Speaker 1
Hello, everyone, and welcome to this episode of the forefront. Biosimilar and Interchangeable Insulins. My name is Jodie Lavin. Tompkins and I'm a nurse and certified Diabetes care and Education specialist and director of Accreditation and Content Development at the Association of Diabetes Care and Education Specialists. Joining me today is Lucia Novak, a nurse practitioner board certified in both adult health and advanced diabetes Management.

Speaker 1
She is the president of Diabetes Consulting Services and is located in North Bethesda, Maryland. We'll be talking about bias, similar insulin and what clinicians need to know in order to help their patients understand biologics, biosimilar and interchangeable products. Welcome right here.

Speaker 2
Thanks, Jodie, and hi to everyone out there listening. Looking forward to this conversation.

Speaker 1
So, Lucia, in order to set the stage for this conversation, I think we should review the terms that we'll be using for our audience. Can you explain what biologics biosimilares and interchangeable products are?

Speaker 2
That's a great question, Jodie. Yes, because this can be very confusing very quickly. So let's start with biologics. Biologics, also known as biological products, are generally made from natural and living sources, such as proteins. Animal and plant cells and also microorganisms such as bacteria and yeast. Biological medications are more complex than synthetic medications and are developed using advanced science.

Speaker 2
As a result, they are often more complicated to process and manufacture. Examples of biologic medications that we are probably all familiar with would include insulin, monoclonal vaccines and blood components. Biosphere. Are biologic products. Biosimilar medications are highly similar to the original FDA approved biologic medication, which is often termed the reference product. These medications have been extensively studied and are just as safe and effective as their reference product compared with their original biologic product.

Speaker 2
Biosimilar medications are made with the same types of natural sources. They have the same treatment benefit and potential side effects. They also have the same dosage and strength and are administered in the same
way. There are no clinically meaningful differences to the reference product in terms of safety, purity and potency. So what are interchangeable? All insulin products are biologics.

Several of them are biosimilar, but not all biosimilar are interchangeable. Interchangeable means that depending on the state pharmacy laws, a biosimilar medication that has the interchangeable designation may be dispense must in place of the reference product at the pharmacy level, meaning not requiring prescriber approval or another prescription to be generated. Kind of like a generic, but not really.

Speaking of generics, I think it might be useful to outline how biosimilars compare with generic medications.

Two, they are both approved via an abbreviated pathway that would avoid duplicating expensive clinical trials. And thirdly, they share similar treatment benefit and potential side effects when compared with the reference product. So what are the differences? Well, as I mentioned before, biosimilars are made from the same natural and living sources such as proteins, animal and plant cells or tissues and the microorganisms such as yeast and bacteria.

Generic medications are made from the same active chemical ingredients of synthetic drugs. Biosimilar medications are more complex than generic synthetic medications and therefore require advanced science and an extensive manufacturing process. So while they are not exact copies of the active ingredient, as are generic drugs, again, there are no clinically meaningful differences to the reference product in terms of safety, purity and potency.

Thank you for that clarification. And Lucia. So now I want to move in to talk about the major benefits of biosimilars for the overall market and for people with diabetes.
Jodie, This is probably the most important aspect of today's talk because we all know how expensive medications have become for our patients, especially when we're looking at insulin in the use of people with diabetes. So one of the major benefits is that biosimilar medications provide additional treatment options for our patients and they are created to help reduce the overall cost and burden to the health care system.

People with diabetes may receive or perhaps even request biosimilar medication at lower cost compared to the reference product. I would encourage the prescriber and the patient to check with the pharmacy for actual out-of-pocket cost for either the biosimilar as well as the reference product to help make an informed decision.

Well, Lucia, as a provider, how do you explain that switch from the reference product to a biosimilar interchangeable product to the other clinicians you work with as well as your patients?

You know, I think one of the most important things that both clinicians and patients need to understand is that a biosimilar is an FDA approved product, and the FDA makes sure that biosimilar medications are as safe and effective as the original biologic. And they do this by approving these medications only after careful review of the studies, the data and the testing.

And there is ongoing monitoring of safety and effectiveness even after their approval has been granted. And they are constantly checking for medication quality during production. They also review patient safety reports that are generated. And it's important to know that interchangeable medications can be used even if you have not been using the reference product previously. This is because the biosimilar interchangeable products are highly similar and provide the same treatment benefit as well as potential side effects as the reference product.

Again, there are no clinically meaningful differences between the biologic, interchangeable with the reference product in terms of safety, purity and potency. So when I am discussing prescribing insulin for patients and we talk about the benefits of insulin, the side effect profile, how to administer it, so on and so forth, I will explain that when they go to the pharmacy to pick up whatever it was that I prescribed, that the pharmacist may actually present them with another
option that is very similar to what I have prescribed that has similar benefits and similar side effects, and that it also may be a more affordable alternative for them and that I am on board with that.

Speaker 2
I want the patients to understand that they are getting standard of care treatment and if it's more affordable for them and they will have similar benefit and similar side effect. What matters to me is that they have access and sometimes cost is the biggest barrier to their ability to access insulin.

Speaker 1
Well, yeah, that's great that you can boil that down for the person with diabetes and I wanted to know how clinicians can find out if a medication is available as a biosimilar or interchangeable product.

Speaker 2
The FDA actually has a purple book that is available, and rather than being a hard copy book, it's actually a searchable online database that contains information about the biologicals, biosimilars, as well as interchangeable biological products as well as the reference products that are currently approved by the FDA. And you can access that by going to Purple Book Search DOT FDA, dot gov.

Speaker 1
Well, it's yeah. Thank you so much for taking the time to join us for this episode of the forefront and sharing your knowledge and experience with our audience. This topic can be somewhat confusing and I think you help clarify what clinicians and people with diabetes really need to know.

Speaker 2
Jodie, thank you so much for having me. I think again, this is a very important conversation to have. Anything we can do to make insulin more accessible for patients is where we all should be. Gay men.

Speaker 1
Yes. And we want to thank our sponsor, Lilly, for their support of this episode of the forefront. Thank you so much for watching. And please join us again for future episodes.