

Transcript Details

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Best Practices for Administering Prescription Strength Capsaicin for Painful DPN of the Feet

Announcer:

Welcome to ReachMD.

This medical industry feature titled, "Best Practices for Administering Prescription Strength Capsaicin for Painful DPN of the Feet", is sponsored by Averitas Pharma.

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QUTENZA® (capsaicin) 8% topical system is indicated in adults for the treatment of neuropathic pain associated with postherpetic neuralgia (PHN) and for neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet.

Do not dispense QUTENZA to patients for self-administration or handling. Only physicians or healthcare professionals under the close supervision of a physician are to administer and handle QUTENZA.

Aerosolization of capsaicin can occur upon rapid removal of QUTENZA. Therefore, remove QUTENZA gently and slowly by rolling the adhesive side inward. Inhalation of airborne capsaicin can result in coughing or sneezing. Administer QUTENZA in a well-ventilated treatment area. Provide supportive medical care if shortness of breath develops. If irritation of airways occurs, remove the affected individual from the vicinity of QUTENZA. If respiratory irritation worsens or does not resolve, do not re-expose the affected healthcare professional or patient to QUTENZA.

If skin not intended to be treated is exposed to QUTENZA, apply Cleansing Gel for one minute and wipe off with dry gauze. After the Cleansing Gel has been wiped off, wash the area with soap and water.

Patients may experience substantial procedural pain and burning upon application and following removal of QUTENZA. Prepare to treat acute pain during and following the application procedure with local cooling (such as a cold pack) and/or appropriate analgesic medication.

When administering QUTENZA, it is important to follow the procedures in the Important Dosage and Administration Instructions in the US Prescribing Information.

Please listen to Select Safety Information at the end of this podcast and for full Important Safety Information visit Qutenza.com.

Here's your host Dr. David M. Simpson.

Dr. Simpson:

Well, hello and welcome. I'm Dr. David M. Simpson and joining me to discuss best practices in administering Qutenza in clinical practice is Dr. Jon T. Gertken and Ms. Stephanie Simon. Both panelists with me today are experts in the application of Qutenza, as well as the management and treatment of painful diabetic peripheral neuropathy of the feet. Thank you for joining me, today.

Ms. Simon:

Thank you for having me.

Dr. Gertken:

Thanks a lot, Dr. Simpson.

Dr. Simpson:

Great. As we know, there are multiple treatment options available for treating pain associated with diabetic peripheral neuropathy of the feet. Many diabetic patients are already taking an average of five to six medications. Therefore, the treatment for painful diabetic peripheral neuropathy can be quite daunting for a physician, as well as the patient. Many medications have adverse effects and potential interactions with medications used to manage diabetes.

For a little background information, in July of 2020, Qutenza, the capsaicin 8% topical system was approved for painful diabetic peripheral neuropathy of the feet. Qutenza is applied to the feet for 30 minutes and has been shown to provide significant relief from pain for up to 12 weeks. As we know, developing best practices for the implementation of a new procedure can often take time and coordination. I'd like to start by asking Dr. Gertken to briefly discuss why he felt it was important to implement Qutenza into his practice.

Dr. Gertken:

I'm in physical medicine and rehabilitation and our field is specifically designed to look after patient's functional improvements and dealing with their functional improvements in a holistic manner to improve pain. I had actually had experience early on with Qutenza during my fellowship with Dr. Atul Patel. He was a wonderful mentor, and he had a very busy PM&R practice. In that practice, I was able to witness the application on patients with postherpetic neuralgia.

The expansion of the, the indications for Qutenza was really almost immediately what piqued my ears and made me interested, um, knowing that I had, off the top of my head, at least ten patients that I thought would perfectly fit for the trial of this unique treatment. The new indication meant there would be a very steady and reliable flow of referrals that I was, because I was already seeing these patients, they were disappointed with the current treatments. This encouraged me to use procedural clinical experience that I already had into an efficient process and made me very quickly decide that we needed to, uh, set up a Qutenza day so that we could get a collection of these patients together and streamline the process.

Dr. Simpson:

Well, thanks very much. That was a, a very helpful background. Um, perhaps just to expand on your response for a moment, you might discuss what you see as the potential advantages of this topical treatment over what we've historically used as systemic oral therapies for pain management.

Dr. Gertken:

The perfect patient population is ones with these, uh, painful neuropathic symptoms but also with a confluence of other medical issues who can't tolerate the oral, um, medications commonly used. And that is a problem we run into very frequently, both because the medications aren't successful by themselves, but also because the medications cause a lot of side effects that affect my patient population specifically, but many people, in general. My patients have all been very excited about the option of not dealing with some of these untoward effects, the dizziness, the gait instability, the problems with thought clarity or fatigue. All of those things are reasons that keep them from taking medications that are used to treat their pain and so the topical system is a wonderful option. Basically, the one of the things that became, uh, important immediately, as well, was the fact that we have many patients that take narcotic analgesics and, of course, as a nation, we're trying to deal with this problem and getting patients off of these medicines by using something that's not addictive and not, uh, systemic in nature was wonderful.

Dr. Simpson:

Great. And just one more, uh, expansion of your answer. That is the logistic issues and the learning curve of taking on a new procedure. Uh, some providers have been, uh, a bit intimidated by this concept of doing something brand new. Are they going to be able to learn how to do it, is the patient going to have any difficulty with the pain?

Dr. Gertken:

I discussed it with our staff at a staff meeting and we had great support from the Averitas Pharma team in doing an inservice. So, within a week or two, we were actually ready to roll out the procedure and had the capability to do this more efficiently, which was to have a dedicated time slot for these patients.

We printed out a Word document that has some basic pointers for the nurses, but also for the patients that we can provide about dos and don'ts. I consult with these potential patients prior to application, so, most of the education is already completed by myself, the diagnosis confirmed and then when they return, we have a system set up so that the patient is evaluated by me, briefly, I answer any last-minute questions and, and take a look at their area that we'll, uh, be applying that topical system to and then it's roughly a five minute encounter for me. My nurses have kitchen timers set on the walls, checking on the patient every 5 to 10 minutes. So, it really hasn't added any significant logistical problems. In fact, it's a lot more efficient than some of the other procedures that I perform

regularly. So, it's been a seamless transition for our practice.

Dr. Simpson:

Well, great. Thank you for that.

Now, moving to you, Stephanie, once a patient has been confirmed to be a candidate for Qutenza, how do you educate your patients about Qutenza and plan for successful application?

Ms. Simon:

Yes, so I typically tell my patients that this is a completely different, kind of, therapy. It's non-systemic non-opioid and it has no drug-to-drug interactions and the goal is to achieve sustained pain relief. Typically, the patients I see have been in so much pain and have tried so many other options out there, they're excited for something new.

My clinic chose to implement a Qutenza day, as well, and this takes place every Thursday. The topical system is in place for about 30 minutes and the patient should expect to be there about an hour. Patients should take their regular medications and avoid shaving or applying any lotion prior to the application process. I recommend having plenty of nitrile gloves, scissors, a timer, surgical markers, towels, and we- as well as a cohesive bandage. Patients should also bring something to keep them occupied during the procedure. It's also very important to keep the patients comfortable during the application, so we supply a comfortable chair and a footstool.

During the consultation, I briefly review the process and tell the patient what to expect. It is normal to experience some discomfort or even pain during the procedure, but this is temporary and will improve. One of the best ways to alleviate the pain while the application is in place is to apply a cold compress over the Qutenza topical system. But many of the patients I see have such severe diabetic peripheral neuropathy that they don't really have too much discomfort during the procedure.

One of the most commonly asked questions I receive from my patients is how much relief are they going to get, um, when are they going to start seeing success and this is very variable from patient to patient. Some patients start seeing a significant relief after the first procedure, others might take three or four applications.

Dr. Simpson:

OK. Well, that was very helpful. Thank you.

In my experience, many times, patients prefer topical treatment. Some patients will mention they have already tried an over-the-counter capsaicin cream without any success, so they're unsure if Qutenza will work. So, this leads to my next question, Dr. Gertken, how do you describe Qutenza's mechanism of action to your patients?

Dr. Gertken:

I often tell people that the nerve, the peripheral nerve is like a communication system from the outside world to our brain to allow us to know what's going on around us. And specifically, the pain nerves warn us, they're an alert system, but when those systems are injured or damaged, those signals that are being fired to the brain don't work appropriately and they sometimes tell us that something hurts even when it doesn't need to tell us that it hurts. So, what we are trying to do with the high dose capsaicin or the Qutenza topical application system is to overwhelm that signal, briefly so that it runs out of the, the ammo to send that message to the brain. And once we've depleted that, the nerve no longer can tell the brain it's injured or it's hurting. And patients often seem to understand this.

Dr. Simpson:

The application of the Qutenza topical system is an in-office procedure. Stephanie, how do you organize your patients, supplies, and your support staff during each Qutenza day?

Ms. Simon:

We have a dedicated Qutenza day, and we have a dedicated hallway that we do the majority of the applications in. Um, initially it took me a little longer, kind of, with getting the application figured out, but now I stagger each patient about every 15 minutes and then we do have the timers and numbers on the doors, so we keep pretty organized as to knowing when each, uh, patient is done. The medical assistants, they do play a very important, integral role. They prep the patient, they monitor the patient, they help to clean the application area and they also monitor the blood pressure, as it can increase during the procedure. My role is to identify the area to be treated and then applying and removing the topical system. And then, when applying the topical system, I find it best to cut them in half before applying over the identified area. After the 30 minutes is up, we'll clean off the foot and use the cleansing gel for at least one minute. And then that will be removed with warm soap and water.

Following the procedure, I tell my patients to avoid massage or pressure to the area for at least 4 hours and to avoid any sort of rigorous activities or sun exposure, but they can shower with soap and water, like normal. I tell them that it is normal to expect some mild pain and soreness in the area, but this will go away. They can alleviate the pain with a cold compress, um, but instruct them not to leave it on

for longer than 10 minutes. They can also use any over-the-counter, um, medications to help alleviate the pain, as well. Uh, the redness and the itching and the pain will resolve with time and it is to be expected; but if the patients have any questions for me, I encourage them to call the office.

Dr. Simpson:

Well, thank you for sharing those important points I agree it does take a few applications before becoming completely comfortable with the entire process, having a team to help is always beneficial to stay organized. From my experience, treating DPN patients with Qutenza, including those enrolled in the STEP trial, I found it easier to fold the topical system over the toes and wrapping it around each toe. This helps save time and was easier for me to apply Qutenza. You only need to apply the topical system where the pain is present.

I've also started a Qutenza afternoon and many of my colleagues are also interested in this idea. I think it is best to schedule the patients on the same day, which seems to be the most efficient use of time because once the supplies are organized, it's helpful to treat multiple patients, versus stopping and starting with each patient on another day of the week. I'm sure we can all agree that it's important to add these procedures to our treatment algorithms.

Stephanie, what effect has Qutenza had on your practice and patients?

Ms. Simon:

Many patients are excited for something that's not just another pill added to their regimen. Um, as soon as I find out a patient is a candidate for Qutenza, we start looking into the benefits and getting the approval.

Many of our patients have found that after the first procedure they notice an improvement in their sleep and I recently had one patient that has severe neuropathy for many years and had very little feeling in her feet and after just one application, she noticed that she was starting to have some feeling.

Dr. Simpson:

Well, thank you for sharing those insights.

Dr. Gertken, can you provide some insights, highlighting how Qutenza has affected your practice and patients?

Dr. Gertken:

I've shared the same experience with both of you that many of our patients are frustrated with the side effects of oral medications, have had a lot of continued pain for years and are limited by this pain. The Qutenza topical application system has allowed me to offer our patients something that is not achievable by oral medications. It has allowed us to provide relief without significant side effects or the need for repeat visits to titrate or wean medications.

Dr. Simpson:

Well, thank you, Dr. Gertken for sharing those wonderful insights and success stories. I think hearing how you and Ms. Simon have successfully incorporated Qutenza into your practices has helped address questions and build confidence for adding another treatment option to help patients living with painful diabetic peripheral neuropathy of the feet.

I think there are many advantages to adding to high-concentration capsaicin 8% topical system to your treatment algorithm. There are multiple ways to incorporate the use of Qutenza into practice, but I think we can all agree that it is a great option for treating painful diabetic peripheral neuropathy of the feet. The application, itself, is only 30 minutes, and treating multiple patients in one day or afternoon can be a very successful and efficient process. And with that, I want to thank Dr. Jon Gertken and Stephanie Simon for joining me, today, in discussing best practices in administering Qutenza in clinical practice, along with their experience treating patients with painful diabetic peripheral neuropathy of the feet with the use of the high-concentration capsaicin 8% topical system with our ReachMD audience.

Ms. Simon:

My pleasure. Thank you for having me.

Dr. Gertken:

Thanks, so much. I appreciate the opportunity.

Announcer:

INDICATION

QUTENZA® (capsaicin) 8% topical system is indicated in adults for the treatment of neuropathic pain associated with postherpetic neuralgia (PHN) and for neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet.

IMPORTANT SAFETY INFORMATION

Do not dispense QUTENZA to patients for self-administration or handling. Only physicians or healthcare professionals under the close supervision of a physician are to administer and handle QUTENZA.

When administering QUTENZA, it is important to follow the procedures in the Important Dosage and Administration Instructions in the US Prescribing Information.

In patients treated for neuropathic pain associated with diabetic peripheral neuropathy of the feet, a careful examination of the feet should be undertaken prior to each application of QUTENZA to detect skin lesions related to underlying neuropathy or vascular insufficiency.

Contraindications

None

Warnings and Precautions

- Unintended exposure to capsaicin can cause severe irritation of eyes, mucous membranes, respiratory tract, and skin in healthcare professionals, patients, and others. Healthcare professionals should ensure that the recommended procedures and protective measures are used when administering QUTENZA.
- For healthcare professionals, wear nitrile gloves when administering QUTENZA and avoid unnecessary contact with items in the room, including items that the patient may later have contact with, such as horizontal surfaces and bedsheets.
- Do not apply QUTENZA to the patient's face, eyes, mouth, nose, or scalp to avoid risk of exposure to eyes or mucous membranes. Accidental exposure to the eyes and mucous membranes can occur from touching QUTENZA, or items exposed to capsaicin, and then touching the eyes and mucous membranes. If irritation of eyes or mucous membranes occurs, flush eyes and mucous membranes with cool water. Remove the affected individual (healthcare professional or patient) from the vicinity of QUTENZA.
- Aerosolization of capsaicin can occur upon rapid removal of QUTENZA. Therefore, remove QUTENZA gently and slowly by rolling the adhesive side inward. Inhalation of airborne capsaicin can result in coughing or sneezing. Administer QUTENZA in a well-ventilated treatment area. Provide supportive medical care if shortness of breath develops. If irritation of airways occurs, remove the affected individual from the vicinity of QUTENZA. If respiratory irritation worsens or does not resolve, do not re-expose the affected healthcare professional or patient to QUTENZA.
- If skin not intended to be treated is exposed to QUTENZA, apply Cleansing Gel for one minute and wipe off with dry gauze. After the Cleansing Gel has been wiped off, wash the area with soap and water.
- Patients may experience substantial procedural pain and burning upon application and following removal of QUTENZA. Prepare to treat acute pain during and following the application procedure with local cooling (such as a cold pack) and/or appropriate analgesic medication.
- Transient increases in blood pressure may occur during and shortly after QUTENZA treatment. Blood pressure changes were associated with treatment-related increases in pain. Monitor blood pressure and provide adequate support for treatment-related pain. Patients with unstable or poorly controlled hypertension, or a recent history of cardiovascular or cerebrovascular events, may be at an increased risk of adverse cardiovascular effects. Consider these factors prior to initiating QUTENZA treatment.
- Reductions in sensory function have been reported following administration of QUTENZA. Decreases in sensory function are generally minor and temporary. All patients with pre-existing sensory deficits should be clinically assessed for signs of sensory deterioration or loss prior to each application of QUTENZA. If sensory deterioration or loss is detected, or pre-existing sensory deficit worsens, continued use of QUTENZA treatment should be reconsidered.

Adverse Reactions

In all controlled clinical trials, adverse reactions occurring in $\geq 5\%$ of patients in the QUTENZA group, and at an incidence at least 1% greater than in the control group, were application site erythema, application site pain, and application site pruritus.

Adverse Event Reporting

Physicians, other healthcare professionals, and patients are encouraged to voluntarily report adverse events involving drugs or medical devices. To make a report you can:

- In the US, visit www.fda.gov/medwatch or call 1-800-FDA-1088; or
- For QUTENZA, you may also call 1-877-900-6479 and select option 1, or press zero on your keypad to talk to an operator to direct your call.

Please visit [Qutenza.com](https://www.Qutenza.com) to view the full Prescribing Information, including Patient Information.

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