Ketamine and CRPS

There is real science and overwhelming evidence to support that ketamine is THE drug to treat cold (chronic) CRPS and its two primary comorbidities – PTSD and treatment resistant depression. The Veterans Administration has embraced it, yet it remains off label for infusion and routine therapy for everyone else meaning insurers will not cover its costs. Why?

Ketamine use in the CRPS going on two decades with thousands of patients provides a strong track record of safety and effectiveness. So, why hasn't the FDA approved it for CRPS/RSD? I have spoken with several FDA officials, and they give two primary reasons:

1. There is no standard of care meaning physicians using ketamine on patients with chronic pain, depression and PTSD have not agreed on a specific treatment protocol including dosages. The lack of self-regulation is problematic for them; and,
2. The FDA requires a study showing that long-term use of ketamine is safe under a standard therapeutic protocol and dosage range. This means that a years-long double-blind study called a PMA, or Pre-Market Assessment, is required to prove that it is safe and effective to use.

From our standpoint, the money does not exist to perform the FDA study because CRPS is an orphan disease. This means that it is in a poor position to raise the millions of dollars required to mount such a long-term study. Furthermore, the study will take years and an investment into the seven figures to perform. These studies are normally done by a drug company, however, since ketamine has been on the market for over 60 years and is relatively cheap, and it is already being used off-label anyway, there is no incentive for drug companies to do so.

Without FDA approval, insurers do not cover ketamine therapy or infusions meaning, in many cases, profiteering is rampant. Some clinics charge as much as $1,000 per day for ketamine infusions while others accept insurance fees for infusion services because ketamine is relatively inexpensive. The rest are in-between. Our community is being hurt financially, physically, and emotionally.

Ketamine nasal sprays, sublingual tablets, extended-release capsules, and topical creams are only available through compounding pharmacies and cost hundreds of dollars per month out of pocket. Quality varies widely as does potency even month to month from the same pharmacy. A recent report on compounding pharmacies was not encouraging, and that is being generous.

Considering the well documented benefits of ketamine in the CRPS/RSD community, its ability to mitigate the use of opiates in long term therapy and to ease widespread suffering, why doesn't the FDA step in to regulate usage by initiating a panel to establish best practices and bring order to the delivery system? Moreover, why does it not follow the lead set by the Veteran's Administration? It is within their regulatory powers, and it would seem to be bad politics and optics to turn a blind eye to this problematic issue.

For now, that is not a consideration.

The logical next step would be to issue an exemption like that used for COVID vaccines, which is extremely unlikely. What is an emergency to us is not to them. Unfortunately, ketamine does not qualify for an exemption under the Humanitarian Use Waiver because the CRPS/RSD community exceeds 8,000

patients. Compassionate use on-label to provide financial relief to chronic pain sufferers while long term safety studies are performed has also been rejected.

So, for the time being, the question for our community is whether the out-of-pocket investment is worth it.

That is a question for your pain management physician. If the answer is that ketamine will likely be of substantial benefit in slowing, stopping, or reversing the progression of CRPS while reducing the intensity of present symptoms, the answer is yes.

As to the science behind this decision, I could add a long discussion about how ketamine is an NMDA pain receptor agonist, which desensitizes those pain receptors reducing the amount of perceived pain from CRPS and how ketamine acts to enhance and prolong the effects of opiates resulting in the need for lower dosages and longer duration between dosages to get the same benefits among others. If you are curious, the science is easily researched. If not, suffice it to say that the benefits overwhelm the cost in almost every case, particularly if you are smart about from whom you choose to purchase the infusion and compounding services.

Shop around. An expert and experienced provider will have ways to have your insurance pay for all or a substantial part of infusion services and compounding pharmacy prices vary widely. Start by asking your doctor who they use and recommend. Then pay close attention to ratings and Better Business Bureau complaints. Search for malpractice suits filed against a pharmacy you are considering. Visit them. Get comfortable. You are a customer, not a victim seeking help.

RSDSA is a resource. If you still have a question, you are welcome to ask me by emailing me at jim@jamesdoulgeris.com.