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Released: 12/16/2024

Valid until: 12/16/2025

Time needed to complete: 15 minutes

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### Finally, I Can Take a Break from My Itch! Optimizing CKD-aP Treatment

#### Announcer:

Welcome to CME on ReachMD. This activity, titled "Finally, I Can Take a Break from My Itch! Optimizing CKD-aP Treatment" is provided by Medtelligence.

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#### Dr. Latus:

Patients with advanced kidney disease undergoing dialysis are frequently affected by chronic kidney disease-associated pruritus, or CKD-aP. This condition has the potential to significantly diminish patients' quality of life and especially impacts their sleep and mental health. Today, we will review the best practices for communicating with these patients about their symptoms and their mental health. We'll also look at how to use shared decision-making strategies to develop personalized CKD-aP treatment plans.

This is CME on ReachMD, and I'm Dr. Jörg Latus.

CKD-aP is a distressing condition experienced by patients with advanced kidney, chronic kidney disease, particularly those receiving hemodialysis, and is associated, we know that from further studies, with an increased risk of hospitalizations, infections, and mortality. These are, let's say, the hard endpoints. But CKD-aP has also been associated with depression, anxiety, sleep disturbance, putting together a reduced health-related quality of life; it's not only pruritus. Patients are unable to go to work and have a significantly reduced life space. So please ask the patients about their quality of life.

And I believe, in regard to CKD-aP, it's very easy to screen, because we see our patients several times a week, providing opportunities to ask patients how they are doing. Regular screening for CKD-aP is not yet routine in dialysis practice. There's a WI-NRS or the 5-D Itch Scale.

Using the WI-NRS, a very easy tool to ask patients about the worst itch in the past 24 hours, is a simple and swift approach for reliably identifying those with bothersome pruritus that also affects their itch-related quality of life.

So please ask your patients about pruritus, about itch symptoms, and sleep, and I think this is very important, for the last 2 weeks. Again, quality of life is more than itching.

#### Dr. Latus:

So tell me a little bit about your life as a dialysis patient. How often do you go to dialysis?

#### Daniel:

I need to go every 2 days to do the dialysis treatment, to undergo the treatments, because you depend on the machine to survive. So every 2 days you need the treatment. And it's a very demanding treatment, because you need to be on the hospital or in dialysis unit. And it's very complicated to consolidate with work and other activities, because it doesn't matter if it's holidays; you need to go every 2 days. It doesn't matter what is the time or the situation.

**Dr. Latus:**

So it's very time consuming. So when we talk about pruritus, what has pruritus changed in your life? How is it affecting you?

**Daniel:**

Yeah, I think it's a distressing condition. Pruritus and the itching is always affecting you 24/7 and can be a source of you are not focused or the lack of focus on your activities, and it doesn't matter this is your work or leisure or with your friends. And it can ruin your life in this sense, because sometimes you feel embarrassed about the itching in front of the people. And at the end, it's a life-changing diagnosis for many, many reasons, in the sense of the sleeping well or to have a rest properly with the itching, because sometimes, especially in the intensity and the severity of the itching, is it can be ruining your life.

And of course, it's affecting you and every single thing that you are doing with your friends or at work, in your daily life activities. And it, of course, is affecting the health-related quality of life and is a life-changing diagnosis because, at the end, the severity and the intensity of the pruritus can modify your behaviors and can modify how you are dealing with every single day.

**Dr. Latus:**

So the pruritus started after you started hemodialysis?

**Daniel:**

Usually you feel before dialysis, even before dialysis at the end of the advanced chronic kidney disease, you can feel it more and more because the toxins on the blood. But of course, in dialysis is even worse. So it's always happening like that.

**Dr. Latus:**

Yeah. So I think this is a very interesting and important point. We have to ask our patients, even if they had no pruritus at the beginning of dialysis, because they can develop CKD-aP when they're on dialysis. And as stated from you, it's very easy. We only have to ask our patients, and we have to talk about quality of life, and I think this is a very, very important thing we have to keep in mind, and we have to talk, whenever we talk about hemodialysis.

So when we talk about pruritus, when I ask you, ranging pruritus symptoms within the last 3 days, ranging from 0 to 10, what would you say?

**Daniel:**

I think it's difficult, because it depends if every person can have the rate or the number, but I think between 6 and 7 could be always. And then it depends if the dialysis treatment can alleviate or not this itching. But I think it's always moderate and sometimes could be severe.

**Dr. Latus:**

Until recently, there were no approved therapies for CKD-aP. There are off-label treatments for pruritus such as oral antihistamines followed by gabapentin or pregabalin, which are prescribed for pruritus. They have limited clinical evidence to support especially their long-term use in treating CKD-aP. And gabapentin cannot be used at a full dose in patients with kidney disease.

Now we have a new drug available, difelikefalin. It's a peripheral kappa-opioid receptor agonist that acts primarily on peripheral neurons and cells of the immune system.

We have two double-blind, placebo-controlled, phase 3 clinical trials, KALM-1 and the KALM-2 studies, involving individuals with moderate to severe pruritus undergoing hemodialysis 3 times weekly. They received intravenous, IV, difelikefalin, and this was found to generate a significantly greater reduction in pruritus intensity and improvement in pruritus-related quality of life compared with placebo. It was also reported as having an acceptable safety profile. And I published a real-world evidence of patients with difelikefalin, and our results are completely in line with the KALM-1 and the KALM-2 study.

So talking about efficacy, difelikefalin significantly reduced pruritus severity compared to placebo, with notable improvements in itch scores. The treatment showed a consistent response across both studies, and the time to response was very short. The patients began experiencing relief from pruritus within 1 week of starting treatment, and most patients within 4 weeks, again, completely, and then with my real-world evidence recently published. Was a very good safety profile, well tolerated. And of course, there are possible side effects like nausea, diarrhea, and dizziness. But again, I think a very good safety profile.

It was approved by the FDA in August 2021 and by the EMA, the European Medicines Agency, in April 2022 for the treatment of moderate to severe CKD-aP in adults undergoing hemodialysis. And I treated my first patients in November 2022 with the drug.

And in this year, we published an open-label, multicenter, single-arm, interventional trial, and we looked for the safety, effectiveness, and health-related quality of life impact on IV difelikefalin in a population of hemodialysis patients with moderate to severe CKD-aP. And one

aspect of our study was, of course, the sleep quality, which was easily assessed using a numerical rating scale. And using DFK, there was a statistically significant improvement in sleep quality from baseline to the end of week 12 of the treatment period, as assessed by the sleep quality. So a total of 66% of the patients reported an at least 3-point improvement, and almost 60% of the patients reported at least 4-point improvement from baseline to week 12 with respect to sleep quality NRS scores. And a total of 19%, nearly 20% of patients achieved complete resolution in sleep quality NRS scores at week 12. So very, very good results in regard to improving sleep quality.

Very recently, in Stockholm, a study from Italy was presented as a poster, and they showed a significant and rapid response within the first months to DFK in regard to sleep quality. And the CENSUS interim analysis showed similar results. I think we are on a good way when we talk about improvement of sleep with the treatment of difelikefalin.

So, of course, time to response is very short. So I think it's a very good tool to interact with the patient to say, yeah, you have pruritus, now we have a new drug available and time to response is very short. I think this is very important when you communicate a new drug, the new therapy, with our patients.

For those just tuning in, you're listening to CME on ReachMD. I'm Dr. Jörg Latus, and I'm reviewing best practices in the assessment and treatment of CKD-aP in your patients.

So when I currently talk to my patients about pruritus, I always start with a sentence, "It's the best time to develop CKD-aP." I believe when we talk to our patients, and I think that shared decision-making is one of the most important things when we talk with our dialysis patients, we have to cover some topics. We have to explain to our patient that there is a new drug available and short time to response with a very good safety profile. Yes, of course, there may be adverse events. There are very few. Maybe diarrhea. And you told us that previously, there's no interaction with drugs. So our dialysis patients, they have a lot of drugs, so we don't have to stop any other drug related to dialysis. And the time to respond is very short. Most of the patients taking the DFK respond within 2 to 4 weeks. So I think this is very important for the patient to know.

**Dr. Latus:**

So, Daniel, I have good news. It is the best time to develop CKD-aP, and I have a new drug for you. It's called difelikefalin. I'm going to give you the drug 3 times a week after hemodialysis, and the time to response is usually very short, so most patients respond within 4 weeks. So I believe we should try the new drug.

**Daniel:**

Well, Dr. Latus, wow. So it sounds amazing there's a new option that we haven't been before in this case, and there's a lot of hope for my quality of life in the future. And I think in only few weeks we can know if the intensity of itching will reduce. So I think it's such a wonderful news. And really excited to be in the treatment.

**Dr. Latus:**

And I can add on, there is a very good safety profile, maybe even a little bit of dizziness or diarrhea, and there is no interaction with the other drugs you take. So I think it could be easily implemented in everyday clinical practice. So yeah, I think we should try it.

**Daniel:**

Yeah, of course, the side symptoms are not interfering anything or my medication, the usual medication of dialysis treatment, so it should be perfect for me.

**Dr. Latus:**

So let's start with the treatment.

**Dr. Latus:**

And again, we see our patients up to 3 or 4 times a week, so please ask for pruritus. And when you start the therapy, don't stop asking for pruritus. So please, when you start the treatment with DFK, continue to ask your patients how they're doing. So please repeat the WI-NRS scale. Very easy, ranging from 0 to 10. Document it. And more important, ask about the quality of life. Is there improvement in quality of life? Sleep disturbance? Ask the last 2 weeks of sleep.

And ask how often patients think about the pruritus, because I think this is one of the most important things.

**Dr. Latus:**

So, good to see you again. We started the therapy 4 weeks ago, and now, of course, I want to ask you, how are you? How is pruritus? How was sleep within the last 2 weeks?

**Daniel:**

I can say that the pruritus and itching have reduced significantly. I feel less, less, and less. And of course, my sleep, and I am resting properly and in a good way. And I feel motivated and really with new energy and to start with the daily life activities and my hanging out with friends. And I used to hide my condition, but now the severity has reduced a lot. And I could say, about maybe from 6 or 7 intensity, now it is only 2 or 3, so I feel better, much better, in a quality of life sense.

**Dr. Latus:**

So now the key takeaways. Only by asking about pruritus, we can make the diagnosis. We have to ask the patients. We must absolutely inquire about the patient's quality of life, and sleep issues are among the most important, I believe. With DFK, we have a well-tolerated and safe therapy that has been shown to reduce/eliminate sleep problems.

That's all the time we have today. Thank you for taking the time to learn about improving the quality of life for our patients with CKD-aP.

**Announcer:**

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