COMMUNICATION

COM-2022-056

27
OCTOBER
2022

PLEASE REVIEW

Drug Information

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252, ext. 220

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Biosimilars and Interchangeability

To date, the Food and Drug Administration (FDA) has approved over 30 biosimilars. A biosimilar is defined as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.

Biosimilars

Biosimilars have been approved in the United States since 2015. The first biosimilar to be approved by the FDA was Zarxio™ (filgrastim-sndz). The currently approved biosimilars are used to treat different types of cancers, autoimmune conditions, ophthalmic conditions, and diabetes. Biosimilars may have fewer indications than the reference product if the reference product has unexpired exclusivity for certain indications. Manufacturers may choose to not pursue all the indications of the reference product for the biosimilar. The Purple Book is a database that contains information about all FDA-licensed biological products including licensed biosimilar and interchangeable products. All nonproprietary names include a four-letter suffix to differentiate the biosimilars from the reference product.

Interchangeable Biosimilar

An interchangeable biosimilar is a biosimilar that meets additional requirements as outlined in the Biologics Price Competition and Innovation Act (BPCIA). The interchangeable product must demonstrate that it produces the same clinical result as the reference biologic in any given patient. The FDA issued guidance for industry in demonstrating interchangeability. According to the guidance, a switching study is expected to demonstrate that if a biosimilar is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating between the biosimilar and reference product is not greater than the risk of using the reference product without switching. The purpose of the switching study is to alleviate concerns regarding reduced safety and efficacy of alternating between the interchangeable and reference products. It is important to mention that the guidance is nonbinding and other approaches can be used to meet the requirements.

Depending on state laws, an interchangeable biosimilar *may be substituted* for the reference product without the prescriber's involvement.

The FDA has approved three interchangeable biosimilar products:

FDA-Approved Interchangeable Biosimilar Products				
Product Name and Manufacturer	FDA Approval Date	Launch Date	Reference Product and Manufacturer	Approved Indications
Semglee™ (insulin glargine-yfgn), *Viatris*	2020; interchangeability: 2021	November 2021	Lantus™, *Sanofi*	Diabetes mellitus
Cimerli™ (ranibizumab-eqrn), *Coherus*	2022	October 2022	Lucentis™, *Genentech*	Neovascular age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, myopic choroidal neovascularization
Cyltezo™ (adalimumab-adbm), *Boehringer Ingelheim*	2017; interchangeability: 2021	Expected to launch July 2023	Humira™, *AbbVie*	Rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis

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PharmPix Drug Information Communication Number COM-2022-056 October 2022

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Pharmacy Benefit Management
Expires 12/01/2022

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3. Center for Drug Evaluation and Research (2017). *Biosimilar and Interchangeable Products.* https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products#:~:text=A%20biosimilar%20is%20a%20biological,existing%20FDA%2Dapproved%20reference%20product.