Qutenza Still a Prescription for Pain

The FDA probably will not approve Qutenza as a treatment for HIV-associated peripheral neuropathy, but the novel pain patches can still be prescribed for anyone who might benefit from them. For many, however, it will ultimately come down to a question of cost and insurance reimbursement.

February 27, 2012 By Tim Horn

Few experts in the HIV community truly expected February 9, 2012, to end the way it did. Though there were lingering questions regarding the effectiveness of Qutenza, a novel patch to manage the debilitating symptoms of HIV-associated peripheral neuropathy, it was expected that the U.S. Food and Drug Administration's Anesthetic and Analgesic Drug Products Advisory Committee would recommend the drug for approval. But alas, the committee unanimously voted against green-lighting what was on track to be the first treatment approved for one of the most common complications among people living with HIV.

Unfortunately, the agony of defeat won't end with the FDA's anticipated decision to follow its advisory committee's decision. Without approval, the estimated 100,000-plus Americans living with painful HIV-associated peripheral neuropathy will continue lacking a new, potentially useful treatment to choose from.

Or will they?

Qutenza is commercially available in the United States, thus it can be prescribed and applied "off label" by health care providers, particularly for patients who either aren't benefiting from or tolerating other unapproved and largely unproven therapies. But a challenge does remain: Getting health insurance providers to pay for patch and the procedure.

What Went Wrong?

Chili peppers and mustards have been used for centuries in topical balms to treat chronic pain. Only during the past few decades, however, have scientists figured out how capsaicin—the chemical that gives chilies their pungency—works as an analgesic: It depletes a neurochemical called substance P responsible for transmitting pain.

NeurogesX, based in San Mateo, California, has spent several years testing capsaicin in skin patches to treat a variety of chronic pain conditions. In May 2009, Qutenza, the company's lead candidate designed to deliver a high concentration of capsaicin to affected areas, was approved for peripheral neuropathic pain in non-diabetic adults throughout Europe. Six months later, it was

approved by the FDA to relieve the pain of post-herpetic neuralgia, a serious complication that can occur after a bout with shingles.

Qutenza's proven usefulness for these indications pointed to tremendous potential for HIV-associated peripheral neuropathy. This was good news for people living with the condition—and for their health care providers, who for years have had very limited success using oral medications with significant side effects, notably anti-seizure medications and narcotic pain relievers. And according to an analysis published by the peer-reviewed online scientific journal PLoS One in 2010, Qutenza was one of only three treatments for peripheral neuropathy with proven efficacy in clinical trials. The others were smoked marijuana—a highly controlled substance and not widely available legally—and recombinant nerve growth factor, an expensive product with important side effects that isn't approved for any indication.

Unfortunately, Qutenza's effectiveness didn't hold up under review by the FDA or its advisory committee. "The singular problem was the efficacy data in the clinical trials," says David Simpson, MD, a professor of neurology at Mount Sinai School of Medicine in New York and a lead Qutenza researcher with a long history of scientific dedication and care for people living with HIV and various neurological problems. "Though there was some evidence of efficacy [in the first clinical trial], it was not by any means a home run. If a second study showed similar or better results, then I suspect there would have been approval." But it was not meant to be, Simpson explains further, noting that the second study failed to meet the FDA-required standard of efficacy. And while post-study analyses "made the data look a little better," Simpson adds, it wasn't enough to carry Qutenza over the finish line.

"I was disappointed for sure," Simpson says. "Many of the folks that have worked with this drug have treated patients clinically, and several of my patients gave testimonials at the hearing about how this drug helped them so much."

FDA and advisory committee reviewers also seemed crestfallen. "Bob Rappaport [director of the FDA's Division of Anesthesia, Analgesia and Addiction Products] said publicly that he was extremely disappointed in the result," Simpson adds. "The advisory committee appeared that they very much wanted to approve this drug for HIV neuropathy, and they struggled with how to deal with the issues on the table."

According to Simpson, it largely came down to precedents. "The FDA and the panel were very clear that they were concerned about setting a precedent, in that there needs to be sufficient efficacy for approval. Their concern was if they lowered the bar for this drug, it could set a precedent for any other drug coming down the pipeline that could argue, 'Well you were easy on Qutenza, and that got approved with lower efficacy than usual, why can't you do the same?'"

What's Next?

The FDA has until March 7 to decide whether to approval NeurogesX's supplemental new drug application for Qutenza for HIV-associated peripheral neuropathy—but the other shoe is fully expected to drop by that date. This will not, however, have any effect on the patch's approval for

post-herpetic neuralgia in the United States.

Qutenza can be prescribed for people living with HIV and peripheral neuropathy. “Off-label” prescription practices are common. After all, the various other agents used by people struggling with HIV-associated peripheral neuropathy are only approved for other indications.

In the HIV clinical trials, patches were applied for 30, 60 or 90 minutes, with the 30-minute application being the basis of NeurogesX’s approval request. The company also proposed that treatment “may be repeated every three months or as warranted by the return of pain.”

“I have used this drug off label for HIV neuropathy as well as for other neuropathic pain syndromes, and by no means does everyone respond,” Simpson says. But he adds, “there are a significant number of very good responders and some excellent responders like one of the patients that gave a testimonial at the [February 9 advisory committee] hearing. I believe his pain intensity level went from 9 to 2”—on a scale of 1 to 10—“and he said it changed his life; he couldn’t go out of the house before using it, and now he can go out of the house. So those kinds of dramatic effects are certainly compelling, and for patients with often little or no alternatives, certainly this is an option.”

The problem is cost. The wholesale price is set at $675 for a one-patch treatment kit and $1,350 for a two-patch treatment kit—which would probably be the minimum required, as HIV-associated peripheral neuropathy affects both feet and may require more than one patch on each foot for necessary coverage. And that doesn’t include the cost associated with application, which must be done by health care providers who rarely work for free.

Because of Qutenza’s questionable efficacy in clinical trials, compounded by its hefty price tag and associated application costs, Simpson explains that insurance reimbursement isn’t promising, but not a forgone conclusion. “Patients often have to pay out of pocket,” he says. “Some insurers are a bit more liberal and will approve it, but I think that without the FDA approval, it certainly will not help the rates of reimbursement.”

Public payers are, unfortunately, restrictive when it comes to medications and devices being prescribed off label. “Medicare,” Simpson offers as an example, “is almost uniformly disapproving any off-label use. My experience is they only approve for post-herpetic neuralgia and will reimburse for that.”

Medicaid reimbursement closely mimics Medicare coverage. As for AIDS Drug Assistance Programs (ADAPs), which are already stretched financially and unable to offer lifesaving antiretrovirals to all who need them, the lack of FDA approval will likely make it difficult for advocates to push for the Qutenza’s inclusion on ADAP formularies.

There is a glimmer of hope for those covered by private insurance policies. “Some commercial payers will occasionally approve the use of the drug in off-label use like HIV,” Simpson says.

A key for health care providers is knowing what to say to insurance companies during

reimbursement pleas. “I can’t say I’m an authority on this, and I can only speak from my experience from writing letters and speaking to medical directors of insurance companies,” Simpson says in prefacing his experience in this regard. “I tell them the facts. First, that there is no FDA-approved drug for this affliction. Second, that the majority of studies and most of the medications that we use for other [forms of] neuropathic pain have shown negative results in HIV neuropathy. Third, there are at least some data to support efficacy in HIV neuropathy, particularly from C107 [the first Phase III clinical trial reviewed by the FDA]. Fourth, there is a very low risk of this drug. Finally, there are a significant number of patients who have responded very well.

“With that information,” Simpson concludes, “some of the insurance companies have been supportive and have reimbursed.”

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