The New Frontier of Interchangeable Biosimilar Insulins

WORD WALL:

**Biologic Product:**
A biological medicine is a large and complex molecule made from living sources (e.g., bacteria, yeast) and other drugs are made from chemicals and smaller molecules that are easy to copy.

**Reference Product:**
A single biological product, already approved by the FDA, against which a proposed biosimilar product is compared.

**Biosimilar Product:**
A biological product that is highly similar to an existing FDA-approved reference product, and has no clinically meaningful difference from the reference product.

**Interchangeable Product:**
A biosimilar product that has met additional requirements by the Biologics Price Competition and Innovation Act and is interchangeable with the reference product. It is expected to produce the same clinical results as the reference product.

What is the difference between biosimilar medicines and conventional medicines?

- Biosimilar medicines come in many varieties similar to conventional medicines and are used to treat common chronic conditions such as arthritis, diabetes, and psoriasis. Examples include vaccines, monoclonal antibodies, and insulin.

- Biosimilar medicines, however, are not chemically synthesized like conventional medicines and require a more complex development process using living cells.

- Conventional generic drugs contain the same active ingredient as the corresponding brand name drug. Biosimilars are highly similar to the reference product and must have no clinically meaningful difference in the safety and effectiveness from the reference product.

Are biosimilar medicines regulated?

- Biosimilar medicines are regulated by the Food and Drug Administration (FDA) and undergo a rigorous evaluation process. Additionally, biosimilars are monitored after approval to ensure ongoing safety and effectiveness.

Data presented to FDA for evaluation and approval

Comparative tests of the toxicity, pharmacokinetics (safety, purity, and potency), and immunogenicity are performed.

Manufacturer demonstrates the structure and function of both the reference product and proposed biosimilar through analytical studies.

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To become interchangeable, a biosimilar medicine is subject to additional scrutiny by the FDA and it is expected to produce the same clinical result as the reference product for any patient, and in situations where the products are switched between each other.

As of June 2021, all U.S. states, the District of Columbia, and Puerto Rico allow pharmacy-level substitution of interchangeable biosimilar products, though some restrictions may apply in certain states. This means the pharmacy can substitute a prescription, at the pharmacy counter, for the reference product with the interchangeable product and vice versa without having to call the provider’s office for approval. This is very similar to how generic drugs may be substituted for brand-name drugs.

What does it mean to be interchangeable?

What medicine is considered an interchangeable biosimilar?

In 2021 the FDA approved the first ever interchangeable biosimilar product, a basal insulin providing broad 24-hour coverage with the reference product being insulin glargine. Like its reference product, the interchangeable biosimilar insulin comes in both a pen and vial. As of March 2022, FDA has approved a total of two interchangeable biosimilar products.
The biosimilar insulin will not be replacing other insulin options on a formulary. Instead, it will provide people with diabetes an additional option to choose from in addition to what is on their formulary. The substitution process is similar to that of generic and brand name drugs. If a prescription is presented to the pharmacy for the reference product, the pharmacy (depending on the state) can substitute the interchangeable biosimilar insulin for the reference product.

What is the benefit to using interchangeable biosimilar insulin?

Clinical outcomes with interchangeable products are the same as reference products; however, interchangeable biosimilar insulin provides people with diabetes more choices for their basal coverage, and it may be a more affordable option. Biosimilar products typically launch with an initial price that is 15-35% lower than the reference product. Additionally, the addition of biosimilar interchangeable products, as a whole, may help drive overall prices of insulin down through increased competition within the marketplace.

Who is good candidate for interchangeable biosimilar insulin?

Any person with diabetes who is using basal insulin is a candidate. Additionally, an individual that is having medication access issues due to financial concerns may benefit from using a more affordable interchangeable biosimilar insulin.
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What are some key points for healthcare professionals to discuss with individuals with diabetes?

As healthcare professionals, it is our responsibility to understand what biosimilar medications are and to educate people with diabetes on not only the background of biosimilar insulins but also on the benefit the product may have for them in managing their chronic condition. Here are some key talking points for interchangeable biosimilar insulin:

- Similar to brand and generic drug substitution, this is an insulin that pharmacies can, (subject to state pharmacy laws), substitute for certain other long-acting insulins without asking your provider for approval.
- This insulin doesn’t take away from existing insurance options. Instead, it provides an added option to choose from for long-acting insulin.
- The biosimilar insulin will help you manage your diabetes the same as other long-acting insulins.

The Bottom Line

These are FDA regulated medications

An interchangeable product has met additional requirements in demonstrating similar efficacy to the reference product

Biosimilar insulin is expected to produce the same clinical outcome as the reference product and adds to the array of choices of basal insulins, potentially increasing affordability and/or driving insulin costs down with market competition