**DOCKET NO. 453-03-1659.M5**
**MRD. NO. M5-02-1951-01**

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| **TEXAS MUTUAL INSURANCE CO., PETITIONER** | § | **BEFORE THE STATE OFFICE** |
| **V.** | § | **OF** |
| **OXYMED, INC. , RESPONDENT** | § | **ADMINISTRATIVE HEARINGS** |

# DECISION AND ORDER

Texas Mutual Insurance Co. (Carrier) appealed the decision of the Texas Workers' Compensation Commission's (Commission) Medical Review Division (MRD), which granted reimbursement for a cryotherapy unit[1] provided by Oxymed, Inc. (Provider) to a workers' compensation claimant (Claimant). Carrier denied reimbursement to Provider claiming the cryotherapy unit was not medically necessary healthcare. This decision finds the cryotherapy unit is not reasonably required or medically necessary care; thus, Carrier is not liable to reimburse Provider.

## I. JURISDICTION, NOTICE, AND PROCEDURAL HISTORY

There were no contested issues of jurisdiction, notice or venue. Therefore, those issues are addressed in the findings of fact and conclusions of law without further discussion here.

The hearing in this matter convened on September 25, 2003, with Administrative Law Judge (ALJ) Tommy L. Broyles presiding. Petitioner and Respondent were represented by their attorneys, Patricia Eads and John Fundis. The Commission did not participate in the hearing. The record remained open until October 30, 2003, pending the filing of closing briefs.

[1]Cryotherapy or cold therapy units and the necessary accessories consist of a small ice chest with a pump, hoses, and pad. Water is cooled by ice in the ice chest and then circulated through the hoses to the pad.

## II. DISCUSSION

### A. Background Facts

On____, Claimant sustained a right calcaneus[2] fracture after falling off a ladder, an injury compensable under the Texas Workers' Compensation Act (the Act). At the time of the compensable injury, Carrier was the workers' compensation insurer for Claimant's employer.

On November 11, 2001, the fracture was treated with open reduction and internal fixation. John Wey, M.D., performed the surgery and prescribed a cryotherapy unit with ankle wrap to decrease post-operative pain and swelling. Provider subsequently billed Carrier $724 for the cryotherapy unit. Carrier denied reimbursement on the basis that the durable medical equipment (DME) was not medically necessary healthcare. Finding medical necessity, the MRD ordered reimbursement of the full $724.

### B. Coding Arguments

Carrier denied reimbursement based on code "U" explaining that the service was deemed unnecessary medical treatment based on a review of the claim file, billing records, and written review protocols established for appropriate health care treatment. Provider argues that code "U" does not include a dispute for cost effectiveness because 1) code "U" concerns only treatment that does not cure or relieve the effects of the injury, promote recovery, or enhance the ability to return to work and 2) neither the code explanation nor the carrier's explanation of benefits includes a sufficient description of the denial as required by Rule 133.304(c).[3]

The ALJ is unpersuaded by Provider's arguments and finds that cost effectiveness is within the analyses made pursuant to the entitlement of all health care *reasonably* required by the nature of the injury.[4] Provider inappropriately limits the analyses to whether treatment will provide medical benefit, failing to consider whether the treatment is reasonable. Not all treatment that will provide medical benefit is necessary. For instance, while water therapy may be necessary treatment to care for an injury, this does not suggest that a carrier should be required to pay for a swimming pool

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[2]The calcaneus is the heel bone.

[3]In part, 28 TAC 133.304(c) requires a carrier to provide sufficient explanation to allow the provider to understand the reasons for the insurance carrier's actions.

[4]TEX. LAB.CODE ANN. §408.021 (a)

ordered by a provider. The swimming pool is neither reasonably required nor necessary when there is a more cost-effective alternative.

## C. Medically Necessary Healthcare Arguments

Neither party contests that cold therapy is generally medically necessary after surgery to decrease swelling and inflamation.[5] Instead, the debate concerns whether a cryotherapy unit was reasonable in this instance, given the availability of a more cost-effective alternative. Two studies were offered into the record by Provider. The first, *Continuous-Flow Cold Therapy for Outpatient Anterior Cruciate Ligament Reconstruction,* compared patients using cryotherapy units to patients using no form of cold therapy (Cold Therapy Study).[6] The study concluded that cryotherapy units are a safe and effective modality to reduce pain for an outpatient ACL reconstruction surgery. The second, *A Comparison of Crushed Ice and Continuous Flow Cold Therapy*, compared patients using ice to those using cryotherapy units (Ice Study).[7] According to this study, Cryotherapy units compare favorably to crushed ice when used as a modality for post-operative pain reduction. Carrier offered the testimony of John Pearce, M.D.; Clark Watts, M.D., J.D., and Masters of Pharmacology; and Nick Tsourmas, M.D. Dr. Pearce testified that cold therapy constricts blood vessels thus reducing swelling and pain. He testified favorably of cold therapy provided by gel packs and cryotherapy units, but not by ice which he indicated may not stay cold long enough. Dr. Pearce cautioned that continuous cold therapy, such as that provided by cryotherapy units, may result in soft tissue necrosis[8] in areas where the already limited blood supply is reduced by the constriction of blood vessels induced by the application of cold.[9] Dr. Pearce thought that cryotherapy units cost $150-$225 and stated that any cool therapy recirculating system that costs in excess of $600 would not be cost effective.

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[5]Carrier's witness, Clark Watts, M.D., testified that he does not support the use of cold therapy after acute surgery such as spinal surgery, as the major surgical entry is several inches into the patient's back and cold therapy, in his opinion, is not effective. He explained that cold therapy will penetrate the epidermis and superficial layers of the subcutaneous tissues for a centimeter or so, but not the deep tissue impacted by spinal surgery.

[6]Provider's Exhibit 16.

[7]Provider's Exhibit 17.

[8]Necrosis is cell damage. As used in this instance, it is similar to superficial frost bite.

[9]Dr. Pearce specifically noted the foot as such an area.

Dr. Tsourmas has instructed patients to use cold therapy for shoulder and foot injuries; he would not do so for spinal surgery. He explained that cold is transferred by physical conduction, cell to cell, but is rapidly dissipated by the blood stream. For this reason, he does not find it beneficial for surgeries where there is a large tissue envelope. Dr. Watts agreed, testifying that there is very little quality science pertaining to cold therapy on spine surgery. He opined that most surgeons would not use cold therapy after spinal surgery, except at the bottom of the neck where the tissue is very thin.

Dr. Tsourmas described the two studies referenced by Provider and authored by Dr. Barber as "junk science" opining that they do not suffice as good scientific experiments. He does not believe the Ice Study contains any useful information for practitioners, noting that it was not randomized, prospective, single-centered, or double-blinded; all characteristics of a "gold standard" study. Dr. Watts agreed, testifying that the two studies were not scientifically valid studies regarding the efficacy of cold therapy provided by a cryotherapy unit. He explained that the studies do not follow the usual and accepted format for clinical studies where you compare one specific entity with another specific entity, eliminating the other factors.[10] Dr. Watts described the Ice Study as "terribly flawed" noting that it compares patients from one study to patients of a totally different study. According to Dr. Watts, this violates the most basic protocols for scientific research and leads to significant discrepancies such that the study should not be relied upon .[11]

When prescribing cold therapy, Dr. Tsourmas recommends ice four to five times per day for the first 24 to 48 hours. He sees no advantage to having a cryotherapy unit over ice. Years ago, Dr. Tsourmas used cryotherapy units but has since quit using them, as have the other surgeons in his practice. He has not received any complaints about using ice. Dr. Watts opined that the use of a $700 tool to provide cold therapy is excessive.

F. Alan Barber, M.D., and Brian Stringer, Sales Representative for a distributor of cryotherapy units, testified on behalf of Provider. Dr. Barber testified that cryotherapy units are far superior to other types of cold therapy. He authored or co-authored both studies discussed above.

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[10] He stated that the study is "pretty good" for the hypotheses that continuous cold is better than no cold but that it does nothing to indicate continuous cold is better than intermittent cold.

[11] For instance, Dr. Watts demonstrated that the data relied on in the study suggest cold is worse than no cold at all leading to a conclusion that crushed ice, a treatment accepted for centuries, is harmful. But, the paper does not acknowledge this conclusion and instead focuses on a determination that cryotherapy units are better than crushed ice.

From his studies and practice, Dr. Barber concluded that cryotherapy units are so superior to crushed ice that the additional cost is justified.

Dr. Barber noted frequent patient frustration with the use of crushed ice from leaking bags and inconveniences associated with obtaining sufficient ice. He has even had patients with frostbite from crushed ice; a condition that he has not encountered with patients using cryotherapy units or gel packs. He pointed out that as opposed to gel packs, cryotherapy units provide a constant temperature over a long amount of time. He finds that patients do not use the gel packs as frequently as prescribed, with many hours where they are not recharged appropriately.

Mr. Stringer described the mechanics of the cryotherapy units and insisted that they are preferred over ice or gel packs. Specifically, Mr. Stringer maintained that the cryotherapy units were easier to operate as the cold lasted up to 8 hours without changing the ice. He also found the cryotherapy units to be more comfortable, particularly with cold-sensitive patients, as the temperature may be regulated.

**D. Analysis**

Based on the record, the ALJ concludes that the cryotherapy unit is neither cost effective nor medically necessary treatment pursuant to TEX. LAB. CODE ANN. § 408.021(a). The preponderant evidence establishes that the use of gel packs is as effective and far more cost effective than cryotherapy units.[12] The ALJ is unable to make the same findings regarding ice bags which, due to the short nature of the cold therapy provided, may not provide an equal modality.

To a great extent, the ALJ's determination rests on the testimony of Drs. Watts and Pearce. Dr. Watts' credentials, particularly in publications, were unmatched by the other witnesses. He demonstrated that the Ice Study not only failed to adhere to scientific methodology, but also appeared biased and contrived as the authors failed to note its clinical limitations and inconsistencies with generally accepted medical practices. Based on Dr. Watts' observations, the Ice Study was accorded no evidentiary weight. While the Cold Therapy Study appears much more scientific, it does nothing more than suggest cold therapy is beneficial, something not contested in this proceeding.[13]

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[12]Mr. Stringer testified that the gel packs cost between $17 and $78, depending on the size.

[13]When asked what he ultimately learned from the Cold Therapy study, Dr. Barber stated that the cryotherapy unit was effective in reducing pain and speeding the postoperative rehabilitation. The ALJ notes this determination does not does address whether cryotherapy units are superior to other forms of cold therapy.

The ALJ also relied upon Dr. Pearce's testimony which was judged to be very forthright.[14] Dr. Pearce strongly recommended the intermittent use of cold therapy for most surgeries, including those at issue in this proceeding. He did not find continuous cold therapy provided by a cryotherapy unit was medically necessary because of other, more cost-effective options. Dr. Pearce testified that a gel pack would remain cold for 3-4 hours. Mr. Stringer's testimony established that a cryotherapy unit would remain cold for 6-8 hours. The preponderant evidence suggested that the difference in time between replacing the gel pack and recharging the cryotherapy unit is insignificant, both medically and in relation to convenience.

Dr. Pearce estimated the cost of cryotherapy units at $150 - $225 and opined that a cryotherapy unit costing in excess of $600 is not cost-effective cold therapy. Provider's witness, Mr. Barber, gave a similar estimation of the cost of a cryotherapy unit at $225. Mr. Barber opined that at this cost the unit was reasonable but would not give an opinion as to whether a unit costing $500-$800 would be reasonable.

Ultimately, the evidence established that Providers' position about cryotherapy units is overstated, lacking support in any acceptable study. The evidence does not suggest cold therapy at a constant temperature is more beneficial than intermittent-temperature cold therapy provided by a gel pack. Nor does the evidence suggest that cold therapy provided by a cryotherapy unit is safer than that provided by a cold pack.[15] Rather, the evidence established that both cold packs and cryotherapy units are preferred over crushed ice, which may melt too quickly depending on the ambient temperature.[16]

For Claimant's post-surgical needs, a gel pack could have provided the cold therapy as effectively as the cryotherapy unit, but at a fraction of the cost. For this reason, the ALJ finds that

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[14]Dr. Pearce testified he has used cryotherapy units for total knee replacements due to the particulars of that surgery and the availability of a pad that wraps completely around the knee. He stated that because there is more soft tissue dissection in this surgery, he tends to keep the area cooler for longer periods of time. He uses gel packs for ACL reconstructions, fractures, shoulder surgery, and foot surgery.

[15]Even Dr. Barber admitted that with gel packs, he has not seen the frost bite problems he associated with ice bags. Conversely, Dr. Pearce noted that with cryotherapy units there is an increased concern of necrosis of the skin due to the potential for continuous cold over a large area. Thus, the evidence in this hearing suggest gel packs are safer than cryotherapy units or ice bags when considering the potential for frost bite.

[16]Dr. Pearce and other witnesses testified that ice may melt in less than an hour while gel packs and cryotherapy units will maintain cold for several hours, reducing the need for attentive care.

the cryotherapy unit was not medically reasonable and necessary and that Carrier should not be required to reimburse Provider $725 for its cost.

## III. FINDINGS OF FACT

1. In___, Claimant suffered a right calcaneus fracture compensable under the Texas Workers' Compensation Act and for which Texas Mutual Insurance Company (Carrier) was the responsible insurer.

2. In November 2001, after Claimant had surgery on his foot, his doctor prescribed the post-surgical use of a cryotherapy unit to provide cold therapy treatment.

3. Oxymed Inc. (Provider) provided a cryotherapy unit to Claimant, consisting of a water circulating pump, hoses, and a pad.

4. Provider billed Carrier $724 for the cryotherapy unit.

5. Provider requested medical dispute resolution after Carrier denied its request for reimbursement for the cryotherapy unit.

6. Carrier appealed the decision of the Texas Workers' Compensation Commission's (Commission) Medical Review Division, which ordered Carrier to reimburse Provider for the cryotherapy unit.

7. Pursuant to the notice of hearing sent by the Commission's Staff, all parties appeared and were represented at the hearing held in this matter on September 25, 2003.

8. Gel packs are as effective as cryotherapy units in providing cold therapy.

9. Gel packs used to provide cold therapy cost substantially less than cryotherapy units used for the same purpose.

10. The potential for frost bite is greater with cryotherapy units than with gel packs.

## IV. CONCLUSIONS OF LAW

1. The Commission has jurisdiction related to this matter pursuant to the Texas Workers' Compensation Act (Act), TEX. LABOR CODE ANN. § 413.031.

2. The State Office of Administrative Hearings has jurisdiction over matters related to the hearing in this proceeding, including the authority to issue a decision and order, pursuant to § 413.031(d) of the Act and TEX. GOV'T CODE ANN. ch. 2003.

3. The hearing was conducted pursuant to the Administrative Procedure Act, TEX. GOV'T CODE ANN. ch. 2001 and the Commission's rules, 28 TEX. ADMIN. CODE § 133.305(g).

4. Adequate and timely notice of the hearing was provided in accordance with TEX. GOV'T CODE ANN. §§ 2001.051 and 2001.052.

5. Pursuant to the Act, an employee who has sustained a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. Included within the determination of "reasonably required" is cost effectiveness. TEX. LAB. CODE ANN. § 408.021(a).

6. Health care includes all reasonable and necessary medical services, which includes a determination of cost effectiveness. TEX. LAB. CODE ANN. §401.011(19)(A).

7. The cryotherapy unit rental for Claimant was not medically necessary because it was not cost-effective.

8. Petitioner is not obligated to reimburse Provider for the cryotherapy unit.

## ORDER

**IT IS ORDERED** that Texas Mutual Insurance Company is not liable for reimbursement of the cost of the cryotherapy unit provided by Oxymed, Inc. to Claimant.

**SIGNED December 17, 2003.**

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**TOMMY L. BROYLES**
**ADMINISTRATIVE LAW JUDGE**
**STATE OFFICE OF ADMINISTRATIVE HEARINGS**