v.

STATE OF VERMONT DEPARTMENT OF LABOR

N. B. Opinion No. 24-08WC

By: George K. Belcher

Hearing Officer

Verizon For: Patricia Moulton Powden

Commissioner

State File No. J-13315

OPINION AND ORDER

Hearing held on May 2, 2008 in Montpelier, Vermont. Record Closed, May 21, 2008

APPEARANCES:

Christopher McVeigh, Esq., for the Claimant J. Christopher Callahan, Esq., for the Defendant

EXHIBITS:

Joint Medical Exhibit: Medical Records of the Claimant

Claimant's Exhibit 1: Photo of Claimant's vehicle following accident Defendant's Exhibit 1: Curriculum Vitae of Dr. Tony Tannoury

ISSUE:

Is Claimant's proposed double disc replacement and single level fusion surgery, to be performed by Dr. Delamarter in Santa Monica, California, a reasonable and necessary treatment option and should such treatment be authorized under Vermont Workers' Compensation Law?

FINDINGS OF FACT:

- 1. This matter was heard as an expedited hearing under Rule 7.4000 or the Workers' Compensation and Occupational Disease Rules.
- 2. The Claimant, Nicholas Bonanno, suffered a work-related injury in a motor vehicle accident during the scope of his employment on December 22, 1995. Following the accident the Claimant had increasing lower back and leg pain. He received extensive, conservative treatment including injections and physical therapy for pain.
- 3. In November of 1998 the Claimant was in another motor vehicle accident on his way to physical therapy. The second accident was accepted as work related by the Defendant.
- 4. The Claimant continued to have lower back and right leg pain and, over time, the injections for pain became less effective. Despite many attempts at conservative treatment, the Claimant's back pain has persisted to the current date.
- 5. In February of 2004 the Claimant had a "discogram". This is a procedure which tests the structural integrity of the discs within the spine. This test determined that he had disc problems at the L5-S1 level and the L4-L5 level. It was proposed that he have a "two-level, 360 degree fusion surgery". This type of surgery greatly concerned the Claimant because the fusion surgery was said to be irreversible with an 80% chance of success. Moreover, the Claimant was concerned that a result of the spinal fusion surgery would be a loss of spinal flexibility. The rigid spine caused by a fusion surgery transmits shocks and vibrations to the next level of spine above or below the fused disc.
- 6. In August of 2005, the Claimant went out of work despite accommodations. He had constant pain and trouble sitting or standing for long periods of time. He has not returned to work since August of 2005.
- 7. In 2007 additional tests were done on the L5-S1 level and it was determined that there was a mild spondylolithesis (slippage) at this level. Likewise it was determined that there were additional disk problems at the L4-L5 and L3-L4 levels. Dr. Rand proposed a three level fusion surgery. (Tab 26, Joint Medical Exhibit)
- 8. The Claimant has researched various back treatments. He learned of Dr. Rick Delamarter who is an expert in synthetic disc replacement surgery. In March of 2007, Dr. Delamarter evaluated the Claimant in California. Additional diagnostic tests were done in August of 2007. Dr. Delamarter determined that the Claimant was a good candidate for synthetic disc replacement surgery in the L4-L5 and L4-L3 levels of his spine. Dr. Delamarter determined that the Claimant would need a fusion surgery of his L5-S1 level. Dr. Delamarter proposed to do a hybrid surgery (one which combines a fusion of one level of the spine with disc replacements at other levels of the spine). The Claimant was scheduled for this surgery to be done on January 22, 2008.

- 9. In mid-November, 2007, the Defendant scheduled the Claimant to be evaluated by Dr. Tony Tannoury. Dr. Tannoury gave the Claimant the recommendation that he have a fusion surgery to the L5-S1 level but that he not have disc replacement or fusion to the other two levels.
- 10. Based upon the opinion of Dr. Tannoury, the Defendant refused to pay for the surgery offered by Dr. Delamarter and the scheduled surgery was cancelled. Thus, the issue in this case is essentially whether the proposed surgery by Dr. Delamarter is reasonable.
- 11. Dr. Rick Delamarter is a board certified orthopedic surgeon. He became board certified in 1989. He has been an Associate Clinical Professor at the UCLA School of Medicine. He is the co-founder and director of the West Coast Spine Institute. He is credited in over 68 professional publications and has presented numerous times concerning artificial disc replacement. He is an instructor for surgeons who desire to be certified in the use of "Prodisc" artificial discs. He participated as a surgeon in one of the 17 centers that studied artificial discs for the U. S. Food and Drug Administration (FDA) approval in the United States.
- 12. The use of synthetic discs in back surgery has been studied in the United States following its use in Europe for some time. Dr. Delamarter is quite familiar with the use of synthetic discs because his workplace was a FDA approved site for the FDA study. The study had one "arm" which studied single level synthetic disc replacement. That study is complete and the FDA has approved the use of single-level, synthetic disc replacements in the United States. The use of synthetic discs in more than one level was another "arm" of the study and has not been acted upon by the FDA because the conclusions of that "arm" of the study have not been completed. The FDA action on this part of the study might not be complete for another 18 months.
- 13. Dr. Delamarter testified that the use of synthetic discs has been approved for single level disc replacements and that double synthetic disc replacements can be done legally "off-label". The term "off-label" refers to the practice of prescribing drugs for a purpose outside of the scope of the drug's label as approved by the FDA. While the FDA approves drugs and medical devices which are safe and effective, once a drug or device is approved, physicians may prescribe the drug or use the device as they deem medically effective. According to Dr. Delamarter, use of devices and drugs "off-label" is a common practice and is legal.¹
- 14. Dr. Delamarter has performed several hundred double disc replacements with synthetic discs. His conclusions are that the synthetic disc replacements are significantly superior to fusions because the resulting range of motion is greater, the recovery time is one-third of the recovery time of fusion surgery, and the cost is less. The disc replacement decreases the "adjacent level process" significantly. According to Dr. Delamarter, under almost every measure, the outcome of synthetic disc replacement is better than fusion for those candidates who qualify. He characterized both the single level and double level synthetic disc replacements as safe and efficacious.

3

¹ For a discussion of the legal effect of "off-label" practice see Conclusion of Law number 5.

- 15. Dr. Delamarter examined the Claimant and is in a treating-physician role with him. He found that the Claimant needed a fusion at the L5-S1 level but that he would benefit from a synthetic disc replacement at levels L4-L5 and L4-L3. Dr. Delamarter was asked whether it might be possible to do the fusion first and then the disc replacements if the fusion surgery did not resolve the Claimant's pain. Dr. Delamarter was unequivocal. His firm opinion was that both the L4-L5 level and L3-L4 were "pain generators" and needed disc replacement. He was also of the opinion that it would not be good practice to do the surgery twice. The scarring and lesions, which would result from the first surgery, would increase risk to the Claimant if the surgery were done in stages.
- 16. Dr. Tony Tannoury is an orthopedic surgeon who became board certified in July of 2005. He completed medical school in 1993. He has been an assistant professor of Orthopedic Surgery at the University of Virginia and Boston University.
- 17. Dr. Tannoury examined the Claimant and his medical records. His examination took place on November 28, 2007. He reviewed two discographies which appear to be those dated February 2, 2004 and March of 2007. (It does not appear that he reviewed the discogram of March of 2008 and it was unclear whether he reviewed the August 2007 discogram since that test report was not referred to by date as were the other discograms referenced in his report.) The CAT scan of March 18, 2008 showed abnormal morphology of the disc at L4-L5. The discogram of March 18, 2008 indicated abnormal disc morphology at L4-L5 and typical central burning pain with pressure (indicating "concordant" pain).
- 18. Dr. Tannoury determined that the L5-S1 level needed a fusion. (In this he agreed with Dr. Delamarter.) He concluded however that the L4-L5 was "mildly degenerative" and not the source of pain. He also concluded that the L3-L4 level was normal. He felt that disc replacement at both of the upper levels would be "excessive".
- 19. Dr. Tannoury has never performed disc replacement surgery although he has attended conferences concerning it, including at least one in which Dr. Delamarter was a presenter. Dr. Tannoury performs a form of minimally invasive, interior fusion surgery which he recommended to the Claimant.
- 20. Counsel for the Claimant expended 128.1 hours of work in representation of the Claimant in this claim and incurred costs in the amount of \$1,314.55.

CONCLUSIONS OF LAW:

- 1. In Worker's Compensation cases the claimant has the burden of establishing all facts essential to the rights asserted. *Goodwin v. Fairbanks*, 123 Vt. 161 (1963).
- 2. When choosing between conflicting medical opinions, the Department has looked at several factors: (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. 37-03 WC (Sept. 17, 2003).
- 3. Applying these criteria to the competing medical opinions of Dr. Tannoury and Dr. Delamarter, it is clear that Dr. Delamarter is the more experienced of the two. He has a longer history of practice, and a wider breadth of practice than that of Dr. Tannoury. Dr. Delamarter is experienced in both fusion surgery and disc replacement, whereas Dr. Tannoury has not performed disc replacement surgery and has no direct experience with it. Dr. Delamarter is the treating surgeon for the Claimant while Dr. Tannoury is not. Dr. Tannoury did not have the benefit of the March 18, 2008 discogram and CAT scan, although portions of it were read to him during his testimony. Dr. Delamarter did have access to this test report before his testimony.
- 4. An employer is required to furnish reasonable surgical and hospital services to an injured employee. 21 VSA Sec. 640(a). The employee may select a health care provider upon notice to the employer of his or her dissatisfaction with any provider selected by the employer. 21 VSA Sec. 640(b). The commissioner retains authority to determine issues of reimbursement and medical necessity. e.g. 21 VSA Sec. 640(b) and (d). See also *Kobel v. C&S Wholesale Grocers*, Opinion No. 28-99 WC (August 2, 1999); *Bertrand v. McKernon Group*, Opinion No. 20-03 WC (April 16, 2003)(expedited hearing regarding cervical fusion surgery); *Morrisseau v. State of Vermont*, Opinion No. 19-04 (May 17, 2004)(expedited hearing denying gastric by-pass surgery).

- 5. A proposed surgery may be found to be reasonable where it is recommended by the treating physician and where the surgery has an objective basis or foundation. Beaudin v. H.P. Hood, Inc. Opinion No. 39-99 WC (September 3, 1999). Surgical treatment for the Claimant's spine has been recommended for three levels by both Dr. Rand and Dr. Delamarter. Dr. Rand, Dr. Delamarter and Dr. Tannoury all recommend fusion surgery for the L5-S1 level of the spine. Dr. Delamarter's recommendation of the hybrid surgery with artificial disc replacement at the L3-L4, and L4-L5 levels has an objective basis and foundation. With significant experience in both types of surgery, his opinion is that the proposed hybrid surgery would have a better result, a quicker recovery period, and a lower cost. Moreover, the argument that this particular type of surgery is beyond the FDA approval, does not mean that the proposed surgery is not reasonable. This same argument was made in the case of State ex rel. Bax Global, Inc v. Indus. Comm., 2007 Ohio 695 (Ohio App. 10th Dist., Feb. 20, 2007). In that case, the court refused to set aside a ruling of the Industrial Commission that the Claimant should have a Charite artificial disc replacement at L3-L4, even though that artificial disc had been approved by the FDA for use at the L4-L5 or L5-S1 levels. The employer argued that the use of an artificial disc at the L3-L4 level was "off-label" and not approved by the FDA. The court approved the Commissioner's determination that the FDA "neither regulates practice of medicine nor restricts uses to those which have been officially approved." Id. Page 10, para. no. 37. An "off-label" use of a FDA approved device can be approved where the claimant's need for the surgery and the propriety of the proposed surgery are shown by competent medical opinions. Id.
- 6. I conclude that the proposed surgery offered by Dr. Delamarter (a hybrid, fusion and double disc replacement) is a reasonable and necessary surgery for the Claimant and that the defendant is obligated to pay for the reasonable costs associated with it.
- 7. The Defendant argues in its Proposed Findings of Fact that the Department has "no jurisdiction to order pre-authorization of medical treatment". (See page 2, Defendant's Proposed Findings of Fact and Conclusions of Law.) This issue has been ruled on in the case of *Bebon v Safety-Kleen/Sedgwick* at both the Department and the Superior Court levels (See *Bebon v. Safety-Kleen/Sedgwick*, State File No. T-19416, Denial of Motion For Summary Judgement dated August 21, 2007 and *Bebon v. Safety-Kleen/Sedgwick*, *CMS*, Chittenden Superior Court Docket No. 1286-05, Entry Order dated January 9, 2007.)

ORDER:

Therefore, based upon the foregoing findings of fact and conclusions of law, the Commissioner determines that:

- 1. The Claimant's proposed hybrid surgery with Dr. Delamarter is reasonable medical treatment and should be paid for by the Defendant, if performed;
- 2. Attorney's fees of 128.1 hours be awarded to the Claimant at the rate of \$90.00 per hour pursuant to the Department's fee schedule. Costs in the amount of \$1,314.55 are also awarded to the Claimant.

Dated at Montpelier, Vermont this 12th day of June 2008.

Patricia Moulton Powden 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. Sec. 670, 672.