

## The Same Medications but Different Labels: The Cost-Saving Role of FDA-Authorized Generics and Unbranded Biologics

There has been much public attention on the cost of medications and therapeutics that are lifesaving but expensive – putting them out of reach for many patients. The good news is that some new non-branded medications have come out, including common insulins and inhaled medications, that provide the same therapeutic benefits for nursing home residents without the high price tag.

What do you need to know about these options and how can they help your residents? Stephen Creasy, PharmD, director of clinical services at PharMerica, offers some answers.

### Are authorized generics and unbranded biologics the same thing?

According to the FDA, an authorized generic refers to a non-biologic product that is “an approved brand name drug that is marketed without the brand name on its label.” If the medication is a tablet or capsule, it may have a different color or marketing and the packaging will have the generic name of the medication on it. Otherwise, it is the same drug product as the brand name because it is approved under the same manufacturer’s New Drug Application (NDA) as the trademarked brand product. Even though an authorized generic is the same product as the name brand, it often is less expensive, much like when a traditional generic comes with a lower cost. Traditional generics are submitted for approval by other manufacturers using an Abbreviated New Drug Application or aNDA.

For biologic products, the official terminology is “unbranded biologic” and, like authorized

generics, they are identical to their branded counterparts made by the same manufacturer but marketed without the brand name on the label. Rest assured, stressed Creasy, “These products are quite literally the same as the brand name ones.” Since they are therapeutically equivalent, unbranded biologics can be substituted for the originally prescribed biologic, holding the potential for cost savings.

### Can all pharmacies automatically substitute authorized generics/unbranded biologics?

Yes, but you need to work with your pharmacy to determine if their dispensing systems are set up to facilitate these automatic substitutions. “Because these products are technically considered brands since they are approved under the same applications as their trademarked counterparts, pharmacy dispensing systems may require some manipulation to allow for automatic substitution,” said Creasy.

It is important to work with your pharmacy to understand how to take advantage as more of these types of products are expected to come to market. For instance, three major insulin manufacturers are rolling back prices on these products. This, Creasy noted, is “good for the consumer and the facility.” By January 1, 2024, expect to see virtually all legacy insulins to be greatly reduced in price.

### Do prescribers and staff already know about these products?

Not necessarily. “You need to educate staff, so if they order a brand name product and get



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something that looks like a generic, they need to understand what they're getting and update the MAR accordingly," said Creasy.

Prescribers should be involved in education as well. While the terminology around unbranded biologics and authorized generics is relatively

new, prescribers need to become familiar with the terms and benefits. "When you look at the high cost of trademarked insulins and inhalers coupled with high utilization," Creasy said, "there is potential for substantial cost savings by using non-branded alternatives without any change in therapeutic effectiveness."



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