

CURE Epilepsy Online Forum
Navigating Prescription Medication Access & Patient Support Programs
(Transcript)

Beth Dean: Welcome everyone. My name is Beth Dean and I am the CEO for CURE Epilepsy. I want to thank you for joining us today. Today we are proud to bring you an online forum to discuss a topic that we get many questions about, navigating prescription medication access and patient support programs. This forum is brought to you thanks to the generous support of Azurity Pharmaceuticals, Jazz Pharmaceuticals, and SK Life Science.

Navigating access to prescription medications and overcoming the financial barriers can be incredibly complex and frustrating for patients with epilepsy and their family members alike. Today you'll learn about the key players in the prescription drug chain, manufacturers, pharmacy benefit managers, insurers, and common barriers to prescription medication access, like prior authorizations and step edits and cost savings strategies for patients. You'll also hear from representatives of SK Life and Jazz Pharmaceuticals who'll provide a brief overview of their programs to support patients in accessing medications.

Cure Epilepsy is proud to be celebrating our 25th anniversary this year. Since our founding in 1998, we have raised over \$90 million to fund epilepsy research that supports our mission, which is to find a cure for epilepsy by promoting and funding patient-focused research. CURE Epilepsy's provided over 280 grants to investigators in 18 countries around the world to support the development of novel research projects and to advance the science and search for a cure and more effective treatments.

We want today's forum to be as interactive and informative as possible. So I'd like to encourage everyone to ask questions. We'll address the questions at the end during the Q&A portion. Keep in mind that you may submit your question any time during the presentation by typing them into the Q&A tab located on your control panel and then click send. We'll do our best to get to the questions. They should be general and not specific to an individual or particular person. Please note that the respondents can't answer specific questions to your individual situation or treatment plan.

So to kick off today's form, I'd like to introduce Phyllis Kidder, PharmD, which is a doctorate of pharmacy and a partner with Blue Fin Group. Phyllis is an experienced biopharmaceutical healthcare and managed care leader with more than 30 years of experience in the industry. Her deep commercial and clinical experience provide her with a unique insight and ability to support both patients as well as industry as a management consultant. She has a deep background in the pharmaceutical industry and has helped launch pharmaceutical brands, both branded and specialty and we'll talk about the differences between those. She's also worked on orphan drugs and rare diseases, and I know that her firm has worked within the epilepsy space. So with that, I would like to turn it over to Phyllis. Thank you very much.

Phyllis Kidder:

Thank you Beth, and good afternoon everybody. So today I'm going to spend a little bit of time, as Beth said, talking about the differences between brands, generics and branded generics, the US pharmaceutical supply chain, and what kinds of pharmacies exist. A brief overview of types of insurers, and then talk a little bit about pharmacy benefit managers because they control a lot of prescription access and speaking of them, we will talk about how they exert those payer controls. And then we'll talk about payer affordability solutions.

Manufacturers produce pharmaceutical products. There's brands, there's generics, and there's branded generic. A brand is a medication that's approved by the FDA and has patent protection for a certain period of time so that nobody but the original manufacturer can make that product during that time. Patent life depends on whether a product is just a small molecule oral, but somewhere in the seven to 11-year range. Examples of that for epilepsy drugs are things like Keppra, Lamictal, Dilantin. Generic drugs are also approved by the FDA and they have the same active drug ingredient as a brand and they've been determined that they're bioequivalent.

Now, one of the things we'll talk about, which I'm sure some of you have experienced, is that some anti-seizure medications can be problematic to switch from a brand to a generic or even between different generics. The inactive ingredients may be different, and when you get a generic, you may notice that the color and shape can be different between the brand and the generic as well as between different generics. Many states and health plans require that mandatory generic substitution, and a pharmacist by law in almost every state, can substitute an equivalent generic for a branded product. And we'll talk about if that's not right for you, what your physician's options are.

A branded generic is a branded medication. It's a medication the generic manufacturer has decided to give a brand name to. So an example of that would be Vigadrone. It's generic for vigabatrin, but they gave that brand name Vigadrone as opposed to the originator product with Stabril. So how does drug get into pharmacies? Manufacturers is a very simplistic overview, but manufacturers make prescription drugs. They're sent to distributors, primary wholesalers who act as a middleman effectively for how product gets from a manufacturer to a pharmacy. And then they go to pharmacies, and there're different types of pharmacies, which we're going to talk about on this slide.

So many shapes and sizes. There's retail pharmacies, which I know you are all familiar with. CVS, Walgreens, Walmart, and there are grocery stores that have pharmacies, Kroger, Hy-Vee, Albertson's. There are what we would call big box pharmacies like Costco, a giant store that sells everything and they also have a pharmacy. Then there are independent pharmacies, Good Neighbor Pharmacy, Medicine Shoppe pharmacies, those are all independent pharmacies that have banded together. And then there are independents that Joe's Pharmacy on the corner of First on Maine, that many of you may go to.

There are mail order pharmacies, which are typically affiliated with your pharmacy benefit manager or your health plans. So Express Scripts Pharmacy, CVS Pharmacy and CVS Caremark and Optum RX. And many times your health plan or PBM will say to you, you might get something in the mail that says if you shift your prescription to mail order, you get a 90-day supply and it's going to cost you less. There are specialty pharmacies which are not common for generic medications, but there are a couple of epilepsy drugs, Epidiolex and Ztalmu, that are distributed through or dispensed through specialty pharmacies. And this is just an example of some of them.

Then there are digital pharmacies. I'm sure you've all heard of Amazon Pharmacy, PillPack by Amazon. There's also Truepill, Carepoint. Both are national pharmacies, and in digital pharmacy, does the same thing that every other pharmacy does except that they use more technology, text messaging, an app, other ways to reach out to patients digitally than some of the other types of pharmacies do. But they provide a similar level of service to a specialty pharmacy. And then you have some regional digital pharmacies like Alto and Capsule that are in specific urban areas and they actually provide courier service to deliver your medication to your house.

Then there are some newer offerings. I'm sure many of you have heard about Mark Cuban's Cost Plus drug company and he primarily does generics, although recently added two brand name medications, not in the epilepsy space but in the diabetes space, which would signal that he may be willing to do that and trying to make agreements to do that more. He's also establishing his own pharmacy network. And then you have something like GoodRx, which GoodRx looks around for what the lowest prices are. They have coupons and discount cards that you can present at a pharmacy and sometimes those prices that they have are actually less than what you would pay if you used your insurance.

Mark Cuban is also cash only pharmacy, but sometimes when using those coupons you end up with a lower out-of-pocket cost than if you used your insurance. And one of the things which many of you may realize, but the price that a particular pharmacy charges is not the same necessarily as another pharmacy. So your copay may be the same, but if you are paying cash for something or what their usual on customary price is, it can really vary from pharmacy to pharmacy.

So if when we talk about payers or insurance companies, they're really cover different types of insurance. So commercial insurance is probably what many of us are familiar with. It's primarily employer-based. It covers people who are employed and their dependents. You can also buy insurance on healthcare exchanges. Medicare is for people age 65 and older as well as people with disabilities. And that was developed in the 1960s. And then in 2006 it was added coverage for prescription drugs. And then Medicaid is funded by a combination of state and federal dollars. Originally was a focus on low-income individuals with originally a focus on women and children, but eligibility was expanded under the Affordable Care Act and there's significant, but every state had the

ability to opt-in or opt-out of that and there's significant state-by-state variation in coverage.

So let's talk a little bit about pharmacy benefit managers in PBM. Before I said that distributors were the middlemen for how physical products got from the manufacturer to pharmacies. PBMs are the middlemen between insurance companies, our payers, pharmacies and manufacturers. You can see them right in the middle here. They negotiate discounts on behalf of health plans from drug manufacturers and because they often negotiate for multiple manufacturers, they can get a better discount. They also negotiate discount. They also have pharmacy networks. So you may know that depending on who your PBM is, you may have certain pharmacies that you can go to that are within your network and certain ones that are not in your network. And they also manage the drug benefit of health plan. So they're in the middle between the manufacturer, the health plan and the pharmacy.

They've been criticized a lot recently and they've been in the news recently because there's a congressional investigation by the House and also a Federal Trade Commission investigation into their practices because they tend not to be very transparent. But if you look at this over time, they have a mass control over many prescription drug transactions and the top three manage more than three quarters of all prescriptions in 2021. And that number's probably growing and you can see that the top three are CVS, Cigna, which is part of Evernorth, or Express Scripts and United Health, which is Optum. So you may have your prescriptions managed by one of these and you have a prescription drug card and you may see my prescription drug card says CVS on it. And so you may look and see who your pharmacy benefit manager is.

So what do PBMs do to manage drugs? Because part of why they came into existence was to try to help health plans and ultimately employers manage drug costs. So what are the tools that they use? So they use a formulary, they use prior authorization and medical exceptions policies and they use step edits and quantity limits. And we're going to talk about each of those in a little bit more depth. So what is a formulary? A formulary is a list of drugs that's covered by a health plan. There's usually tiers on a formulary. There can be anywhere from three to six tiers on a formulary. Generics are usually on the lowest tier. Sometimes some formularies have two tiers for generics for the really low cost generics and for more expensive generics. Branded products are usually sort of in the middle and specialty products are at the highest tiers.

As I mentioned before, many states and health plans have automatic generic substitution. So if you need a brand or you want a brand or your doctor says, I don't want you to change from the brand because you're well controlled and you've had perhaps challenges when you've having your seizures controlled, your doctor needs to write either dispense as written or do not substitute on the prescription when they send it in. And they can do that electronically when they send an electronic prescription to a pharmacy. I know many of us, the doctor says to you, "What pharmacy do you want me to send this to you?" And

you say, "I want you to send it to the Walgreens here." They can include that dispenser's written language on that prescription.

When they do that, then you will go to the pharmacy and you can get the brand name drug. You would obviously pay the brand name copay and some insurance plans, depending on how your plan is written, may also have you pay that difference between the cost of the brand and the cost of the generic. That doesn't usually happen, but it can. Tier placement, we talked about there's multiple tiers. That dictates what your particular out-of-pocket is dollar-wise for that prescription. And it can either be a copay, which is a fixed amount, so you pay \$25 or you pay \$10 for a generic or co-insurance, which is a percentage of the product cost. That's especially common if for Medicare plans that anything that's a specialty or over a certain dollar threshold can be anywhere from 15% at the low end to up to a third of the cost of the drug, which obviously can be challenging for some people to afford. And we'll talk about affordability of the options in a little bit.

What are prior authorization and medical exception? What does it mean when the pharmacy says to you this drug requires a prior authorization? Well, that means your doctor has to complete a form and it can be electronics sometimes or a paper form and send it to the health plan for them to approve it. Sometimes pharmacies will help with this specialty pharmacy, digital pharmacies, some of the smaller independent retail pharmacies will help. Sometimes what they will do is use a tool that physicians are used to using and send it electronically to that physician that says, here, you have to do this and here's the form. The requirements can include anything from documenting the diagnosis you have, what else do you have tried and hasn't worked. Some medications are only approved for a certain age group, so the age could be required. Obviously, if your doctor has to go through this and then it has to get sent to the health plan and approved, that can result in delays for starting therapy.

If your prior authorization is denied, your doctor can appeal that. It can first be an internal appeal to the medical director of the health plan. They'll have to fill out additional paperwork documenting why you need this product. And then that medical director can say yes or no. And if it's really needed, you can have an external appeal to the state board of insurance. All of that obviously takes time if you have to go down that road. So medical exception sometimes, when new drugs come out, health insurance companies don't even evaluate them right away. And so they're in a not covered category or they may not be listed on the formulary at all. It may not be that they're on a tier and require prior authorization, they're just not on the formulary, but your doctor says this is the product that you need.

So they can request a medical exception. They need to do what's called a letter of medical necessity. They submit documentations documenting why this product is medical medically necessary for you as a patient and why everything else that's on that list cannot be used. Sometimes it's either you can't tolerate

those drugs, they don't work on any other medic medical rationale. And then that again gets submitted to the health plan. If that gets approved, your cost share is usually at a higher non-formulary tier, so it would cost you more. And again, obviously this is a manual process and it can result in delays in starting therapy.

So step edits and quantity limits. Step edits means you've tried and failed another product. You have to try and fail something else before you can get there. Usually it's a generic, and it doesn't have to be the generic of that product. In a particular category, they could have three generic products listed and there's a brand name that's not the same drug, but the health plan could say, well, we want you to try this first. Sometimes you can have to step through more than one. If you're been in a health plan for a while in their pharmacy system, they can look back and say, oh yes, you tried this before and you tried this before and we can see that you've tried that. And then that's a fairly automatic process. If you have switched health plans, then your doctor will have to provide that documentation that you have tried and failed those previous drugs because they don't have that history to be able to look back.

Quantity limits basically say for each prescription you can only get this many tablets, capsules, this much solution. An example would be that if you normally take a drug twice a day, you can only get 60 tablets in each fill. Sometimes people need a higher dose than what is normally prescribed. In that case, your doctor would need to write to request an override to that quantity limit and that would have to go through sort of a similar kind of prior authorization process. It's often designed to prevent abuse or also if there are products that it's sort of unclear as to whether there's a lot of possibility that a patient may not tolerate it. Sometimes there's quantity limits for that reason.

So what if you can't afford your medication? What help is there? I'm going to talk a little bit about samples and vouchers or free trials. Samples are free drugs that are provided to a doctor's office voucher. They hand you a coupon that you take to a pharmacy. There are commercial copay support options for manufacturers, which I know you're going to hear about. There are patient assistance programs and then there's also third-party foundation support.

We'll talk about each of those a little bit more. Samples and vouchers are usually for one fill of a prescription. Sometimes they're more but a sample ... Many of you've probably gotten a sample in your doctor's office. Manufacturers provide samples. They say on it for sample use only and they're provided for free. A physician can give them to any patient that they so choose, and it's intended to allow both a doctor and the patient to see if the medication works or you can tolerate it before you can get a prescription filled. Because if it doesn't work and or you can't tolerate it, then it just gives you a chance to figure that out.

Vouchers and free trial essentially accomplish the same thing. It's a coupon that the manufacturer provides and then the doctor gives that to you, the patient to

get a free trial of medication. Some voucher programs work that you can take the voucher to any pharmacy and some of them work that they have to go to a particular pharmacy. And then you get whatever quantity of medication is allowed by that voucher and free trial. It eliminates the need to stock and monitor samples at a doctor's office because samples can sit there and expire and the intent is similar, but again, it eliminates some of that monitoring and the manufacturer has a little bit more insight into how much is being used.

Commercial copay support is provided by manufacturers for patients who have commercial insurance. There are rules that prevent patients who are on Medicare, Medicaid or TRICARE from getting manufacturer copay support. That's the federal government and the office of the Inspector General have been very clear about that. There are two primary structures of copay support. One provides a fixed buy down, fixed amount per month. So you can say your copay is, if someone could provide you \$200 a month or \$100 a month to buy down the copay and however much that buys it down, that's what you then would pay. Or it could buy it down to a certain dollar amount. So no matter where you started, you would pay no more than \$25 or you would pay no more than \$10 or some manufacturers have you pay nothing.

It's up to the manufacturer for how they set those programs up. There's often an annual cap regardless of the mech mechanism that you use sometimes. And those annual caps vary widely, depends a lot on the cost of the particular medication. And these are provided, these can be applied automatically at the pharmacy. So patient assistance programs, they are typically for financially needy patients. Most manufacturers provide some kind of patient assistance. It's usually based on the family income as some percentage of the federal poverty level. Income verification may be required. Sometimes you have to provide documentation of your income, sometimes you don't and you need to generally reapply every year. And that the patients in government-sponsored insurance programs, i.e. Medicare, Medicaid, and TRICARE may also be excluded from this.

And lastly, foundation support. Foundation support isn't provided by any particular manufacturer. Manufacturers donate funds to foundations, but they're not able to be earmarked for any particular product. Every foundation has its own eligibility criteria, diseases they cover, and funds and foundations can actually run out of money during a calendar year. They can run out and then they can reopen. These are some examples of foundations, there are more foundations than this, but NORD, which is the National Orphan and Rare Disease Foundation, so they have rare care, supports patients with rare diseases, PAN supports multiple diseases and the Assistance Fund supports about 80 diseases including epilepsy. And you apply for these and then they can give you a grant to help you pay for your medication. And that's all that I have to share today. So thank you so much for your time and when there's questions, I'll be happy to answer any of that pertaining to me.

Beth Dean: Thank you so much, Phyllis. That was incredibly informative and a great overview of how the prescription drug supply system in the US works. So really, really appreciate that. The next thing I'd like to do is introduce Meghan Szczech, the executive director of patient services and trade with SK Life Science, who will share with you some information about the specific patient assistance programs that are available through SK Life. So Meghan, the floor is yours.

Meghan Szczech: Thank you so much, Beth. Hello everyone. Nice to speak with you this afternoon. I want to share a little bit about our patient assistance program and patient support programs called SK Life Science Navigator. SK Life Science is committed to helping patients get their XCOPRI and how we've done that is multiple avenues. The first one is working with the payers to make sure that we have coverage. So we've gone out and we have tremendous formulary coverage for all types of insurance, commercial, Medicare and Medicaid. XCOPRI has really good coverage so we know that you're able to get it through your insurance. We also, as going through Phyllis's presentation, I was thinking of all the things we have. There are samples for XCOPRI available in some doctor's offices. As she mentioned, not every doctor's office has samples. There are some facilities and specifically educational institutions that are unwilling or unable to accept a sample.

So the samples are there for our first titration pack, which is a 12-and-a-half 25 pack. But to help those patients who aren't able to get a physical sample, we have created a voucher that will provide a free month of product for our patients initiating therapy. Those vouchers are available in HCP offices, so your doctor can hand one out to you as they prescribe our drug, or you can go to our website and you can print that out. And I've been assured by Beth and the rest of the Cure Epilepsy group that they will send you all of the links of what I'm talking about after this, so I can send you a link directly to that voucher. We also do provide copay assistance for our commercially insured patients. The way that we have this set up is a little bit nontraditional, so I'm sure you've all seen the commercials or a website where you have to sign up and put all your information in and you print out a card to bring your pharmacy.

We do it a little bit differently with SK Life Science and for XCOPRI, what we do is we have worked with the pharmacy switch systems, the computer systems behind the retail pharmacies, and we've embedded a coupon into the background of their system. So if you are eligible, you automatically will get support. For those commercial patients who are eligible, most patients pay no more than \$20, up to \$3,500 over the course of the calendar year. So we want to make sure that cost is not going to prohibit you from getting your XCOPRI. We do know that insurance companies can be a little bit challenging. So our SK Life Science Navigator program is available to help do a benefit verification and investigation for you. They'll call your insurance, they can talk about what does your coverage look like, what is the expected out of pocket, is there a prior authorization required?

And they'll share that information with both you and your doctor. We can't do the prior auth on your behalf, but we can provide your doctor with the information so that they can do it. And then we also have our patient assistance program, and as Phyllis very clearly explained, there are multiple pieces of our criteria. So we have four. The first one is that you are a US resident. The second one is you have an on-label diagnosis. The third is you meet our financial threshold, which is a percentage of the FPL, as Phyllis mentioned, and then the fourth one, there are three options. The first option is you're completely uninsured, you have no insurance and you really need the support because you don't have another option. The second is that you are underinsured or you have insurance, but XCOPRI is not covered by your insurance or the prior auth and the appeals have been denied.

And then the last is if you have a financial hardship. And as Phyllis mentioned, a lot of times we see that with our Medicare Part D patients. So if you have a co-insurance and you have a high out-of-pocket, we can help you and evaluate you for our patient assistance program. Any patients who are part of the Patient assistance program will receive free product, free drug shipped directly from SK LSI navigator to your doorstep.

Our program is open Monday through Friday from 9:00 AM to 6:00 PM Eastern time. We have a website that has all this information for you and all of the documents that you'll need, including our enrollment form and where the doctor can send a prescription or an e-prescription for your drug. And then for the patient, a patient authorization, a patient assistance application, and our financial hardship template letter. And the greatest thing is we have submission available multiple ways so we can accept it online through our website via DocuSign signatures. We can accept emails, faxes or even snail mail. So we're happy to help and we look forward to helping you if you are prescribed at XCOPRI. Thanks, Beth.

Beth Dean: Thank you so much, Meghan. Appreciate that. Want to remind everyone if you have questions, put them in the Q&A. I'm going to introduce our final speaker and then we will get to those questions. So I'd like to introduce Randy Brown, who is the patient marketing director with Jazz Pharmaceuticals and he'll share some information about their programs. Randy? Randy, are you there?

Randy Brown: Yes, can you hear me?

Beth Dean: Yes. Thank you.

Randy Brown: Thank you, Beth. Appreciate it and thanks for having me this afternoon. I'm excited to be here to share some information about Epidiolex Engage, which is our patient support program for individuals who have been prescribed Epidiolex. As you see here, these programs are really designed to help patients, caregivers, as well as providers and the office staff navigate the evolving landscape within managed care, really address and overcome any of those barriers or hurdles to get coverage for Epidiolex as well as affordability.

A couple of the services you can see highlighted on here, insurance plan coverage details, so we can help navigate, again, do that benefits verification investigation, find out what the path to coverage is for a specific patient, educate the office staff, educate the patient caregiver on what those steps are. Prior authorization, as Phyllis talked about, we have prior authorization and appeal support. Again, we are limited in our ability to be able to submit or do that prior authorization on your behalf, but can certainly serve up the information, the forms, and help to get that process started.

Epidiolex is only available through specialty pharmacies and select specialty pharmacies. So we do have a pharmacy finder, so if there's any questions around which pharmacies you have the option of filling or getting your Epidiolex through, we have that ability to identify pharmacies, whether they be national, local, regional pharmacies that are able to dispense. In the next couple slides, I'll walk through a couple of our patient affordability programs and go into some more detail there. So I won't touch on that here. We don't have samples for Epidiolex currently, but we do have a quick start program for patients that are working through navigating the path to coverage, but certainly recognize, given the severity of the disease, that waiting an extra day week to get on therapy can be challenging. So I want to make sure we support patients to get on as quickly as possible.

What you see here is the details of our copay card. Similar to what Meghan had talked about, we don't have a physical card. There's no application, there's no download, there's no signup required for the Epidiolex copay program. It is for commercially insured patients. The offer is pay as low as \$0 for initial prescription as well as subsequent refills, whether they be 30, 60 or 90 day refills. All prescriptions or all fills through the copay program are \$0. It is applied at the specialty pharmacy.

One important thing to note here as well. Most of the specialty pharmacies will automatically apply the copay savings program. There are some, based on their contracts that they have with the payers, that aren't able to automatically apply. So for those commercially insured patients, if you have commercial insurance, filling an Epidiolex script, it is important in that communication with the SP or with the specialty pharmacy to inquire and ask, make sure that that copay savings has been applied. And again, if you have any copay outside of \$0, please reach out to the Epidiolex Engaged team. We'll provide the contact info and a couple slides here and they'll be able to help navigate through that process.

Similarly, we also have a patient assistance program, and this is for eligible either underinsured, uninsured patients or those patients that do have coverage but have financial hardship with their out-of-pocket cost. Important here, any commercial, Medicaid, Medicare, all the different types of insurance coverage. We do accept in our PAP program and obviously there are requirements there around being a resident of the United States. We also have an income threshold that's based on a percentage of FPL as well as a valid prescription from a provider. And it's important that the physician has to sign that prescription or

sign that form and send it in. These forms are available through Epidiolex Engage. They're available on our [epidiolex.com](https://www.epidiolex.com) website where you can download and get that process started.

I would encourage you, if you have any questions about your eligibility or ability to participate in that program, please reach out. It is a very broad program as far as the amount of patients that we are able to help through our PAP program. And last certainly not least, how do you get in touch with us in order to get support and utilize these resources? You see here our contact information, so the Epidiolex engage programs open from 8:00 AM to 8:00 PM Monday through Friday. You see the phone number there as well as email. And then certainly we have a website that's really more to get process started. You can kick off a case, put your information in, and we can get started working on the path to coverage or in those cases where it is an out of pocket concern, no insurance, the PAP process is available there as well. Thank you, Beth.

Beth Dean:

Awesome. Thank you Randy. And thank you Meghan. It's really helpful, I think, to hear about programs at both of the organizations and they are really strong programs to help people get access. I thought I would share a personal anecdote before I got to the questions. I had a little fall broke my leg, had some surgery a couple weeks ago, and before surgery, they put you on a blood thinner and they phone in the pharmacy. I get a text, it's going to cost me \$75. So because I'm frugal, I get on the web and go to Xarelto's webpage and they have a copay card. The doctor's office didn't say anything and it wasn't going to be automatically applied at the pharmacy like we heard about some of these programs. So I ended up paying and still pay \$10 a month copay because I found that card.

So I do think there is value in empowering yourself with information and going to the websites for branded drugs and looking for discounts because sometimes they're great and they're automatically applied on the backend, but oftentimes you need to sign up for a program or get a physical copay card in order to get those discounts. But you can save money by educating yourself and looking for options. I don't know if any of you've looked at Mark Cuban's Cost Plus drug site, but there are a lot of anti-epileptic drugs on there and it's a great way to save money. We've shared it on social media, but there are ways out there that you have to do a little legwork but can benefit you. So I thought I would share that.

So let me ask our first question. I think Phyllis, this is probably for you. It says that most formularies have seemed to have excluded brand Depakote. I've been able to get our private insurer to continue to cover the brand name Depakote. But when we have to switch to Medicaid and Medicare, is there any reason to thank them to be as reasonable? So do we think that you can make a case to Medicaid Medicare, like you can a private insurer like Blue Cross, to get them to allow you to have brand?

Phyllis Kidder: I hate to say it depends, but it does. I think that Medicare, you probably, most Medicare prescription plans are managed by the same insurance companies that manage commercial insurance. UnitedHealthcare, Humana, CVS, Optum, I mean all of them. Aetna, some of the Blues plans all have that. So you probably can there. Medicaid is likely to be more challenging. Medicaid tends to be very budget constrained, and so it may be more challenging from a Medicaid perspective.

Beth Dean: Great. And Phyllis, another one or two for you. Has the FDA made any improvements to its oversight of foreign generic manufacturers? Do you have any insight on that?

Phyllis Kidder: They're trying. I think that a lot of it is inspections of facilities and that continues to be a problem and it continues to be I think a manpower issue, which has not helped at all during the COVID pandemic. So I think it's still a little bit of a challenge.

Beth Dean: Thank you. Another question, kind of COVID-related. Back in the throes of the pandemic, we would hear about drug shortages and supply chain issues. And I'm just wondering if that has pretty much resolved itself. Are there still issues out there within the supply chain for medications?

Phyllis Kidder: There are definitely still issues out there in the supply chain for medications. It's not quite as bad as it was during COVID, but some of it has to do with the previous question. You get an foreign manufacturing facility that gets shut down for quality issues and then you have a problem with drug supply or you have some generic manufacturers make a decision that they're not going to make that product anymore. And so there are definitely still supply chain constraints.

Beth Dean: And the next question maybe for Phyllis and then Randy and Meghan, if you want to maybe speak specifically to your products, that could be helpful, but the question is about how to get access to a drug when it's not on label. So Phyllis, you talked about some of those things, but I think the question is probably getting at, what does it take, what kind of argument do you have to make in order to get the access?

Phyllis Kidder: So if you're saying that your doctor's using it for an indication that's not on the prescription label, that it wasn't approved for, okay. Generally they need to be able to cite documentation in the literature that it works so that there's been studies or some kind of medical literature documentation that the drug is approved ... Not approved, but the drug has shown effectiveness in the indication that they want to use it for, and also why those medications that are approved are not appropriate for you and or don't work. They'll have to document both sides of that, why the approved drugs aren't working and give literature documentation that this drug, there's data that it's effective. And that still may not be enough, but that's the minimum that they're going to have to do.

- Meghan Szczech: I would agree with Phyllis. It's a very hard situation. What I will say is it's going to have to be fought by your doctor. So doctors have the ability to prescribe however they deem appropriate. As manufacturers, we can only support on-label diagnoses. So unfortunately our patient assistance programs and other support can't be used off-label, but your doctor, if they feel like there's a true medical need and they can explain that to your insurance, they do have a chance of getting it covered for you.
- Randy Brown: Agree with both Phyllis and Meghan, what we've seen is the physicians that are willing to go toe to toe with the insurance company provide that documentation. Typically, it is trial and failure of other formulary drugs that they are recommending. They're typically, in our situation with Epidiolex, I can only speak to that there is a path to coverage for the broader refractory epilepsy. When you start to look at use across other disease states, not a bunch of success there with getting a coverage or obtaining coverage through the insurer.
- Beth Dean: Okay. Another question around formulary. So maybe Phyllis, if you can take this one at least to lead, how do they determine what gets on a formulary and what tier it's at?
- Phyllis Kidder: Every health plan has a slightly different process, but the general process is that they have what's called a pharmacy and therapeutic committee, and that's made up of physicians, pharmacists from the health plan. They get information from the manufacturer, they do their own literature review and they compare it across multiple areas. They look at it clinically to see is it different, does it differentiate itself from a clinical capability perspective, does it differentiate itself from a safety and tolerability perspective?
- Then they usually come to a conclusion of must add meaning it's clinically superior and or better tolerability in some significant way, may add, which means it's sort of equivalent to other things, or do not add. If it's must add it's on and then they do a financial analysis and think about what tier they put it on. If it may add, then it may come down to the finances of what that particular manufacturer is willing to offer in terms of a discount compared with everything else. And then they make a decision that way.
- Beth Dean: Great. And I have one last question. What happens when you change from being a college student to getting a new job in new insurance? Is there a waiting period before you can start the new insurance?
- Phyllis Kidder: That depends on your employer and the way your employer has your coverage set up. Some employers have you wait 90 days. Some employers offer you insurance right away. That's really how it's structured between your employer and their insurance provider. Almost every time you change a situation like that, you can have what's called COBRA, which is expensive, but you pay for that and you can stay on your old insurance until you get new insurance coverage.

Beth Dean:

And I lied. We have one more question. It's in the chat and give me one second because I am not seeing it. We're good. I'm sorry, I'm not seeing the chat but it's a question I have. So unless anyone wants to quickly type in any others, I think that is it for our program. Again, I want to thank Phyllis, Meghan, and Randy for their time in sharing their expertise. We will send out follow-up information and I would also like to highlight that we actually have a whole new section on our website with content that explains a lot of what Phyllis talked about in more detail with examples. So it's a great resource for you to go and check out.

I think you'll also be able to download a transcript to discuss with your medical professionals or share with others if this information is helpful. So thank you very much for joining us. Please fill out the feedback if you get the prompt, and we are here to answer questions. So if anything pops up in your mind later, please don't hesitate to contact us. We're proud to be part of this community and want to ensure that people get access to the medications they need to achieve seizure freedom. So thank you again, Phyllis, Meghan, and Randy, thank you all for joining us, and be well.