

**DECISION AND ORDER**

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and Rules of the Division of Workers' Compensation adopted thereunder.

**ISSUE**

A benefit contested case hearing was held on September 10, 2008, to decide the following disputed issue:

Is the preponderance of the evidence contrary to the decision of the IRO that the claimant is not entitled to three Hyalgan injections in his right ankle for the compensable injury of \_\_\_\_\_?

**PARTIES PRESENT**

Requestor, claimant, appeared and was assisted by ombudsman, IG. (Carrier) appeared and was represented by CF, attorney

**BACKGROUND INFORMATION**

It is undisputed that Claimant sustained a significant injury when he fell 22 feet and hit a cement floor during the course and scope of his employment on \_\_\_\_\_. Claimant sustained multiple injuries, including serious injuries to both ankles. The medical records show that he sustained a distal radial fracture, left talus fracture, and right comminuted calcaneal fracture; and, that he initially underwent ORIF procedures for the fractures. He subsequently underwent a left ankle arthrodesis and right subtalar joint arthrodesis due to posttraumatic degenerative changes. He underwent physical therapy and rehabilitation, and controls his pain with analgesics enough to allow him to increase his daily functions. He has continued to experience instability, pain, popping and grinding in his right ankle.

Claimant currently treats with a chiropractor (Dr. P), a podiatric surgeon (Dr. D) and an anesthesiologist specializing in pain management (Dr. N). Dr. D requested a series of three Hyalgan injections for treatment of Claimant's right ankle problems.

The first utilization review doctor, Dr. S, a DO in occupational and preventive medicine, cited the ankle and foot as well as knee and leg chapters of the ODG and noted that Hyalgan is indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and to simple analgesics. Dr. S opined that because the Hyalgan injections requested by Dr. D were for the ankle rather than the knee, and there was no diagnosis of osteoarthritis, and because there was not enough documentation of failed conservative care, the requested injections were denied.

The utilization review doctor who reviewed the request on reconsideration, Dr. G, an orthopedic surgeon, also denied the requested treatment. He noted that there is no reference in the ODG to

Hyalgan injections for the ankle. He did note a February 24, 2005 pilot study which suggested the five weekly intraarticular injections of Hyalgan provided sustained relief of pain and improved ankle function in patients suffering from osteoarthritis of the ankle. He opined, however, that the records did not reflect enough clinical support for the requested procedure.

An IRO reviewer and board certified orthopedic surgeon, denied the requested services because Hyalgan treatment is FDA approved for osteoarthritis of the knee, not the ankle; and viscosupplementation as a form of treatment for ankle arthritis is not mentioned in the ODG.

## DISCUSSION

**Texas Labor Code Section 408.021** provides that an employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. **Section 401.011(22-a)** defines health care reasonably required as “health care that is clinically appropriate and considered effective for the injured employee’s injury and provided in accordance with best practices consistent with: (A) evidence based medicine; or (B) if that evidence is not available, generally accepted standards of medical practice recognized in the medical community.” “Evidence based medicine” is further defined, by **Section 401.011(18-a)** as the use of the current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts, and treatment and practice guidelines in making decisions about the care of individual patients.

The Division of Workers’ Compensation has adopted treatment guidelines under Division **Rule 137.100**. That rule requires that health care providers provide treatment in accordance with the current edition of the *Official Disability Guidelines (ODG)*, and treatment provided pursuant to those guidelines is presumed to be health care reasonably required as mandated by the above-referenced sections of the **Texas Labor Code**.

### *ODG*

The initial inquiry, therefore, in any dispute regarding medical necessity, is whether the proposed care is consistent with the *ODG*. As the utilization review and IRO doctors have stated (and the requesting doctor acknowledges) the *ODG* states that Hyalgan injections are indicated for treatment of osteoarthritis of the *knee* joints.

The *ODG* Procedure Summary for the Knee addresses the use of Hyalgan (Hyaluronic acid injections) as follows:

Recommended as an option for osteoarthritis. Hyaluronic acids are naturally occurring substances in the body's connective tissues that cushion and lubricate the joints. Intra-articular injection of hyaluronic acid can decrease symptoms of osteoarthritis of the knee; there are significant improvements in pain and functional outcomes with few adverse events. The number of injections should be limited to three. ([Leopold, 2003](#)) ([Day, 2004](#)) ([Wang, 2004](#)) ([Aggarwal, 2004](#)) ([Arrich, 2005](#)) ([Karatosun, 2005](#)) ([Blue Cross Blue Shield, 2005](#)) ([Petrella, 2005](#)) Compared with lower-molecular-weight hyaluronic acid, this study concluded that the highest-molecular-weight hyaluronic acid may be more efficacious in treating knee OA. ([Lo-JAMA, 2004](#)) These more recent studies did not. ([Reichenbach, 2007](#)) ([Jüni, 2007](#)) The response to hyaluronan/hylan products

appears more durable than intra-articular corticosteroids in treatment of knee osteoarthritis. ([Bellamy-Cochrane, 2005](#)) Viscosupplementation is an effective treatment for OA of the knee with beneficial effects: on pain, function and patient global assessment; and at different post injection periods but especially at the 5 to 13 week post injection period. Within the constraints of the trial designs employed no major safety issues were detected. ([Bellamy-Cochrane2, 2005](#)) ([Bellamy, 2006](#)) Intra-articular viscosupplementation was moderately effective in relieving knee pain in patients with osteoarthritis at 5 to 7 and 8 to 10 weeks after the last injection but not at 15 to 22 weeks. ([Modawal, 2005](#)) This study assessing the efficacy of intra-articular injections of hyaluronic acid (HA) compared to placebo in patients with osteoarthritis of the knee found that results were similar and were not statistically significant between treatment groups, but HA was somewhat superior to placebo in improving knee pain and function, with no difference between 3 or 6 consecutive injections. ([Petrella, 2006](#)) The combined use of hyaluronate injections with a home exercise program should be considered for management of moderate-to-severe pain in patients with knee osteoarthritis. ([Stitik, 2007](#)) Patients with moderate to severe pain associated with knee OA that is not responding to oral therapy can be treated with intra-articular injections. Intra-articular injections of hyaluronate are associated with delayed onset of analgesia but a prolonged duration of action vs injections of corticosteroids. ([Zhang, 2008](#)).

It is undisputed that the *ODG* does not address the use of Hyalgan injections for the *ankle*. As noted previously herein, “health care reasonably required” means health care that is clinically appropriate and considered effective for the injured employee’s injury and provided in accordance with best practices consistent with evidence-based medicine or if that evidence is not available, generally accepted standards of medical practice recognized in the medical community.

As the *ODG* does not address the requested treatment for the ankle, and that is the sole reason for the IRO upholding the denial of the requested Hyalgan injections, an analysis of the evidence-based medicine supporting the requested treatment is required.

### ***Other Evidence Based Medicine***

Dr. D is a podiatric physician and surgeon. She has given an opinion, which demonstrates in specific, scientific detail why she believes the requested injections are clinically appropriate for Claimant’s injury. In a report dated June 10, 2008, Dr. D outlined Claimant’s condition and her recommendations for treatment. She noted that a September 28, 2007 CT scan of the right ankle showed a possible linear fracture involving the lateral aspect of the calcaneus close to the tip of a previously placed screw, as well as post-traumatic changes within the ankle joint and disuse atrophy.

Dr. D also explained that a left ankle MRI showed osteochondritis dissecans involving the medial talar dome as well as fusion of the calcaneus and talus or subtalar joint.

Dr. D stated that Claimant already had subtalar joint fusion to the right foot, and a fusion of the right ankle joint would leave him very stiff with the probability of increased stress on the left foot and ankle. For these reasons, Dr. D opined that a total fusion of the right ankle was not a good option. She recommended Hyalgan injections. She explained that Hyalgan is off-label for the ankle, but since it is a viscous material that is used for cushioning, it might be another alternative for Claimant in lieu of surgery. She recommended against steroid injections as they might provide temporary relief, but had the potential to erode any existing cartilage in the joint.

Dr. D explained that Hyalgan's current indication was for the knee joint, but as the ankle joint is a weight-bearing structure, she hoped to obviate the need for surgery, which would result in a very stiff limb. She explained that Hyalgan is a viscous solution consisting of high molecular weight fractions of purified natural sodium hyaluronate and buffered sodium chloride. Hyaluronic acid is a natural complex sugar of the glycosaminoglycan family and is a long chain polymer. Hyalgan is indicated for the treatment of pain in patients with knee pain that have failed to respond adequately to conservative non-pharmacologic therapy and analgesics; and, is usually injected directly into the joint to restore the cushioning and lubricating properties of normal joint fluid. It was Dr. D's opinion that the injection would benefit Claimant because the other alternative, specifically surgery, would result in no motion in the rear foot and ankle and continued pain.

Dr. D stated that she was initially told that the injection would be approved. In fact, the Hyalgan *prescription* was filled and Claimant has the injectable product in his possession. It is the injection *procedure* which is in dispute herein.

Dr. N, an anesthesiologist and Claimant's pain management doctor, agreed with Dr. D. In a report dated July 14, 2008, he stated that Claimant's options were somewhat limited in that he can have a fusion of his right ankle, which will leave him with an extremely stiff and rigid extremity, and would cause increased stress and possible future problems with the left foot and ankle. He further agreed that steroid injections would be a short-term fix and possibly cause further damage to the existing ankle cartilage. He stated that there "are many studies showing Hyalgan injections to be effective in the treatment of osteoarthritis of the ankle and referenced the study cited by Dr. G." He stated that although the use of Hyalgan for ankle pain and degenerative ankle disease is off-label, there have been preliminary studies that show good results. Finally, Dr. N acknowledged that Hyalgan injections for the ankle were not mentioned in the *ODG*, but stated that Claimant had failed to respond to all conservative non-pharmacologic therapy and analgesics, and recommended the injections in lieu of additional surgery.

Dr. D also acknowledged that the procedure is "off-label" for treatment of ankle joint conditions, but offered a compelling argument for the treatment as an alternative to surgery, which she opined will cause more harm than good to not only Claimant's right ankle, but also to his left ankle, due to the resulting immobility of the right ankle.

The results of a randomized, double-blind, placebo controlled pilot study were presented to the American Academy of Orthopaedic Surgeons 2005 Annual Meeting. That study concluded that Hyalgan injections provided sustained relief of pain and improved ankle function in patients suffering from osteoarthritis of the ankle.

When weighing medical evidence, the hearing officer must first determine whether the doctor giving the expert opinion is qualified to offer it, but also, the hearing officer must determine whether the opinion is relevant to the issues in the case and whether the opinion is based upon a reliable foundation. An expert's bald assurance of validity is not enough. *See Black v. Food Lion, Inc.*, 171 F.3<sup>rd</sup> 308 (5<sup>th</sup> Cir. 1999); *E.I. Du Pont De Nemours and Company, Inc. v. Robinson*, 923 S.W.2d 549 (Tex. 1995). When determining reliability, the hearing officer must consider the evidence in terms of (1) general acceptance of the theory and technique by the relevant scientific community; (2) the expert's qualifications; (3) the existence of literature supporting or rejecting the theory; (4) the

technique's potential rate of error; (5) the availability of other experts to test and evaluate the technique; (6) the clarity with which the theory or technique can be explained to the trial court; and (7) the experience and skill of the person who applied the technique on the occasion in question. *Kelly v. State*, 792 S.W.2d 579 (Tex. App.-Fort Worth 1990).

In the instant case, the *ODG* does not cover the topic of Hyalgan injections for treatment of the ankle. The IRO incorrectly took the position that a topic not covered by the *ODG* is never authorized. That is not the standard provided by the statute.

The treatment plan set out and discussed in detail by Dr. D, and approved by Dr. N is supported by credible scientific studies, including peer-reviewed medical literature. The treatment plan is supported by the *ODG*'s recommendation for the use of viscosupplementation for joint osteoarthritis and the 2005 pilot study. Although a commentary on the study published in the *Journal of Bone and Joint Surgery* in 2006 questioned the methodology of the study; the writer noted that the study confronted a common condition for which there are few good therapeutic options (ankle osteoarthritis); used randomization to allocate treatments (which the writer acknowledged was a good approach not used enough in publications); and, resulted in sufficient raw data to aid calculations in future studies. The doctors, a podiatric surgeon and anesthesiologist, are qualified to give the opinions they rendered; and, Dr. D explained her theory and the proposed technique with great clarity and specificity. Her recommendations were echoed by Dr. N, who also gave a clear and reliable scientific basis for his opinion regarding the treatment herein.

The opinions of Dr. D and Dr. N, in combination with the pilot study referenced herein, are relevant to the issues in the case and based upon a reliable foundation. As stated previously, the *ODG* is silent on the use of Hyalgan for treatment of the ankle; however, it does not prohibit that treatment. In fact, the *ODG* recommends intra-articular injection of hyaluronic acid for the knee and states that such injections can decrease symptoms of osteoarthritis of the knee. The *ODG* also notes significant improvements in pain and functional outcomes with few adverse events, when Hyalgan is used in the knee joint. Dr. D has recommended three injections to the ankle joint, which is exactly the number of injections the *ODG* recommends for the knee. The recommended treatment is to treat ankle joint degeneration caused by the compensable injury. The fact that the *ODG* recommends such injections for joint degeneration in the knee lends further support to the opinions of Dr. D and Dr. N.

Claimant has shown, through evidence-based medicine that the requested service herein is health care reasonably required by the nature of the compensable injury. As such, the preponderance of the evidence is contrary to the decision of the IRO that the claimant is not entitled to three Hyalgan injections to the right ankle for the compensable injury of \_\_\_\_\_.

Even though all the evidence presented was not discussed, it was considered. The Findings of Fact and Conclusions of Law are based on all of the evidence presented.

### **FINDINGS OF FACT**

1. The parties stipulated to the following facts:
  - A. Venue is proper in the (City) Field Office of the Texas Department of Insurance, Division of Workers' Compensation.

- B. On \_\_\_\_\_, Claimant was the employee of (employer) when he sustained a compensable injury.
- C. The IRO determined that the requested services were reasonable and necessary health care services for the compensable injury of \_\_\_\_\_.
2. Carrier delivered to Claimant a single document stating the true corporate name of Carrier, and name and street address of Carrier's registered agent which was admitted into evidence as Hearing Officer's Exhibit Number 2.
  3. Dr. D, a podiatric surgeon, recommended three Hyalgan injections to the right ankle as treatment for the compensable injury.
  4. The ODG does not address Hyalgan injections as treatment for the ankle.
  5. The IRO decision upheld the Carrier's denial of the requested Hyalgan injections because it viscosupplementation as a form of treatment for ankle arthritis is not mentioned in the ODG.
  6. The treatment plan set out and discussed in detail by Dr. D, and approved by Dr. N is supported by credible scientific studies, including peer-reviewed medical literature.
  7. The *ODG* recommends the use of viscosupplementation for joint osteoarthritis.
  8. A pilot study concluded that Hyalgan injections provided sustained relief of pain and improved ankle function in patients suffering from osteoarthritis of the ankle.
  9. Three Hyalgan injections for the right ankle is health care reasonably required for the compensable injury of \_\_\_\_\_.

### **CONCLUSIONS OF LAW**

1. The Texas Department of Insurance, Division of Workers' Compensation, has jurisdiction to hear this case.
2. Venue was proper in the (City) Field Office.
3. The preponderance of the evidence is contrary to the decision of IRO that three Hyalgan injections for the right ankle is not health care reasonably required for the compensable injury of \_\_\_\_\_.

### **DECISION**

Claimant is entitled to three Hyalgan injections for the right ankle for the compensable injury of \_\_\_\_\_.

**ORDER**

Carrier is liable for the benefits at issue in this hearing. Claimant remains entitled to medical benefits for the compensable injury in accordance with Section 408.021.

The true corporate name of the insurance carrier is **ATLANTIC MUTUAL INSURANCE COMPANY** and the name and address of its registered agent for service of process is

**CT CORPORATION SYSTEM  
350 NORTH ST. PAUL STREET  
DALLAS, TEXAS 75201**

Signed this 16<sup>th</sup> day of September, 2008.

Erika Copeland  
Hearing Officer