LVBCH SM
Employers for Healthcare Value Since 1980

News Notes

• www.LVBCH.com •

VOLUME 17 | ISSUE 4 | WINTER 2021

GUEST ARTICLE: ELMC Rx Solutions

ELMC Rx Solutions

The Biosimilar vs. Generics Challenge: Understanding the Difference

Pharmacy costs continue to increase at an alarming rate as new drugs come to the market. The challenge of controlling costs while maintaining quality remains a top priority for both employers and individuals. Historically, the “silver bullet” solution has been to increase generic drug utilization to take advantage of their lower cost.

In the early days, generics coming to market replaced non-specialty medications such as antibiotics, cholesterol medications, etc. The adoption rate was extremely low due to consumer apprehension and skepticism. The two primary concerns were (1) lack of efficacy because generics were less expensive, and (2) generics being manufactured by a different company which created the impression that the drug impacts on patients would be different.

Over the past few of decades, generic dispensing rates have increased from an average of 40% to 88% as consumer and employer perception changed, allowing success in leveraging generic strategies that reduced cost.

As Specialty drug prices continue to skyrocket and dominate the pipeline, the anticipation of lower cost specialty medications should have led to a more rapid adoption of biosimilar alternatives. Unfortunately, we face the same hurdles that were faced when non-specialty generics were introduced. The reluctance on the part of prescribing physicians and patients is heightened because of the complex conditions for which these medications are prescribed - cancer, autoimmune disorders, multiple sclerosis, and various rare diseases. These concerns combined with the emotional and physical impact the patient may have experienced at the beginning of their original therapy, have hampered the adoption of these drugs.

When faced with taking medications that are critical to maintaining quality of life, there can be an increased reluctance to adopt a new, lower cost medication. Additionally, there is still a generic “hangover” from the perceived lack of efficacy associated with generic and biosimilar alternatives.

Understanding the difference between all the different types of medications in the market is not simple. At its core there are two types of Specialty Drugs: small molecule drugs and large molecule (aka, “biologic”) drugs. These two types of drugs have vastly different characteristics. They are manufactured differently

LVBCH SM
Employers for Healthcare Value Since 1980

News Notes
• www.LVBCH.com •

VOLUME 17 | ISSUE 4 | WINTER 2021

and look different. It's also important to note that when referencing alternatives for each type, the term "generic" is used for small molecule drugs and "biosimilar" is used for large molecule drugs.

The approval process for both small molecule drugs and their corresponding generics and large molecule "biologics" and their corresponding biosimilars is complex and cumbersome.

When referring to biologic drugs and their corresponding alternatives there are three main terms to remember:

- Reference Product – The originator product, already approved by the FDA, against which a proposed biosimilar product is compared
- Biosimilar Product – A biological product that is highly similar and has no clinically meaningful differences from an existing FDA-approved reference product
- Interchangeable Product – An interchangeable product is a biosimilar product that meets additional requirements

Interestingly, a biosimilar is not required to have interchangeability status to be FDA approved, and most of the biosimilars on the market today in the U.S. do not have it. There is a perception that the word "interchangeable" does help to ease doubts surrounding the use of a biosimilar. This interchangeability makes the manufacturing of biosimilar medications far more expensive for manufacturers than Specialty generics. Without interchangeability status for most of these products, prescribers, patients, and payers must be educated about why biosimilars are clinically appropriate to treat the same conditions as reference i.e., brand products.

Although more biosimilars continue to be approved, only about 70% have reached the U.S. market. The biggest obstacles continue to be patent litigations and court settlements between the reference product and biosimilar product manufacturers.

Biosimilar drugs have achieved higher adoption rates and utilization internationally. We continue to be a nation centered around brand loyalty, perceived value, and bias. Even so, progress is being made. As more biosimilars have launched, mostly in the provider-administered segment, the adoption rate has increased. This is due largely to increased education within the prescriber community.

LVBCH SM
Employers for Healthcare Value Since 1980

News Notes

• www.LVBCH.com •

VOLUME 17 | ISSUE 4 | WINTER 2021

We are on the cusp of seeing more self-administered biosimilars in the not-so-distant future—insulins and Humira® , to name a few. Current estimates are that biosimilars in the U.S. could produce a savings of approximately $54 billion from 2017 to 2026. As a result, it is more critical than ever that we become comfortable with biosimilars to ensure patients have access to more affordable treatment options.

It is important to create a strategic plan to help influence the use of biosimilar medications, including educating both prescribers and patients. Please feel free to contact John Adler at jadler@elmcgroup.com with questions or for assistance.