BIOSIMILARS
— A Podcast Series —

The New Era of Management in Gastroenterology and Rheumatology

Interchangeability & Switching of Biosimilars

Host:
Gabriella McCarty, NP

Guest:
Janette Villalon, PA

Learning Objective	Podcast Discussion Summary
Define Interchangeability	An interchangeable biosimilar product is a biosimilar that meets additional requirements outlined by the law that allows for the FDA to approve biosimilar and interchangeable biosimilar medications. An interchangeable biosimilar product may be substituted without the intervention of the healthcare professional who prescribed the reference product.
Illustrate the Required Info for a Biosimilar to Be Deemed Interchangeable	The main additional component for biosimilar manufacturers to complete for an interchangeable designation is conducting switching studies. These studies involve evaluating what happens when patients switch back and forth between the biosimilar and the reference product. The main goal is to ensure that these switches don't result in any unexpected adverse effects or a loss of treatment effectiveness.
Recognize How Interchangeability Studies Are Conducted	After recruitment for a specific condition, participants are randomly assigned to different groups. Some will start with the reference product and then switch to the biosimilar, while others will start with the biosimilar and switch to the reference product. Some may also start and stay in the reference product group to act as a comparator arm. These studies usually involve multiple switches between the biosimilar and the reference product over a specific period. Throughout the study period, patients are closely monitored for any changes in their condition, adverse reactions, or other relevant factors. The results must show no decrease in effectiveness or increase in safety risk associated with switching for a biosimilar to be considered for the interchangeability designation.
Analyze What Interachangability & Switching Mean for HCPs	Interchangeability and switching are crucial in healthcare as they imply that the biosimilar has been shown to produce the same clinical result as the original biologic in any given patient, offering flexibility and potentially more cost-effective treatment options. APPs should be aware of when their patients have undergone a switch and clinically monitor for any differences in outcome. However, given the extensive testing, this occurrence should be infrequent.

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