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HEPATITIS C PRIOR AUTHORIZATION: TRICKS OF THE TRADE

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Hepatitis C Prior Authorization: Tricks of the Trade [video transcript]

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Dr. Lee currently works with an interdisciplinary team focused on providing access to high costs hepatitis C medications, as well as pertinent patient in education regarding potential drug interactions, proper medication administration, and appropriate follow up. She's helped over 1000 patients initiate hepatitis C medication regimen. She'll also be joined by Ciarra Leocadio, who is a patient navigator with the REACH program at Mount Sinai. Ciarra provides linkage to care, care coordination, and co-leads to Harm Reduction Support group for people who use drugs and people who have Hepatitis C. She's a recent graduate of Vanderbilt University. Dr. Lee, I turn it over to you.

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Thank you so much, Jeff. Hello, everyone. Thank you for joining us. Today's topic is titled Hepatitis the Prio-Authorization Tricks of the Trade. I have nothing to disclose. The learning objective for today is to discuss the tests needed to apply for hepatitis C. Therapy prior authorizations, identify essential resources for patients approved for the medications, and to describe options for patients denied for hepatitis C therapy. For those that deal with Hep prior authorizations, on a day to day basis, I hope that through this talk, your daily workload will be simplified. And also for those that have nothing to do with prior authorizations. I just have to say you're very blessed. But regardless, I hope your questions regarding prior authorization will be answered. So let's get started.

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So why are we having this talk about prior authorization. So when the hepatitis C medications came out that oral third generation direct acting antivirals, press like this came out, FDA approved new \$1,125, a pill, Hep C drug. And then patients started suing the insurance companies for this life saving medications. And then the America's most expensive prescription list. Of course, hepatitis C medications were on there. So this is why we're having this talk. We're talking about prior authorizations so that you can help your patients get life-saving medications. So what is a specialty medication? The definition is very free for all meaning the insurance companies can have their own definitions. There's really no set. But these are a few definitions that you can go by. for hepatitis C medications. The cost of the medication really defines its definition for specialty medications. So what do we have in our armamentarium we have many drugs. The ones that are crossed out are antiquated, so we do not use those anymore. So really, we have five in our armamentarium that we use. Currently, we have sofosbuvir Ledipasvir , which is Harvoni. We have elbasvir grazoprevir, which is zepatier. We have sofosbuvir velpatasvir, which is Eplclusa, and we have sofosbuvir velpatasvir voxilaprevir, which is vosevi and this is our salvage treatment, meaning you don't use it in treatment naive patients. Glecaprevir pibrentasvir, which is Mavyret, which is also a salvage treatment, and but also you could use it in treatment naive patients. So the cost of these medications are pretty horrendous. As you can see, in 2019, just this year in January, Gilead, the makers of Harvoni and Eplclusa released their brand generic. So what that means is, the manufacturer holds the patent, but releases the formula for a generic medication to be produced under their sister company. So their cost for Harvoni brand generic and also

includes a brand generic is 24,000 for 12 week treatment, which is somewhat comparable to the mavyret which for eight weeks, it's 26,000 and change. So these are the medications that are available in currently and that is being currently used. So what is the prior authorization process and how does it look? So this is the flow. Initially the patient visits the physician, the physician orders the appropriate lab work that needs to identify patients having Hepatitis C virus and the prescription is processed. The prior authorization is sent If required, and then the appeal for second and third may need to be sent to the insurance company if it's the last final appeal would be sent to the New York State Finance Department. And finally, if it's approved, the patients will hopefully get the medication but also financial assistance may or may not play a role because the copay might be in the 1000 and not in the one to \$2 range. In our facility here at the Sandra Atlas Bass Center for Liver Diseases I'm a pharmacist here at the doctor's office. So our patients at our office get a patient pharmacist led counseling session, which is about a 15 to 30 minute counseling session led by myself to describe to the patient what the medication is what takes back when to do bloodwork, and when to follow up with the prescriber, pretty much the whole nine yards. And so I'm able to do this because I do have a legal agreement with our physicians. It's called a CDTM, and that allows me to order the prescriptions that allows me to order medications If required, and lab work as well. The approval time may take three days or three months or greater than three months.

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And so really, it is insurance specific to the approval time. So when a prescription is sent to the pharmacy, usually in New York state we e-prescribe, right so through our electronic medical records, a prescription is sent to the pharmacy, it may be approved, which means Okay, the pharmacy needs to figure out which pharmacy is going to fill the medication because sometimes these medications are so expensive, that they're that the patient's insurance company will mandate that it'd be filled at a mail order pharmacy, not a local pharmacy. So if that's the case, the prescription that was sent to a local pharmacy cannot be filled in has to be sent over to a mail order pharmacy. Again, if it's approved, we really need to think about copay. When you get that approval letter for the patient, you can't say hooray yet because the copay may be in the 1000s of dollars. And if that's the case, financial assistance should be connected to the patient. If it's denied, it needs the next page because there may be many, many reasons why it may be denied. So if the prescription is denied, the prescription may be denied for many, many different reasons, as we could see here, a prior authorization may be required. And if that's denied, an appeal may be required as well. In 2014, it was very difficult. But now 2019 we usually are able to get medications approved just by the prior authorization process. Seldomly do we need to send an appeal And regardless, we really need to think about the patient's copay, because even if it's, it goes through all these processes of the copay is unmanageable for the patient, the patient cannot start the medication. So what documentations does do we need to send over to the insurance company. So you have a here checklist. My prior authorization packet looks like about 15 to 20 pages depending on how much information we have on the patient. But I made sure that all of the checklists is present if required. The only things that may not be 100% required for the different insurance companies may be the drug resistance test, treatment and readiness and the assessment form and illicit drug test.

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The medical necessity is an appeal letter, so it may or may not be required. But again, as long as your packet is the most comprehensive in regards to proving that the patient has hepatitis C and their fibrosis score, the faster you can get your patients the medication, it is a very very manual process. It could be done through fax or it could be done through electronic PA you cannot think that you send the prior authorization and the insurance company will reach out to you and tell you whether it's approved or not, doesn't work that way. You need to call the insurance company and follow up pretty much three to seven days after to make sure you find out what the status of the prior authorization is whether that be denied or approved. Again, if it's approved, we need to figure out the copay through the pharmacy and if it's denied appeal has to be sent. So the electronic prior authorization so our division has started using the electronic prior authorization really starting this year. Last year definitely this year through cover my meds cover my meds is a online free service. So anyone could really make an account. You pretty much put your physician's information their NPI and To set up an account for yourself, you can have many different physicians under your account. And you pretty much put the patient's insurance information ID group in PCN, whatever you have, the more you have, the more detailed, it will narrow it down to cover, my meds will narrow down the insurance plan. And it will give you a electronic prior authorization form. If they don't have the most updated one, they'll end up actually faxing over a updated prior authorization form through the fax number that you put on there. But it really does save a lot of time. Sometimes if you get lucky, you can get an approval within 60 seconds through cover my meds, but most of the time, it does still take about a week, three to seven days. So the prior authorization packet proves a lot of things. So through the chart note you have the diagnosis code for the diagnosis code for hepatitis C it is B one 8.6 I'm sorry, B one 8.2. On the chart note, it proves if the patient is treatment naive meaning never treated for hepatitis C prior or are they treatment experience and if so what were they treated with? CBC tells us if they're anemic, if it requires ribavirin and the treatment which we usually don't use, nowadays, we need to check for the hemoglobin. The comprehensive metabolic panel really tells us okay, does the patient have good kidneys or creatinine clearance less than 30 then some of the medications cannot be used as a sofosbuvir containing regimens. And then we also with the CBC figure out if the patients are decompensated or not and we'll go into what that means. The Hepatitis C genotype proves which genotype but some of the medications are pangenotypic like the mavyret vosevi and Eplclusa. And the viral load some insurance companies do want to hepatitis C viral load that six month within six months apart so that they prove the patient has chronic hepatitis C. So hepatitis C testing so the New York State in 2014 made it a law public health law that patients would be born in the age group of 1945 to 1965 be tested for hepatitis C because they actually hold the majority of the nation's Hep C population. About 75% of all Hep C patients in the United States were born in this age cohort. In New York City in 2017. They made it a law where the hepatitis C antibody will reflex to hepatitis C RNA if the hepatitis C antibody is positive, so how the Hep C testing goes is first they Hep C antibody needs to be tested. If this is positive, it tells us that the patient has been exposed to hepatitis C. And if that is positive, a Hep C RNA has to be done. In the past, you would need the patient to come to the doctor's office or to the lab twice, meaning once to get an Hep C antibody and then a second time to get a Hep C RNA. The New York City law in 2007 allowed that the labs itself can reflex if the Hep C antibody is positive, it could just automatically test the hepatitis C RNA, which saves the patient a trip to either the doctor's office or to the lab.

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The liver fibrosis score. So the insurance companies want to see how scarred is the patient's liver. So a healthy liver should look like this a smooth F Zero is what we want. And that's a healthy smooth liver at when the liver starts getting bumpy. Those are scar tissues. And to your right is cirrhotic liver or F4. That's stage four. And those are very, very scarred liver. So you have direct liver fibrosis testing or indirect liver fibrosis testing. The gold standard is a liver biopsy, which is a big needle going through the liver to see if you have any fibrosis or any scarring in the liver. Even though it's a gold standard. Most people do not want a big liver or a big needle to go through their body. So a fiber scan would be the next runner up. It feels like an ultrasound to the patient and it really tells us more accurate f score. So F Zero being a healthy liver and F four being a cirrhotic liver indirect test. So if you don't have a fancy fiber scan in your office, you can do a fibrosure which is a blood test or even if you don't have access to that you could do a pre score which is a calculation And we'll go over that. But sometimes an ultrasound may not be enough. This is an emblem prior authorization form. And sometimes they do really want you to have a more direct test to prove the patient's fibrosis. So this is what the fiber scan looks like to your left, it really took a patient feels like an ultrasound, and the F score is calculated through kilopascals and then scored through F zero through F four. So a pretest is aspartate aminotransferase to platelet ratio index to platelet ratio index. So this a pretest is pretty much taking the patient's CBC NC MP and calculating the ASD over a patient's AST over AST, and the upper normal limit of AST and the patient's platelet count times by 100. To tell us if the patient has f Zero through F4. So the results are calculated this way. So compensated versus decompensated cirrhosis. So remember that picture with the really really bumpy bumpy liver. So the patients can have compensated cirrhosis. So the liver is still bumpy, but the liver is functioning just fine and these patients will be Child Pugh A or you can or even B or decompensated would definitely be C or sometimes even B so the B is kind of a gray area. So the Child Pugh score really calculates specific and nonspecific information or objective or a non objective information. So the objective information will really be the bilirubin, the albumin and then the INR, and then the presence of ascites and encephalopathy and when you put in all of your information, it will calculate a number and the number will correlate to a Child Pugh a B or C. So if a patient is a Child Pugh, a and b, the liver function will be normal, meaning the ASD It may be just fine and the patient's liver is functioning Okay, despite its very bumpy, bumpy liver, and the patients may or may not have symptomatic liver, the patient's liver is just functioning fine whereas if you're decompensated, you are experiencing encephalopathy ascites and even portal hypertension.

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And the prognosis for the compensated patient are good whereas decompensated is bad. So this you need to know this because the protease inhibitors cannot be used in decompensated cirrhosis. So these are the medications that are ends in a previr p r e v i r so we're talking about the medications that are zepatier, vosevi and mavvyret. So these medications have a protease inhibitors and it cannot be used in decompensated cirrhotic patients, sometimes the NS5A is required and so really refer to the AASLD guideline and only the three drugs that need NS5A testing is the elbasvir grazoprevir, which is the zepatier, ledipasvir sofosbuvir which is Harvoni, and the sofosbuvir velpatasvir which is eplclusa. So this is

what a NS5A test will look like. So the NS5A resistance will be tested for these NS5A drug so daclatasvir ledipasvir ombitasvir, and if it is present, it will say detected or present. And then in regards to the clinically important DRAS or drug resistant associated substitutions, these are the ones for the specific Hepatitis C genotype and for the medication regimens that are significant or important. But regardless, a lot of these medications overcome the drug resistance. So depending on the medication and the patient's genotype, these NS5A test being NS5A drug resistant associated substitution may not may or may not be clinically important. These are the codes just for your reference if you do need to have your patients do an NS5A test through quest or labcorp. This is the most updated codes. I verified it just yesterday. Sometimes the patient's insurance company if it's especially a Medicaid patient, I haven't seen this in the last I would say six months but sometimes they will request a patient readiness score. And so the one that you're going to do is to cage aid, it takes about three minutes. Whereas some of the other tests will take about 30 minutes. So cage-aid is the questionnaire that's here with the four questions. So if the insurance companies asked for patient treatment readiness assessment form or a questionnaire, you would want to go for the cage aid drug with a drug test. So, insurance companies really should not be requiring drug test any longer, but if they do, the urine test will be sufficient. And when you look at some of the data, like the Ion-3 trial trials through sofosbuvir, ledipasvir, which is harvoni, the illicit drug use, they really did not impact the treatment outcome, meaning the patient's cured hepatitis C regardless of the use of illicit drug use. So why is it important to cure hepatitis C? hepatitis C does not just affect the liver it is it affects a lot of other organs. So some of the strongly associated extrahepatic manifestations of hepatitis C have been lymphoproliferative disorders, neuropathy, neuropathy, neuropathy, and vasculitis. And there are some other possibly associated diseases, like a very common type two diabetes, or autoimmune thrombocytopenia. So you can't just think that hepatitis C is a liver disease, it affects a lot more organs than we know. It is cheaper to treat the not to treat. So when you get the patient to that cirrhotic category, which really patients should not get to the cost of treating these patients become a lot more expensive. So treating them now is so much more prudent than treating them many years later.

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So when you think about hepatitis C treatment, and you ask what is the right hepatitis C treatment for my patient? These are some of the things that go through my mind. What is the patient's insurance, Hep C formulary drug of choice. So that's really number one, because when it comes to efficacy, all the medications that are available, are pretty much equivalent in regards to the cure rate of Hepatitis C. So really, you want to figure out, call the insurance company prescription insurance company and figure out which is their formulary. Some of the other questions that come to mind is does a patient have decompensated cirrhosis? So that rules out in my mind all the drugs that end with a purveyor? So again, this is zepatier, this is mavyret and this is vosevi, you do not want to use it in decompensated cirrhotic patients you only want to use it in Child Pugh A patient's renal insufficiency. Does the patient have creatinine clearance less than 30? If they do, you do not want to use sofosbuvir containing regimen. So we're talking about Harvoni. We're talking about eplusa and also vosevi. And you also want to think about drug interactions? Is my patient on amiodarone then you can't use the sofosbuvir containing regimens? Is the patient on a statin then you really need to do your drug interactions because a lot of the hepatitis C medications are either contraindicated or you need to reduce the dose, and also with

some of the PPIs, or the PPIs with the sofosbuvir containing regimens. So now I'm gonna turn the mic over to Ciarra.

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Yep. So as we're talking about this, often, we have to think about the patient's perspective. And once they found out that they have hepatitis C, a lot of things run through their mind, including, are they going to die, can they start tomorrow, not realizing that there's this large hepatitis C prior authorization process, or a lot of people are excited, they're happy to finally get cured, and maybe they run up run into some roadblocks to get getting cured previously. And as we're doing the prior authorization, it's really important to kind of make sure that we're setting realistic expectations. Next slide. So there are a lot of barriers to hepatitis C cure. And we know through the care cascade that we often lose patience in between. So from the time that someone is screened to, to the time that someone receives their test results. Often someone we can't get in contact with them. So a lot of the time I'm doing testing in the field and we'll do hepatitis C antibody tests, and we'll do the dry blood spot test so we can figure out if they have an active viral load, but we don't have the right contact info. So then we can't call them to give them the results that they have an active virus. Maybe they have received the test results, but then they're actively using different types of drugs, and so that, you know, create some chaos and they aren't able to make it to an appointment, maybe we linked them to care. But then, you know, it turns out that they might have decompensated cirrhosis, and we need to send them to a specialist. Or maybe it requires an additional blood test. Often, a lot of times we are finding out that patients are also drinking alcohol. And you know, they might have this fear that they can't disclose that to us, because we're not going to treat them at the REACH program, we still will treat them but we also want to advise them about their alcohol use, maybe we initiate therapy, but then, you know, it requires an on treatment viral load to get the rest of the medications. And even if someone is adhering to therapy, and it shows that they're a good candidate, we still might need to do a PA extension, or we might have to work through a restriction through a pharmacy. And all of these processes, though, a lot of the times patients become lost the follow up. And I think that that's a really special and unique part of our program that we have patient navigators, because we know our patients through different aspects of their life, we might know them from a methadone program, we might know them from just seeing them in the field. And that is a way that we can re-engage those patients. Next slide. I think, as we were talking about this, the timeline is also really important. And I want to echo something that Susan said it can take from three days to over three months. Sometimes, you know, the prior authorization is very quick. And you know, we might get a denial, but we can change the medication to what's on the formulary, and then we'll get an approval, or let's say our appeal is denied, it might take an additional 30 to 90 days to do an internal appeal. Or if we do an internal external appeal, it might be three to five days. But I think one thing that's important to note is that we're not getting as many denials in these days, because a lot of the time we know what's on the formulary, we're sending what's on the formulary, and the prior authorizations are being approved. So it's much quicker than it used to be. Next slide. So how do we relieve the patient's anxiety, I think the biggest piece of this is finding out who's the patient's go to person and there's a variety of different people that that could be at different places, it might be the secretary, it might be the nurse and the REACH program, I think it's the navigator and I kind of want to go into what the role of the Navigator is. So as the REACH program, Patient Navigator, there are four patient navigators and we have a hotline phone. So that isn't an advantage for us, because we can give the patients the phone

number and they're able to call us. And we are able to engage the patients in the field and in the clinic is someone who's a continuous force for them. If we see them at their methadone program, if we see them at the syringe exchange program that they go to the place that we tested them we often revisit, and so we can refine those patients there. We're the point person for all of the patients questions. So if they need more education, if they need to know more about hepatitis C, if they need to know what how, where they are in the process, we can answer that question because we are really the people who are handling the prior authorizations. We're making sure that the paperwork in addition with our nurse nurse who sends the prior authorization, we're working with her to make sure that they're submitted, and that we're contacting the specialty pharmacies, the insurance companies, and then the patient assistance programs to help troubleshoot all of the problems that really pop up where the patient might not, you know, know where they are in the process, we can, you know, fill in that gap and tell them the information that they need to know. And so I think that's the special part of having a navigator. But there's also the special part of having a specialty pharmacy that a lot of

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organizations are building up relationships with, because when you have a specialty pharmacy that can handle all of the prescriptions that you're sending for hepatitis C paid prior authorizations, they are able to help, you know, expedite that process they can provide the providers and the patient an additional support system, specialty pharmacies also can help with accreditations. They have trained staff who are able to answer patient questions and they can provide educational materials that, you know, patients can look at and say, hey, look, this is where I am and I and they can, you know, use that when they are talking to their other friends who also might have hepatitis C, they can also, you know, tell us right away, they'll flag us and say, Hey, we see that this patient is on all of these medications, there might be a drug drug interaction, are you sure that this is the medication that you want to send, and they can assist with the prior authorization process in its entirety. And that really does help, you know, relieve some of the work that has to go into the patient navigator or their nurses or whoever is really submitting the prior authorizations because they're working directly with the insurance company and they are able to expedite the process for us. And they know that local pharmacies often do have hepatitis C medication. So specialty pharmacies really do fill that role of making sure that we can, you know, get the specialty medications to our patients. specialty pharmacies also assist in the appeal process. A lot of the time we depend on them for writing us, letters of medical necessity that are already pre written then that we can fill in information that are specific to our patients. And they can provide the they can guide the providers through the appeal process. They can assist in all of the follow up that's needed, especially when you're unsure of like who to go through. A lot of A time, you'll have a company like CVS Caremark who does the prescriptions, but they're not the insurance company. And so they can really guide you to tell you who you need to call. Like I said that they can provide patient education. And they're also the primary contact for hepatitis C for prescription updates, because formularies change all of the time. And so one, you know, one week, the insurance companies might prefer mavyret, and the next week they prefer harvoni. Um, and lately, we really haven't been seen anybody who's being prescribed mavyret and being approved for it, despite, you know, the FDA approving it for even just for eight weeks, even for people who previously might have needed 12 weeks of treatment, and they also can do medication counseling, they can really walk the patients through how they need to take the medication, they can help, you know, make making sure that the descriptions on the medications about how to take the medications

are right. And it's really helpful to have a specialty pharmacy that you can rely on next slide. So I really wanted to talk about this approval process. Because Susan actually created this really great chart, where we can see that in the prescription process, only about 5% of people are being approved, there in the vast majority of people are requiring prior authorizations at this point, so it's really important to know some tips and tricks so that you are able to get your patient successfully through. Even though 73% are approved through the prior authorization process, there's still a large group of people about 19% that need an appeal. And nowadays, like the appeals are much easier to deal with. But I think that there's still a group of people that are requiring appeals and knowing how you can expedite that process is really helpful. Um, there are patients, Yes, go ahead. That's fine. So the appeal process, it's a lot of paperwork, you do have to send a lot. But it's really important to note that you need to stay organized, have all of the patient information available, and really are streamlining your information that you're giving to the insurance company and the specialty pharmacy. So here are some reasons for denials. Some people are getting denied, they'll get an initial adverse determination based on the fact that we prescribe the medication that's not on the formulary. And that's a really quick fix, all you have to do is like Susan said, call the the prescription coverage company and ask them what is on the formula. And often they're really happy to give you give you what it is. And then if you change the medication, it's almost like starting the prior authorization process over and then you won't have to go through this long appeal process. Sometimes we'll also get approval for only 14 to 30 days. But that doesn't make sense, because patients are needing eight and eight and 12 weeks of treatment. So you'll have to make sure that you're doing this of this process over and over again, sometimes you'll have to apply for the reauthorization at the end of the first month, which is, you know, fine, but it does come sometimes create a disruption for the patient. Because if you're not able to get the medication in time, that can, you know, cover a lapse in treatment, and that creates a problem or a patient can become lost to follow up in that process. And then the last reason that really has been popping up is that the labs have expired. And sometimes we know that our patients who might be actively using drugs might come in at one point, but then be ready for treatment at another time. But insurance companies really require that the the labs are within the last six months. And so if you haven't, you might have to have a patient come back in and get new lab.

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Next. So there are some special circumstances, sometimes patients are half self funded or self insured plans. But this is not under the jurisdiction of New York State's finance department and often the human resource department is a great place to go for the patients. Union plans notoriously were really difficult to work with including like plans like 1199 local or DC 37. And a large part of the prior authorization process for those patients was learning what the union's process was, who do you need to contact? How does the prior authorization gets sent? How do you find there prior authorization forms. And I know in my case, I worked with a patient where it took about four months for us to get approval and he had previously gone to three different programs and was not able to get was not able successfully to get medications. But now we know that the union Office is like an independent reviewer of the medication approval separate from a prescription company or prescription coverage. And often they still require you to work through a specialty pharmacy. And then you also have patients who have no prescription coverage. And they're required to utilize manufacturer assistance programs like through mavyret or through Gilead, who like who can make sure that the patients can get medications, and then also can help with the financial assistance. And I just wanted to show one more thing, which is a letter from DC

37. Because they knew that, you know the process was so hard for patients before as of September of this year, they've made it clear that they have added two different medications which are harvoni and mavvyret to their formulary. So patients who previously had a really difficult time getting hepatitis C medications now are able to be prescribed one of those two and should have a much easier time. I'm getting approval and being treated for their hepatitis C. So now I'm going to hand it back over to Susan to kind of talk about the financial assistance process.

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Okay, thank you. So if you have not prepared a pen and paper, I think at this time, you might want to prepare a pen and paper only because this information will help your hepatitis C patients, but you can actually use this information for a lot of patients that have high co pays on different types of medication. So let's talk about financial assistance for hepatitis C medications approved may not mean approval. What I mean by that is okay, you get that letter of approval from the insurance company that says you your patient has been approved. Hooray. But when you actually have the pharmacy process, the prescription, the copay could come back as 1000 something 5000 something today we were just dealing with two different patients. One had a commercial, retired firefighters, insurance and that patient's copay came out to \$20,000 per copay. So, number one \$20,000, a copay number two \$20,000. And copay. Number three was another 20,000. So \$60,000 out of pocket. So approval may not mean approval, there may be a big deductible. So some patients, if they're getting Hep C medications at the beginning of the year, or even if it's not a beginning of the year, because it's a specialty medication, it may require a deductible it may be few hundred, maybe a few thousand. It really depends on the plan, the insurance may pay only 10,000 annually for a specialty medication. Well for medication for that fire, retired firefighter men that I thought that I was speaking to today. For him \$10,000 does not mean much of anything, because he would still be left with \$50,000 out of pocket. So we really need to figure out the finances and connect the patients to the right resources. Some patients insurance companies, they may cover 75% of the patient's costs, it would it's great 75% sounds great. But if the copay is so high, even that patients may not be able to pay out of pocket. So we looked at a 300 patients within northwell health, because I have the privilege to talk to our patients and our patients. I do ask them, you know what was your first month co payment because most of the time these patients have received the medication, pay that copay and then have the counseling session with me before they start the medication. Most patients that have Medicaid, pay really an average of \$2.33, minimum \$0, maximum \$23. If they have Medicare, they pay an average of \$300 minimum being zero, up to \$16,000 maximum copay. And if they have commercial plan, they pay a little shy of \$900, minimum being zero and the maximum being \$26,000. So there's a big range. But no one really pays the list price. I think of our over 1000, almost 2000 patients that we're heading now, we only had about three patients that had to pay out of pocket. And that's because either they didn't have insurance, or they were part of a union. And they really, the union did not cover much of anything. So this is really what the copayments our patients are dealing with. So what financial assistance do our patients have access to? So we have in the United States, again, three major insurance plans right Medicaid, which is our underserved Medicare, which is our either disabled patients or aged 65 and older, and then our commercial plans, which are people in the work work field, right. These are patients that are receiving the insurance, either through work or they're paying out of pocket to get their insurance. So these financial assistance manufacturer coupons so these are the coupons that have the name and then it will say something like pay no more than \$5

and you may see this not just for Hep C drugs, but you may see it for many other brand name drugs. So the manufacturing companies

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give out these coupons, but you can only use it for commercial plans. Again. So these are patients that get their insurance either through work or they pay out of pocket to get their own insurance. So these patients if their copay was \$1,000, it's okay because these copay cards that are funded by the manufacturing companies do cover a big chunk, meaning I think a lot of them cover up to 10,000, 15, \$20,000 for the whole, not just a first fill, but for the duration of treatment. So if the patient's copay number one, two, and three are about a few 1000. Hopefully, the copay card will allow the patient just to pay five or \$0. For the full duration of treatment, whether that be to fills eight being eight weeks, or three, fills being on 12 week treatment, the discount card, so these are prescription discount card. So I actually had to really research on this because I didn't know what these were so GoodRx, you may have heard about this a lot, and blink health. So these are companies that pretty much contract the drug prices with the manufacturing companies directly. If you are to utilize GoodRx, or blink or any of the prescription discount cards, you would have to not use your insurance. It may sound really bad, but for patients that are having these horrendous co pays. So like our, my firefighter man that I spoke to today that had the \$60,000 copay for the full duration of treatment. For this patient, the good RX may be a good option because the good RX if you pay through good RX without your prescription insurance per month, his medication will be about 5000 and change, it really differs with the medication that you choose. But the specific medication that he will be on will be about 5000 and change. So 5000 times three, it's about 15,000 for the full duration versus if he were to go through his retired firefighter firefighters insurance, he would have to pay \$60,000 out of pocket. So this is a really helpful resource for patients that are getting these horrendous copays through their insurance company. So it might be beneficial for them to go through these prescription discount cards without the insurance plan, which will help them pay less out of pocket. Blink health it works like Good RX. So Good Rx, you just bring this information to the pharmacy, the pharmacy processes it like a secondary insurance card, whereas Blink, you actually pay online. So you pay on your phone or on your computer. And you bring that paper that states that you paid for drug x, you bring it to the pharmacy that participates in these programs. And then you get the medication that way. So it's a little different. Sometimes the insurance companies or the pharmacies will have prescription discount cards as well. I'm not sure how I've never used had a patient use the CBS prescription discount cards. But I would think that it will work very similarly as like a secondary insurance or a discount card to really bring the price down. In New York State for our Medicare patients. So 65 and older, we have access to New York State epic EPIC stands for elderly pharmaceutical insurance coverage. So New York state program for seniors that get insurance through Medicare Part D. But this is a supplemental plan that really helps them pay less than what their copay is just through Medicare Part D. So our patients that have Medicare Part D and their co pays are still coming out to a lot you can utilize the epic, but you do have to financially qualify for this as well.

44:19

The manufacturing, companies have programs that are supportive to the manufacturing coupons. So for patients that qualify for financial assistance, and all the all the programs are a little bit different in regards to what the amount is per household. For example, one program may say, if there are two people under the household that makes less than \$70,000, you may qualify where another program may say if there's, you know, to under the household making less than \$65,000 then you qualify. So you've been have to just reach out to them. But if the patient's copays are high, then this may be another resource. So, for the union plans that are commercial, you may utilize the manufacturing coupons plus this financial assistance resource to get their co pays down. There are foundations so these are not the insurance companies. These are not the manufacturing companies. These are, you know, third party companies that get money donated to them. So we have patient access network, we have healthwell PAF, Patient Advocate Foundation, Good Days. So these are all organ organizations that get money pulled in from different resources, meaning money that are donated to these companies. And these companies are able to give funds or foundation funds to patients. So, for example, they may give like a \$15,000 grant to a patient that needs assistance. And sometimes they may even extend it a second time around if the first grant does not cover them for the full duration of treatment. So this is very resourceful for patients that need financial assistance for their very high co pays. So what do you need to prove? In order for you to get access to some of these foundations or find financial assistance program that are supported by the manufacturing companies? You need a diagnosis? All right. So in this case, it would be hepatitis C, ICD 10, code B, one, B one 8.2. So that's how chronic hepatitis C, you need to know the medication you need to tell them if you have insurance, meaning does the patient have prescription insurance or not? And also financial qualification, so they may ask for proof of household income and how household size most patient most programs do not require a social security number or citizenship proof, but they do need to know that you live at a specific address. So let's say there's no other option. Let's say you try to connect them to as many resources so you try and connecting them to the copay coupon plus the foundation plus the manufacturing sponsored financial assistance program and their co pays are still you know, very high. What do you do at this point, you can either change prescription insurance plan, and for most patients that may not be feasible, especially if they work at a specific job, and there's only one type of plan. But if they are paying for their own insurance, then they may be able to change their prescription plan, bench time, meaning if the patient's formulary, and their copay amount is a certain amount this year, and they cannot change their prescription plan. Let's wait a year. And let's try this process again and hope that next year's copay will be like less. So we've played this game with a few of our patients insurance companies, and it has worked for a few. Unfortunately, some patients are still in this category, meaning the middle class patients that are that do not qualify for financial assistance. We have about less than 10 patients that are in this category because they cannot qualify for financial assistance and because the copay

48:40

coupons, the manufactured copay coupons are not sufficient in covering their copay amount. We have a few patients that are in bed bench time. So every year we try again to process the prescription is through prior authorization process and hope that the copay is less so that they can start. If there is no other options, you can connect our patients to the attorney general's office. So this is when insurance

companies are playing games. Meaning if let's say there is a medication on formulary, but they're making it ever so hard for these patients to get access to hepatitis C medications, there is a help health care helpline. So this is the number here. This is an older form, but the number is the correct number. So if they call this helpline, the patients can tell their story and if the New York State Attorney General's Office deems that they can help they will call the insurance companies they will call the specialty pharmacy and really have them jump we've had patients use this line and we've had about two patients where they did get help with their situation. So it is a resource resourceful number for situations. Where the patients are really not being attended to. So after the approval, you can't really just say, okay, the patient must be fine, they can start and we don't need to worry again. Because sometimes during the patients fill number one, it gets filled through, let's say, pharmacy one. And then fill number two, the patient's pharmacy has to be switched because of what the insurance patient's prescription insurance mandates. So mid treatment, let's say the patient has to get three different fills. The patient has to switch pharmacies because the insurance company requires it. Which means that the pharmacist first pharmacy has to contact the doctor's office, the doctor's office has to prescribe the prescription to the right mail order pharmacy most of the time, and then the mail order pharmacy has to get the patient's registration and schedule the delivery and hope that the patient doesn't mistreatment in between. So this may happen. So just be aware that it may happen. We haven't seen this in a long time. But sometimes the pharmacies cannot fill more than 14 days supply of such a high cost item. So this may happen. Insurance companies may require a viral load to prove that the patients on treatment Fidelis is kind of notorious for this. And the prior authorization may have to be extended, especially for our patients that are getting financial assistance, they may not be able to start right away because even though their approval was like two months ago, they're still trying to get financial assistance kind of pieced together so that they can afford that copay. So the approval process may have expired. And so mid treatment, you may have to acquire another prior authorization to extend that approval period so that the pharmacy can fill that medication. Patients may have unexpected hospitalization, not because of hepatitis C, but maybe because they broke a leg or whatever that may happen. We have to remind our patients, if you are going somewhere overnight, whether that be the hospital or on vacation, bring your medication. These medications are so expensive, not a hospital or a another pharmacy is just going to give you the medication, the subsequent co pays so for example, the copay number one may be \$1. But the copay number two and three may be 1000s of dollars. So especially for our Medicare patients, I have our patients figure out if the copay number one is high, or even if it's not, I just have them figure out copay number one, two and three because I don't want this to happen mid treatment.

52:56

So in conclusion, discussed the test needed to apply for hepatitis C therapy for prior authorization. Please note that a complete prior authorization packet will save you time a lot of time. So try to give a most comprehensive packet when you send over that prior authorization packet. Our objective number two was to identify essential resources for patients approved for the medication or treatment. Approval may not mean copay is reasonable use all options, all resources to decrease that copay. Our objective number three describe options for patients denied for hepatitis C therapy. My advice is just try again next year or have the patients look into different insurances if that's an option, but persistence is going to be key in trying to get these patients the medications. These are additional resources in regards to knowing more about the disease or medications or access or if you want to get involved with some of

the public health initiatives. These are great resources for you to look into. This is the CEI phone number. So if you have any questions about hepatitis C, and also any of these other disease states that are listed, please call the CEI helpline they are very helpful. And if you're interested in training on any of these disease state, please visit the CEI training.org. So at this point, we'll take questions. Thank you.

54:41

I just wanted to add one more thing for people who are interested in making sure that people are have access to hepatitis C treatment that do not have insurance. New York state funds 10 over 10 different programs in New York State for care and treatment programs. It's for patients who don't have insurance that wants to be treated for hepatitis C, and they will pay for the costs of hepatitis C visits, and the medications so that way more people have access to getting hepatitis C treatment. And the REACH program is one of those programs. So if you guys have questions about that, you totally can act in the chat.

55:17

Thank you, Ciarra. Thank you so much, Dr. Lee, we have about five minutes for questions. So I would invite anyone to either type in a question to q&a chat, or you can also raise your hand. And I can unmute you so you can speak to us. And while we're waiting for questions to come in, I just want to raise it was a great presentation on prior authorizations. But I want to raise the issue of doing away with prior authorizations. I think a few states might have done that through some innovative models of acquiring Hep C medications for insured patient populations. And I know some of our members of our activist community in New York are looking at efforts to do away with this, you know, obstacle really to patients initiating treatment. So Dr. Lee, any thoughts about if we're getting closer to eliminating prior authorizations?

56:19

That would be wonderful. If we could, as long as you know, the medications are correctly being prescribed meaning it's for the correct Genotype and for the correct duration. I think that would be wonderful. Because, again, hepatitis C not only affects the liver, but the whole body. We just don't realize it. So that would be great if we could get rid of it. But I don't think the insurance companies will be very happy because prior authorization is a break for the insurance companies to really assess Yes, correctly assess if the patients are getting the right medication, but it's also a hurdle for the prescribers and for the patients.

57:07

Thank you. I see a raised hand from Dr. Vu. So first question is has generic harvoni helped with PAs? Dr. Lee

57:24

It has, but it really depends on what the insurance prescription insurance prefers. So if the prescription insurance prefers generic brand, generic harvoni or Epclusa, then that's what we would prescribe. There aren't too many patients that are paying out of pocket to get the brand generic. But there are certain

situations if their co pays are very, very high. We had one patient. He actually ended up getting the brand generic of the Eplclusa, because his third copay was a whole lot. And so he got the brand generic through the good Rx, which still came out to 5000, but 5000 versus 10,000. So for that one specific patient, it was very helpful because it did save that patient about \$5,000. But it really again, goes back to what is the patient's insurance formulary of choice for hepatitis C?

58:39

Thank you. And we're gonna take one final question from. Dr. Lee, thanks for the presentation. I'm a care coordinator at VOCAL with Sinai as well. So my question is, how common is it that the foundation's route is used as a financial support compared to other methods for folks needing that assistance?

59:05

It's actually used very often. So, for example, for our Medicare patients, if their co pays are coming out to \$1,000, or \$5,000, they're going to need assistance. And most of our Medicare patients do qualify for that because, you know, they do make less than what they're, what the qualifications are for these foundations. So we can go two routes, we can connect them to the manufacturing companies Financial Assistance Program, or we can go through the foundations and for our patients, it's been actually less tedious to go through the foundations than to go through the manufacturing companies. So we connect a lot of our Medicare patients through the foundations.

59:56

Okay, thank you so much, Dr. Lee.

[End]