CAN DO MULTIPLE SCLEROSIS | PODCAST

Biosimilar Medications and MS: What You Need To Know

Episode 155 – Podcast Transcript

[(0:23)] Stephanie Buxhoeveden: Welcome to the Can Do MS podcast. I'm your host Stephanie Buxhoeveden. I live with MS, and I'm also a clinician and MS researcher. This is episode 155, and today we're going to talk about biosimilar medications. We'll discuss what biosimilars are, how they're made, FDA standards, and what to ask your doctor. I'm happy to be having today's discussion with Dr. Derrick Robertson, who's a neurologist and director of the MS division at the University of South Florida. Welcome Derrick.

[(0:50)] Dr. Derrick Robertson: Thanks Stephanie. I'm looking forward to a good conversation.

[(0:52)] Stephanie: Great. I wanted to first start by saying that Can Do MS does not endorse any particular treatment, but we do want to help educate everyone on this important topic because it could impact you or someone you love. The FDA recently approved the first biosimilar MS medication called Tyruko, which is a biosimilar of Natalizumab or Tysabri, and Derrick I don't know about you, but this is something I had to spend a little time researching because while I know biosimilars are not new to medicine, they are new to MS, and I'll admit I didn't know much about them until recently.

[(1:24)] Derrick: Yeah, I'm right there with you, so, uh, I've been taking care of patients with immunologic-based therapies for years and years and years, but this is unchartered territory for us as a field and, um, me-me specifically, so I'm... I was happy to kind of dive into the medical literature, and we'll unpack this as we go, um, with-with our talk today, but, uh, I've learned a ton and-and this is so timely that we're doing this, so I'm look-looking forward to it.

[(1:52)] Stephanie: Great. Now, as you mentioned, some generic medications for MS are already available. That includes Copaxone or Glatiramer acetate, the generic. We have generics for Gilenya or Fingolimod and for Tecfidera and Aubagio, and so many of our listeners might already be taking a generic DMT, or other generic

medications for their symptoms or other medical conditions, and the first point we want to stress today is that biosimilar medications are not the same as generics.

They are key differences in the way that they're made and the way that they're developed, so we're going to spend today's episode talking about how they're made, the process of FDA approval and their safety and effectiveness, so Derrick could you start by telling us how biosimilar drugs are made?

[(2:39)] Derrick: Yeah, no, that's a, that's a great launching point here because, uh, there are some differences that again, I think we should unpack, um, as we get going, but I think the first thing is to understand that biologics have... uh, and there's a, there's a bunch that we use to help our-our patients that have MS, so just to list a few, so Natalizumab or-or Tysabri, Ocrelizumab or Ocrevus. Ublituximab is a newer one, um, and, uh, called Briumvi so, and again, many others.

We're very familiar, I think with helping our patients and patients over years and years and years for the treatment of their, of-of their multiple sclerosis have come to understand that biologics are very effective and generally really safe, and they have pros and cons. Um, and so that is, I think the good starting point is that that would be considered the reference drug and biosimilars are made from those reference drugs, so kind of as a, as a comparator let's say.

They're usually infusions or injectable medications. Um, and it takes a long time upwards of close to a decade for them to kind of navigate through, uh, proving kind of their-their safety and-and then sometimes, uh, efficacy, but again, um, with their reference drug or that biologic being kind of their comparator, that they have to be similar to again biosimilar, so how they're made, so they're made by reproducing growing copies of specifically engineered living cells in a carefully controlled facility.

It's a complex system. It's developed with the-the use of proteins that make up the drug. Then their growth can sometimes take several weeks. It's constantly being monitored, then it's extracted, purified, and that the final biologic drug-drug is obtained, so for comparison, so smaller things like say aspirin can be very tiny and are made up of things called atoms that can be on the order of twenty, thirty atoms, something like that.

Whereas these complex, uh, medications, biologics, um, and then biosimilars can be on the order of twenty-five plus thousand, uh, atoms, so, again, often much, much more complex to-to make, which is again, why that sometimes up to a decade, uh, would be kind of what that would look like. Making these manu-... again, they're manufactured using living cells, so it's impossible to guarantee that each batch will

be identical, but that's how it is now with-with current biologics, so that's same with biologics as it'll be for-for biosimilars.

Um, and that these small differences are kind of built into the... they're baked into the, to the meal, so they're-they're-they're, they're-they're already that way with biologics and they will be that way with-with, uh, with biosimilars.

[(5:29)] Stephanie: Great. Thanks for that overview. It certainly sounds like a more complicated process, so how does that compare to making a generic medication?

[(5:38)] Derrick: Well, that's the million dollar question, and this is, I think what I've struggled with that the-the best way I've... because I've used generics for years and years to help, uh-uh, lots and lots of patients, not just with their MS, but for high blood pressure, high cholesterol, or, um, to help with symptomatic medication relief with things like muscle spasms and-and nerve pain.

We're quite familiar with the use of generics. We encourage it in our practice. I am a huge fan of it because it can help kind of reign in healthcare costs for both the system, but also the individual patient making medications more affordable. Um, but there are differences between generics and-and-and biosimilars. Um, I think the best analogy that I've, that I've heard is that it's kind of... so generics would be like, uh-uh, making a car, car assembly line.

Tires are the same. The body of the... body's the same, the engine's the same, so what rolls off the-the-the production line is a full car, and that generics would use that same type of process using all the same type of parts to make a car that is essentially a facsimile of-of the branded, uh, medication. Um, and that's the generic process. Since we're talking about living cells and biologics and biosimilars it's different, so biologics, uh, and then, and then by definition biosimilars would be more like, and I-I live in Florida, so the analogy that one of my friends, uh, used was like an, like an orange tree.

Particularly like an orange grove, so you have lots and lots of planted orange trees, and then over time they start producing fruits, but the branches are a little different. How many oranges come from 1 or the other where they are in the tree, so it had time to be cultivated, and so the-the end product is still very tasty oranges, but kind of how we got there is going to be different in that grove by an order of magnitude. Every tree is going to look a little different.

The end product is still... the reference range of an orange is still the same, so that-that made it kind of crystallize in my brain, and I-I can see that the facsimile of a car

coming off the assembly line, consistent, reproducible identical for lack of a better term. Whereas there could be some slight differences with the finished product of orange trees and an orange grove and the oranges that come from those, so I think that analogy kind of made it so to me is that, that that's the slight difference 'cause one is living cells and one is facsimile and kind of made in a lab.

[(8:06)] Stephanie: Yeah, I think that's a brilliant way of putting it, so what standards must biosimilars meet, and how are they evaluated by the FDA?

[(8:14)] Derrick: Yeah, yeah, so the FDA is, uh, is very instructive on this process, so when I was research-researching kind of biosimilars as they're kind of getting into the-the-the field that I help with, uh, patient care with-with MS, I want to understand, well what-what does that process look like, and thankfully, and not surprisingly, it's-it's pretty rigorous. Um, and so biosimilars as a biologic product have a very similar pathway, um, to generics. It's actually just seems to be slightly more rigorous, and I-I viewed that as actually as a positive.

The FDA will only approve biosimilar medication if it has the same mechanism action of-of what again, that reference medication would be, the biologic, the route of administration has to be the same, the dosage form has to be the same, the strength has to be the same, and its indication has to be identical, compared to the-the reference drug.

Um, and there was a law that was passed in 2009 that biologic medications must be demonstrated to be biosimilar if the data shows the medication is highly similar to that of already approved biologic, um, medication, has no clinically meaningful difference in terms of safety, purity and potency of the reference medication, and that the proposed biosimilar is expected to produce the same clinical results, so again, pretty high bar, but that's where the bar needs to be for us to feel comfortable having conversations with patients and then using it to help treat their-their chronic condition.

[(9:47)] Stephanie: Absolutely. The stakes of MS are incredibly high, so I completely agree. Rigorous processes do definitely put my mind at ease too. Now, in the same vein are biosimilar drugs as safe and effective as brand biologics?

[(10:02)] Derrick: Well, that's where this conversation's leading and I, and I sure hope so, so again, not having experienced myself yet prescribing these drugs I can't speak to on my experience for years and years using these medications. There's a, there's a comfort in that once we fast forward a handful of years, um, to be able to-to use that-that your own kind of clinical experience. Um, and so that does give me a pause

if I'm, if I'm being honest, having said that, the... what we just talked about, so that biosimilar pathway approval through the FDA with that high bar being the safety, the purity, the potency.

It's got to be proven in a series of tests and trials performed by the pharmaceutical manufacturing company that's-that's bringing the biosimilar through that process has to be similar, the biosimilar to that reference product, and if it's not, it won't get approved, and so again, since we have that regulatory body that helps maintain that standard, that gives me comfort.

Again, when my clinical experience is robust enough to be able to talk to that, that'll be where I drive conversations with the patients about, well, I've had patients on these medicines for a long time now and they've done well, so until that day comes where I can reference that, I'm-I'm comforted by the fact that there is that-that rigorous approval process.

[(11:24)] Stephanie: That's great. Thank you for sharing your perspective, so brand name biologic drugs, often what we call black box warnings or serious, potentially life-threatening side effects that need to be watched for with regular checkups with their neurologists or blood tests and or MRIs, so will biosimilar drugs have the same strict safety standards once they're released onto the market?

[(11:46)] Derrick: Yeah, so the short answer is absolutely that they will, and again, that is on both sides of that, of that conversation, so the comfort level with the healthcare provider, um, understanding the science and then wanting to use the medication, um, it... that comfort level would need to be there, that there's safety mechanisms to help our patients, but equally, if not more important is that from the patient's perspective, is that those safeguards are there for their, for their benefit, and so when medications have black box warnings, that's serious.

That we need to know that as healthcare providers distill that down into a, uh, a meaningful way where patients can understand what that means for the medication. Whether it's extra lab monitoring requirements, um, you know, extra clinic visits to assess. Um, sometimes there's these things called REMS programs where there's extra monitoring requirements, not just for the prescriber of the medication, the doctor or the-the nurse practitioner.

Or the PA but also, um, from the patient's perspective and education piece, the pharmacies that dispense the medication, sometimes the infusion centers themselves that are, um, uh, administering the medications, there's extra, um, requirements, so all of that is kind of baked into what's necessary to be able to have

it be a biosimilar if those extra requirements are there, and so for the one that's going to be, um, something we could start to use soon for-for patients with MS, um, the Natalizumab biosimilar Tyruko that you mentioned, all of those safety monitoring requirements are going to be, um, a-again in place, so the necessity of, uh, a REMS program for that.

Having that be kind of having that black box warning and REMS requirement is-is crucial for us to feel comfortable prescribing it for our patients and then following them over time while they're on that-that-that type of therapy.

[(13:34)] Stephanie: Great. Thank you, so as we've already mentioned, biosimilars are new to MS, but they've been used worldwide for other purposes like for treating cancer and other autoimmune diseases. In the United States, less than 2% of all the prescriptions written in the country are biologic medications, but that 2% accounts for over a third of all drug spending in the country, which is mind-blowing. Everyone with MS knows that the medications to treat it are extremely expensive, so how much do biosimilar drugs cost compared to the brand?

[(14:10)] Derrick: Well, the-the healthcare economic, uh, driving forces behind cost of care for chronic illnesses is-is huge, and MS being right up there, a lot of it you're correct, driven by the pharmaceutical cost, uh, of delivering that kind of healthcare, so I'm right there with you. Um, I think the jury's still out on its eventual impact in MS, but I am cautiously optimistic. I-I... we've seen it, um, starting anyway with the use of generics over years now in MS that it's potentially starting to help drive down some of that overall, per patient cost to both the healthcare system.

Um, but also kind of the worry for patients being hit with kind of the sticker shock of what some of these medications can cost. It is undeniable when you reference those other, those other conditions, so cancer is other autoimmune condition where the use of biosimilars has been helpful at kind of saving the overall healthcare system, um, the-the high amount that these medications, uh, cost. Um, but again, it's eventual benefit in MS and what impact, we'll-we'll see. Uh, but again, I'm-I'm cautiously optimistic

[(15:21)] Stephanie: Me too, and hopeful that the introduction of biosimilars will allow more and more people to access these fabulous, wonderful disease modifying therapies that we have, so what happens if somebody is already on a brand drug? Will their out-of-pocket costs change if they have to switch to a biosimilar?

[(15:40)] Derrick: Yeah, I mean, what we can use is... as a knowledge for something as short. I-I don't know, let me start there because I think that's a fair thing to say out

loud because we're-we're going to learn together over the coming months to year or so, um, when patients, uh, are going to be on biosimilars for the use of-of their MS. Kind of how that process plays out. Um, if we use generic experience, it medica...generic medication experience with MS patients as a, as a platform to learn from, um, it went pretty well in our experience.

There was some bumps along the way when you take care of lots of patients and-and they're kind of using generics, uh, for the first time. There was some patients that had higher out-of-pocket costs. I don't know if that'll translate for biosimilars, but when we fast forward over time, it has become very much a minor issue in that these medications end up being affordable and not a huge budget buster for-for patients, and-and elfishly caring a lot about my patients and what they pay out of pocket, that would be a deal breaker for me.

If I, if I wanted to use a medication, it ends up having to be a biosimilar and it's going to be a huge out-of-pocket cost for a patient, then it might as well not get approved, and we'll just have to revisit what else could we do to help take care of their MS, and so by necessity for us to feel comfortable as healthcare providers prescribing it, it's going to need to be something that is manageable and affordable for-for our patients.

[(17:07)] Stephanie: Absolutely, and the MS community has been fighting for a long time for those affordable medications, and I know it can be extremely scary to be told that you have to switch from a brand medication. Maybe that's been working well for you for years to a generic or to a biosimilar medication, and you've talked a lot about the facts of biosimilars. You've shared some of your personal experience and opinions, but overall, how do you view biosimilars? What's your takeaway?

[(17:36)] Derrick: Yeah, so again, comforted by the, by the-the rigorousness of the approval process, cautiously optimistic that it will be significantly more expensive for our patients. Lots of patients give us this horror stories already with branded medications, and so not letting that continue to play out could only be a good thing, and I'm-I'm hopeful that we'll see that not play out. Whereas biosimilars become more of a mainstay to help our-our-our patients.

Um, so I-I... my view is generally favorable, but, uh, I think it'll be a time will tell thing, but again, starting with knowledge of what they are is I think a good learning point for both us as future prescribers of these medications, doctors, PAs, nurse practitioners, um, and then helping to educate our patients about, uh, how they can be helpful, uh, for their disease.

[(18:26)] Stephanie: Definitely knowledge is the key. I know I learned something about MS almost every day, and it's a lot of work to keep up with the latest in what's happening in the field, but that's exactly why we're extremely thankful for you being here today to help us out with that, so lastly, any other advice about what someone should ask their doctor or consider before potentially switching to a biosimilar?

[(18:49)] Derrick: Uh, that's my favorite question you've asked me so far, so my patients are my best source of information. Uh, because they-they-they help ask the questions that probably is on many, many, many more patients' minds, um, than they're letting on. Um, and so I learned the most actually from-from my own patients. Um, and I think challenging your healthcare provider with questions is your job. It's the expectation, uh-uh, really when-when you go for your clinic visits, um, should be forcing us to be better healthcare providers to you. Um, and so this is the perfect example.

There's going to be a knowledge gap. Be-be nice to your doctors and NPs and PAs because we're all learning this together to, for, to help you with-with your MS. Um, but-but come in armed with the knowledge that you learned from us, uh, from Stephanie and I today. Um, and then keep an open mind of helping your healthcare providers learn along the way. I'll do my part, so I-I'm in, uh, an educational role and wear lots of different hats, teaching lots of different doctors in training medical students.

Um, my colleagues around-around the, um, United States that at c m s patients, so I'll be doing my part to help, kind of help bring us all up to speed on what biosimilars mean to help our MS patients and patients should be doing the same.

[(20:08)] Stephanie: Thank you so much for your knowledge and your candor on this topic. We really appreciate your time here today.

[(20:14)] Derrick: Sure thing. Thanks Stephanie.

[(20:16)] Stephanie: Thank you. Thank you for listening to this episode of the Can Do MS podcast. If you liked this episode, please leave us a rating and review on Apple Podcasts, and if you're interested in learning more about biosimilars, you can check out the Can Do MS article, generics and biosimilars. seven important questions answered. The link to this article is in the episode description. Lastly, we'd like to thank Sandoz, Biogen, and all our generous sponsors for their support of this episode of the Can Do MS podcast. Until next time, be well and have a great day.

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