STATE OF VERMONT
DEPARTMENT OF LABOR

Travis Weston

v.

Velan Valve Corporation

Opinion No. 17-16WC

By: Phyllis Phillips, Esq.
Administrative Law Judge

For: Anne M. Noonan
Commissioner

State File No. EE-53319

OPINION AND ORDER

Hearing held in Montpelier on November 6, 2015
Record closed on April 4, 2016

APPEARANCES:

Christopher McVeigh, Esq., for Claimant
Keith Kasper, Esq., for Defendant

ISSUE PRESENTED:

Does the use of compounded ketamine cream constitute reasonable medical treatment for Claimantôs August 30, 2012 compensable work injury?

EXHIBITS:

Joint Exhibit I:	Medical records
Joint Exhibit II:	Stipulation
Claimantôs Exhibit 1:	Preservation deposition of Timothy Lishnak, M.D. (with exhibits), January 14, 2016
Defendantôs Exhibit A:	Connolly, S. *et al*., A Systematic Review of Ketamine for Complex Regional Pain Syndrome, *Pain Medicine* 2015; 16:943-999
Defendantôs Exhibit B:	Lynch, M. *et al.*, Topical 2% Amitriptyline and 1% Ketamine in Neuropathic Pain Syndromes, *Anesthesiology* 2005; 103:140-6.

CLAIM:

Medical benefits pursuant to 21 V.S.A. §640(a)
Costs and attorney fees pursuant to 21 V.S.A. §678

FINDINGS OF FACT:

1. At all times relevant to these proceedings, Claimant was an employee and Defendant was his employer as those terms are defined in Vermontôs Workersô Compensation Act.

2. Judicial notice is taken of all relevant forms and correspondence contained in the Departmentôs file relating to this claim.

3. Claimant worked for Defendant, a manufacturer of industrial valves. His duties included working at a ñlapping machine,ò polishing and deburring the insides of twenty-ton valves used at nuclear power plants.

Claimant's August 2012 Work Injury, Medical Course and Current Status

4. On August 30, 2012 Claimant was working at the lapping machine when a heavy steel rod fell on his right (dominant) hand. As a result, he sustained a soft tissue crush injury to the metacarpophalangeal (MCP) joint ï in laymanôs terms, the second knuckle ï of his right middle finger. Defendant accepted this injury as compensable and began paying workersô compensation benefits accordingly.

5. Within just a few weeks after the injury, Claimant complained of symptoms that prompted concern among his treating providers that he might be developing complex regional pain syndrome (CRPS). Over the ensuing months, these came to include excruciating pain out of proportion to objective findings, swelling, sweating, color and temperature changes and allodynia (hypersensitivity to light touch) in his right hand.

6. Claimant treated for his injury with a variety of providers, including Dr. Lishnak, his primary care provider, Dr. Durant, a hand surgeon, and Dr. Roberts, a pain management specialist. Given his CRPS symptoms, he was determined not to be a surgical candidate. Instead he underwent multiple courses of physical therapy and a series of stellate ganglion blocks. None of these treatments provided completely effective, long-term relief of his symptoms.

7. Concurrent with treatment for his hand injury, Claimant also continued to treat for a lower back injury he had suffered in 2003 while working for a previous employer. In 2004, his treating pain specialist, Dr. Erickson, had prescribed ketamine cream to be applied topically to his lower back, following which Claimant reported a noticeable decrease in his symptoms. Claimant was forced to discontinue this treatment in early 2005, because the responsible insurance carrier refused ongoing payment.

8. Ketamine has a somewhat controversial history. Approved by the federal Food and Drug Administration in 1970, it was first used by forward medical units in the Vietnam war as a ñbattlefield anesthetic.ò[1] Today it is commonly used in hospitals to initiate and maintain general anesthesia, and in sub-anesthetic dosages to provide pain relief while surgically treating burns and other wounds. Particularly when dispensed orally or intravenously, the medication poses a risk of serious side effects, including liver toxicity, nausea and hallucinations. As discussed *infra*, Finding of Fact Nos. 20 and 26, in its topical application ketamine appears not to cause any such adverse effects.

9. Dr. Lishnak again prescribed ketamine cream for Claimantôs low back pain in 2011, but as was the case previously, without insurance coverage he was unable to afford it on an ongoing basis. As a result, he relied on narcotic pain medications to manage his low back pain.

10. In April 2013 Claimant expressed to Dr. Lishnak his interest in trying ketamine cream as treatment for his right hand CRPS symptoms. Ketamine inhibits the action of the same neurotransmitters that are thought to trigger CRPS-type pain, and for that reason researchers have sought to evaluate its efficacy as a treatment option for the condition.[2] Thus, noting that in its topical application the medication ñhas been reported as useful for these types of cases before and is something [Claimant] has taken, did well on and tolerated before for his back,ò Dr. Lishnak prescribed a trial of ten-percent compounded ketamine cream.[3] Concurrently, he maintained Claimant on Percocet to address his ongoing low back pain.

11. Claimant used the ketamine cream for approximately two months thereafter. He credibly testified that while the Percocet prescribed for his low back pain helped his right hand pain ñto a certain extent,ò the ketamine cream was far more effective at providing focused symptom relief and improved function. He could tie his shoes, for example, and was able to manage using his hand for other daily living activities as well. The improvements were short-lived, however; after Defendant discontinued payment for the cream in July 2013, his symptoms returned.

12. Claimant treated with Dr. Lishnak for both chronic low back pain and chronic CRPS-related pain in his right hand at various times throughout 2013 and 2014. For his low back pain, Dr. Lishnak continued to prescribe narcotic pain medications, including Percocet, buprenorphine, morphine and fentanyl. For his right hand, for a time Claimant reported some limited symptom improvement with medical marijuana derivatives. Although he still exhibited CRPS-type symptoms in his hand, including swelling, pain, discoloration and sweating, these were less severe than they had been in the past.

---

[1] Connolly, S. *et al*., A Systematic Review of Ketamine for Complex Regional Pain Syndrome, *Pain Medicine* 2015; 16:943-999, at p. 943.

[2] *Id.* at p. 944.

[3] The medical record for this office visit includes a journal abstract of a study involving the use of topical ketamine in twenty CRPS patients. The researchers concluded that the study ñshows promise for use of topical ketamine as opposed to parenteral and oral forms which often result in undesirable side effects.ò Finch, PM *et al*., Reduction of Allodynia in Patients with Complex Regional Pain Syndrome: A Double-Blind Placebo-Controlled Trial of Topical Ketamine, *Pain* 2009 Nov; 146 (1-2), 18-25. Presumably this is the report to which Dr. Lishnak referred in his office note.

13. In December 2014 Dr. Lishnak wrote an additional prescription for compounded ketamine cream, but lacking insurance coverage Claimant was unable to fill it.

14. Dr. Lishnakôs office notes reflect that his treatment in 2015 has been directed primarily at managing Claimantôs chronic low back pain. In his deposition testimony, he acknowledged that Claimant hadnôt complained of hand pain since February 2015, and that the condition ñhasnôt been the topic of conversation at recent visits.ò He agreed that Claimant no longer exhibits sufficient CRPS symptoms to justify the diagnosis. Instead, he now characterizes Claimantôs condition as chronic pain due to the sequelae of his crush injury.

15. Regardless of the current diagnosis, Dr. Lishnak still expects that ketamine cream will decrease Claimantôs chronic neuropathic pain to a level where his ability to function will improve. I find this analysis credible.

16. Claimant credibly testified that while his right hand symptoms have abated somewhat, they have never completely resolved. As was demonstrated at the formal hearing, the second knuckle of his right third finger remains visibly swollen, ñto the size of a golf ball,ò even three years later. He still experiences a constantly pulsating, burning pain in his hand, ñlike somebody is taking a knife and just dragging it through tendons and bone, itôs horrifying.ò Occasionally his right palm and fingers sweat excessively. His ability to use the hand for routine tasks ï starting his car, for example ï varies, with periods of waxing and waning symptoms and corresponding increases and decreases in function. Claimant testified that if ketamine cream was made available to him, he would ñabsolutelyò use it in the hopes of ameliorating these symptoms.

Expert Medical Opinions Regarding Reasonableness of Ketamine Cream Treatment

(a) Dr. Lishnak

17. As noted above, Finding of Fact No. 10 *supra*, Dr. Lishnak initially prescribed ketamine cream as treatment for Claimantôs CRPS-related hand symptoms in April 2013. He did so based first on the medicationôs reported efficacy when Claimant had used it previously for his low back pain, and second, on his review of medical literature indicating that it was a potentially useful adjunctive treatment for his hand injury.

18. Central to Dr. Lishnakôs analysis was his determination that, in contrast to its oral or intravenous applications, topical ketamine is very well tolerated, with a low risk of side effects. From a safety perspective, he thus views it as a treatment alternative that is unlikely to cause harm. In his opinion, where, as here, the risk of harm is fairly low, the question whether it is reasonable then becomes whether and to what extent it might benefit a particular patient. This is a determination that can only be made by trying it. I find this analysis credible.

19. Claimant having already derived relief of his low back symptoms by using topical ketamine in the past, in Dr. Lishnakôs opinion it is medically reasonable for him to do so again, in the hopes that it will provide similar benefit in the context of his right hand pain. This is true even if the most appropriate diagnosis for his symptoms is no longer CRPS specifically, but rather a more generalized chronic pain condition referable to his August 2012 crush injury. I find this analysis credible.

20. To support his opinion regarding the efficacy of topical ketamine for treatment of chronic pain conditions such as Claimantôs, in his deposition testimony Dr. Lishnak referenced a 2015 medical journal review of 34 studies, 12 of which involved randomized controlled trials.[4] The studies involved widely varying compounded formulations, in different concentrations, with different cream bases, co-analgesics and application frequencies. As a result, direct data comparison was difficult. Despite this variation, none of the studies described any systemic side effects. This finding was critical to the reviewersô conclusion:

> Topical use of . . . ketamine cream or gel up to 20% [concentration] has been successfully used in the treatment of chronic pain with few or no side effects when used according to prescription and medical supervision . . . Topical ketamine seems to be a valuable therapeutic option in the treatment of various chronic pain syndromes, especially in localized neuropathic pain. Further clinical trials . . . are recommended, as well as comparator trials.[5]

(b) <u>*Dr. Ensalada*</u>

21. At Defendantôs request, in May 2013 and October 2014 Claimant underwent independent medical examinations with Dr. Ensalada, a board certified pain management specialist. In conjunction with his clinical exams, Dr. Ensalada reviewed Claimantôs pertinent medical records. He also researched the medical literature concerning the use of ketamine as treatment for CRPS.

22. On the basis of his May 2013 examination, Dr. Ensalada concluded that Claimant met the so-called ñHardenò criteria for a diagnosis of CRPS. In this regard, he thus concurred with the diagnosis proffered by Claimantôs treating providers at the time, including Dr. Lishnak.

23. Dr. Ensalada disagreed with Dr. Lishnakôs suggestion that ketamine cream was a reasonable treatment option, however. In his opinion, because ketamine has not been shown to be a safe and effective treatment for CRPS regardless of the form in which it is administered, its use in Claimantôs case is not medically reasonable.

---

[4] Kopsky, DJ, *et al.*, Analgesic effects of topical ketamine, *Minerva Anestesiologica* 2015; 81:440-9.
[5] *Id.* at 447.

24. Dr. Ensalada cited two medical journal articles in support of his opinion. In one, a double-blind, randomized, placebo-controlled three-week study evaluated the efficacy of topical two-percent amitriptyline, one-percent ketamine and a combination of both in treating patients with neuropathic pain.[6] The results revealed no difference among the three groups. Notably, however, the researchers qualified their findings with reference to another study, in which higher concentrations of the two drugs combined produced significant pain relief with no additional risk of side effects.[7] Thus, they concluded, ñOptimization of doses may be required.ò[8]

25. In the second study, researchers reviewed 45 journal articles in which various methodologies (other reviews, randomized placebo-controlled trials, observational studies and case reports) had been used to test ketamineôs effectiveness as a treatment for CRPS.[9] In general, the reviewers rated the studies as moderate to low quality. Largely for that reason, they determined that the evidence regarding the medicationôs efficacy is inconclusive, and therefore that it ñcannot be considered a first line optionò for treating CRPS symptoms.[10]

26. Only five of the articles reviewed in the second study involved the use of topical (as opposed to oral, subcutaneous or intravenous) ketamine. Unlike oral or intravenous usage, the utility of which was ñlimited by its side effect profile,ò[11] none of the topical ketamine studies reported any side effects. The researchers concluded that the risk-to-benefit ratio militated against experiments with high-dose protocols, but weighed in favor of additional topical application trials.

27. Dr. Ensalada again examined Claimant in October 2014. This time, Claimant reported marked improvement in his ability to perform daily living activities ï he could make a full fist, start his car and operate an automatic shift, and he had less difficulty sleeping. Although he was not entirely asymptomatic, his condition had improved to the point where Dr. Ensalada concluded that he no longer met the criteria for a CRPS diagnosis. As noted above, Finding of Fact No. 14 *supra*, Dr. Lishnak has since reached the same conclusion.

---

[6] Lynch, M. *et al.*, Topical 2% Amitriptyline and 1% Ketamine in Neuropathic Pain Syndromes, *Anesthesiology* 2005; 103:140-6.

[7] The referenced study involved a combination of four-percent amitriptyline and two-percent ketamine. Dr. Lishnakôs prescription called for a significantly higher (ten percent) concentration, but still well below the outer range of the formulations tested in the study upon which he relied in his deposition testimony, Finding of Fact No. 20 *supra*.

[8] *Id.* at 146.

[9] Connolly, S. *et al*., A Systematic Review of Ketamine for Complex Regional Pain Syndrome, *Pain Medicine* 2015; 16:943-999.

[10] *Id.* at 950.

[11] *Id.* at 949.

28. As was the case with Dr. Lishnak, the change in Claimantôs diagnosis has not impacted Dr. Ensaladaôs analysis of ketamineôs usefulness in any respect. Dr. Lishnak continues to believe it is medically reasonable to trial a topical application as treatment for Claimantôs ongoing symptoms, given the low risk of side effects and the positive results he experienced previously. Dr. Ensalada continues to believe there is no basis for doing so absent high quality evidence establishing that the medication is both safe and effective for this purpose.

CONCLUSIONS OF LAW:

1. The disputed issue in this claim is whether the use of compounded ketamine cream as prescribed by Claimantôs treating physician constitutes reasonable medical treatment for the symptoms he continues to experience in his right hand as a consequence of his August 2012 work-related crush injury.

2. Vermontôs workersô compensation statute obligates an employer to pay only for those medical treatments that are determined to be both ñreasonableò and causally related to the compensable injury. 21 V.S.A. §640(a); *Cahill v. Benchmark Assisted Living,* Opinion No. 13-12WC (April 27, 2012); *MacAskill v. Kelly Services,* Opinion No. 04-09WC (January 30, 2009). The Commissioner has discretion to determine what constitutes ñreasonableò medical treatment given the particular circumstances of each case. *Id.* A treatment can be unreasonable either because it is not medically necessary or because it is not related to the compensable injury. *Baraw v. F.R. Lafayette, Inc.*, Opinion No. 01-10WC (January 20, 2010).

3. The determination whether a treatment is reasonable must be based primarily on evidence establishing the likelihood that it will improve the patientôs condition, either by relieving symptoms and/or by maintaining or increasing functional abilities. *Cahill, supra; Quinn v. Emery Worldwide*, Opinion No. 29-00WC (September 11, 2000). An injured workerôs subjective preferences cannot render a medically unreasonable treatment reasonable. *See, Britton v. Laidlaw Transit,* Opinion No. 47-03WC (December 3, 2003). As is the case with many aspects of medical decision-making, however, there can be more than one right answer, and thus more than one reasonable treatment option for any given condition. *Lackey v. Brattleboro Retreat*, Opinion No. 15-10WC (April 21, 2010).

4. The treatment issue here revolves solely around the medical necessity question. Both partiesô experts agree that Claimantôs current condition is causally related to his compensable injury. Where they disagree is as to whether topical ketamine is a medically appropriate treatment option for his chronic pain and other symptoms.

5. Where expert medical opinions are conflicting, the Commissioner traditionally uses a five-part test to determine which expertôs opinion is the most persuasive: (1) the nature of treatment and the length of time there has been a patient-provider relationship; (2) whether the expert examined all pertinent records; (3) the clarity, thoroughness and objective support underlying the opinion; (4) the comprehensiveness of the evaluation; and (5) the qualifications of the experts, including training and experience. *Geiger v. Hawk Mountain Inn*, Opinion No. 37-03WC (September 17, 2003).

6. Considering these factors here, I conclude that both experts were well qualified, by training and experience, to express an opinion on the disputed issue. Both adequately familiarized themselves with Claimantôs pertinent medical history and conducted comprehensive evaluations. As the treating physician, Dr. Lishnak has been better positioned to observe Claimantôs symptoms over time and evaluate his response to previously recommended treatments. Both experts made good use of the available medical research to support their opinions.

7. I have carefully reviewed the medical journal articles submitted by both experts. Notably, the articles upon which Dr. Lishnak relied dealt specifically with the use of ketamine in its topical application, while the ones that Dr. Ensalada cited encompassed oral, intravenous and subcutaneous delivery systems as well. As to these, I acknowledge that more high quality research is necessary to determine if the medicationôs efficacy in treating neuropathic pain and CRPS-type symptoms outweighs the risk of troubling side effects.

8. As all of the studies concluded, however, no adverse side effects have yet been associated with the use of topical ketamine. As Dr. Lishnak credibly explained, the risk/benefit ratio weighs differently, therefore. In its topical application, the medication appears to be safe. That being the case, the medically necessary next step is to determine whether it will benefit the patient. According to Dr. Lishnak, the only way to do that is to try it. I concur, and for that reason I conclude that his opinion is the most persuasive.

9. Dr. Ensaladaôs analysis began and ended with his determination that the research on ketamineôs efficacy is not yet of sufficiently high quality to justify its use as a treatment for chronic neuropathic pain conditions such as Claimantôs. His opinion reflects an approach to medical practice commonly referred to as ñevidence based medicine,ò but only in part. The intent of evidence based medicine is to optimize medical decision-making by emphasizing the use of evidence from research studies that are both well designed and effectively conducted. As Dr. David Sackett, who is widely regarded as a ñpioneerò of evidence based medicine, described it:

> Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.[12]

[12] Sackett, *et al.*, ñEvidence based medicine: what it is and what it isnôt,ò *BMJ* 312 (7023): 71-2.

10. The concept of evidence based medicine thus incorporates *not only* the best scientific research into a doctorôs decision-making process, *but also* ñthe proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice.ò As Dr. Sackett explained:

> Evidence based medicine is not ñcookbookò medicine. Because it requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patientsô choice, it cannot result in slavish, cookbook approaches to individual patient care. External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision.[13]

11. Dr. Ensaladaôs opinion focused exclusively on the strength of the external clinical evidence as to ketamineôs efficacy as a treatment for neuropathic pain, and not at all on how that evidence might reasonably have been integrated into a clinical decision. Dr. Lishnakôs analysis was far more discriminating, and in that sense it more fully adhered to the concept of evidence based medicine as Dr. Sackett has described it. For that reason, I conclude that it is the most persuasive.

12. I conclude that the use of topical ketamine cream as treatment for the chronic neuropathic pain associated with Claimantôs August 2012 work-related right hand crush injury is medically necessary, and therefore reasonable under 21 V.S.A. §640(a).

13. As Claimant has prevailed on his claim for benefits, he is entitled to an award of costs and attorney fees under 21 V.S.A. §678. In accordance with 21 V.S.A. §678(e), Claimant shall have 30 days from the date of this opinion within which to submit his itemized claim.

[13] *Id.*

ORDER:

Based on the foregoing findings of fact and conclusions of law, Defendant is hereby **ORDERED** to pay:

1. All medical and prescription drug costs associated with the use of compounded ketamine cream as treatment for Claimantôs August 30, 2012 compensable work injury, in accordance with 21 V.S.A. §640(a); and

2. Costs and attorney fees in amounts to be determined, in accordance with 21 V.S.A. §678.

DATED at Montpelier, Vermont this 20th day of October 2016.

_____
Anne M. Noonan
Commissioner

Appeal:

Within 30 days after copies of this opinion have been mailed, either party may appeal questions of fact or mixed questions of law and fact to a superior court or questions of law to the Vermont Supreme Court. 21 V.S.A. §§670, 672.