars. For instance, Humira, Enbrel and Stelara, if you watch any amount of television, it is likely you have seen a commercial for one of these and, yes, these are biological drugs. In this article we will discuss what biological and biosimilar drugs are, what makes them different from conventional drugs, and specific examples related to workers’ comp.

Biological drugs, also referred to as biologics, are pharmaceutical products derived from natural systems such as human, animal or microorganisms and, according to the U.S. Food and Drug Administration (FDA), may be produced by biotechnology methods and other technologies. Biologics can be comprised of cells, tissues, proteins, sugars, nucleic acids, or a combination of these making them highly complex in structure and requiring highly specialized manufacturing processes. This contrasts with conventional drugs that are, for the most part, chemically synthesized in a lab.

Many biological drugs also have strict storage requirements and may lose efficacy quickly if not stored properly. Conventional drugs have more forgiving storage requirements and remain stable for longer periods of time. Some examples of biological drugs that may be seen in work comp are Botox for migraines, Xolair for asthma or Procrit for anemia. Biologics may not be seen in workers' comp as often as conventional drugs, but when they do show up it is noticeable because of the high cost. One reason for the sustained high cost of biologics is because many are still the original innovator product, or reference product, and there is no competition in the market to bring the price down. This is where biosimilar drugs come in.

The FDA definition of a biosimilar medication is “a biological product that is highly similar to and has no clinically meaningful differences in terms of safety or effectiveness from an existing FDA-licensed (approved) reference product.” Once biosimilars are approved by the FDA, the increased market competition helps bring the cost down. One additional layer to this is something called interchangeable biological products. These biological products have met additional requirements allowing them to be substituted for the original reference product at the pharmacy without the prescriber having to rewrite the prescription. Biologics and any approved biosimilars or interchangeable biosimilars can be found online at https://purplebooksearch.fda.gov/.

One example is the reference product Lantus. If the prescriber writes a prescription for Lantus the pharmacy may substitute for Rezvoglar or Semglee without having the prescription re-written since they are interchangeable biosimilars to the reference product. One way to think of it is, interchangeable biosimilars are to biologics as generics are to brands. It is important to note, however, that the standards and requirements to become an FDA-approved interchangeable biosimilar are different from becoming an FDA-approved generic. Many new biologics and biosimilars are likely to hit the market in coming years as advances in biomedical technology continue. The medical community is hopeful that previously untreatable conditions and complex illnesses will have treatment options made possible by biological drugs in the future.

This information is meant to serve as a general overview, and any specific questions or concerns should be more fully reviewed with your health care professional such as the prescribing doctor or dispensing pharmacist.

Do you have a workers’ compensation or auto related pharmacy question? Send us an email at AskThePharmacist@mitchell.com.

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